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

Form 10-K

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

For the fiscal year ended December 31, 2001

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

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 preceeding 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 ☑ No ☐

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 ☐

As of March 18, 2002, the aggregate market value of the Registrant's Common Stock held by non-affiliates, based upon the average bid and asked price of $0.91 as of such date, was $17,032,039. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect to direct or cause the direction of management or policies of the Registrant, or that this person is controlled by or under common control with the Registrant. There were 21,427,699 shares of the Registrant's Common Stock issued and outstanding as of March 18, 2002.

Documents Incorporated By Reference

Portions of the Registrant's Definitive Proxy Statement for the 2001 Annual Meeting of Shareholders to be held on or about June 17, 2002, are incorporated by reference in Part III hereof.

Item 1: ***Description of Business:***

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 are intended to identify forward-looking statements. Forward-looking statements address or may address the following subjects:

- **The sufficiency of our current cash resources to fund operations until September 2002;**
- **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;**
- **Our expectation of the benefits that will result from the ongoing research we are funding at Sheffield University;**
- **Our expectation that we will continue to experience losses until our genetic testing revenues grow 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 obtain adequate capital, competitive risks and those risks set forth within the section titled "Factors Affecting Future Performance" beginning on page 12 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.

GENERAL OVERVIEW

THE COMPANY

Overview

Interleukin Genetics, Inc., a Delaware corporation ("ILGN" or the "Company"), is a functional genomics company focused on personalized medicine. We believe that by identifying individuals at risk for certain diseases and combining this knowledge with specific therapeutic interventions, better healthcare decisions can be made, reducing costs and greatly improving patient health outcomes. We have a growing portfolio of patents covering the genetics of a number of common 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 medicine for those diseases differently than others. Until doctors are able to understand the underlying causes for such variability in chronic diseases, the practice of medicine will remain largely constrained to the current approach of prescribing therapies based on broad, sweeping recommendations in which very large groups of people with the same stage of disease all receive the same treatment. This approach to medicine is, in many ways, quite impersonal and it is often ineffective.

Until now, scientific study of chronic diseases has largely focused on identifying factors that initiate or "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 always 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 way that results in a problem.

We believe that the recent expansion in understanding of human genetic information coming from programs like the Human Genome Project will likely change the impersonal way medicine is practiced. This is because the response of an individual's body to the common disease initiating factors is largely determined by their specific genes. By using the new tools of the genomic era, scientists will be able to study how differences in a specific individual's genetic information directs their body to respond to these disease initiating factors in different ways. This is likely to be true for identifying both who is most likely to develop one disease or another but also for who is most likely to respond to one or another medicine. It has long been recognized that individual responses to most drugs vary from person to person in ways that may be clinically very important yet are usually unpredictable. While one person may receive great benefit from a drug at one dose, a second person may require 2-3 times that dose, while yet another may be unable to tolerate treatment due to side effects even at the lowest dose. Until recently, the tools to unravel the biological basis for this wide variability in drug response have been very limited. In fact, doctors and their patients have been forced to accept that a simple "trial and error" approach was the only effective way to select the most appropriate therapy. However, because the ways that our bodies respond to drugs are ultimately determined by our genes, a better understanding of the interactions between our genes and the drugs we use holds the promise of ending this non-specific way of prescribing medicines. Since it is our genes that make us unique, at least in the biologic sense, we believe that tailoring medical therapy based on knowledge of our genetic tendencies will enable doctors to move beyond the one size fits all approach to prescribing medicines which are more "personalized" to each of us based upon our unique genetic make-up.

Our first genetic test, PST®, a test predictive of risk for periodontal disease, is currently marketed in the United States and Europe. Other products under development include tests predictive of risk for osteoporosis, coronary artery disease and a test to determine the best drug treatment for advanced cases of rheumatoid arthritis.

We have also developed and licensed medical research tools, including BioFusion®, to pharmaceutical and biotech companies. BioFusion is a computer modeling system that integrates genetic and other sub-cellular behavior, biological functions, and clinical symptoms to simulate complex diseases. This system allows useful information to be derived from rapidly increasing databases of gene expression being generated in companies and academic centers worldwide. We are currently developing new medical research tools which we hope will contain detailed information regarding variations in the Interleukin-1 (IL-1) gene cluster and the Tumor Necrosis Factor Alpha (TNFα) as they relate to human inflammatory processes and diseases.

In August 2000, we entered into an agreement with Kenna Technologies, Inc. ("Kenna") whereby we granted Kenna a perpetual, non-exclusive license to certain disease information system technology and to certain biological modeling technology, including our Biofusion system. In consideration for these license rights, Kenna paid us a non-refundable initial licensing fee of $80,000 and has agreed to pay royalties based upon net sales from certain of the licensed technology, as defined, for periods ranging from five to ten years.

We have followed a strategy of working with strategic 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 a strategic alliance with the Department of Molecular and Genetic Medicine at Sheffield University ("Sheffield") in the United Kingdom. Under this alliance, Sheffield has provided us with the fundamental discovery and genetic analysis from their research laboratories, and we have focused on product development, including clinical trials, and the commercialization of these discoveries.

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 the PST test in all countries outside of North America and Japan. Hain has extensive experience in commercializing genetic tests on its DNA-STRIP Technology Platform in several fields as well as a specific commitment to marketing products directly to dentists. Hain's central facility offers excellent turnaround times, high quality laboratory operations and a

sales and technical staff to support clinical users. We can terminate this agreement if certain minimum sales levels are not met.

In March 1999, we had entered into an exclusive agreement with the Straumann Company, a leading supplier of dental implants, to market and sell PST in the United States and Puerto Rico. In September 2000, we amended this agreement to be non-exclusive and we entered an agreement with Kimball Genetics, Inc. for Kimball to process and analyze all PST tests in the United States and Puerto Rico. In December 2001, the agreement with Straumann expired and was not renewed. Kimball is now our sole marketing partner within the United States. We believe that through our partners we have adequate coverage in the sales, distribution and processing of PST. We do not expect the expiration of the Straumann contract to have any impact on sales levels.

During 2000, we changed our strategy for marketing and distributing PST. We no longer market, distribute or process PST ourselves. We now use third party marketers and distributors from whom we earn royalties. We believe that while this has reduced revenues in the short-term it has also improved margins and reduced operating costs.

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. 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.

Current Financial Condition

Since inception, we have incurred cumulative net losses of approximately $30.5 million, including losses of approximately $4.5 million during 2001. For the year ended December 31, 2001, we had negative cash flows from operating activities of approximately $4.5 million and at December 31, 2001 we had cash and cash equivalents of approximately $3.9 million.

In January 2001, we sold in a private placement 1.2 million shares of Common Stock for $2.50 per share. The purchasers of the common stock also received warrants to purchase 600,000 shares of Common Stock exercisable at $3.00 per share. We generated net proceeds of approximately $2.9 million from this transaction. Under the terms of this private placement we are required to adjust downward the price per share paid in the offering, by issuing additional shares, to match any offering price paid in subsequent offerings during the following 24 months.

In December 2000, we sold in a private placement 542,373 shares of Common Stock at $3.69 per share. The purchasers of the common stock also received warrants to purchase 135,593 shares of Common Stock exercisable at $4.83 per share. We generated net proceeds of approximately $1.9 million from this transaction. Under the terms of this private placement we are required to adjust downward the price per share paid in the offering, by issuing additional shares, to match any offering price paid in subsequent offerings during the following 24 months. Following the January 2001 offering, described above, we issued an additional 257,627 shares of common stock to the purchasers in the December 2000 offering, and new warrants to purchase 264,407 shares of Common Stock exercisable at a price of $3.13 to replace the previously issued warrants to purchase 135,593 shares of Common Stock.

In January 2000, we sold in a private placement 832,667 shares of Common Stock for a price of $6.00 per share in a private placement. We generated net proceeds of approximately $4.7 million from this transaction.

We anticipate that our existing cash and cash equivalents, together with anticipated revenue and interest income will be sufficient to conduct operations as planned only until approximately September 2002. As a result, there is significant doubt about our ability to continue as a going concern. Our future capital requirements are anticipated to be substantial, and we do not have commitments for additional capital at this time. Such capital requirements are expected to arise from the commercial launch of additional genetic tests, continued research and development efforts, the protection of the intellectual property rights (including preparing and filing of patent applications), as well as operational, administrative, legal and accounting

expenses. THERE IS NO ASSURANCE THAT WE WILL BE ABLE TO RAISE ADDITIONAL CAPITAL ON TERMS ACCEPTIBLE TO US, IF AT ALL. IF ADDITIONAL AMOUNTS CANNOT BE RAISED AND WE ARE UNABLE TO SUBSTANTIALLY REDUCE OUR EXPENSES, WE WOULD SUFFER MATERIAL ADVERSE CONSEQUENCES TO OUR BUSINESS, FINANCIAL CONDITION AND RESULTS OF OPERATIONS AND WOULD LIKELY BE REQUIRED TO SEEK OTHER ALTERNATIVES UP TO AND INCLUDING PROTECTION UNDER THE UNITED STATES BANKRUPTCY LAWS.

Strategy

Our objective is to be a leading genetics research and development company focused on the discovery and development of risk assessment and risk stratification tests and to improve health outcomes by linking these tests to therapeutic interventions. We are also focused on developing genetic tests that help identify patients most likely to respond to a specific drug. Our strategy is to develop products for research and clinical use and to commercialize these products through strategic collaborations. These products will include tests that are predictive of disease risk and that identify patients' response to therapy and functional biological information for use in drug development. We intend to generate testing revenues, licensing fees, research and development funding, and fee-for-service or participatory revenues pursuant to contracts with our collaborative partners. In the long term, we believe we will generate royalty payments from our corporate partners for new genetic tests and therapeutic products. We believe that this strategy allows us to generate near-term revenues and diversify risk, while building a proprietary product portfolio with significant long-term potential. One of our core strengths is our ability to identify genetic variations, or markers, and correlate them to clinical utility in a wide range of common chronic diseases.

Development System and Approach

Many factors, both environmental and genetic, contribute to most common diseases. Importantly, some genetic factors are sufficiently strong that they influence the onset and progression of a disease despite many other variables. These genetic factors control aspects of the biology that have high leverage on the disease. We have focused our research and product development efforts on genetic factors that significantly influence the clinical course of common, chronic diseases.

The body responds to various challenges by means of chemicals produced by the cells. One of the first chemicals produced following any stimulus is IL-1. It then activates multiple biochemical reactions that lead to inflammation, wound healing, bone and tissue growth and repair, and many other biological processes. IL-1 therefore has great leverage on other parts of the biology. We have identified variations in the IL-1 genes that either amplify or decrease the biological processes that are switched on by IL-1, thereby providing ways to predict who is more susceptible to certain chronic diseases and providing novel opportunities to select optimal drug therapy and design new drugs.

PRODUCT PIPELINE AND PROPRIETARY POSITION

GENETIC TESTING

Risk Assessment Tests

We have completed clinical trials and patent applications have been filed or patents have been issued on the role of genetic factors in several diseases, however, in the short-term we are focusing our development efforts only in the areas of cardiovascular disease and osteoporosis. We introduced PST, a test predictive of disease risk for severe gum diseases (periodontitis), commercially in the U.S. in the fourth quarter of 1997. Clinical trials are ongoing in the area of cardiovascular disease and osteoporosis. We expect one or more of these studies will be completed by the end of 2002.

Risk Stratification Tests

A second area that we believe has great promise is the area of stratifying the risk among patients with a particular disease or condition to predict which patients will develop complications from their condition and

which will not. We are currently developing a test that we believe will allow physicians to determine which diabetic patients are at high risk of developing complications associated with cardiovascular disease.

Pharmacogenetics Tests

Pharmacogenetics is the linking of specific therapies to specifics in genetic code. We believe that Pharmacogenetics represents the future of medicine. With Pharmacogenetics, in the future, instead of all patients at a specific stage of disease receiving the same treatment, a patient may be able to first receive a genetic test to predict which treatment will be most effective.

We are currently developing a test to determine the best treatment for patients in advanced stages of rheumatoid arthritis. We intend to do the development work with a large health management organization and other academic institutions during 2002 and a portion of 2003. We expect clinical trials to begin early in 2002.

THERAPEUTICS

We are very interested in the prospect of developing therapeutics that will be effective in the treatment of persons of a particular genotype. We are actively investigating possible candidate compounds for those that may be most promising to bring to market. These compounds may come from several sources, including, (i) off-patent drugs that can be re-patented as a treatment for a specific genotype, (ii) drugs that have failed their Phase III clinical trials because they did not prove efficacious for the general population but might gain approval if we were able to identify the specific patients for whom it will work or (iii) new chemical entities which our greater understanding of genetics may allow us to develop.

