### UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 FORM 10-K ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE Х SECURITIES AND **EXCHANGE ACT OF 1934** For the fiscal year ended December 31, 2009 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF 0 THE **SECURITIES EXCHANGE ACT OF 1934** For the transition period from to Commission File Number: 001-32715 INTERLEUKIN GENETICS, INC. (Name of Registrant in its Charter) Delaware 94-3123681 (State or other jurisdiction of (I.R.S. Employer incorporation or organization) Identification No.)

135 Beaver Street, Waltham, MA (Address of principal executive offices)

02452 (Zip Code)

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

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

Common Stock, \$0.001 par value per share

NYSE Amex LLC

.

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES o NO x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. YES o NO x

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES o NO o

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer o Non-accelerated filer o Smaller reporting (Do not check if a smaller reporting company) Smaller reporting

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES o NO x

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of the last business day of the registrant's most recently completed second quarter was \$16,645,635.

As of March 18, 2010 there were 36,494,890 shares of the registrant's Common Stock and 5,000,000 shares of the registrant's Series A Preferred Stock, issued and outstanding.

Documents Incorporated By Reference

Portions of the registrant's Definitive Proxy Statement for the 2010 Annual Meeting of Shareholders to be held on or about June 17, 2010, are incorporated by reference in Part III hereof.

# INTERLEUKIN GENETICS, INC.

## FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2009

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#### PART I

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K and, in particular, the description of our Business set forth in Item 1, the Risk Factors set forth in Item 1A and Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in Item 7, and the documents incorporated by reference into this report contain or incorporate certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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 "may," "will," "could," "should," "potential," "continue," "expect," "intend," "plan," "estimate," "anticipate," "believe," "project," "likely," words or expressions or the negatives of such words or expressions are intended to identify forward-looking statements. We base these statements on our beliefs as well as assumptions we made using information currently available to us. Such statements are subject to risks, uncertainties and assumptions, including those identified in Item 1A "Risk Factors" and elsewhere in this report, as well as other matters not yet known to us or not currently considered material by us. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, estimated or projected. Given these risks and uncertainties, prospective investors are cautioned not to place undue reliance on such forward-looking statements. Forward-looking statements do not guarantee future performance and should not be considered as statements of fact. All information set forth in this Form 10-K is as of the date of filing this Form 10-K and should not be relied upon as representing our estimate as of any subsequent date. While we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so to reflect actual results, changes in assumptions or changes in other factors affecting such forward-looking statements.

#### Item 1. Business

#### Overview

Interleukin Genetics, Inc. is a personalized health company that develops condition-focused, unique genetic tests. Our overall mission is to provide genetic test products that can help individuals maintain or improve their health through preventive measures. Our vision is to use the science of applied genetics to empower individuals and physicians to better understand the set of actions and steps necessary to guide lifestyle and treatment options. We believe that the science of applied genetics can help companies provide improved services to their customers, empower individuals to personalize their health and assist in improving outcomes in drug development and use by identifying subpopulations that are more responsive to the therapy. We currently have two primary focus areas to our business. The first is personalized health, focused on providing genetic test products and services via third party partners or directly to end users. These products are developed with the goal of providing guidance to individuals interested in improved wellness. The second is research and development, focused on developing genetic tests linked to a partner's products in medical and dental channels. Both contribute toward our overall mission of providing products that can help individuals maintain or improve their health through preventive or treatment measures. Our revenue is derived from;

- selling our genetic tests to the end users;
- receiving royalties from partners selling our products;

•processing genetic risk assessment tests in our Clinical Laboratory Improvement Amendments of 1988, or CLIA,-certified lab for partners;

conducting research to develop new genetic risk assessment tests for us and partners.

We believe that by providing important genetic information such as the identification of variants in one or more genes, combined with a set of actions and recommendations about possible interventions and guided therapies that may be used based on those variants, we can help individuals improve their health outcomes. We have patents covering the influence of certain gene variations for a number of common chronic diseases and conditions.

We believe that one of the great challenges confronting healthcare today is to better understand why some people are more prone than others to develop various medical conditions and why some people respond to treatments for those conditions differently than others. Until individuals or their providers are able to understand the underlying causes of such variability, healthcare will remain largely constrained by the current approach of broad treatment rather than customized prevention and treatment. Most recommendations for a given condition do not consider genetic differences among individuals and, as a result, individuals whose conditions may be different because of genetic variation all receive the same treatment. Until recently, scientific study of chronic health conditions has largely focused on identifying initiating factors that are causative and ways to alter or reverse the cause or condition. Common examples of altering or reversing initiating factors include calorie reduction in the case of being overweight, reducing levels of cholesterol in the case of heart disease, elimination of bacteria in the case of periodontal disease and reducing estrogen levels in the case of osteoporosis. However, the mere presence of initiating factors does not necessarily mean a person will develop an illness or that a set of actions will work well for everyone the same way. Many common conditions arise in part as a result of how our bodies respond to various environmental factors.

# Genetic Test Products

We believe that a common misconception today is that genetics dictate how an individual will look or feel and that there is nothing one can do to change the destiny set by one's genes. While it is true that genetics have a strong influence on a person's appearance or condition (referred to as a phenotype), it is not true that a person is powerless to influence the outcome. An active field of research in healthcare today is to better understand the interaction between our environment and our genes. This relationship between genetics and environmental factors such as lifestyle and diet is referred to as epigenetics. The scientific community is learning more each day about the role and significance of genetic variations, such as single nucleotide polymorphisms, or SNPs, and haplotypes, on an individual's health. SNP and haplotype analysis coupled with detailed knowledge of environmental factors now is an important area of study in order to improve human health. A SNP may cause a gene to make a different amount of a protein for a given condition, change the timing of protein synthesis or make a variant form of the protein; each of these changes may lead to a discernible physiological impact. However, certain lifestyle changes can influence significantly whether a set of genes are activated or deactivated despite the variation in the gene. Thus while the propensity for physiological impact is always present for a given set of genes and their variants, whether or not the condition manifests itself may be controlled by our environment and the lifestyle choices we make.

We have focused our research, development commercialization efforts on the SNP variations associated with inflammation and metabolic disease for which there is biological understanding. We have worked with several universities including the University of Sheffield in the United Kingdom to identify several SNPs and other factors that influence the body's inflammatory response. Sir Gordon Duff, one of the pioneers in the understanding of the role that genetics plays in inflammatory disease pathways, continues to serve as a member of our scientific advisory board. In addition, we have conducted clinical studies throughout the world involving over 22,000 individuals to make these research findings clinically useful. To date, some of our clinical research collaborations include, or have included, studies at Stanford University, the University of North Carolina at Chapel Hill, the Mayo Clinic; Brigham & Women's Hospital (Harvard Medical College); University of Sheffield, UK; Yonsei University Medical Center, Seoul Korea; Tongji Medical College, Wuhan China; and Tuft's University Medical Center. We have also conducted research with the Geisinger Clinic.

### Metabolism and Inflammation

Metabolism is the physical and chemical processes in an organism by which the organism's material substances are produced, maintained or destroyed and by which energy is made available. These processes maintain life and permit organisms to grow and reproduce as well as respond to their environments. Metabolism consists of two different categories; catabolism which breaks down organic matter to release energy and anabolism which uses energy to construct components of cells such as proteins, nucleic acids, or other components. The speed of metabolic processes can influence how much food an organism will require to live. Recent scientific results have shown that there are significant SNP variations in the genes that control various metabolic pathways and processes.

A person's weight or their nutritional needs can be governed by the genetics involved in various metabolic pathways. The onset of a metabolic condition such as diabetes or obesity has been shown to be linked to lifestyle as well as genetic factors. Thus one's diet, exercise and nutrition choices have a strong effect on how the genetics that influence metabolism behave and thereby influence one's overall health and well-being.

Inflammation is one of the body's most basic protective mechanisms and the understanding of the role of inflammation in disease and various other conditions has increased over the past few years. It is generally accepted that many chronic conditions begin with a challenge to the tissues of the body and that the inflammatory response system of an individual mediates the clinical manifestation. It is also now thought that SNP variations in the genes that influence the inflammatory process can have an important impact on a person's risk/trajectory of a disease for the same set of initiating events or conditions.