PHARMACOGENETIC TOOLS

We believe that the knowledge we have developed over the past several years regarding the IL-1 gene cluster and other gene clusters can be developed into a tool for researchers involved in study of inflammation and genetics and how they relate to risk of disease and drug responses. We have developed and licensed medical research tools, including our proprietary BioFusion system, to pharmaceutical and biotech companies. We are currently receiving license and royalty revenues from the sale of BioFusion. We are also developing a computer model containing detailed structure, function and variation information of the IL-1 gene cluster as they relate to human inflammatory processes and diseases.

In each clinical disease field, our development program is focused on understanding how genetic risk factors relate to overall risk for the disease and establishing clear links to treatment. By combining genetic risk assessment with specific therapeutic strategies, we believe improved clinical outcomes and more cost-effective management of these common diseases can be achieved. These genetic factors are also of value in both identifying response patterns during clinical trials for the enhancement of existing therapeutic agents and for developing new therapeutics directed at specific immuno-inflammatory components of several common diseases.

We have spent $2,687,000, $2,167,000 and $3,571,000 on research and development during the years ended December 31, 2001, 2000 and 1999, respectively.

Clinical Utility

We believe in the advantages a genetic approach to medicine offers in the prevention, management and treatment of disease. We believe our predictive tests and research tools are of value to:

- Pharmaceutical companies, that may use them to speed new drug development, to improve the efficacy of their drugs, to develop new therapeutics and to target patients most likely to respond to their drugs.
- Payors and organizations that provide health care services, which may use them to stratify patients by risk and more effectively allocate resources for the greatest benefit.
- Physicians and other healthcare professionals, who may use this information to assess the risk involved for their patients and adopt appropriate treatments or preventive strategies.

- Patients committed to staying healthy, who may use this information to make better choices and set priorities based on personal knowledge of their individual risk for common diseases.

PRODUCT ON THE MARKET

Test Predictive of Disease Risk for Periodontal Disease

Our first genetic susceptibility test, PST, identifies patients at risk for 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.

PST is the result of a scientific breakthrough in which an association was discovered between a specific IL-1 genetic marker (i.e., a genetic variation or polymorphism associated with increased disease incidence or severity) and severe periodontal disease. IL-1 is a cytokine or 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 and our experience to date, we estimate that approximately 30% of the population will test positive for this genotype.

We have developed PST under the terms of a project agreement with Sheffield University. In November 1997, a patent related to the detection of genetic predisposition to periodontal disease was issued to the Company. We initiated commercial sales of PST in October 1997. In December 1998, we entered into an agreement with Washington Dental Service, a member of Delta Dental Plans Association, for the purchase of 1,200 PST tests to be used in a study sponsored by Washington Dental Service, in collaboration with the University of Washington School of Dentistry. The study is designed to quantify the relationship between PST genotype status and the utilization of dental services by patients in a dental plan. The study, which began in early 1999, was completed during 2001. The data from this study are currently being analyzed. It is hoped this data will provide scientific and financial information about PST in a reimbursement system. If patients who are at increased risk for periodontal disease can be identified early using PST, services can be provided which could minimize the progression of disease and the cost and complications of its consequences. The most costly dental procedures are usually those associated with tooth loss due to advanced disease (i.e., bridges, partial dentures, implants, etc.). Therefore, we believe early identification and intervention of high-risk patients is in the patients' and payer's best interest. We believe that the results of this study will provide important scientific and financial data regarding the use of PST as a treatment- planning tool to assess risk before actual damage occurs.

We are currently evaluating the use of PST as a tool to determine which patients with gingivitis or early periodontitis should increase their frequency of dental visits. We believe that not all patients with early signs of disease will develop the full level of periodontitis in a short period of time. We believe that PST can identify the patients most likely to have a high trajectory of the disease.

PRODUCTS UNDER DEVELOPMENT

Test Predictive of Disease Risk for Osteoporosis

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 18 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. Direct financial expenditures for the treatment for osteoporotic fractures are estimated at $10 to $15 billion annually in the United States alone.

We have conducted several collaborative research projects with major osteoporosis epidemiologic centers. Results of these studies have indicated 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 fracture in post-menopausal women. Currently, we are confirming these results by additional, focused studies with national and international osteoporosis epidemiologic study centers, with the ultimate objective of developing a genetic predisposition test to determine a woman's risk for vertebral fracture.

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 will enable therapeutic intervention or recommendations for changes in lifestyle or diet at an early stage, so that bone loss and fracture is minimized or prevented.

We have completed extensive market research analyses, involving women's focus groups, physician's and consumer's surveys which show there is enthusiasm for such a test.

By the end of 2002, we anticipate completing one or more clinical studies to confirm our initial results of association of polymorphisms in the IL-1 gene cluster with signs and symptoms of osteoporosis.

Test Predictive of Disease Risk for Complications from Diabetes

Another genetic susceptibility test we are currently developing is a test to determine susceptibility to complications from diabetes. These complications include increased risk of cardiovascular disease, susceptibility to sight-threatening retinopathy, kidney disease, and neuropathy, a nerve disease that can result in the need to amputate a foot or leg.

Diabetes mellitus is among the most serious and common chronic diseases in the world today. Although the name implies to many people simply a problem with "sugar in the blood", the true health burden of diabetes is enormous. In fact, diabetes mellitus is a serious metabolic disorder that puts people with the disease at substantially increased risk of cardiovascular disease and specific complications to the eyes, kidneys and nervous system. According to the American Diabetes Association, people with diabetes are 2-4 times more likely to have heart disease and 2-4 times more likely to experience a stroke. Diabetes is the leading cause of blindness among adults ages 20-40 and is the leading cause of end stage kidney disease leading to dialysis. In addition, more than 56,000 people lose their foot or leg to diabetes each year.

Along with the extensive health problems of diabetes comes a staggering economic burden. Diabetes affects approximately 16 million people in the United States alone, almost 6% of the population. The American Diabetes Association reports that total costs of diabetes care in 1997 were approximately $98 billion with per capita health costs for those with diabetes nearly fourfold the costs for people without diabetes. Since the incidence of diabetes increases with age, the continual aging of the "baby boom" population is expected to continue to substantially expand the number of individuals with diabetes over the coming decades. We are working with leaders in the field of diabetes to develop a genetic test that we believe will aid in identifying people with diabetes who are at particularly high risk of experiencing the severe and costly complications of the disease. By identifying these individuals earlier than we can currently, better-targeted therapy may be started sooner in an effort to delay, or prevent, the complications before they develop.

If our diabetes program is successful we expect to have a test predictive of cardiovascular complications from diabetes on the market early in 2003.

Test to Determine the Most Effective Treatment for Rheumatoid Arthritis

Rheumatoid Arthritis is a disease that affects approximately 2.1 million Americans. The most common sufferers are women between the ages of 25 and 40 years old. According to the Arthritis Foundation 50% of people with rheumatoid arthritis are on disability within ten years of the conditions onset. The final drug treatments that are usually prescribed by physicians for patients with RA are anticytokine treatments.

We are currently developing a test that we believe may help rheumatologists select the best anticytokine therapy for each rheumatoid patient. Different anticytokine therapies act very differently on a patient's biology. Two of the three anticytokine therapies used to treat Rheumatoid Arthritis are anti-TNFα drugs; the other affects the IL-1 gene. We believe that depending upon the specific genetics of individual patients, it can be predicted which class of drug would be most effective. Neither class of drug works for all individuals and the cost of prescribing the incorrect drug is very high in terms of both pain and suffering for the patient and increased cost of medical intervention.

We believe this test represents an excellent example of what the future of personalized medicine may look like, with physicians first conducting genetic tests to determine the best course of treatment before prescribing expensive, invasive therapies that often may not be fully effective.

Knowledge Database

We believe that the proprietary information and knowledge base we have developed over the past several years regarding the IL-1 gene cluster and other gene clusters can be developed into a tool for researchers involved in study of inflammation, genetics and how these relate to risk of disease and to drug responses. We are developing a user-friendly, web-based knowledge tool containing detailed structure, function and variation information of the IL-1 gene cluster and other genes critical to the range of human inflammatory processes. This tool, as we are developing it, will combine our extensive proprietary database with selected non-proprietary data to create a comprehensive base of knowledge. We plan to continue to develop this knowledge base on the IL-1 and other regions of genetic code during 2002. We plan to begin marketing access to this knowledge base to academic researchers, pharmaceutical and biotechnology companies, drug manufacturers and nutraceutical companies as a research tool in the near future.

Testing Procedure

Each of our genetic susceptibility tests requires dentists or physicians to follow a specific protocol. To conduct a genetic susceptibility test, the doctor does a sample cheek swab and submits it to the laboratory of our strategic partner. The laboratory then performs the test following our specific protocol and informs the dentist or physician of the results. The dentist/physician in turn, informs the patient and determines the appropriate course of action.

Pre-Marketing Trials/Status of Predictive Tests

As an internal procedural standard, we conduct three categories of clinical trials in conjunction with our genetic susceptibility tests. The first trial is called a proof of principle 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 principle trial. The third category of 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.

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 (i.e., detecting genetic susceptibility) but also lead to additional practical uses of the susceptibility tests (e.g., use of the susceptibility tests to determine a patient's responsiveness to a given drug).

Product Development

We have ongoing research to continue to identify other genetic factors that appear to be associated with other diseases. We plan on filing additional patent applications to cover these discoveries. It is our intent to bring these discoveries to market in the form of tests predictive of disease risk or medical research tools.

We have also come upon certain genetic factors that might be likely candidates to serve as therapeutic targets. Drug agents might act upon these genetic factors to reduce or increase biological actions to assist in the treatment of diseases or disease symptoms. We are considering certain collaborative long-term relationships with pharmaceutical companies as a method to provide for either the licensing of these discoveries or to assist in the research and development of future products.

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. This strategy has given us access to discoveries while reducing up-front research expenses.

SHEFFIELD UNIVERSITY

Since 1994, we have had a strategic alliance with the Department of Molecular and Genetic Medicine at Sheffield University in the United Kingdom ("Sheffield"). Sheffield is a world leader in the genetic aspects of common diseases with an inflammatory component. Under this alliance, Sheffield has provided to us the fundamental discovery and genetic analysis from Sheffield's research laboratories and we have focused on product development, including clinical trials, and the commercialization of these discoveries.

In October 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 this new 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, this agreement requires 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 is in place. Sheffield is entitled to additional options to purchase 10,000 shares of stock at the current market price each June 30th for each patent that is filed on our behalf during the previous twelve months.

DELTA DENTAL

In December 1998, we signed an agreement with Washington Dental Service, a member of the Delta Dental Plans Association, for the purchase of 1,200 PST tests. The tests were used be used in a study, sponsored by Washington Dental Service, in collaboration with the University of Washington School of Dentistry and us. The study was designed to quantify the relationship between PST genotype status and the utilization of dental services by patients in a dental plan.

The study began in March 1999 and was completed in July 2001. It is expected to provide scientific and financial information about PST in a reimbursement system. This study is also expected to provide scientific and financial data regarding the use of PST as a treatment-planning tool to assess risk. The data from the study are currently being analyzed.

KENNA TECHNOLOGIES, INC.

In November 2000, we issued to Kenna Technologies, Inc a non-exclusive license for the worldwide commercialization of our patented Biological Disease Modeling System, BioFusion, and its user interface technologies, the Integrated Disease Information System (IDIS). The transaction included an upfront license fee and royalties based upon sales of the product. Currently, Kenna is offering BioFusion tools for the research exploration of bone remodeling and metabolism (e.g. osteoporosis, periodontal disease), middle ear infections and certain cancers.

KAISER PERMANENTE

In December 2001, we entered into a research collaboration with Kaiser Permanente's Center for Health Research to study genetic risk factors for chronic diseases that are affected by inflammation. We believe that

knowledge resulting from this work will enable us to develop new diagnostic tools that physicians and health care organizations can use to assess their patients' genetic risk for many diseases. The first product to be developed under this collaboration will be a test to assess the risk of cardiovascular complications from diabetes. We expect this program to be completed by the end of 2002. We expect that we will be performing additional studies with Kaiser during 2002.

PST COMMERCIAL PARTNERSHIPS

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. Hain has extensive experience in commercializing genetic tests on its DNA-STRIP Technology Platform in several fields as well as a specific commitment to marketing products directly to dentists. Hain's central facility offers excellent turnaround times, high quality laboratory operations and a sales and technical staff to support clinical users. We can terminate this agreement if certain minimum sales levels are not met.

In March 1999, we had entered into an exclusive agreement with the Straumann Company, a leading supplier of dental implants, to market and sell PST in the United States and Puerto Rico. In September 2000, we amended this agreement to be non-exclusive and we entered an agreement with Kimball Genetics, Inc. to process and analyze all PST tests in the United States and Puerto Rico. In December 2001, the agreement with Straumann expired and was not renewed. Kimball is now our sole marketing partner within the United States. We believe that through our partners we have adequate coverage in the sales, distribution and processing of PST. We do not expect the expiration of the Straumann contract to have any impact on sales levels.

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 nine issued U.S. patents, which have projected expiration dates between 2015 and 2018 and have 20 pending U.S. patent applications, which are based on novel genes or novel associations between particular gene sequences and certain inflammatory diseases, and disorders. Of the nine issued patents, six relate to genetic tests for periodontal disease, osteoporosis, asthma, coronary artery disease, sepsis and disease associated with IL-1 inflammatory haplotypes and three relate to BioFusion, our biologic modeling software.

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 susceptibility test. Our proprietary technology is subject to numerous risks, which we discuss in "Factors Affecting Future Performance" beginning on page 12 of this report.

Competition

The genetics field is broad with diverse business segments. The field may be generally segmented into: a) services, including sequencing, informatics, etc.; b) technology platforms, including chip makers, genotyping equipment, etc.; c) drug target and drug development companies; d) diagnostic companies that will distribute DNA tests, and e) content companies that will discover genes and gene variations that influence diseases and drug responses.

We are involved in the discovery and commercialization of genetic variations that influence inflammatory diseases and the therapeutic responses to these diseases. Despite this segment's relatively young age, other companies do exist which have research programs seeking disease related genes for therapeutic and susceptibility testing purposes, including some that involve treatable/preventable disease. The technologies for discovering genes which predispose individuals to major diseases and approaches for commercializing those discoveries are new and rapidly evolving. Rapid technological developments could result in our potential

services, products, or processes becoming obsolete before we recover a significant portion of the related research and development costs and capital expenditures.

Our 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, including those receiving funding from the Human Genome Project. The following list of companies may be considered a partial list of our potential competitors: Myriad Genetics, Millennium Predictive Medicine, Genaissance Pharmaceuticals, Variagenics and Oxagen. Myriad has a test for breast cancer and has announced research programs for osteoporosis and coronary artery disease. Many of our potential competitors have considerably greater financial, technical, marketing and other resources than us, 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 the Human Genome Project. The Human Genome Project is a federally funded program focused on sequencing the human DNA and enriching the sequence data with information about its biological function. To the extent our competitors receive data and funding from the Human Genome Project 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 susceptibility tests) multiple competitors may accelerate market acceptance and penetration through increasing awareness. Moreover, two different genetic susceptibility 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 each of the above-referenced companies is performing gene-identification research for pharmaceutical companies for therapeutic purposes, with genetic susceptibility testing being a secondary goal. In contrast, our primary business focus is developing and commercializing genetic susceptibility tests for common diseases, with only an ancillary drug discovery program.

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 the auspices of the Clinical Laboratory Improvement Act of 1988 ("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 susceptibility 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 susceptibility 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.

Employees

As of March 18, 2002, we had 20 full-time and part-time employees. Of our employees, 13 are engaged directly in the research, development and commercialization of tests and 7 are engaged 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.

Factors Affecting Future Performance

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 financial resources are adequate to maintain our current and planned operations through September 2002. If we cannot raise additional capital prior to September 2002, we will be unable to fund our business operations and will be required to seek other strategic alternatives or we will be required to declare bankruptcy.

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.

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 the foreseeable future. We incurred losses from operations of $6.2 million in 1999, $5.2 million in 2000 and $4.8 million in 2001. As of December 31, 2001, our accumulated deficit was $35.5 million. Our losses result primarily from research and development and selling, general and administrative expenses. We have not generated significant revenues from product sales, and we do not know if we will ever generate significant revenues from product sales. We will need to generate significant revenues to continue our research and development programs and achieve profitability. We cannot predict when, if ever, we will achieve profitability.

THE MARKET FOR GENETIC SUSCEPTIBILITY TESTS IS UNPROVEN

The market for genetic susceptibility tests is at an early stage of development and may not continue to grow. Both we and the general scientific community have 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 susceptibility test we currently market is PST, and it has produced only minimal revenues 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 susceptibility tests.

The success of our genetic susceptibility 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 payors, such as insurance companies and the government. We can achieve broad market acceptance only with substantial education about the benefits and limitations of genetic susceptibility 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 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 susceptibility 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 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.

WE RELY HEAVILY ON THIRD PARTIES TO PERFORM RESEARCH AND DEVELOPMENT ON OUR BEHALF, WHICH COULD LIMIT OUR EFFORTS TO SUCCESSFULLY DEVELOP PRODUCTS

We have limited research and development capabilities. In July 1999, we entered into a new contractual arrangement with the University of Sheffield, replacing the research and development agreement that had been in place since 1996. Under our arrangement with Sheffield, we will undertake the business development and commercialization of discoveries resulting from Sheffield's research. The agreement is non-cancelable for those discoveries on which Sheffield and we have reached a specific business development agreement, but otherwise either party can end the arrangement upon six months' notice. This agreement with Sheffield has a five-year term with an automatic yearly renewal. As part of this arrangement, we issued an aggregate of 475,000 shares of our common stock to Sheffield and its researchers in exchange for patent rights and other interests held by Sheffield and its researchers under our previous project agreements. Our agreement with Sheffield requires us to fund agreed upon research and development activities at the University of Sheffield on our behalf based upon annual budgets. We also entered into a five-year consulting agreement with Sheffield's key collaborator, Dr. Gordon Duff.

Reliance on third-party research and development entails risks we would not be subject to if we performed this function ourselves. These risks include reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of agreements by third parties because of factors beyond our control and the possibility of terminations or nonrenewals of agreements by third parties, based on their own business priorities, at times that are costly or inconvenient for us. We may in the future elect to perform all research and development ourselves, which will require us to raise substantial additional funds and recruit additional qualified personnel.

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 Sheffield 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 PAYORS, THEN OUR PRODUCTS AND SERVICES WILL NOT BE COMMERCIALLY VIABLE

The availability and levels of reimbursement by governmental and other third-party payors affect the market for any healthcare service. These third-party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for medical products and services. Our ability to successfully commercialize our existing genetic susceptibility test and others that we may develop depends on obtaining adequate reimbursement from third-party payors. The extent of third-party payor reimbursement will likely heavily influence physicians' and dentists' decisions to recommend genetic susceptibility 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 payors 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 payors have agreed to reimburse patients for genetic susceptibility tests, and we do not know if third-party payors will, in the future, provide full reimbursement coverage for these genetic tests. If third-party payors do not provide adequate reimbursement coverage, then individuals may choose to directly pay for the test. If both third-party payors and individuals are unwilling to pay for the tests, then the number of tests we can sell will be significantly decreased, resulting in reduced revenues 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 nine issued U.S. patents and have 20 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 which 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, we or our collaborators 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 BE OBSOLETE

Our competitors may develop susceptibility 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 DELISTED FROM NASDAQ RESULTING IN A LIMITED PUBLIC MARKET FOR OUR COMMON STOCK AND VOLATILITY IN OUR STOCK PRICE

Our common stock is currently listed on the Nasdaq SmallCap Market and the Boston Stock Exchange. During 1999, we received several notices from Nasdaq stating that we were not in compliance with their continued listing requirements. In addition, the price of our common stock has been extremely volatile and has at times fallen below Nasdaq's $1.00 minimum bid price requirement. If our stock price is below the minimum bid price requirement for 30 consecutive trading days, we would have 180 days to regain compliance with this requirement or face delisting. Accordingly, we may not be able to maintain our continued listing on the Nasdaq or the Boston Stock Exchange.

If Nasdaq or the Boston Stock Exchange delists our shares, then trading would be conducted in the over-the-counter market in the so-called "pink sheets" or the OTC Bulletin Board. Selling our common stock will be more difficult because of reduced trading volume and transaction size, transactions could be delayed, and security analysts' and news media's coverage, if any, of ILGN will be reduced. These factors may result in lower prices and larger spreads in the bid and ask prices for our shares. The delisting of our shares would also greatly impair our ability to raise additional necessary capital through equity or debt financing.

Historically, our common stock has experienced low trading volumes. The market price of our common stock has been highly volatile, and it may continue to be highly volatile, as has been the case with the securities of other public biotechnology companies. Factors such as announcements by us or by our competitors concerning technological innovations, new commercial products or procedures, proposed government regulations and developments or disputes relating to patents or proprietary rights are likely to affect the market price of our common stock. Changes in the market price of our common stock may bear no relation to our actual operational or financial results.

WE HAVE COMPLETED FINANCIAL TRANSACTIONS THAT MAY REQUIRE US TO ISSUE MORE SHARES TO EXISTING SHAREHOLDERS WHICH WILL DILUTE THE VALUE OF THE STOCK

In December 2000 and January 2001 we sold in private placements a total of 2 million shares of our common stock for $2.50 per share and warrants to purchase 864,407 shares of common stock exercisable at $3.00 and $3.13. Under the terms of these private placements we are required to adjust downward the price per share in the offering, by issuing additional shares, to match any offering price paid in subsequent offerings during a 24-month period following completion of the private placements. The price of our common stock has been volatile and has recently been trading at or below $1.00 per share. This low share price will make it very difficult to raise additional capital at a price matching that of the private placements. Therefore, it is likely that we will need to issue additional shares to the purchasers in these offerings, if we are to raise additional capital. This might significantly dilute the value of the outstanding common stock.

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, 2001, we had net operating loss carryforwards of approximately $27.9 million for federal and state income tax purposes, expiring in varying amounts through the year 2021. We also had a research tax credit of approximately $397,000 at December 31, 2001, that expires in varying amounts through the year 2021. 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 experienced a change in ownership interest in June 1999. As a result, approximately $15.6 million of our net operating loss carryforwards are limited in utilization to approximately $825,000 annually. 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 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, in conjunction with the University of Sheffield, do not discover disease predisposing genes and commercialize these discoveries before our competitors, then our ability to generate sales and revenues 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 analysis 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 susceptibility 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 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 susceptibility 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 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 health care companies, as well as universities and nonprofit research organizations in the highly competitive Boston, Massachusetts business area. Loss of the services of Dr. Philip R. Reilly, our Chairman and CEO, Dr. Kenneth Kornman, our President, or Dr. Paul M. Martha, our Chief Medical Officer, could delay our research and development programs and damage our business. We have entered into employment agreements with three to five year terms with Drs. Reilly, Kornman and Martha. Any of these employees can terminate his employment upon 30 days notice. We do not maintain key man life insurance on any of our personnel.

BECAUSE OUR PRINCIPAL SHAREHOLDERS, OFFICERS AND DIRECTORS CONTROL A LARGE PERCENTAGE OF OUR VOTING POWER, OTHER STOCKHOLDERS' VOTING POWER MAY BE LIMITED

As of February 28, 2002, our directors, executive officers and certain of their affiliates beneficially owned approximately 18% of our outstanding common stock. Accordingly, these shareholders, individually and as a group, may be able to influence the outcome of shareholder 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. These shareholders may make decisions that are adverse to other shareholders' interests. This ownership concentration may also adversely affect the market price of our common stock.

WE DO NOT EXPECT TO PAY DIVIDENDS FOR THE FORESEEABLE FUTURE AND YOU SHOULD NOT EXPECT TO RECEIVE ANY FUNDS WITHOUT SELLING YOUR SHARES, 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***

In 2000 we completed a move of our Corporate and Research and Development offices from San Antonio, Texas to Waltham, Massachusetts. Our offices are located at 135 Beaver Street and contain approximately 6,000 square feet of space. Our lease on this space expires in June 2006.

Our former corporate headquarters and research and development offices, located at 100 N.E. Loop 410, Suite 820, San Antonio, Texas, contain 8,131 usable square feet held under a lease expiring May 31, 2003 and has been subleased by us until the expiration of this lease.

Item 3. ***Legal Proceedings***

We are not currently a party to any material legal proceedings.

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, 2001.

PART II

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

Market Information

The Company's 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, the Company's Common Stock symbol changed to "ILGN" on the NASDAQ SmallCap Market and "ILG" on 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 bid prices for the Common Stock, as reported by the NASDAQ SmallCap Market.

	High	Low
2001:		
First Quarter	$3.594	$1.344
Second Quarter	$3.150	$1.125
Third Quarter	$3.100	$1.390
Fourth Quarter	$2.250	$1.100
2000:		
First Quarter	$8.000	$6.060
Second Quarter	$0.563	$3.000
Third Quarter	$6.500	$3.125
Fourth Quarter	$5.000	$2.250

NUMBER OF SHAREHOLDERS

As of March 18, 2002, there were approximately 140 record holders of the Company's Common Stock.

Dividends

The Company has not declared any dividends to date and does not plan to declare any dividends on its common stock in the foreseeable future.