Typical inflammatory diseases include rheumatoid arthritis, periodontitis and osteoarthritis. In recent years, inflammation has been found to affect several other major diseases of aging. Chronic inflammation can influence the process that leads to acute heart attacks. For example, an individual that has a strong inflammatory response may be more successful in clearing a bacterial infection than an individual with a less robust inflammatory response. However, that strong inflammatory response may actually cause that individual to be at increased risk for a more severe course in one or more of the chronic diseases that generally affect people in mid to later life, such as cardiovascular disease, osteoporosis, osteoarthritis, asthma, periodontal disease and Alzheimer's disease. Individuals' gene variations influence the severity of the risks and predispositions to these diseases.

### Intellectual Property

Our intellectual property is focused on the discoveries that link variations in key inflammation and metabolic genes to various conditions or illnesses. We initially had concentrated our efforts on variations in the genes for the interleukin family of cytokines, because these compounds appear to be one of the strongest control points for the development and severity of inflammation. Our patents also cover genetic variations in the Perilipin family of proteins and others that are involved in fat storage and metabolism.

We have patents issued on single SNPs and SNP patterns in gene clusters as they relate to use for identifying individuals on a rapid path to several medical conditions or for use in guiding the selection of diets, exercise, vitamin needs, preventive care and also therapeutic agents. Groups of SNPs are often inherited together as patterns called haplotypes. We have a U.S. patent issued on haplotypes in an interleukin gene cluster and their biological and clinical significance. We believe these patents are controlling relative to interleukin SNPs and haplotype patterns that would be used for genetic risk assessment tests.

We currently own rights in fifteen issued U.S. patents, which have expiration dates between 2015 and 2020, and have twenty-four additional U.S. patent applications pending, which are based on novel associations between particular gene sequences and certain inflammatory diseases and disorders. The fifteen issued U.S. patents relate to genetic tests for periodontal disease, osteoporosis, asthma, coronary artery disease, sepsis and other diseases associated with interleukin inflammatory haplotypes. Our newest patent applications relate to the commercial use of SNP panels in the fields of weight management, periodontal disease, osteoporosis and osteoarthritis. If granted, we expect many of these patents are likely to expire until between 2027 and 2030.

Our intellectual property and proprietary technology are subject to numerous risks, which we discuss in the section entitled "Risk Factors" of this report. Our commercial success may depend at least in part on our ability to obtain appropriate patent protection on our therapeutic and diagnostic products and methods and our ability to avoid infringing on the intellectual property of others.

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.

Our Approach to Test Development

We seek to develop products that will benefit individuals seeking preventive or treatment guidance for their particular conditions or illnesses. In order to do so, we believe a genetic test must be useful, understandable, credible and provide actionable guidance. The action resulting from the information we seek to provide through our genetic tests could be either some form of medical treatment, dietary alteration, lifestyle change, or more careful monitoring of the person's condition. We make it a priority to understand the market potential for our genetic tests before developing them. Finally, we must be able to launch and sell a given product effectively.

Multiple genes and complex gene interactions along with environmental factors determine the risk for the common diseases. We may develop a test based on our proprietary genetic markers including important SNPS we have identified if: a) clinical studies show that their effect has a critical and unique influence on the clinical expression of disease, or b) our genetic markers guide the development or use of lifestyle, preventive measures or therapeutic agents that modulate the specific actions of those genetic factors. The risk effects of our genetic factors must be sufficiently powerful so that these genetic markers cannot be excluded from a test panel without substantially reducing the practical clinical usefulness of the test. For example, clinical studies have shown that in patients with a history of heart disease, higher levels of inflammation (as measured by certain markers such as C-reactive protein, a transient marker for inflammation) are predictive of future heart attacks. Indeed, studies published toward the end of 2008 indicated that chronic underlying inflammation has been shown to be a critical factor for increased heart attack risk. We believe that our proprietary genetic variations reliably identify those individuals who have a lifelong tendency to experience elevated inflammation and therefore to have higher risk for heart disease. Development efforts will to continue to use our proprietary genetic technology as part of a broader genetic panel that predicts an individual's risk for disease as they age or predicts a patient's likelihood of severe complications from disease or response to specific treatment if they have already been diagnosed with disease.

For each targeted clinical disease area that meets our criteria, we may develop proprietary tests that are anchored by our intellectual property, plus additional candidate genes that have been validated and shown to be of value. Other genes that are added to a test panel may be in-licensed or may be available from the public domain. For example, the osteoporosis risk assessment panel we launched in December 2009 includes multiple SNPs covered by our intellectual property, plus additional genes that have been validated as risk factors for osteoporosis. Since knowledge about the genes involved in human health will continue to evolve over many years, we may introduce test panels that initially have our proprietary genetic factors with successive versions of additional genes.

We also believe that combining, in non-obvious ways, single gene variations to create a unique or novel tool may result in new, proprietary intellectual property for us. For example, the weight management genetic test panel we introduced in June 2009 involves five SNPs in four genes. Patent applications covering this product have been filed.

In the past few years, the use of haplotypes has become a standard approach to genetic risk assessment for complex diseases. Haplotypes are blocks of SNPs that are inherited together from one parent and in some cases the specific block of SNPs has functional significance beyond the biological functions attributable to the individual SNPs. The same SNP may have very different effects on gene function in different individuals depending on the haplotype context. We believe that we have expertise, experience and intellectual property related to the use of haplotypes in assessing genetic risk for complex diseases and we have filed patents in this area as well.

# **Business Strategy**

We expect our revenue model to consist of:

- sales from our Inherent Health® brand of genetic tests either directly to end users or through partnerships such as the Amway Global channel;
- fees for processing genetic risk assessment tests of the Gensona brand of tests sold in Canada by Amway Global, the North American division of the Alticor Corporation;
- •royalties or profit sharing from sales of genetic test products developed by us and marketed by a partner such as LABEC Pharma and Quest Diagnostics' OralDNA Labs division;
  - •

fees for contract research with third parties; and

• license fees for our intellectual property and products.

In August 2008, we entered into a nonexclusive license agreement with OralDNA Labs, Inc., now a division of Quest Diagnostics to market our PST genetic risk assessment test for the prediction of periodontal disease. Quest Diagnostics sells the PST test directly to dentists throughout the United States. We earn a royalty and a processing fee from each sale of the PST test.

In April 2009, we entered into an exclusive license agreement with LABEC Pharma for Spain and Portugal to market our heart health genetic risk assessment test for the prediction of early heart attack in Spain and Portugal. The test will be marketed under the brand name CardiohealthTM. In January 2010, European regulatory authorities authorized LABEC Pharma to begin selling the CardioHealth product. In June 2009, we launched our own brand of consumer genetic tests under the name Inherent Health®. Our business strategy is to develop test products for our own business needs under the Inherent Health® brand and perform R&D services for partners interested in developing genetic tests to support their products. In addition, we plan to commercialize R&D test products and services through strategic alliances. We plan to continue to grow the Inherent Health® business and to continue to launch products in new channels, including through distribution partners. We are also interested in in-licensing products or intellectual property to create new products. Our genetic testing business will continue to explore large potential markets such as weight management, osteoporosis, and arthritis, where there is a clear unmet medical need for improved care. We expect that our research and development initiatives will continue to enhance our intellectual property position, ensure commercial and technical success of our products, and help partners to develop formulary solutions that enable our partners to offer prevention and intervention therapeutics in a consumer and/or medical segment

In October 2009, we entered into a Merchant Network and Channel Partner Agreement with Alticor's Amway Global Company to market our Inherent Health® genetic assessment tests. Under this agreement, Amway Global's independent business owners, or IBOs, are able to purchase the Inherent Health® brand of genetic tests via a hyperlink from the Amway Global website to the Inherent Health® website. We believe our proprietary genetic test brands supports the efforts of Amway Global to develop personalized consumer products for their IBO's customers. Sales with Amway global through this new business arrangement began in December 2009.

Our Products and Product Development Pipeline

Our current business plan includes focusing our efforts on commercializing our existing genetic test products and developing additional genetic test products. Our plan is to commercialize and develop test products that (1) identify healthy individuals who are at increased risk for early or more severe health risks, (2) allow for an individual to understand which lifestyles will be best suited for their needs and (3) may be used in patients who have already been diagnosed with a specific disease to identify those patients who are more likely to develop severe disease complications and to guide better treatment.

### Inherent Health® Brand of Genetic Tests

In September 2008, we were successful in negotiating a new agreement with Alticor whereby Alticor's license to our technology became non-exclusive. The agreement continued to allow Interleukin Genetics to have exclusive ownership of all inventions relating to genetic tests arising from research programs between the companies. In addition, under the new agreement, we were able to obtain the rights to market all IP, including the genetic tests, outside of the Alticor channel. As a result, in 2009, we created and launched our own brand of genetic test products under the Inherent Health® brand name, which consists of the following genetic tests products:

•Our Weight Management Genetic Test takes the guesswork out of finding an effective diet and exercise solution by revealing actionable steps to achieve weight goals based on your genetics. The test determines whether a low fat, low carbohydrate or balanced diet may be best for you, and whether you need normal or vigorous exercise to most efficiently lose existing body fat. The test provides new information beyond traditional assessments to help you understand the genetic factors that lead to weight gain, so that you can tailor your nutritional intake and fitness routine for improved, sustainable results.

On March 3, 2010 we and researchers from Stanford University announced findings from a retrospective clinical study collaboration involving our Weight Management Genetic Test during a presentation at the American Heart Association's annual epidemiology and prevention conference. According to Stanford University researchers, the differences in weight loss that were observed in individuals who followed a diet matched to their genotype versus one that was not matched to their genotype "is highly significant in numerous categories and represents an approach to

weight loss that has not been previously reported in the literature."

- •Our Bone Health Genetic Test will identify whether you are more likely to be susceptible to spine fractures and low bone mineral density associated with osteoporosis. Although typically starting later in life, early intervention can help prevent osteoporosis. Preventative measures can reduce the risk for bone loss and fractures, which in the case of vertebral fractures leads to a hunched over appearance.
- Our Heart Health Genetic Test identifies your genetic predisposition to heart attack based on inflammation. The genetic analysis identifies individuals that have a lifelong tendency to overproduce certain chemicals in the body that lead to inflammation. Overproduction of these chemicals can start a chain reaction that ultimately may lead to a heart attack. Knowing your genetic risk will enable you to take specific actions to decrease your overall risk.

•Our Nutritional Needs Genetics Test identifies DNA variations in genes crucial to B-vitamin metabolism and the ability to manage oxidative stress. Individuals that show suboptimal results for the genes can be at increased risk for ineffective utilization of B-vitamins and potential for cell damage caused by oxidative stress, both of which can in some cases lead to increased risk for certain diseases and cancers.

# Medical Genetic Tests

•PST® Periodontal Genetic Susceptibility Test – The PST® Genetic Test analyzes two Interleukin-1 (IL1) genes for variations that identify an individual's predisposition for over-expression of inflammation and risk for periodontal disease. The test is sold through a licensing agreement with OralDNA Labs, Inc., a Quest Diagnostics company.

### Gensona Genetic Tests

We had research agreements with Alticor, which concluded in 2009, to develop certain genetic tests, which Alticor's IBOs marketed to consumers through its channel under their Gensona® brand. In 2006, we provided two genetic risk assessment tests under these agreements. In 2009, Amway Global discontinued sale of the Gensona® brand in the United States. The brand is still selling in Canada and will continue to be supported. Samples received from test kits previously sold in the United States and Canada that have not yet been redeemed will continue to be processed. There were two tests that were developed under the Gensona brand name. The first was the Gensona Heart Health Genetic Test, which uses SNP testing of two genes to identify persons who may have an over-expression of inflammation and therefore may be at increased risk for cardiovascular disease. The second Gensona test was the General Nutrition Genetic Test, which identifies SNPs of potential importance in two genes that affect vitamin B metabolism and four genes involved in responding to oxidative stress. These two tests have now been rebranded under the Inherent Health® name and our company is free to partner these products with third parties.

### Genetic Test Product Pipeline

In addition to the genetic tests listed above that we are currently marketing, we are also focusing our genetic test development efforts on the following programs:

- Obesity Management Genetic Test North America populations; Medical channel
  - Osteoarthritis Genetic Test North America populations; Medical channel
- Periodontal Disease Genetic Test (version 2.0) North America and International populations; Medical and Dental channel
  - Other consumer focused genetic tests

### Obesity Management Genetic Test

Obesity has become an increasingly important clinical and public health challenge worldwide. According to the International Obesity Taskforce estimates, there are about 1.1 billion overweight and 350 million obese individuals worldwide and these numbers are expected to grow significantly in the next decade. In the US, prevalence of obesity has more than doubled in the past 25 years. Nearly two-thirds of adults are believed to be overweight or obese. Overweight and obese subjects are at a higher risk of developing one or more serious medical conditions including hypertension, dyslipidemia, heart diseases and diabetes. In the past few years public health agencies have been developing strategies and methods to combat this complex etiology.

Development of obesity is a linear progression in otherwise healthy individuals with an overweight condition as an intermediary condition. Overweight/obesity is characterized as an excess of adipose tissue. The World Health Organization (WHO) and other public health agencies recommend measurement of three different parameters to determine overweight/obesity status for an individual, namely, body mass index (BMI), total body fat and waist/hip ratio (WHR). The cutoff points for each of these parameters have been well defined.

Human obesity arises from the interactions of multiple genes, environmental factors and behaviors and renders management and prevention of obesity very challenging. According to WHO, the lack of physical activity and easy availability of palatable foods are the principle modified characteristic of our modern lifestyle that has contributed to obesity worldwide. Despite the fact that we are all exposed to the same environment, not everyone is becoming obese. This could be attributed to individual genetic differences. Genetics determines an individual's susceptibility to become obese when exposed to an unfavorable environment as well as the way a person can respond to diet and exercise. There have been multiple reports describing the heritability of obesity and also exploring genetic association studies to identify the gene-gene, gene environment and gene-diet interactions involved in the development of obesity. These studies have identified a certain number of SNPs that respond to diet or exercise. For example, certain SNPs make some people more sensitive to the amount of fat in the diet, while other SNP's make some people more resistant to exercise-induced weight loss.

Under development in weight management is a genetic test designed to assist with medical and surgical management of obese individuals. Interleukin Genetics is developing proprietary genetic tests that have been shown in multiple studies to predict which obese patients were resistant to weight loss when placed on a medically supervised calorie-restricted diet.

### Osteoarthritis Genetic Test

Osteoarthritis (OA) is the most common adult joint disease, increasing in frequency and severity in all aging populations. The estimated U.S. prevalence is 20-40 million patients or 5 times that of rheumatoid arthritis. The most common forms of OA involve the hand, knee, hip and spine. Total knee replacements number over 250,000 per year and total hip replacements number over 300,000 per year in the United States. OA may involve a single joint or multiple joints in the same individual, with current therapy focused on pain relief, as there is no FDA-approved therapy that arrests or reverses the joint deterioration. The etiology of OA is multifactorial involving both mechanical and biochemical factors. OA progression is associated with accelerated cartilage degradation leading to joint space narrowing, painful joint disruption, and functional compromise. The pattern of manifestation of OA in many ways mimics that of osteoporosis in that it is more common in women than in men, and it appears to be related to postmenopausal changes with hormone replacement therapy suppressing cartilage degradation. OA disease progression is characterized by a proinflammatory gene expression pattern in cartilage and in joint synovial fluid, with a reactive increase in bone density in the subchondral bone. Large amounts of data provide support for a central role of interleukins in the pathogenesis of OA including animal susceptibility models, models of IL-1-targeted therapy, genetic association studies, and elevated interleukin gene expression in patients with generalized OA. Genetic variations in the interleukin gene cluster have been previously determined to be associated with multiple clinical phenotypes in OA. Our OA program plans to investigate whether interleukin gene variations together with several other inflammatory gene variations is associated with the occurrence of multijoint OA for the development of a genetic risk assessment test.