Sale of Unregistered Securities

On July 1, 2001, the Company issued an option to purchase 35,000 shares of common stock, $.001 par value (the "Sheffield Option"), at a per share exercise price of $2.85 to the University of Sheffield, U.K. ("Sheffield") and an option to purchase 25,000 shares of common stock, $.001 par value (the "Duff Option"), at a per share exercise price of $2.85 to Sheffield's key investigator, Dr. Gordon Duff. The Sheffield Option was issued pursuant to the Company's collaborative arrangement with Sheffield and the Duff Option was issued pursuant to a consulting agreement between the Company and Dr. Duff. Under the terms of the arrangement with Sheffield, the Company is to grant to Sheffield on each July 1 during the term of the arrangement options to purchase 25,000 shares of common stock of the Company and options to purchase an additional 10,000 shares of common stock of the Company for each patent application filed during the preceding 12 months. Under the terms of the consulting agreement with Dr. Duff, the Company is obligated to grant Dr. Duff on each July 1 during the term of the agreement options to purchase 25,000 shares of common stock of the Company. The Sheffield Option and the Duff Option are exercisable for a period of five years from the date of grant. The Sheffield Option and Duff Option were not registered under the Securities Act of 1933, as amended (the "Securities Act"), pursuant to Section 4(2) of the Securities Act and Regulation D promulgated thereunder, and pursuant to Rule 903 and Rule 904 of regulation S. The Company relied on certain representations and warranties of Sheffield and Dr. Duff, including among other things, their ability to evaluate the merits and risks of an investment in the Company's securities, their status as "accredited investors" (as that term is defined in Rule 501 (a) of Regulation D), that their residence, domicile and/or principal corporate office is Sheffield, England and the securities were acquired solely for their own account for investment and not with a view to distribution..

Item 6. *Selected Financial Data*

The following table sets forth financial data with respect to the Company as of and for each of the five years ended December 31, 2001. The selected financial data as of and for each of the five years ended December 31, 2001 have been derived from the financial statements of the Company. The financial statements and the related reports as of December 31, 2001 and 2000 and for the years ended December 31, 2001, 2000 and 1999 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,				
	2001	2000	1999	1998	1997
Statement of Operations Data:					
Revenue	$ 202,942	$ 256,387	$ 477,497	$ 412,942	$ 197,928
Cost of Revenue	48,674	183,833	201,182	216,284	168,442
Gross Profit	154,268	72,554	276,315	196,658	29,486
Operating Expenses:					
Research and development	2,686,621	2,167,409	3,570,845	2,799,220	1,223,468
Selling, general and administrative	2,244,274	3,093,379	2,904,210	7,220,444	2,868,057
Total operating expenses	4,930,895	5,260,788	6,475,055	9,999,664	4,091,525
Loss from operations	(4,776,627)	(5,188,234)	(6,198,740)	(9,803,006)	(4,062,039)
Other income (expense):					
Interest income	263,435	280,298	107,446	379,054	53,889
Interest expense	(9,818)	(22,514)	(59,189)	(94,597)	(485,062)
Other income (expense)	304	(48,377)	11,880	10,274	—
Net loss	$(4,522,706)	$(4,978,827)	$ (6,138,603)	$(9,508,275)	$(4,493,212)
Beneficial conversion attributable to preferred stock	—	—	(5,000,000)	—	—
Net loss applicable to common stock	$(4,522,706)	$(4,978,827)	$(11,138,603)	$(9,704,415)	$(4,493,212)
Basic and diluted net loss per common share	$ (0.21)	$ (0.27)	$ (1.15)	$ (1.75)	$ (1.19)
Weighted average common shares outstanding	21,049,437	18,315,320	9,720,621	5,540,895	3,773,474

	As of December 31,				
	2001	2000	1999	1998	1997
Selected Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$3,922,736	$5,390,601	$2,656,116	$2,432,271	$1,212,772
Working capital	3,270,667	4,457,828	1,967,943	1,462,748	11,186,863
Total assets	4,393,126	5,694,511	3,176,159	3,672,890	12,823,376
Long term debt and capital lease obligations, less current portion	11,091	46,989	99,246	604,507	580,739
Stockholders' equity	3,550,548	4,493,805	2,153,178	1,846,348	11,286,889

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

General Overview

Interleukin Genetics, Inc., a Delaware corporation ("ILGN" or the "Company"), is a functional genomics company focused on personalized medicine. We believe that by identifying individuals at risk for

certain diseases and combining this knowledge with specific therapeutic interventions, better healthcare decisions can be made, reducing costs and greatly improving patient health outcomes. We have a growing portfolio of patents covering the genetics of a number of common diseases and conditions.

Our first genetic test, PST®, a test predictive of risk for periodontal disease, is currently marketed in the United States and Europe. Other products under development include tests predictive of risk for osteoporosis, coronary artery disease and a test to determine the best drug treatment for advanced cases of rheumatoid arthritis.

We have also developed and licensed medical research tools, including BioFusion®, to pharmaceutical and biotech companies. BioFusion is a computer modeling system that integrates genetic and other sub-cellular behavior, biological functions, and clinical symptoms to simulate complex diseases. This system allows useful information to be derived from rapidly increasing databases of gene expression being generated in companies and academic centers worldwide. We are currently developing new medical research tools which we hope will contain detailed information regarding variations in the Interleukin-1 (IL-1) gene cluster and the Tumor Necrosis Factor Alpha (TNF∝) as they relate to human inflammatory processes and diseases.

In August 2000, we entered into an agreement with Kenna Technologies, Inc. ("Kenna") whereby we granted Kenna a perpetual, non-exclusive license to certain disease information system technology and to certain biological modeling technology, including our Biofusion system. In consideration for these license rights, Kenna paid us a non-refundable initial licensing fee of $80,000 and has agreed to pay royalties based upon net sales from certain of the licensed technology, as defined, for periods ranging from five to ten years. We are recognizing the initial licensing fee of $80,000 as revenue ratably over the term of the agreement.

We have followed a strategy of working with strategic 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 a strategic alliance with the Department of Molecular and Genetic Medicine at Sheffield University ("Sheffield") in the United Kingdom. Under this alliance, Sheffield has provided us with the fundamental discovery and genetic analysis from their research laboratories, and we have focused on product development, including clinical trials, and the commercialization of these discoveries. We have issued 475,000 shares of common stock to Sheffield and its investigators, which was valued at $1,128,125 and was charged to research and development expense in the third quarter of 1999. In addition, we are required to issue Sheffield and its investigators 50,000 options to purchase common stock each June 30th during the period of time the arrangement is in place, and 10,000 additional options to purchase common stock each June 30th for each patent which is approved during the previous twelve months.

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. Hain has extensive experience in commercializing genetic tests on its DNA-STRIP Technology Platform in several fields as well as a specific commitment to marketing products directly to dentists. Hain's central facility offers excellent turnaround times, high quality laboratory operations and a sales and technical staff to support clinical users. We can terminate this agreement if certain minimum sales levels are not met.

In March 1999, we entered into an exclusive agreement with the Straumann Company, a leading supplier of dental implants, to market and sell PST in the United States and Puerto Rico. In September 2000, we amended this agreement to be non-exclusive and we entered an agreement with Kimball Genetics, Inc. for Kimball to process and analyze all PST tests in the United States and Puerto Rico. In December 2001 the agreement with Straumann expired and was not renewed. Kimball is now our sole marketing partner within the United States. We believe that through our partners we have adequate coverage in the sales, distribution and processing of PST. We do not expect the expiration of the Straumann contract to significantly decrease sales levels. Revenue for PST sales has been $186,000, $237,000 and $457,000 for the years ended December 31, 2001, 2000 and 1999 respectively.

During 2000, we changed our strategy for marketing and distributing PST. We no longer market, distribute or process the PST tests ourselves. We now use third party marketers and distributors from whom

we earn royalties. We believe that while this has reduced revenues in the short-term it has also improved margins and reduced operating costs.

Results of Operations

Comparison of Year Ended December 31, 2001 to Year Ended December 31, 2000

Revenue for the year ended December 31, 2001 was $202,942 as compared to $256,387 for the year ended December 31, 2000, representing a decrease of $53,445 or 21%. In the year ended December 31, 2001, the Company recorded revenue based on 4,012 PST tests processed compared to 1,209 PST tests processed during the year ended December 31, 2000. Gross profit margin in 2001 was 76% compared to 28% for the year earlier period.

The decrease in revenue and cost of revenue and the improvement in gross margin was the result of a change in our strategy for marketing, distributing and processing PST in 2000. We no longer market, distribute or process PST tests ourselves. We now use third parties to perform these functions on our behalf and we earn a royalty on end-user sales. The decrease in revenue was partially offset by revenue produced by a study of PST that was conducted by Washington Dental University. The number of processed tests associated with this study was 1,150. This study ended in July 2001 and revenue from this source has not continued after that time.

For the year ended December 31, 2001, the Company had research and development expenses of $2,686,621 compared with $2,167,409 for the same period in 2000, representing an increase of $519,212 or 24%. The increase was due to increases in personnel costs and increases in the cost of outside research projects. The 2001 expense included approximately $597,000 for outside research projects. These projects related to DNA sequencing and an investigation of the genetic control of inflammatory responses. The total compares to approximately $354,000 for outside research projects during the same period of 2000.

We have recently completed a research project with Genome Therapeutics, Inc. to provide us with DNA sequencing information, including identifying SNP (Single Nucleotide Polymorphism) variations in the region of the IL-1 genes. The program focused on those key genes in this very specific chromosomal region that we and others have shown to be associated with risk for inflammatory diseases, including Alzheimer's disease, asthma, cardiovascular disease, diabetes, gastric cancer and osteoporosis.

We have begun a new research project with Genome Therapeutics to provide DNA sequencing information within the TNF∝ (Tumor Necrosis Factor alpha) gene. We believe that the understanding of variations within this gene group will further our understanding of how a small area of genetic code, which primarily relates to diseases of inflammation, affects individual risk of specific common diseases. It is expected that this study will be completed within the first half of 2002.

We are also funding research at Sheffield University in support of several research projects including the following: A study to determine the haplotypes, or sets of genetic variations that are inherited together, that exist within the IL-1 gene cluster; A study to discover novel drug targets for inflammatory diseases by discovering genes involved in the responses of cells after they have been activated by IL-1; the development of a system that measures the net IL-1 biologic activity of blood or any tissue fluid and the discovery of the genetic variations that control patient to patient differences in inflammatory mechanisms. We believe that the completion of these studies will greatly enhance our understanding of the IL-1 gene cluster and the relationship of this gene cluster to inflammatory responses and disease risk. During 2001, we funded $244,000 for research completed at Sheffield, including related payments to collaborators at Sheffield, compared to $273,000 in 2000.

During 2001, we substantially completed the physical construction of our new research laboratory located at our corporate offices at 135 Beaver Street in Waltham, Massachusetts. The lab became operational during February of 2002. The cost of construction of the laboratory was approximately $250,000. We plan to undertake the following research activities within the laboratory:

- Identification of functional SNPs: A project to determine which of the SNPs within the IL-1 gene cluster leads to an alteration in the expression of the IL-1 genes.

- Create IL-1 genotype and haplotype specific cell models that can be used for studying drug responses. These models will be critical proprietary reagents for the analyses of genotype related drug response for use in future partnerships and collaborative projects for the development of new drugs.
- Investigate IL-1 genotype and haplotype influences on the expression of inflammatory response genes derived from tissues of individuals with diseases that we are studying clinically.

During the calendar year 2002 we anticipate undertaking additional research projects in the areas of rheumatoid arthritis, osteoporosis, complications from Diabetes and Alzheimer's disease. We anticipate total research and development expenses, including clinical costs, to be between $4 and $5 million for the calendar year 2002. Actual costs may vary from this estimate as a result of changes in technology, the success of current and future research projects, the success or failure of our current or future strategic alliances and collaborations, the identification of new business opportunities and our ability to raise additional capital. We have not made an attempt to finalize an estimate of our research and development expenses for beyond 2002 due to the factors listed above.

Selling, general and administrative expenses were $2,244,274 during the year ended December 31, 2001 compared to $3,093,379 during the same period last year, a decrease of $849,105 or 27%. The decrease was primarily the result of a reduction in administrative, sales and marketing expense related to the sale and distribution of PST. As mentioned above, we no longer market, sell, distribute or process PST directly. We now use third parties to perform these activities on our behalf. This has significantly reduced our operating expenses as they relate to PST.

Interest income during 2001 was $263,435 compared to $280,298 during 2000. This decrease was due entirely to the lower interest rates in 2001 in comparison with 2000. Interest expense of $9,818 was incurred during the year ended December 31, 2001, compared to $22,514 during 2000.

Comparison of Year Ended December 31, 2000 to Year Ended December 31, 1999

Revenue for the year ended December 31, 2000 was $256,387 as compared to $477,497 for the year ended December 31, 1999, representing a decrease of $221,110 or 46%. In June 1999 we received an up-front payment of $150,000 from Dumex-Alpharma A/S for the rights to distribute our genetic susceptibility test for periodontal disease PST® in nine European countries. We recognized $85,000 of this payment as revenue during 1999 and no revenue from this source during 2000. The decrease in revenue is also the result of an October 2000 change of our method of distributing PST. Since October 2000, we license the marketing rights for PST and collect only royalties. This has reduced our revenue and cost of revenues per test but has increased our gross profit margin.