Interleukin Genetics in November 2009 published in the Annals of Rheumatic Diseases new findings on the genetics of OA. We reported that a panel of genetic markers was highly predictive of which patients with knee OA were likely to develop severe disease as they age. The studies were done as a collaboration between Interleukin and New York University Hospital for Joint Diseases. These findings were similar in two studies. We believe this information may allow pharmaceutical companies that are developing the first disease-modifying drugs for OA (DMOADs) to screen patients and include in their clinical trials only those patients who have progressive disease. There is currently no mechanism for selecting high risk patients, and multiple clinical DMOAD studies have failed due to excessive numbers of patients with no progression of disease. The results may be useful for setting the dose of hyaluronic acids in the treatment of osteoarthritis pain. The genetic test could help identify those patients who need increased frequency dosing regimens or higher doses of the compound. This genetic information may also assist the rheumatologist in managing the medical and surgical options of individual patients. Additional studies identified a

different set of genetic markers that were predictive of which patients started with knee OA and subsequently developed hand problems. We intend to perform additional studies to clarify the clinical utility of these tests and to search for marketing and sales partners to introduce the tests into the medical channel.

### Laboratory Testing Procedure

To conduct a genetic risk assessment test, the end-user collects cells from inside the cheek on a brush and submits it by mail to our laboratory. Samples are only processed with a requisition signed by a physician. Our clinical laboratory then performs the test following our specific protocol and, depending on the regulations in the particular state or (in Canada) province, informs the consumer and the customer's designated health care provider, of the results.

During 2004, we completed the construction of our genetic testing laboratory (for which we obtained registration under CLIA in 2005) to process the test samples. The regulatory requirements associated with a clinical laboratory are addressed under the section titled "Government Regulation." In early 2007, we obtained a clinical laboratory permit from the State of New York for our Cardiovascular Genetic test. In 2009 we upgraded the systems and processes for the laboratory with the addition of high volume analytical equipment. In addition, in 2009 we received approval to market and distribute our PST test in the state of New York.

### Marketing and Distribution Strategy

We market our Inherent Health® brand of genetic tests using our e-commerce website and under contract with Amway. Two of our genetic tests, the Heart Health Genetic Test and the General Nutrition Genetic Test, are marketed and distributed in Canada by Amway Global under the GENSONA® brand through our strategic partnership with Alticor. We also market and distribute our PST® tests directly to dentists and periodontists via Quest Diagnostic's subsidiary, OralDNA Labs in the US. In Spain and Portugal, we market our Heart Health test with LABEC Pharma under the brand name CardioHealth<sup>TM</sup>.

We intend to develop tests with partners in the pharmaceutical, biotechnology and other industries. Once tests are developed and launched, reimbursement may come from various sources including insurance companies, partners or directly from consumers.

### E-commerce

In 2009, we invested in the development and creation of a complete e-commerce solution for our Inherent Health® brand of genetic tests, www.inherenthealth.com. In addition a completely new test kit package was designed and engineered based on extensive market research. We have subcontracted with a fulfillment center to distribute tests to customers ordering via our online store. The e-commerce solution has provided a friendly and easy to use method for the purchase of our genetic tests.

### Partnerships with Academic Researchers

We have (or have had) research collaborations with Stanford University, University of Sheffield (UK), Tufts University, New York University, Harvard University, the Mayo Clinic, California Pacific Medical Center, Boston University, the University of Arkansas, Tongji Medical College (China), University of North Carolina and Yonsei University (Korea). Through these collaborations, we have been able to take advantage of research conducted by these third parties in connection with the development of our genetic risk assessment tests and other possible products.

### Competition - Genetic Tests

The competition in the field of personalized health is changing. The markets and customer base are not well established. There are a number of companies involved in identifying and commercializing genetic markers. The companies differ in product end points and target customers. There are companies that market individual condition genetic tests for complex diseases to consumers and those that sell only to physicians. There are companies that market testing services for rare monogenic diseases mainly to physicians. There are companies that sell genome scanning services to provide customers (usually the consumer directly) reports on 1,500,000 SNPs to the person's entire genome. There are also technology platform companies that sell SNP testing equipment.

The key competitive factors affecting the success of any genetic test is its utility, price (potentially including availability of reimbursement) and the level of market acceptance. In the case of newly introduced products requiring "change of behavior" (such as genetic risk assessment tests), we believe the presence of multiple competitors may

accelerate market acceptance and penetration through increasing awareness. Moreover, two different genetic risk assessment tests for the same disease may in fact test or measure different components, and thus, actually be complementary when given in parallel as an overall assessment of risk, rather than being competitive with each other. Furthermore, the primary focus of most companies in the field is performing gene-identification research for pharmaceutical companies for therapeutic purposes, with genetic risk assessment testing being a secondary goal. In contrast, our primary business focus is developing and commercializing genetic risk assessment tests for health risks and forward-integrating these tests with additional products and services.

For a discussion of the risks associated with competition, see "Risks Related to Our Business, Our Financial Results and Need for Financing - We could become subject to intense competition from other companies, which may damage our business." under "Risk Factors" below in Part I, Item 1A of this Form 10-K.

### Government Regulation

### CLIA and Other Laboratory Licensure

Laboratories that perform testing on human specimens for the purpose of providing information for diagnosis, prevention or treatment of disease or assessment of health are subject to the Clinical Laboratory Improvement Amendments of 1988, or CLIA. This law imposes quality standards for laboratory testing to ensure the accuracy, reliability and timeliness of patient test results. The United States Food and Drug Administration, or FDA, is responsible for the categorization of commercially marketed in vitro diagnostic tests under CLIA into one of three categories based upon the potential risk to public health I reporting erroneous results. The categories were devised on the basis of the complexity of the test to include waived tests, tests of moderate complexity and tests of high complexity. Laboratories performing moderate or high complexity testing must meet the FDA requirements for proficiency testing, patient test management, quality control, quality assurance and personnel.

Under CLIA, certified laboratories are required to hold a certificate applicable to the type of work they perform and to comply with standards covering personnel, facilities administration, quality systems and proficiency testing. CLIA-certified laboratories are typically subject to survey and inspection every two years to assess compliance with program standards.

In addition to CLIA certification, laboratories offering clinical testing services are required to hold certain federal, state and local licenses, certifications and permits. For example, many CLIA-certified laboratories also seek accreditation by the College of American Pathologists, or CAP, and licensure by states that require state-specific licensure for a laboratory that intends to test clinical samples from residents of that state. The CAP Laboratory Accreditation Program is an internationally recognized program that utilizes teams of practicing laboratory professionals as inspectors, and accreditation by CAP can often be used to meet CLIA and state certification requirements.

### Food and Drug Administration

Laboratory Developed Tests. Although the FDA has consistently claimed that it has the regulatory authority to regulate laboratory-developed tests that are validated by the developing laboratory and has imposed labeling requirements for the results of tests utilizing analyte-specific reagents, it has generally exercised enforcement discretion in not otherwise regulating most tests performed by high complexity CLIA-certified laboratories. In recent years, the FDA indicated that it was reviewing the regulatory requirements that will apply to laboratory developed tests, and in September 2006, the FDA published a draft guidance document, which it revised in September 2007, or the Draft Guidance, that describes the FDA's current position regarding potential regulation of In Vitro Diagnostic Multivariate Index Assays, or IVDMIAs, and the revision provided additional examples of the types of tests that would be subject to the Draft Guidance. An IVDMIA is a test system that employs data, derived in part from one or more in vitro assays, and an algorithm that usually, but not necessarily, runs on software, to generate a result that diagnoses a disease or condition or is used in the cure, mitigation, treatment or prevention of disease.

Although the FDA has not yet issued the final Guidance, it, the U.S. Congress and the in vitro diagnostic industry continue to consider the appropriate level of regulation for laboratory developed tests. In December 2008, Genentech, Inc. submitted a Citizen Petition to the FDA in which it argued that all in vitro diagnostic tests intended for use in therapeutic decision making be held to the same scientific and regulatory standards. Since that time, a number of other

companies and organizations have submitted comments supporting or opposing the citizen Petition. The FDA is required to rule upon each appropriately filed petition within 180 days of receipt and may approve it in whole or in part, deny it, or provide a tentative response indicating why it has been unable to reach a decision on the petition. To date, the FDA has not taken any public action with respect to the Citizen Petition, but if it grants the petition, it will likely promulgate regulations which could increase the amount of FDA regulation to which laboratory developed tests will by subjected.