Cost of revenues was $183,833 for the year ended December 31, 2000 as compared to $201,182 for the same period in 1999, representing a decrease of $17,349 or 9%. This decrease is primarily the result of the decrease in revenue discussed above. Gross margin decreased to 28% in 2000 from 58% in 1999 primarily as a result of the fee from Dumex-Alpharma A/S recognized in 1999 mentioned above.

For the year ended December 31, 2000, we had research and development expenses of $2,167,409 as compared to $3,570,845 for 1999, a decrease of $1,403,436 or 39%. This decrease was primarily due to $1,128,125 of non-cash expense in 1999 associated with issuance of 475,000 shares of common stock to the University of Sheffield and its investigators in conjunction with the new arrangement entered into in October 1999.

For the year ended December 31, 2000, we had selling, general and administrative expenses of $3,093,379 as compared to $2,904,210 for 1999, an increase of $189,169 or 6%. The increase is primarily the result of costs of approximately $200,000 associated with our relocation to Waltham, Massachusetts.

Interest income increased to $280,298 in 2000 from $107,446 in 1999, an increase of $172,852 or 161%. This increase is attributable to the increase in cash and investments resulting from the completion of private placements in January and December 2000. The reduction in our debt obligations is the primary reason for the decrease in interest expense from $59,189 in 1999 to $22,514 in 2000, a decrease of $36,675 or 62%.

Net loss applicable to common stock was $4,978,827 in 2000 compared to $11,138,603 in 1999, a decrease of $6,159,776 or 55%. The decrease is due primarily to a $5,000,000 charge in 1999 for the beneficial conversion feature of preferred stock issued in our June 1999 Private Placement. Upon Shareholder approval of the Private Placement in August 1999 all of the preferred stock converted to common stock.

Liquidity and Capital Resources

As of December 31, 2001, we had cash and cash equivalents of $3,922,736. Cash, cash equivalents and marketable securities generated interest income of $263,435 for the year ended December 31, 2001. Net cash used in operating activities was $4,545,967 during the year ended December 31, 2001 as compared to $4,182,050 used during 2000. Cash was used primarily to fund operating losses.

Investing activities provided cash of $2,736,973 in 2001 and used cash of $1,044,746 in 2000. During the year ended December 31, 2001 cash was provided from the maturity of marketable securities. During 2000 we used cash to purchase marketable securities as we shifted excess cash from cash and cash equivalents into marketable securities to earn a higher interest rate.

Financing activities provided cash of $3,340,169 for the year ended December 31, 2001 and $6,949,741 for the year ended December 31, 2000. During 2001, we received $2,911,267 in net proceeds from the issuance of common stock and warrants, net of expenses and $476,199 from the exercise of warrants and employee stock options. During 2000, we received $6,682,772 in net proceeds from the issuance of common stock and warrants, net of expenses and $578,018 from the exercise of warrants and employee stock options. We made capital lease payments of $54,342 in 2001 and $67,473 in 2000.

We currently do not have any commitments for material capital expenditures. Our obligations at December 31, 2001 for capital lease payments totaled $41,307, of which $11,091 is classified as long-term and $30,216 is classified as current. These capital lease obligations mature through August 2003 at various interest rates.

We anticipate that our existing cash and cash equivalents, together with anticipated interest income and revenue, will be sufficient to conduct operations as planned only until September 2002. As a result, there is significant doubt about our ability to continue as a going concern. We are actively pursuing additional capital investment; however, our future capital requirements are anticipated to be substantial, and we do not have commitments for additional capital at this time. Such capital requirements are expected to arise from the commercial launch of additional genetic tests, continued research and development efforts, the protection of our intellectual property rights (including preparing and filing of patent applications), as well as operational, administrative, legal and accounting expenses. We plan to raise capital through equity and/or debt issuance when, and if, such capital is available to us. THERE IS NO ASSURANCE THAT WE WILL BE ABLE TO RAISE ADDITIONAL CAPITAL ON TERMS ACCEPTABLE TO US, OR AT ALL. IF ADDITIONAL AMOUNTS CANNOT BE RAISED AND WE ARE UNABLE TO SUBSTANTIALLY REDUCE OUR EXPENSES, WE WOULD SUFFER MATERIAL ADVERSE CONSEQUENCES TO OUR BUSINESS, FINANCIAL CONDITION AND RESULTS OF OPERATIONS AND WOULD LIKELY BE REQUIRED TO SEEK OTHER ALTERNATIVES UP TO AND INCLUDING PROTECTION UNDER THE UNITED STATES BANKRUPTCY LAWS.

Critical Accounting Policies

Our significant accounting policies are described in Note 2 to the consolidated financial statements included in this report. We believe our most critical accounting policies are in the areas of revenue recognition, cost estimations of certain ongoing research contracts and our decision to expense all patent related costs as incurred.

Revenue recognition:

Revenue from genetic susceptibility tests is recognized when the tests have been completed and the results reported to the doctors. To the extent test kits have been purchased but not yet submitted for test

results, we defer recognition of revenue. This amount is presented on our balance sheet as deferred revenue. Contract revenues are recognized ratably as services are provided based on a fixed contract price or on negotiated hourly rates. Fees for the sale or licensing of product rights are recorded as deferred revenue upon receipt and recognized as revenue on a straight-line basis over the period that the related products or services are delivered or obligations as defined in the agreement are performed.

Cost estimates:

Much of our research and development is done on contract by outside parties. It is not unusual that at the end of an accounting period we need to estimate both the total cost of these projects and the percent of that project which was completed as of the accounting date. We then need to adjust those estimates when actual final invoices are received. To date, these adjustments have not been material to our financial statements, and we believe that the estimates that we made as of December 31, 2001 are reflective of the actual expenses incurred as of that date. However, readers should be cautioned that the possibility exists that certain research projects might cost more than we have estimated and that these higher costs will be reflected in future periods.

Patent expenses:

We have made the decision to expense patent expenses as incurred due to the possibility that we will never be able to derive any benefits from our patents. As noted in the section titled Intellectual Property on page 10 of this report we have exclusive rights in nine issued U.S. patents and have twenty pending U.S. patents applications. We have also been granted a number of corresponding foreign patents and we have a number of foreign counterparts of our U.S. patents and patent applications pending. Since inception we have expensed close to $2 million in the effort to obtain patent protection for our intellectual property including $300,000 during the year ended December 2001. If we had decided to record the costs of developing patent protection as an intangible asset on the balance sheet it would have had a material effect on the presentation of our financial statements. In future periods we may decide to change this presentation as the realizability of return on this investment becomes more certain.

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

As of December 31, 2001, the only financial instruments we carried were cash and cash equivalents. We believe the market risk arising from holding these financial instruments is not material.

Some of our sales 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 Report, appears on pages F-2 through F-18 of this report. See the "Index to Financial Statements" on page F-1 of this report.

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

None.

PART III

Item 10. ***Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(A) of the Exchange Act.***

Information required under this Item will be contained in the Company's Proxy Statement for its 2002 Annual Meeting, which is incorporated herein by reference.

Item 11. ***Executive Compensation***

Information required under this Item will be contained in the Company's Proxy Statement for its 2002 Annual Meeting, which is incorporated herein by reference.

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

Information required under this Item will be contained in the Company's Proxy Statement for its 2002 Annual Meeting, which is incorporated herein by reference.

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

Information required under this Item will be contained in the Company's Proxy Statement for its 2002 Annual Meeting, which is incorporated herein by reference.

PART IV

Item 14. ***Exhibits, Financial Statement Schedules, and Reports on Form 8-K.***

(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 public accountants 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. See the Index of Exhibits included with the Exhibits filed as a part of this report.

Exhibit No.	Identification of Exhibit
2.1	Plan of Reorganization and Merger dated July 12, 2000 by and between Interleukin Genetics, Inc., a Texas Corporation, and Interleukin Genetics, Inc., a Delaware Corporation. (incorporated herein by reference to Exhibit 2.1 of the Company's Quarterly Report on Form 10-Q filed August 14, 2000).
3.1	Articles of Incorporation of the Company, as amended (incorporated herein by reference to Exhibit 3.1 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 the Company's Quarterly Report on Form 10-Q filed August 14, 2000).
4.1	Form of Stock Certificate representing Common Stock, $.001 par value, of the Company (incorporated herein by reference to Exhibit 4.1 the Company's Quarterly Report on Form 10-Q filed August 14, 2000).
4.2	Form of Representative's Warrant (incorporated herein by reference to Exhibit 4.2 of the Company's Registration Statement No. 333-37441 on Form SB-2 filed October 8, 1997).

Exhibit No.	Identification of Exhibit
4.4	Form of Warrant Agreement (incorporated herein by reference to Exhibit 4.5 of the Company's Registration Statement No. 333-37441 on Form SB-2 filed October 8, 1997).
4.5	Form of Warrant Certificate (incorporated herein by reference to Exhibit 4.6 of the Company's Registration Statement No. 333-37441 on Form SB-2 filed October 8, 1997).
4.6	Warrant dated June 15, 1999, granted to Fine Equities, Inc. (incorporated herein by reference to Exhibit 4.2 of the company's Quarterly Report on Form 10-QSB field August 16, 1999).
10.1	Lease Agreement dated March 21, 1996, between the Company and Koll Center Newport Number 9 (incorporated herein by reference to Exhibit 10.14 of the Company's Registration Statement No. 333-37441 on Form SB-2 filed October 8, 1997).
10.2@	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).
10.3@	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).
10.4@	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).
10.5@	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).
10.6†	Distribution Agreement between the Company and The Straumann Company dated March 25, 1999 (incorporated herein by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-QSB filed May 17, 1999).
10.7@	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).
10.8	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).
10.9†	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).
10.10†	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).
10.15@	Non-Qualified Stock Option Agreement dated November 30, 1999 between the Company and Philip R. Reilly (incorporated herein by reference to Exhibit 4.5 to the Company's Registration Statement No. 333-32538 on Form S-8 filed March 15, 2000).
10.16@	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).
10.17@	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).
10.18	Lease Agreement between the Company and Clematis LLC. (incorporated herein by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-QSB filed August 14, 2000).
10.19	First Amendment to a Commercial Lease Between the Company and Clematis LLC. (incorporated herein by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-QSB filed August 14, 2000).
10.20@	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-QSB filed August 14, 2000).

Exhibit No.	Identification of Exhibit
10.21@	Form of Nonqualified Stock Option Grant (incorporated herein by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-QSB filed August 14, 2000).
10.22@	Form of Incentive Stock Option Grant (incorporated herein by reference to Exhibit 10.5 of the Company's Quarterly Report on Form 10-QSB filed August 14, 2000).
10.23@	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-QSB filed August 14, 2000).
10.24@	Employment Agreement dated November 20, 2000 between the Company and Paul Martha. (incorporated herein by reference to Exhibit 10.24 of the Company's Annual Report on Form 10-K filed March 26, 2001).
10.25	Purchase Agreement dated December 5, 2000 (incorporated herein by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed March 7, 2001).
10.26	Registration Rights Agreement dated December 5, 2000 (incorporated herein by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed March 7, 2001).
10.27	Purchase Agreement dated January 26, 2001 (incorporated herein by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed March 7, 2001).
10.28	Registration Rights Agreement dated January 26, 2001 (incorporated herein by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed March 7, 2001).
10.29	Consent, Waiver and Amendment Agreement dated January 26, 2001 (incorporated herein by reference to Exhibit 10.7 of the Company's Current Report on Form 8-K filed March 7, 2001).
10.30	Warrant to purchase 330,000 shares dated January 26, 2001 (incorporated herein by reference to Exhibit 10.6 of the Company's Current Report on Form 8-K filed March 7, 2001).
10.31	Warrant to purchase 160,000 shares dated January 26, 2001 (incorporated herein by reference to Exhibit 10.7 of the Company's Current Report on Form 8-K filed March 7, 2001).
10.32	Warrant to purchase 110,000 shares dated January 26, 2001 (incorporated herein by reference to Exhibit 10.8 of the Company's Current Report on Form 8-K filed March 7, 2001).
10.33	Warrant to purchase 264,407 shares dated January 26, 2001 (incorporated herein by reference to Exhibit 10.9 of the Company's Current Report on Form 8-K filed March 7, 2001).
10.34*	Amendment to the Lease Agreement between the Company and Clematis LLC.
21.1*	Identification of Exhibit Subsidiaries of the Company.
23.1*	Report of Independent Public Accounants
99.1*	Letter to Commissioner pursuant to Temporary Note 3t

* 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.

@ Management contract or compensatory plan, contract or arrangement

(b) Reports on Form 8-K

The Company did not file any reports on Form 8-K during the fourth quarter of the fiscal year ended December 31, 2001.