In Vitro Diagnostics. The type of regulation to which our tests and diagnostics will be subject will depend in large part on how we intend to commercialize them. Diagnostics that will be commercialized through direct product sales as in vitro diagnostic kits will be subject to review by the FDA and must be cleared or approved before they can be marketed. Tests that are available as clinical laboratory services have generally not been subject to regulation by the FDA but are subject to other requirements. The FDA regulates the sale or distribution of medical devices, including in vitro diagnostic test kits and some in vitro diagnostic tests. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on haw the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls, including labeling, pre-market notification and adherence to FDA's quality system regulation, which are device-specific good manufacturing practices. Class II devices are subject to general controls, including performance standards and post-marketing surveillance. Class III devices are subject to most of the previously identified requirements as well as to pre-market approval. Most in vitro diagnostic kits are regulated as Class I or II devices and are either exempt from premarket notification or require a 510(k) submission as described below.

510(k) Pre-market Notification. A 510(k) notification requires the sponsor to demonstrate that a medical device is substantially equivalent to another marketed device that is legally marketed in the United States and for which a pre-market approval, or PMA, was not required. It does not generally require supporting clinical data. A device is substantially equivalent to a predicate device if it has the same intended use and technological characteristics as the predicate; or has the same intended use but different technological characteristics, where the information submitted to the FDA does not raise new questions of safety and effectiveness and demonstrates that the device is at least as safe and effective as the legally marketed device.

The FDA may require information regarding clinical data in order to make a decision regarding the claims of substantial equivalence. If the FDA does not believe that the device is substantially equivalent to a predicate device, it will issue a "Not Substantially Equivalent" letter and designate the device as Class III, which will require approval of a PMA application in order to be marketed.

Pre-Market Approval. The PMA process consists of a scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. The PMA process is considerably more time consuming and expensive than the 510(k) route, and the application must be supported by scientific evidence including clinical data, to demonstrate the safety and efficacy of the medical device for its intended purpose.

Although we are not currently offering or developing IVDMIAs or in vitro diagnostic kits, the FDA's interest in the degree of appropriate regulation of laboratory-developed tests could lead to periodic inquiry letters from the FDA and increased costs and delays in introducing new tests, including genetic tests. It is possible that a changing regulatory climate could require us to seek regulatory clearance or approval prior to the launch of genetic risk assessment tests, which could have a material adverse effect on our business.

# HIPAA and Other Privacy Laws

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established for the first time comprehensive federal protection for the privacy and security of health information. The HIPAA standards apply to three types of organizations ("Covered Entities"): health plans, health care clearing houses, and health care providers who conduct certain health care transactions electronically. Covered Entities must have in place administrative, physical and technical standards to guard against the misuse of individually identifiable health information. Additionally, some state laws impose privacy protections more stringent than those of HIPAA. There are also international privacy laws, such as the European Data Directive, that impose restrictions on the access, use, and disclosure of health information. Any of these laws may impact our business. We are not currently a Covered Entity subject to the HIPAA privacy and security standard. It is possible that in the future we will become a Covered Entity (for example if any of the tests that we perform become reimbursable by insurers). Regardless of our own Covered Entity status, HIPAA may apply to our customers.

Our activities must also comply with other applicable privacy laws. For example, there are also Canadian and other international privacy laws that impose restriction of the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws could significant impact our business and our future business plans.

### **GINA** Legislation

In 2008, the Congress passed and the President signed into law, the Genetic Information Non-discrimination ACT or GINA. This law protects individuals from discrimination due to a genetic predisposition for disease or any other genetic condition. The law protects individuals who take a genetic test from insurance companies or employers that may wish to discriminate against a person due to a genetic condition or predisposition for disease. GINA may also prevent companies from conferring benefits on persons due to a genetic condition.

### FTC

The FTC regulates the marketing practices and advertising of all our products. In recent years, the FTC instituted enforcement actions against several dietary supplement companies for false and misleading marketing practices and advertising of certain products. These enforcement actions have resulted in consent decrees and monetary payments by the companies involved. Although the FTC has never threatened an enforcement action against us for the advertising of our products, there can be no assurance that the FTC will not question the advertising for our products in the future.

We believe that we are currently in compliance with all applicable government regulations. We cannot predict what new legislation or regulations governing our operations will be enacted by legislative bodies or promulgated by agencies that regulate its activities, or what changes in interpretations of existing regulations may be adopted by the FDA or the FTC.

### Other Information

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

### Item 1A. Risk Factors

Risks Related to Our Business, Our Financial Results and Need for Financing

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

We have experienced significant operating losses since our inception and expect these losses to continue for some time. We incurred losses from continuing operations of \$5.4 million in 2007, \$6.9 million in 2008 and \$9.2 million in 2009. As of December 31, 2009, our accumulated deficit was \$91.6 million. Our losses result primarily from research and development, selling, general and administrative expenses and amortization of intangible assets. Although we have recently begun to generate revenues from sales of our genetic risk assessment tests, this may not be sufficient to result in net income in the foreseeable future. We will need to generate significant revenue to continue our research and development programs and achieve profitability. We cannot predict when, if ever, we will achieve profitability.

Our operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.

Our operations to date have been largely limited to research and development of our technologies and products related to the filed of personalized health. We have not yet demonstrated an ability to successfully commercialize our genetic tests or products. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history. In addition, we completed the acquisition of the business of the Alan James Group in 2006, and sold substantially all of its assets before the opening of business on July 1, 2009, which makes it difficult to analyze our pre and post transaction results of operations and to compare them from period to period. Period-to-period comparisons of our results of operations may not be meaningful due to these transactions and possible future transactions and are not indications of our future performance. Any future transactions may make our results difficult to compare from period to period in the future.

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 expect that our current and anticipated financial resources, including the amount available under our credit facility with Pyxis and the \$4.9 million in net proceeds we received from our March 2010 registered direct offering, are adequate to maintain our current and planned operations for at least the next 18 months. We expect that we may need significant additional capital in the future to fund our research and product development programs and operations. Our future capital needs depend on many factors. We may need capital for the commercial launch of additional genetic tests, continued research and development efforts, obtaining and protecting patents and administrative expenses. Based on current economic conditions additional financing may not be available when needed, or, if available, it may not be available on favorable terms. In addition, the terms of any financing may adversely affect the holdings or the rights of our existing shareholders. For example, if we raise additional funds by issuing equity securities, further dilution to our then-existing shareholders may result. Debt financing, if available, may involve restrictive covenants that could limit our flexibility in conducting future business activities. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, tests or products in development. 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.

The current economic conditions and financial market turmoil could adversely affect our business and results of operations.

As widely reported, economic conditions and financial markets have been experiencing extreme disruption including, among other things, extreme volatility in prices of publicly traded securities, severely diminished liquidity, severely restricted credit availability, rating downgrades of certain investments and declining valuations of others. Governments have taken unprecedented actions intended to address these extreme market conditions. Many economists have predicted that the United States economy, and possibly the global economy, has entered into a prolonged recession. We believe the current economic conditions and financial market turmoil could adversely affect our operations. Uncertainty about current and future economic conditions may cause consumers to reign in their spending generally, the impact of which may be that they stop or delay their purchases of our genetic tests and consumer products. If these circumstances persist or continue to worsen, our future operating results could be adversely affected, particularly relative to our current expectations.

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

The field of personalized health is highly competitive. Our potential competitors in the United States and abroad are numerous and include, among others, major pharmaceutical and diagnostic companies, consumer products companies, specialized biotechnology firms, universities and other research institutions. Many of our competitors have considerably greater financial, technical, marketing and other resources. Furthermore, many of these competitors are more experienced than we are in discovering, commercializing and marketing products. These greater resources may allow our competitors to discover important genes or genetic markers before we do. If we do not discover genes that are linked to a health risk, 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 our competitors, then our ability to generate sales and revenue will be reduced or eliminated, and could make our products obsolete. We expect competition to intensify in our industry as technical advances are made and become more widely known.

The market for personalized health generally and genetic risk assessment tests in particular is unproven.

The markets and customer base in the field of personalized health are not well established. Adoption of technologies in this emerging field requires substantial market development and there can be no assurance that channels for

marketing our products can or will be successfully developed by us or others. As a result, there can be no assurance that our products will be successfully commercialized or that they can be sold at sufficient volumes to make them profitable. If our potential customers do not accept our products, or take a longer time to accept them than we anticipate, it will reduce our anticipated sales, resulting in additional losses.