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: March 26, 2002

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)	March 26, 2002
/s/ KENNETH S. KORNMAN Kenneth S. Kornman	President and Director	March 26, 2002
/s/ FENEL M. ELOI Fenel M. Eloi	Chief Financial Officer, Secretary & Treasurer (Principal Financial and Accounting Officer)	March 26, 2002
Thomas A. Moore	Director	
/s/ EDWARD M. BLAIR, JR. Edward M. Blair, Jr.	Director	March 26, 2002
/s/ GARY L. CROCKER Gary L. Crocker	Director	March 26, 2002
/s/ JOHN GAROFALO John Garofalo	Director	March 26, 2002

INTERLEUKIN GENETICS, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To Interleukin Genetics, Inc.:

We have audited the accompanying consolidated balance sheets of Interleukin Genetics, Inc. (a Delaware corporation), as of December 31, 2000 and 2001, and the related consolidated statements of operations, stockholders' equity and comprehensive loss and cash flows for each of the three years in the period ended December 31, 2001. 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 auditing standards generally accepted in the 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 financial statements referred to above present fairly, in all material respects, the financial position of Interleukin Genetics, Inc., and subsidiaries as of December 31, 2000 and 2001, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and believes that its existing cash resources, absent additional debt or equity financing, will be depleted by September 2002. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ ARTHUR ANDERSEN LLP

Boston, Massachusetts
February 14, 2002

INTERLEUKIN GENETICS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	December 31, 2001	December 31, 2000
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,922,736	$ 2,391,561
Marketable securities	—	2,999,040
Accounts receivable, net of allowance for doubtful accounts of $14,000 and $77,000 in 2001 and 2000, respectively	75,982	46,870
Prepaid expenses and other current assets	103,436	174,074
Total current assets	4,102,154	5,611,545
Fixed assets, net	178,904	68,853
Other assets	112,068	14,113
Total Assets	$ 4,393,126	$ 5,694,511
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 181,554	$ 297,178
Accrued expenses	477,368	603,072
Deferred revenue	142,349	204,807
Current portion of capital lease obligations	30,216	48,660
Total current liabilities	831,487	1,153,717
Capital lease obligations, less current portion	11,091	46,989
Total liabilities	842,578	1,200,706
Stockholders' equity:		
Preferred stock, no par value — 5,000,000 shares authorized; none issued or outstanding	—	—
Common stock, $0.001 par value — 50,000,000 shares authorized; 21,452,326 and 19,067,427 shares issued and 21,427,699 and 19,042,800 outstanding in 2001 and 2000, respectively	21,452	19,067
Additional paid-in capital	39,292,936	35,702,628
Treasury stock — 24,627 shares in 2001 and 2000, at cost	(250,119)	(250,119)
Accumulated deficit	(35,513,721)	(30,991,015)
Other comprehensive income	—	13,244
Total stockholders' equity	3,550,548	4,493,805
Total liabilities and stockholders' equity	$ 4,393,126	$ 5,694,511

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

INTERLEUKIN GENETICS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,		
	2001	2000	1999
Revenue	$ 202,942	$ 256,387	$ 477,497
Cost of revenue	48,674	183,833	201,182
Gross profit	154,268	72,554	276,315
Expenses:			
Research and development	2,686,621	2,167,409	3,570,845
Selling, general and administrative	2,244,274	3,093,379	2,904,210
Total operating expenses	4,930,895	5,260,788	6,475,055
Loss from operations	(4,776,627)	(5,188,234)	(6,198,740)
Other income (expense):			
Interest income	263,435	280,298	107,446
Interest expense	(9,818)	(22,514)	(59,189)
Other income (expense)	304	(48,377)	11,880
Total other income	253,921	209,407	60,137
Net loss	(4,522,706)	(4,978,827)	(6,138,603)
Beneficial conversion feature attributable to preferred stock	—	—	(5,000,000)
Net loss applicable to common stock	$(4,522,706)	$(4,978,827)	$(11,138,603)
Basic and diluted net loss per share	$ (0.21)	$ (0.27)	$ (1.15)
Weighted average common shares outstanding	21,049,437	18,315,320	9,720,621

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

INTERLEUKIN GENETICS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY AND COMPREHENSIVE LOSS

For the Years Ended December 31, 2001, 2000 and 1999

	Preferred Stock		Common Stock		Additional Paid-in Capital	Treasury Stock		Accumulated Deficit	Other Comprehensive Income (loss)	Total
	Shares	Amount	Shares	$0.001 par value		Shares	Amount			
Balance as of December 31, 1998	—	—	5,548,470	$ 5,548	$16,714,384	—	$ —	$(14,873,585)	—	$1,846,347
Net loss	—	—	—	—	—	—	—	(6,138,603)	—	(6,138,603)
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	(12,499)	(12,499)
Comprehensive loss										(6,151,102)
Preferred stock issued in private placement	2,200,000	4,706,927	—	—	—	—	—	—	—	4,706,927
Common stock issued:										
Preferred stock conversion	(2,200,000)	(4,706,927)	11,000,000	11,000	9,695,927	—	—	(5,000,000)	—	—
For services rendered	—	—	475,000	475	1,127,650	—	—	—	—	1,128,125
Exercise of employee stock options	—	—	199,314	199	379,746	—	—	—	—	379,945
Employee stock purchase plan	—	—	518	1	599	—	—	—	—	600
Stock options issued to non-employees for services rendered	—	—	—	—	242,337	—	—	—	—	242,337
Balance as of December 31, 1999	—	—	17,223,302	17,223	28,160,643	—	—	(26,012,188)	(12,499)	2,153,179
Net loss	—	—	—	—	—	—	—	(4,978,827)	—	(4,978,827)
Unrealized gain on marketable securities	—	—	—	—	—	—	—	—	25,743	25,743
Comprehensive loss										(4,953,084)
Common stock issued:										
Private placements	—	—	1,375,040	1,375	6,681,397	—	—	—	—	6,682,772
Cashless exercise of warrants	—	—	140,691	141	(141)	—	—	—	—	—
Exercise of employee stock options	—	—	326,835	327	577,691	—	—	—	—	578,018
Employee stock purchase plan	—	—	1,559	1	8,339	—	—	—	—	8,340
Stock options issued to non-employees for services rendered	—	—	—	—	274,699	—	—	—	—	274,699
Purchase of treasury stock	—	—			—	(24,627)	(250,119)	—	—	(250,119)
Balance as of December 31, 2000	—	—	19,067,427	19,067	35,702,628	(24,627)	(250,119)	(30,991,015)	13,244	4,493,805
Net loss	—	—	—	—	—	—	—	(4,522,706)	—	(4,522,706)
Unrealized loss on marketable securities									(13,244)	(13,244)
Comprehensive loss										(4,535,950)
Common stock issued:										
Private placements	—	—	1,457,627	1,458	2,909,809	—	—	—	—	2,911,267
Exercise of warrants	—	—	875,000	875	436,625	—	—	—	—	437,500
Exercise of employee stock options	—	—	46,964	47	38,652	—	—	—	—	38,699
Employee stock purchase plan	—	—	5,308	5	7,040	—	—	—	—	7,045
Stock options issued to non-employees for services rendered	—	—	—	—	198,182	—	—	—	—	198,182
Balance as of December 31, 2001	—	$ —	21,452,326	$ 21,452	$39,292,936	(24,627)	$(250,119)	$(35,513,721)	$ —	$3,550,548

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

INTERLEUKIN GENETICS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,		
	2001	2000	1999
CASH FLOW FROM OPERATING ACTIVITIES			
Net loss	$(4,522,706)	$(4,978,827)	$(6,138,603)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	57,416	159,736	194,611
Unrealized gain (loss) on marketable securities	(13,244)	25,743	24,375
Issuance of stock options to non-employees for services rendered	198,182	274,699	242,335
Issuance of stock to non-employees for services rendered	—	—	1,128,125
(Gain) loss on disposal of fixed assets	(3,355)	74,986	—
Account receivable, net	(29,112)	56,131	22,084
Prepaid expenses and other current assets	70,638	(41,514)	(5,134)
Accounts payable	(115,624)	162,210	(143,805)
Accrued expenses	(125,704)	202,791	(33,578)
Deferred revenue	(62,458)	(118,005)	47,491
Net cash used in operating activities	(4,545,967)	(4,182,050)	(4,662,099)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of fixed assets	(164,112)	(19,093)	(15,810)
Increase in other assets	(97,955)	(14,113)	—
Purchases of marketable securities	—	(3,955,246)	(4,024,374)
Proceeds from maturity of marketable securities	2,999,040	2,943,706	2,530,000
Net cash provided by (used in) investing activities	2,736,973	(1,044,746)	(1,510,184)
CASH FLOW FROM FINANCING ACTIVITIES			
Proceeds from private placements of common stock	2,911,267	6,682,772	—
Proceeds from exercise warrants and employee stock options	476,199	578,018	379,945
Proceeds from sale of preferred stock	—	—	4,706,927
Proceeds from employee stock purchase plan	7,045	8,340	600
Purchase of treasury stock	—	(250,119)	
Increases in (payments of) notes payable, net	—	(1,797)	10,688
Principal payments of long-term debt	—	—	(585,992)
Principal payments of capitalized lease obligations, net	(54,342)	(67,473)	(103,540)
Net cash provided by financing activities	3,340,169	6,949,741	4,408,628
Net increase (decrease) in cash and equivalents	1,531,175	1,722,945	(1,763,655)
Cash and cash equivalents, beginning of year	2,391,561	668,616	2,432,271
Cash and cash equivalents, end of year	$ 3,922,736	$ 2,391,561	$ 668,616
Supplemental disclosures of cash flow information:			
Cash paid for interest	$ 9,818	$ 22,514	$ 59,189
Cash paid for income taxes	$ —	$ —	$ —
Supplemental disclosure on noncash investing and financing activity:			
Cashless exercise of warrants	$ —	$ 61,840	$ —
Conversion of preferred stock to common stock	$ —	$ —	$ 9,706,927

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

INTERLEUKIN GENETICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Company Background and Uncertainties

Organization and Line of Business

The Company develops genetic diagnostic tests and medical research tools. As of December 31, 2001, the Company has commercially introduced one such product and is in various stages of development for several others. Additionally, the Company provides research services under contract to pharmaceutical companies. Such research services contributed less than 10% of total revenue to the Company in 2001, 2000 and 1999.

The Company is subject to numerous risks and uncertainties, including the need to raise additional capital to fund operations, research and development efforts and commercialize its products. Since its inception, the Company has incurred cumulative net losses of approximately $30.5 million including losses of approximately $4.5 million during 2001, $5.0 million during 2000 and $6.1 million during 1999. The Company believes that it current cash resources, absent additional equity or debt financing, will be depleted by September 2002. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management is actively pursuing several sources of additional financing to address this uncertainty. There can be no assurances that management can secure additional financing under terms that are acceptable to the Company or at all. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Commercial success of genetic susceptibility 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 third-party payers. It is uncertain whether current genetic susceptibility tests or others that the Company may develop will gain commercial acceptance on a timely basis, if at all.

Research in the field of disease predisposing genes and genetic markers is intense and highly competitive. The Company has many competitors in the United States and abroad that have considerably greater financial, technical, marketing, and other resources available. If the Company does not discover disease predisposing genes or genetic markers and develop susceptibility tests and launch such services or products before their competitors, then revenues may be reduced or eliminated.

The Company's ability to successfully commercialize genetic susceptibility tests depends on obtaining adequate reimbursement for such products and related treatment from government and private health care insurers and other third-party payers. Doctors' decisions to recommend genetic susceptibility tests will be influenced by the scope and reimbursement for such tests by third-party payers. If both third-party payers and individuals are unwilling to pay for the test, then the number of tests performed will significantly decrease, therefore resulting in a reduction of revenues.

The Company was incorporated in Texas in 1986 and re-incorporated in Delaware in March 2000.

Note 2 — Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Interleukin Genetics, Inc., and its wholly-owned subsidiaries, Medical Science Systems France E.U. and Interleukin Genetics Laboratory Services, Inc. All material intercompany accounts and transactions have been eliminated.

Management Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenues and expenses during the reported periods. Actual results could differ from

Note 2 — Summary of Significant Accounting Policies — (Continued)

those estimates. The Company's most critical accounting policies are in the area of revenue recognition, cost estimations of certain ongoing research contracts and the Company's decision to expense all patent related costs as incurred. These critical accounting policies are more fully discussed in these notes to financial statements and in the section of the Company's Form 10-K entitled *Management's Discussion and Analysis of Financial Condition and Results of Operations.*

Revenue Recognition

Revenue from genetic susceptibility tests is recognized when the tests have been completed and the results reported to the doctors. To the extent test kits have been purchased and paid for but not yet submitted for test results, the Company defers recognition of all related revenue. These amounts are presented as deferred revenue in the accompanying consolidated balance sheets. Contract revenues are recognized ratably as services are provided based on a fixed contract price or on negotiated hourly rates. Provision for anticipated losses on fixed-price contracts is made in the period such losses are identified.