The market for genetic risk assessment tests, as part of the field of personalized health, is at an early stage of development and may not continue to grow. The scientific community, including us, has only a limited understanding of the role of genes in predicting disease. The success of our genetic risk assessment tests will depend upon their acceptance as being useful and cost-effective to the individuals who purchase these products, the physicians and other members of the medical community who recommend or prescribe them, as well as third-party payers, such as insurance companies and the government. We can only achieve broad market acceptance with substantial education about the benefits and limitations of genetic risk assessment tests while providing the tests at a fair cost. Furthermore, while positive media attention resulting from new scientific studies or announcements can spur rapid growth in individual segments of the market, and also impact individual brands, news that challenges individual segments or products. The marketplace may never accept our products, and we may never be able to sell our products at a profit.

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

Genetic testing has raised concerns 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 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 could decrease demand for our products.

Technological changes may cause our tests to become obsolete.

We have to date focused our efforts on genetic tests based on a small number of candidate genes. It is now possible to use array technology to conduct whole genome association studies for risk assessment, which may make our technologies obsolete. To date, our tests have been developed on behalf of, and marketed to, our primary customer, Alticor. In order to develop new customers and markets for our genetic risk assessment tests, we will be required to invest substantial additional capital and other resources into further developing these tests.

We have limited experience and capabilities with respect to distributing, marketing and selling genetic risk assessment tests on our own.

We have historically relied upon Alticor, which is also our largest stockholder, for sale and distribution of our genetic risk assessment tests, and we have very limited experience and capabilities with respect to distributing, marketing and selling genetic risk assessment tests on our own. In June 2009, we announced the launch of our new Inherent Health® brand of genetic tests. On October 26, 2009, we entered into an agreement with Amway Global, pursuant to which it will sell the company's Inherent Health® brand of genetics tests through its e-commerce Web site via a hyperlink to our e-commerce site. In addition, we have started to market and sell our genetic tests through other health care and professional channels, and we may attempt to negotiate marketing and distribution agreements with third parties, although there can be no assurances we will be able to do so. We have, to date, had very limited success in marketing and selling our genetic tests, and we can provide no assurance that our current or planned commercialization efforts will be successful.

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

Entering into additional strategic alliances for the development and commercialization of products and services based on our discoveries is an important element of our business strategy. We face significant competition in seeking appropriate collaborators. If we fail to maintain our existing alliances or to 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 deliver products with defects, our credibility may be harmed, market acceptance of our products may decrease and we may be exposed to liability in excess of our product liability insurance coverage.

The manufacturing and marketing of professional diagnostic involve an inherent risk of product liability claims and associated negative publicity. Any defects could harm our credibility and decrease market acceptance of our products. We currently maintain product liability insurance, but it is often difficult to obtain, is expensive and may not be available in the future on economically acceptable terms. In addition, potential product liability claims may exceed the

amount of our insurance coverage or may be excluded from coverage under the terms of our policy. We may become subject to product liability claims that, even if they are without merit, could result in significant legal defense costs to us. If we are held liable for claims for which we are not indemnified or for damages exceeding the limits of our insurance coverage, those claims could materially damage our business and our financial condition. Any product liability claim against us or resulting recall of our products could create significant negative publicity.

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

Our success depends on the ability, experience and performance of our senior management and other key personnel. If we lose one or more of the members of our senior management or other key employees, it could damage our development programs and our business. In addition, our success depends on our ability to continue to hire, train, retain and motivate skilled managerial and scientific personnel. The pool of personnel with the skill that we require is limited. Competition to hire from this limited pool is intense. We compete with numerous pharmaceutical and healthcare companies, as well as universities and non-profit research organizations in the highly competitive Boston, Massachusetts business area. Our current senior management team is employed by us under agreements that may be terminated by them for any reason upon adequate notice. There can be no assurances, therefore, that we will be able to retain our senior executives or replace them, if necessary. We do not maintain key man life insurance on any of our personnel.

If Alticor enters a business in competition with ours, certain of our directors might have a conflict of interest.

In conjunction with our strategic alliance with Alticor, we have agreed to certain terms for allocating opportunities as permitted under Section 122(17) of the Delaware General Corporation Law. This agreement, regulates and defines the conduct of certain of our affairs as they may involve Alticor as our majority stockholder and its affiliates, and our powers, rights, duties and liabilities and those of our officers and directors in connection with corporate opportunities. Except under certain circumstances, Alticor and its affiliates have the right to engage in the same or similar activities or lines of business or have an interest in the same classes or categories of corporate opportunities as we do. If Alticor or one of our directors appointed by Alticor and its affiliates and us, to the fullest extent permitted by law, Alticor and its affiliates will not have a duty to inform us about the corporate opportunity. In addition, Alticor will not be liable to us or to you for breach of any fiduciary duty as a stockholder of ours for not informing us of the corporate opportunity, keeping it for its own account, or referring it to another person.

Additionally, except under limited circumstances, if an officer or employee of Alticor who is also one of our directors is offered a corporate opportunity, such opportunity shall not belong to us. In addition, we agreed that such director will have satisfied his duties to us and not be liable to us or to you in connection with such opportunity. The terms of this agreement will terminate on the date that no person who is a director, officer or employee of ours is also a director, officer, or employee of Alticor or its affiliates.

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, 2009, we had gross net operating loss and research tax credit carryforwards of approximately \$73.2 million and \$1.3 million, respectively, for federal income tax purposes, expiring in varying amounts through the year 2029. As of December 31, 2009, we had a research tax credit carryforward of approximately \$0.7 million for state income tax purposes, expiring in varying amounts through the year 2029. As of December 31, 2009, we had a research tax credit carryforward of approximately \$0.7 million for state income tax purposes, expiring in varying amounts through the year 2024. Our ability to use these net operating loss and credit carryforwards is subject to restrictions contained in the Internal Revenue Code which provide for limitations on our utilization of our net operating loss and credit carryforwards following a greater than 50% ownership change during the prescribed testing period. We have experienced two such ownership changes. One change arose in March 2003 and the other was in June 1999. As a result, our net operating loss carryforwards that relate to periods prior to March 2003 and June 1999 are limited in utilization. The annual limitation may result in the expiration of the carryforwards prior to utilization. In addition, in order to realize the future tax benefits of our net operating loss and tax credit carryforwards, we must generate taxable

income, of which there is no assurance.

### Risks Related to Our Intellectual Property

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 likely decrease our sales and market share.

Our success will 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 rights to fifteen issued U.S. patents and have a number of additional U.S. patent applications pending. We have also been granted a number of corresponding foreign patents and have a number of foreign counterparts of our U.S. patents and patent applications pending. Our patent positions, and those of other pharmaceutical and biotechnology companies, are generally uncertain and involve complex legal, scientific and factual questions. Our ability to develop and commercialize products and services depends on our ability to:

obtain patents;
obtain licenses to the proprietary rights of others;
prevent others from infringing on our proprietary rights; and
protect trade secrets.

Our pending patent applications may not result in issued patents and any issued patents may never afford meaningful protection for our technology or products or provide us with a competitive advantage. If the patents are not issued to us, we can only rely on common law trademark rights to protect these trademarks and our trade dress. Common law trademark rights do not provide the same level of protection as afforded by a United States federal registration of a trademark. Also, common law trademark rights are limited to the geographic area in which the trademark is actually used. Further, others may develop competing products, which avoid legally infringing upon, or conflicting with, our patents. There is no assurance that another company will not replicate one or more of our products, and this may harm our ability to do business. 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, with confidentiality agreements. The third parties we contract with may breach these agreements, and we may not have adequate remedies for any breach. If they do not protect our rights, third parties could use our technology, and our ability to compete in the market would be reduced. We also realize that our trade secrets may become known through other means not currently foreseen by us. Our competitors may discover or independently develop our trade secrets.

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

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

If third parties believe our products or services infringe upon their patents, they could bring legal proceedings against us seeking damages or seeking to enjoin us from testing, manufacturing or marketing our products or services. For example, we have been named as one of nine defendants in a complaint filed on February 11, 2010 by Genetic Technologies Limited, or GTL, in the United States District Court for the Western District of Wisconsin and we were served with the complaint on March 24, 2010. The complaint alleges that each of the defendants make, use or sell products or services that infringe one or more claims of a patent owned by GTL, which expires on March 10, 2010. In our case, the complaint alleges that we offer and provide genetic risk assessment testing services that utilize methods set forth in one or more claims of the patent. While we believe that we have substantial defenses to the claims asserted in the complaint, this litigation or any other litigation, even if without merit, 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 costly license.

# Risks Related Development, Clinical Testing and Regulatory Approval of Our Tests

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

We are subject to a variety of regulatory laws enforced by both the federal government and the states in which they, and we conduct, or will conduct, business, including the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and state clinical laboratory licensure laws and regulations, and the Federal Food, Drug, and Cosmetic Act and related regulations.

The growth of our business may increase the potential of violating these laws. The risk of us being found in violation of these laws and regulations is further increased by the fact that many of these laws and regulations have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us, or any business partners, for violation of these laws or regulations, even if we or they successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If their or our operations are found to be in violation of any of these laws and regulations, they or we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, and they or we could be required to curtail or cease operations. Any of the foregoing consequences could seriously harm our business and our financial results.

If we do not comply with governmental regulations applicable to our CLIA-certified laboratory, we may not be able to continue our operations.

The establishment and operation of our laboratory, as well as our ongoing research and development activities occurring in this laboratory, are subject to regulation by numerous federal, state and local governmental authorities in the United States. The laboratory holds a CLIA certificate of compliance and is licensed by the Commonwealth of Massachusetts, and other states as required, which enables us to provide testing services to residents of most other states.

Failure to maintain state regulatory compliance, or changes in state regulatory schemes, could result in a substantial curtailment or even prohibition of the operations of our laboratory and could have a material adverse effect on our business. CLIA is a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. To renew CLIA certification, laboratories are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of these laboratories. If we were to lose our CLIA certification or our state licenses, whether as a result of a revocation, suspension or limitation, we would no longer be able to continue our testing operations which would have a material adverse effect on our business.

Any tests that may be developed by us may be subject to regulatory approval, which can be lengthy, costly and burdensome.

Clinical laboratory tests that are developed and validated by a CLIA–certified laboratory for its own use are known as laboratory developed tests, or LDTs. Our currently marketed tests were launched as LDTs our CLIA–certified clinical laboratory operating in Waltham, Massachusetts. We expect that our future LDTs will be launched as well at our CLIA-certified laboratory. While in vitro diagnostic tests and test kits that are sold and distributed through interstate commerce are subject to clearance or approval by the U.S. Food and Drug Administration, or FDA, most LDTs currently are not subject to this type of FDA regulation. While we believe that our currently marketed tests and our future LDTs should not be subject to regulation under current FDA policies, these policies may change which may result in these tests becoming subject to more extensive FDA regulation.

Although our currently marketed tests were, and future clinical laboratory tests are being developed as LDTs regulated under CLIA and state laboratory laws, these tests may fall under more extensive FDA regulation in the future. In September 2006, the FDA issued draft guidance on a new class of tests called "In Vitro Diagnostic Multivariate Index Assays," or IVDMIAs. Under this draft guidance, some LDTs, that we may be developing may be determined to be IVDMIAs and could be classified as Class II or Class III medical devices, which would require FDA pre-market review or approval depending upon the intended use and on the level of control necessary to assure the safety and effectiveness of the test. In July 2007, the FDA posted revised draft guidance on IVMDIAs that includes an 18-month transition. The comment period for this revised guidance expired in October 2007, and it is not clear whether or when FDA will finalize this draft guidance.

We cannot provide any assurance that FDA regulation, including pre-market review or approval, will not be required in the future for LDTs. If pre-market review or approval is required, our business could be negatively impacted because our CLIA-certified laboratory may be required to stop offering these LDTs pending pre-market clearance or approval.

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Tests based on our technology may require clinical trial testing, which can be lengthy, costly and burdensome.

If the FDA decides to require pre-market clearance or approval of tests based technology, it may require us to perform clinical trials prior to submitting a regulatory marketing application. If we are required to conduct pre-market clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase development costs and delay commercialization. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population and the nature of the disease or condition being studied.

Our collaborators may be unable to obtain regulatory approval of any therapeutic product that they may develop.

Any therapeutic product that our collaborators may develop will be subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization. Rigorous preclinical testing and clinical trials and an extensive regulatory review process are required to be successfully completed in the United States and in many foreign jurisdictions before a new therapeutic product can be sold. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. The time required to obtain FDA and other approvals for therapeutic products is unpredictable but typically exceeds several years. It is possible that none of the therapeutic products our collaborators may develop will obtain the appropriate regulatory approvals necessary for us or our collaborators to begin selling them.

Furthermore, any regulatory approval to market a therapeutic product may be subject to limitations on the indicated uses. These limitations may limit the size of the market for the therapeutic product. Any therapeutic product that our collaborators may develop will also be subject to numerous foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Therefore, approval by the FDA of a therapeutic product does not assure approval by regulatory authorities outside the United States or vice versa.

If we fail to comply with regulatory requirements, we could be subject to enforcement actions, which could affect our ability to market and sell our tests and may harm our reputation.

If we in the future fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect the ability to successfully develop, market and sell our tests and could harm our reputation and lead to reduced acceptance of such tests or products by the market. These enforcement actions include:

warning letters;
recalls, public notification or medical product safety alerts;
restrictions on, or prohibitions against, marketing such tests or products;
restrictions on importation of such tests or products;
suspension of review or refusal to approve new or pending applications;
withdrawal of product approvals;

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product seizures;

•	injunctions; and
•	civil and criminal penalties and fines.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research and development activities involve the use of hazardous and chemicals materials, and we maintain quantities of various flammable and toxic chemicals in our facilities. We believe our procedures for storing, handling and disposing these materials in our facilities comply with the relevant local and Federal guidelines. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

### Risks Related to Our Common Stock

We may be delisted from the NYSE Amex resulting in a more limited market for our common stock.

In December 2008, we were notified of our failure to comply with the continued listing standards of the NYSE Amex, referred to herein as the Exchange, under section 1003(a)(iii) of the Exchange's Company Guide because our stockholders' equity was less than \$6,000,000 and we have had losses from continuing operations and net losses in our five most recent fiscal years. As of December 31, 2008 and 2009 our stockholders' equity was \$4.5 million and (\$5.8) million, respectively. On January 27, 2009, we submitted to the Exchange a plan to regain compliance with its continued listing requirements. This plan consists of several elements, but is primarily focused on increasing the sales of our products and services and raising additional equity capital. On March 27, 2009, after a review of the compliance plan initially submitted by us, the Corporate Compliance Staff of the Exchange determined that the compliance plan did not make a reasonable demonstration of our ability to regain compliance with the continued listing standards within the compliance period. We appealed the determination.

On May 11, 2009, upon further review by the Exchange, we were notified that the plan to meet the Exchange's continued listing standards was accepted and the Exchange granted us an extension through December 31, 2009 to become compliant. As a result of the Staff's extension, we were not required to attend a hearing before the Listing Qualifications Panel. In December 2009 we submitted additional information to the Exchange and have requested another extension. The Exchange continued to review our progress and on March 17, 2010 granted us an extension through June 23, 2010 to regain compliance. Failure to make significant progress consistent with the plan or to regain compliance with the continued listing standards could result in delisting from the Exchange. If the NYSE Amex delists our common stock, we anticipate that our common stock would be quoted on the OTC Bulletin Board or possibly the so-called "pink sheets." Even if our common stock is quoted on such systems, a delisting by the NYSE Amex could hurt our investors by reducing the liquidity and market price of our common stock. Additionally, a delisting could negatively affect us by reducing the number of investors willing to hold or acquire our common stock, which could negatively affect our ability to raise capital.

Our stock price has been and is likely to continue to be volatile and the market price of our common stock may drop.