The Company has entered into agreements with outside parties for the distribution of genetic susceptibility tests, both domestically and internationally. Distributor fees are received based on the terms of each agreement and are recognized ratably over the applicable agreement period. Distributor fees received in advance totaled $0 and $74,000 at December 31, 2001 and 2000, respectively.

Fees for the sale or licensing of product rights are recorded as deferred revenue upon receipt and recognized as revenue on a straight-line basis over the period that the related products or services are delivered or obligations as defined in the agreement are performed.

Revenue from milestone or other contingent payments is recognized when earned in accordance with the terms of the related agreement. Royalties are recognized when earned under the Company's royalty agreements when amounts are fixed or determinable and payment is reasonably assured.

Staff Accounting Bulletin No. 101 (SAB No. 101), *Revenue Recognition*, was issued in December 1999. SAB No. 101 requires companies to recognize certain up-front non-refundable fees and milestone payments over the life of the related alliances when such fees are received in conjunction with agreements that have multiple elements. The Company's adoption of this new accounting principle in fiscal 2000 had no impact on the Company's consolidated financial statements.

Research and Development

Research and development costs are expensed as incurred.

Basic and Diluted Net Loss per Common Share

The Company applies Statement of Financial Accounting Standards ("SFAS") No. 128, *Earnings per Share* ("SFAS 128"), which establishes standards for computing and presenting earnings per share. Basic and diluted net loss per share was determined by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted loss per share is the same as basic loss per share for all the periods presented, as the effect of the potential common stock equivalents is antidilutive due to the loss in each period. Potential common stock excluded from the calculation of diluted net loss per share consists of stock options and warrants as described in the table below:

	2001	2000	1999
Options outstanding	2,652,069	1,826,943	1,722,130
Warrants outstanding	1,345,952	1,492,138	1,536,545
Total	3,998,021	3,319,081	3,258,675

Note 2 — Summary of Significant Accounting Policies — (Continued)

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from nonowner sources. Other than the reported net loss, the Company had one item of comprehensive income (loss), which was unrealized holding gains (losses) on marketable securities. Comprehensive income (loss) is disclosed in the accompanying consolidated statements of stockholders' equity and comprehensive loss.

Fair Value of Financial Instruments

The Company using available market information has determined the estimated fair values of financial instruments. The estimated fair values of cash and cash equivalents, accounts receivable and accounts payable approximate fair value due to the short-term nature of these instruments. Marketable securities are carried at fair market value, as determined by current market values. The carrying amounts of the Company's capital lease obligations also approximate fair value.

Cash Equivalents and Marketable Securities

Cash equivalents consist of short-term, highly liquid investments purchased with original maturities of 90 days or less. Investments with an original maturity of greater than 90 days are classified as marketable securities. Marketable securities have been designated as available-for-sale and are stated at fair market value with any unrealized holding gains or losses included as a component of stockholders' equity and any realized gains or losses recorded in the statement of operations in the period in which the securities are sold. The Company held no marketable securities as of December 31, 2001. The amortized cost, unrealized gains and the fair value of marketable securities as of December 31, 2000 with maturity dates ranging up to 6 months are as follows:

Security	Maturity	Cost	Unrealized Gain	Fair Value
U.S. Treasury Note	6/30/2001	$1,987,500	$ 12,500	$2,000,000
U.S. Treasury Bill	1/4/2001	998,296	744	999,040
Total		$2,985,796	$ 13,244	$2,999,040

Fixed Assets

Fixed assets are stated at cost, less accumulated depreciation and amortization. Depreciation and amortization are provided using the straight-line method over estimated useful lives of three to five years. Leasehold improvements are amortized over the life of the lease or the estimated useful life of the asset, whichever is shorter (see Note 5).

Long-Lived Assets

The Company applies the provisions of SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of*. SFAS No. 121 requires that the Company evaluate its long-lived assets for impairment whenever events or changes in circumstances indicate that carrying amounts of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. Any write-downs, based on fair value, are to be treated as permanent reductions in the carrying amount of the assets. The Company believes that no impairment exists related to the Company's long-lived assets at December 31, 2001.

Note 2 — Summary of Significant Accounting Policies — (Continued)

Patents

The Company expenses patent costs as incurred as their realizability is uncertain.

Stock-Based Compensation

Stock options issued to employees under the Company's stock option and stock purchase plans are accounted for under Accounting Principles Board Opinion No. 25 (APB 25), *Accounting for Stock Issued to Employees*. All stock-based awards to non-employees are accounted for at their fair value in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation*, and Emerging Issues Task Force (EITF) Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees*.

New Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, *Business Combinations*, which applies to all business combinations initiated after June 30, 2001. This statement requires that all business combinations be accounted for by the purchase method and defines the criteria used to identify intangible assets to be recognized apart from goodwill.

In June 2001, the FASB issued SFAS No. 142, *Goodwill and Other Intangible Assets*, which is effective for fiscal years beginning after December 15, 2001, except for goodwill and intangible assets acquired after June 30, 2001, which are subject immediately to the non-amortization and amortization provisions of this statement. Under the new rules, goodwill and intangible assets deemed to have indefinite lives will no longer be amortized but will be subject to annual impairment tests in accordance with the statement. Other intangible assets will continue to be amortized over their estimated useful lives.

In August 2001, the FASB issued SFAS No. 143 *Accounting for Asset Retirement Obligations*, effective for fiscal years beginning after June 15, 2002. This statement addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the retirement costs.

In October 2001, the FASB issued SFAS No. 144 *Accounting for the Impairment or Disposal of Long-lived Assets*, effective for fiscal years beginning after December 15, 2001. This statement addresses financial accounting and reporting for the impairment or disposal of long-lived assets.

The Company does not expect the effect of complying with these new accounting pronouncements to have a material impact on its financial statements.

Note 3 — Sheffield University Master Agreement

In July 1999, the Company entered into an agreement with Sheffield University (Sheffield), whereby the Company will undertake the development and commercialization of certain discoveries resulting from Sheffield's research. For certain of the discoveries, the parties have reached a specific non-cancelable agreement of development and commercialization. However, for new discoveries on which the parties have not yet reached specific agreement, the agreement may be terminated with or without cause by either party upon six months' notice. If Sheffield terminates the agreement, such termination could make the discovery and commercial introduction of new products more difficult or unlikely.

The agreement with Sheffield is a five-year agreement with an automatic yearly renewal. During 1999, in accordance with this agreement, the Company issued 275,000 shares of common stock to Sheffield for transferring all rights and title of certain patents. The value of the common stock of $653,125 was charged to research and development expense in the third quarter of 1999. Additionally, each year beginning July 1, 2000, Sheffield will receive 25,000 fully vested options to purchase common stock at the then current market price, plus 10,000 fully vested options to purchase common stock for each new patent application filed in the previous 12 months. During the year ended December 31, 2001, 35,000 fully vested options to purchase common stock were granted under this agreement and the Company charged approximately $69,000 to research and development expense based upon the fair value of the options determined using the Black-Sholes

Note 3 — Sheffield University Master Agreement — (Continued)

option-pricing model. These options have a five-year exercise period. In 1999, the Company signed another research agreement with Sheffield that automatically renews in one-year increments. This agreement requires the Company to pay the cost of agreed upon research projects conducted at Sheffield. For the year ended December 31, 2001 the Company funded and expensed approximately $244,000 for research conducted at Sheffield. This includes funding to the University and to collaborators at the University. Both agreements with Sheffield can be canceled if a certain key collaborator leaves Sheffield.

In September 1999, a five-year consulting agreement was entered into with Sheffield's key collaborator. In accordance with the consulting agreement, the key collaborator received 200,000 shares of common stock for relinquishing interests in previous research agreements. The value of the common stock of $475,000 was charged to research and development expense in the third quarter of 1999. The key collaborator will also receive 1% of the first $4 million of net sales under the PST Technology and 2% for sales above $4 million. During 2001, this collaborator received $2,213 in royalty payments for sales of PST. On July 1, 2000 and 2001, in consideration for future services, the key collaborator received 25,000 fully vested options to purchase common stock at the then current market price. These options have a five-year exercise period from the date of grant. During 2001, the Company charged to research and development expense approximately $50,000 related to the issuance of these options based upon the fair value determined using the Black-Sholes option-pricing model. This collaborator will continue to receive 25,000 fully vested options to purchase common stock each July 1 during the period that this agreement is in effect.

Note 4 — Accounts Receivable

The changes in the allowance for doubtful accounts consisted of the following:

	Year Ended December 31,		
	2001	2000	1999
Beginning of year	$ 77,000	55,000	$ 21,000
Provision charged to expense	9,000	33,000	48,000
Accounts written off, net of recoveries	(72,000)	(11,000)	(14,000)
End of year	$ 14,000	$ 77,000	$ 55,000

Note 5 — Fixed Assets

The fixed assets' useful lives and balances at December 31, 2001 and 2000 consisted of the following:

	Useful Life	2001	2000
Computer and office equipment	3 years	$ 83,889	$52,157
Lab equipment	5 years	120,281	6,578
Furniture and fixtures	5 years	10,233	10,233
Leasehold improvements	5 years	12,098	—
Equipment under capital leases	3 to 5 years	149,042	173,563
		375,543	242,531
Less — Accumulated depreciation and amortization		196,639	173,678
Total		$178,904	$68,853

Note 6 — Income Taxes

The Company accounts for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes*, which requires the recognition of taxes payable or refundable for the current year and deferred tax liabilities and assets for the future tax consequences of events that have been recognized in the financial

Note 6 — Income Taxes — (Continued)

statements or tax returns. The measurement of current and deferred tax liabilities and assets is based on provisions of the enacted tax law; the effects of future changes in tax laws or rates are not anticipated.

As of December 31, 2001, the Company had net operating loss (NOL) and research tax credit carryforwards of approximately $27,900,000 and $397,000, respectively, for federal and state income tax purposes, expiring in varying amounts through the year 2021. The Company's ability to use its NOL and tax credit carryforwards to reduce future taxes is subject to the restrictions provided by Section 382 of the Internal Revenue Code of 1986 (the "Code"). These restrictions provide for limitations on the Company's utilization of its NOL and tax credit carryforwards following a greater than 50% ownership change during the prescribed testing period. As of December 31, 2001, the Company has had one such change. As a result, approximately $15,619,000 of the Company's NOL carryforwards are limited in utilization to approximately $825,000 annually. The annual limitation may result in the expiration of certain of the carryforwards prior to utilization.

As of December 31, 2001 and 2000, the approximate income tax effect of the Company's deferred tax assets (liabilities) consisted of the following:

	2001	2000
Net operating loss carryforwards	$ 9,417,000	$ 7,892,000
Research tax credit carryforwards	397,000	337,000
Accrual to cash adjustments	286,000	301,000
Disqualifying dispositions and non-qualified stock option exercises	157,000	117,000
Loss on sale of assets	(50,000)	(50,000)
Depreciation	67,000	38,000
Patents	16,000	50,000
Total deferred tax assets	10,290,000	8,685,000
Valuation allowance	(10,290,000)	(8,685,000)
Net deferred tax assets	$ —	$ —

Due to the uncertainty regarding the timing and realization of the Company's net deferred tax asset, a full valuation allowance has been established against the Company's deferred tax assets.

Note 7 — Capital Stock

Authorized Common and Preferred Stock

At December 31, 2001, the Company had authorized 5,000,000 shares of undesignated preferred stock of which none are outstanding. At December 31, 2001, the Company had authorized 50,000,000 shares of $0.001 par value common stock of which 21,427,699 shares were outstanding and approximately 3.5 million shares were reserved for the exercise of authorized and outstanding stock options, approximately 1.3 million shares were reserved for the exercise of authorized and outstanding warrants to purchase common stock and approximately 493,000 shares were reserved for the exercise of rights held under the Employee Stock Purchase Plan.

Private Placements of Common Stock

In January 2001, the Company sold in a private placement 1.2 million shares of common stock for $2.50 per share. The purchasers of common stock also received warrants to purchase 600,000 shares of common stock exercisable at $3.00 per share. The Company generated net proceeds of approximately $2.9 million from this transaction. Under the terms of this private placement, the Company is required to adjust the price per share paid in this offering, by issuing additional shares, to match any offering price paid, if lower, in subsequent financings during the following 24 months.

Note 7 — Capital Stock — (Continued)

In December 2000, the Company sold in a private placement 542,373 shares of common stock for $3.69 per share. The purchasers of common stock also received warrants to purchase 135,593 shares of common stock exercisable at $4.83 per share. The Company generated net proceeds of approximately $1.9 million from this transaction. Under the terms of this private placement, the Company is required to adjust the price per share paid in this offering, by issuing additional shares, to match any offering price paid, if lower, in subsequent financings during the following 24 months. Following the January 2001 offering described above, the Company issued an additional 257,627 shares of common stock to the purchasers in the December 2000 private placement, and a new warrant to purchase 264,407 shares of common stock exercisable at a price of $3.13 to replace the previously issued warrant to buy 135,593 shares of common stock.

In January 2000, the Company sold in a private placement 832,667 shares of common stock, which generated net proceeds of approximately $4.7 million.

Employee Stock Purchase Plan

Effective October 14, 1998, the Company's Board of Directors approved an Employee Stock Purchase Plan for qualified employees of the Company. Under the terms of the Employee Stock Purchase Plan, an employee may purchase up to $25,000 per calendar year of the Company's stock at a price equal to 85% of the fair market value of the stock (as quoted on the NASDAQ national quotation system) on either the first or last day of a calendar quarter. The Company has reserved 500,000 shares of common stock for purchases to be made under the Employee Stock Purchase Plan. During the years ended December 31, 2001, 2000 and 1999, 5,206, 1,559 and 518 shares were purchased under the Employee Stock Purchase Plan at an average purchase price of approximately $1.28, $5.35 and $1.16 respectively, per share.

Preferred Stock

In June 1999, the Company issued 2,200,000 shares of preferred stock in a private placement for total proceeds of $4,706,927. Each share of preferred stock was convertible into five shares of common stock at the option of the holder. Because the fair value of the common stock into which the preferred stock was convertible exceeded the purchase price paid by the preferred stockholders, the Company recorded a beneficial conversion in the amount of $5,000,000. In August 1999, the preferred stockholders exercised their right to convert their preferred stock into a total of 11,000,000 shares of common stock with an aggregate fair value of $9,706,927

Note 8 — Stock Option Plans

In June 2000, the Company's shareholders approved the adoption of the Interleukin Genetics, Inc. 2000 Employee Stock Compensation Plan (the "2000 Plan"). The 2000 Plan provides for the award of nonqualified and incentive stock options, restricted stock, and stock awards to employees, directors, officers, and consultants of the Company. A total of 2,000,000 shares of the Company's common stock have been reserved for award under the 2000 Plan of which approximately 680,000 were available for future issuance at December 31, 2001.

In June 1996, the Company's shareholders approved the adoption of the 1996 Equity Incentive Plan (the "1996 Plan"). The 1996 Plan provides for the award of nonqualified and incentive stock options, restricted stock and stock bonuses to employees, directors, officers and consultants of the Company. A total of 1,300,000 shares of the Company's common stock have been reserved for award under the 1996 Plan of which approximately 170,000 were available for grant at December 31, 2001.

Nonqualified and incentive stock options with a life of 10 years are generally granted at exercise prices equal to the fair market value of the common stock on the date of grant. Options generally vest over a period of three to four years.

Note 8 — Stock Option Plans — (Continued)

A summary of the status of the Company's stock options, issued both under the 1996 and 2000 Plans and outside of these plans, at December 31, 2001, 2000 and 1999, and changes during these years is presented in the tables below:

The following table details all stock option activity:

	2001		2000		1999	
	Shares	Weighted Avg Exercise Price	Shares	Weighted Avg Exercise Price	Shares	Weighted Avg Exercise Price
Outstanding, beginning of year	1,826,943	$2.83	1,722,130	$2.11	1,174,383	$2.20
Granted	904,798	1.68	600,000	4.23	1,061,781	2.05
Exercised	(46,964)	0.85	(326.835)	1.95	(199,314)	1.98
Canceled	(32,708)	4.34	(168,352)	2.15	(314,720)	2.15
Outstanding, end of year	2,652,069	$2.47	1,826,943	$2.83	1,722,130	$2.11
Exercisable, end of year	1,457,126	$2.55	1,108,684	$2.44	889,852	$1.99

The following table details further information regarding stock options outstanding and exercisable at December 31, 2001:

	Stock Options Outstanding			Stock Options Exercisable	
Range of Exercise Price:	Shares	Weighted Avg Remaining Contractual Life (Years)	Weighted Avg Exercise Price	Shares	Weighted Avg Exercise Price
$0.50 – $0.99	244,921	7.40	$0.52	244,921	$0.52
$1.00 – $1.49	546,000	8.98	1.22	16,000	1.25
$1.50 – $1.99	172,435	5.85	1.81	138,435	1.82
$2.00 – $2.49	198,100	7.69	2.23	112,450	2.28
$2.50 – $4.72	1,490,613	7.62	3.35	945,320	3.23
	2,652,069	7.77	$2.47	1,457,126	$2.55

The Company applies the disclosure-only alternative of SFAS No. 123, "Accounting for Stock-Based Compensation" (SFAS 123), which defines a fair-value-based method of accounting for employee stock options or similar equity instruments. Under the fair-value-based method, compensation cost is measured at the grant date based on the value of the award and is recognized over the service period of the award, which is usually the vesting period. However, SFAS 123 also allows entities to continue to measure compensation costs for employee stock compensation plans using the intrinsic value method of accounting prescribed in APB 25. The Company has elected to continue to follow the accounting prescribed by APB 25 and has made the required disclosures prescribed by SFAS 123.

Note 8 — Stock Option Plans — (Continued)

Had compensation cost for the Company's employee stock awards been determined consistent with SFAS 123, the Company's net loss applicable to common stock and net loss per share would have been as follows:

	Years Ended December 31,		
	2001	2000	1999
Net loss applicable to common stock			
As reported	$(4,522,706)	$(4,978,827)	$(11,138,603)
Pro forma	$(6,255,848)	$(6,579,648)	$(12,024,156)
Basic and diluted net loss per share			
As reported	$ (0.21)	$ (0.27)	$ (1.15)
Pro forma	$ (0.30)	(0.36)	(1.24)

The fair value of each option grant is estimated on the date of grant using the Black-Sholes option-pricing model, for a stock that does not pay dividends with the following assumptions.

	Years Ended December 31,		
	2001	2000	1999
Risk free interest rate	4.56% - 5.41%	5.17%	4.7% - 6.2%
Expected life	7 years	7 years	7 years
Expected volatility	100%	242%	156%

Using these assumptions, the weighted average grant date fair value of options granted in 2001, 2000 and 1999 was $1.31, $4.28 and $2.48, respectively.

Note 9 — Employee Benefit Plan

In 1988, the Company adopted a profit sharing plan covering substantially all of its employees. Under the profit sharing plan, the Company may, at the discretion of the Board of Directors, contribute a portion of the Company's current or accumulated earnings. In September 1998, the Company amended and restated the profit sharing plan to include provisions for Section 401(k) of the Internal Revenue Code, which allowed for pre-tax employee contributions to the plan. Under the amended and restated plan, the Company may, at the discretion of the Board of Directors, match a portion of the participant contributions. Company contributions, if any, are credited to the participants' accounts and vest over a period of four years based on the participants' initial service date with the Company. During the year ended December 31, 2000, $10,726 was contributed to the plan. During the years ended December 31, 2001 and 1999, no contributions were made to the plan.

Note 10 — Warrants

In January 2001, in association with a private placement of common stock, a warrant to purchase 600,000 shares of common stock exercisable at $3.00 per share was issued (see Note 7). This warrant remains outstanding.

In December 2000, in association with a private placement of common stock, a warrant to purchase 135,593 shares of common stock exercisable at $4.83 per share was issued. This warrant was canceled in January 2001 and replaced with a warrant to purchase 264,407 shares of common stock exercisable at $3.13 per share (see Note 7). This warrant remains outstanding.

In June 1999, in association with a private placement of preferred stock warrants to purchase 1,000,000 shares of common stock exercisable at $0.50 per share were issued. All of these warrants to purchase common stock have been exercised.

In November 1997, in association with the Company's initial public offering, a warrant to purchase 180,000 shares of common stock exercisable at $14.85 per share was issued. This warrant remains outstanding.

Note 10 — Warrants — (Continued)

In August and September 1997, warrants to purchase 356,545 shares of common stock exercisable at $5.50 per share were issued. Warrants to purchase 55,000 shares have been exercised to date and warrants to purchase 301,545 shares remain outstanding.

In accordance with EITF Issue No. 00-19 *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, the Company has determined that each of the warrants described above should be classified as permanent equity in the financial statements and should not be marked to market over the life of the warrant.

Note 11 — Commitments and Contingencies

In July 2000, the Company completed a move of its corporate and research and development offices from San Antonio, Texas, to Waltham, Massachusetts. The Company leases its office space under a non-cancelable operating lease expiring June 2006.

The Company's former corporate headquarters and research and development offices, located in San Antonio, Texas, are held under a lease expiring May 31, 2003 and have been subleased by the Company until the expiration of this lease. The sublease income is aggregated with the net rent expense and included in other income and expense in the consolidated statements of operations.

The Company also leases certain office furniture and equipment under capital lease obligations. Future minimum lease commitments, net of sublease income, under lease agreements with initial or remaining terms of one year or more at December 31, 2001, are as follows:

Year Ending December 31,	Operating Leases	Capital Leases
2002	$ 436,372	$34,564
2003	340,519	14,796
2004	271,331	—
2005	267,320	—
2006	132,192	—
	$1,447,734	49,360
Less — Amount representing interest		8,053
Less — Current portion		30,216
Long-term portion		$11,091

Rent expense, net of sublease income, was $190,163, $138,064 and $199,346 for the years ended December 31, 2001, 2000 and 1999, respectively.

Employment Agreements

The Company has entered into employment agreements with certain key employees of the Company which range from one to five years and provide for severance ranging from three months to one year upon termination of employment.

Note 12 — Segment Information

The Company follows SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information* (SFAS 131) which establishes standards for reporting information about operating segments in annual and interim financial statements, and requires that companies report financial and descriptive information about its reportable segments based on a management approach. SFAS 131 also establishes standards for related disclosures about products and services, geographic areas and major customers. In

Note 12 — Segment Information — (Continued)

applying the requirements of this statement, each of the Company's geographic areas described below was determined to be an operating segment as defined by the statement, but have been aggregated as allowed by the statement for reporting purposes. As a result, the Company continues to have one reportable segment, which is the development of genetic susceptibility tests and therapeutic targets for common diseases.

During 2000, the Company closed its foreign operations. Therefore, the Company no longer derives or reports any revenue or expense from outside of the United States. As of December 31, 2001 and December 31, 2000, substantially all of the assets of the Company were located in the United States.

The following table presents information about the Company by geographic area:

	For the Years Ended December 31,		
	2001	2000	1999
Total Revenues:			
United States	$ 202,942	$ 256,387	$ 281,239
France	—	—	38,846
Other foreign	—	—	157,412
Total	$ 202,942	$ 256,387	$ 477,497
Operating Loss:			
United States	$(4,776,627)	$(5,188,234)	$(3,650,968)
France	—	—	(504,288)
Other foreign	—	—	(2,043,484)
Total	$(4,776,627)	$(5,188,234)	$(6,198,740)

Concentrations of Risk

The Company sells products and provides contract services for customers primarily in the United States and Europe and extends credit based on an evaluation of the customer's financial condition, generally without requiring collateral. The Company monitors its exposure for credit losses and maintains allowances for anticipated losses. As of December 31, 2001, a single customer accounted for 91% of the total accounts receivable. As of December 31, 2000, no single customer accounted for more than 10% of the total accounts receivable.

During the year ended December 31, 2001, one customer accounted for 56% of total revenue and another accounted for 22% of total revenue. During the years ended December 31, 2000 and 1999, no one customer accounted for more than 10% of total revenues. The increase in concentration of risk is the result of our change in strategy in selling PST. We no longer market PST directly; we now sell to a few large distributors who market PST to individual physicians and patients.

Note 13 — Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2001	2000
Legal	$ 50,000	$ 90,000
Vacation	100,282	68,270
Other	327,086	444,802
Total	$477,368	$603,072

Note 14 — Selected Quarterly Financial Data (Unaudited)

The following are selected quarterly financial data for the years ended December 31, 2001 and 2000.

	Quarter Ended			
	March 31, 2001	June 30, 2001	September 30, 2001	December 31, 2001
Revenue	$ 40,291	$ 118,654	$ 24,978	$ 19,019
Loss from operations	$(1,244,381)	$(1,223,685)	$(1,183,294)	$(1,125,267)
Net loss	$(1,140,043)	$(1,146,149)	$(1,135,880)	$(1,100,636)
Basic and diluted net loss per share	$ (0.06)	$ (0.05)	$ (0.05)	$ (0.05)

	Quarter Ended			
	March 31, 2000	June 30, 2000	September 30, 2000	December 31, 2000
Revenues	$ 85,830	$ 82,119	$ 38,141	$ 50,297
Loss from operations	$(1,279,641)	$(1,385,537)	$(1,214,476)	$(1,308,580)
Net loss	$(1,246,036)	$ (1289,637)	$(1,130,255)	$(1,312,899)
Basic and diluted net loss per share	$ (0.07)	$ (0.07)	$ (0.06)	$ (0.07)