In the two years ended December 31, 2009, our stock price has fluctuated from a low of \$0.13 to a high of \$3.00. Furthermore, the stock market has recently experienced significant volatility. The volatility of stocks for companies in our industry often does not relate to the operating performance of the companies represented by the stock. Some of the factors that may cause the market price of our common stock to fluctuate include:

- demand for and acceptance of our products;
- our ability to develop new relationships and maintain and enhance existing relationships with strategic partners;
  - regulatory developments or enforcement in the United States and foreign countries;
    - developments or disputes concerning patents or other proprietary rights;
  - introduction of technological innovations or new products or services by us or our competitors;
- failure to secure adequate capital to fund our operations, or the issuance of equity securities at prices below fair market price;
  - changes in estimates or recommendations by securities analysts, if any cover our common stock;

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litigation;

	• future sales of our common stock;
	• general market conditions;
	economic and other external factors or other disasters or crises;
•	period-to-period fluctuations in our financial results; and
	overall fluctuations in U.S. equity markets.

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These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

Our Series A Preferred Stock has certain rights that are senior to common stockholder rights and this may reduce the value of our common stock.

Our Series A Preferred Stock, which was issued to Alticor in March 2003, accrues dividends at the rate of 8% of the original purchase price per year, payable only when and if declared by the Board of Directors and are non-cumulative. If we declare a distribution, with certain exceptions, payable in securities of other persons, evidences of indebtedness issued by us or other persons, assets (excluding cash dividends) or options or rights to purchase any such securities or evidences of indebtedness, then, in each such case the holders of the Series A Preferred Stock shall be entitled to a proportionate share of any such distribution as though the holders of the Series A Preferred Stock were the holders of the number of shares of our common stock into which their respective shares of Series A Preferred Stock are convertible as of the record date fixed for the determination of the holders of our common stock entitled to receive such distribution. As of December 31, 2009, our Series A Preferred Stock was convertible into 28,160,200 shares of our common stock, which is subject to standard antidilution protections as well as adjustments in the event we issue any shares of capital stock for a price lower than the conversion price of the Series A Preferred Stock.

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

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

As of December 31, 2009, Alticor was our largest stockholder and owned, or had rights to acquire, approximately 59% of our outstanding common stock. Accordingly, this stockholder may be able to determine the outcome of stockholder votes, including votes concerning the election of directors, the adoption or amendment of provisions in our Certificate of Incorporation or By-Laws and the approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets. This stockholder may make decisions that are adverse to other stockholders' interests. This ownership concentration may also adversely affect the market price of our

common stock. Four of our seven directors are individuals chosen by this single stockholder and this stockholder has the right to choose an additional director. These directors might pursue policies in the interest of this single stockholder to the detriment of our other stockholders.

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

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

### Item 2. Properties

Our office and laboratory are located at 135 Beaver Street, Waltham, Massachusetts 02452. In February 2004, we entered into a new lease expanding our space to approximately 19,000 square feet and extended the term of the lease through March 2009. In November 2008 we entered into an amendment to our current lease extending the term through March 2014. As part of our sale of substantially all of the assets of the Alan James Group in July 2009, we relinquished a lease for 4,156 square feet of office space in Boca Raton, Florida. As of December 31, 2009, Waltham, Massachusetts is our only corporate location.

## Item 3. Legal Proceedings

On February 11, 2010, Genetic Technologies Limited, or GTL, filed a complaint in the United States District Court for the Western District of Wisconsin. The complaint names Interleukin and eight other corporations as defendants in an alleged patent infringement lawsuit (Genetics Technologies Limited vs. Beckman Coulter, Inc., et. al., Civil Action No. 10-CV-00069, W.D. Wis., filed February 11, 2010). We were served with the complaint on March 24, 2010. The complaint alleges that the defendants make, use or sell products or services that infringe one or more claims of the patent owned by GTL, U.S. Patent No. 5,612,179, or the '179 Patent, which expires on March 10, 2010. In Interleukin's case, the complaint alleges that we offer and provide genetic risk assessment testing services that utilize methods set forth in one or more claims of the '179 Patent. We believe that we have substantial defenses to the claims asserted in the complaint.

Item 4. [RESERVED]

#### PART II

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

#### Market Information

Our common stock currently trades under the symbol "ILI" on the NYSE Amex (formerly known as the NYSE Alternext US). The following table sets forth, for the periods indicated, the high and low sales prices for our common stock, as reported by the NYSE Amex.

	I	High	Low
2009:			
First Quarter	\$	0.50	\$ 0.17
Second Quarter	\$	0.85	\$ 0.21
Third Quarter	\$	3.00	\$ 0.36
Fourth Quarter	\$	1.31	\$ 0.60

	H	Iigh	Low
2008:			
First Quarter	\$	1.65	\$ 0.94
Second Quarter	\$	1.75	\$ 1.00
Third Quarter	\$	1.47	\$ 0.80
Fourth Quarter	\$	1.05	\$ 0.13

#### Stockholders

As of March 18, 2010, there were approximately 134 stockholders of record and according to our best estimate, approximately 3,300 beneficial owners of our common stock.

#### Dividends

We have not declared any dividends to date and do not plan to declare any dividends on our common stock in the foreseeable future. Furthermore, our credit facility with Pyxis prohibits us from paying cash dividends without Pyxis' consent.

Sales of Unregistered Securities

None that have not been previously reported.

Issuer Purchases of Equity Securities

None.

Item 6. Selected Consolidated Financial Data

The following table sets forth selected consolidated financial data as of and for each of the five years ended December 31, 2009. The selected consolidated financial data as of and for each of the five years in the period ended December 31, 2009 has been derived from our audited consolidated financial statements. Prior to the opening of

business on July 1, 2009 the Company and its wholly-owned subsidiary AJG Brands, Inc. sold substantially all of the assets of AJG Brands, Inc. operating results for AJG Brands, Inc. are reflected in discontinued operations. This data should be read in conjunction with our audited consolidated financial statements and related notes that are included elsewhere in this Annual Report on Form 10-K and with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7 below.

	Year Ended December 31,									
		2009		2008		2007		2006		2005
Statement of Operations Data:										
Continuing Operations										
Total revenue	\$	1,078,430	\$	2,620,687	\$	2,827,284	\$	2,680,762	\$	22,877
Cost of revenue		1,203,647		940,241		975,770		1,212,831		_
Gross profit (loss)		(125,217)		1,680,446		1,851,514		1,467,931		22,877
Operating expenses:										
Research & development		3,213,115		3,560,002		2,928,249		3,262,349		3,127,086
Selling, general & administrative		5,575,911		5,012,345		3,970,869		3,616,859		2,916,858
Amortization of intangibles		115,453		100,693		73,223		54,332		36,921
Total operating expenses		8,904,479		8,673,040		6,972,341		6,933,540		6,080,865
Loss from continuing operations		(9,029,696)		(6,992,594)		(5,120,827)		(5,465,609)		(6,057,988)
Other income (expense):										
Interest Income		10,183		158,773		414,493		275,122		131,655
Interest Expense		(158,760)		(130,253)		(231,992)		(230,495)		(182,617)
Other income (expense):			_	_		(456,223)		(461,874)		(461,874)
Total other income (expense)		(148,577)		28,520		(273,722)		(417,247)		(512,836)
Net loss from continuing operations										
before income taxes		(9,178,273)		(6,964,074)		(5,394,549)		(5,882,856)		(6,570,824)
Provision (benefit) for income taxes			_	31,000		(31,000)		_	_	
Net loss from continuing operations	\$	(9,178,273)	\$	(6,933,074)	\$	(5,425,549)	\$	(5,882,856)	\$	(6,570,824)
Discontinued Operations										
Profit (loss) from discontinued										
operations, net of income taxes		(27,928)		281,689		(793,236)		(1,063,900)		_
Loss on sale of discontinued operations										
including impairment charge of										
\$3,251,838 in 2009		(1,346,202)		_	_	_	_	_	_	_
Profit (loss) from discontinued										
operations	\$	(1,374,130)	\$	281,689	\$	(793,236)	\$	(1,063,900)		_
Net loss	\$ (	10,552,403)	\$	(6,651,385)	\$	(6,218,785)	\$	(6,946,756)	\$	(6,570,824)
Basic and diluted net profit (loss) per										
common share from:										
Continuing operations	\$	(0.29)	\$	(0.22)	\$	(0.20)	\$	(0.23)	\$	(0.28)
Discontinued operations	\$	(0.04)	\$	0.01	\$	(0.02)	\$	(0.04)		
Net loss	\$	(0.33)	\$	(0.21)	\$	(0.22)	\$	(0.27)	\$	(0.28)
Weighted average common shares										
outstanding, basic and diluted		32,007,826		31,354,198		27,723,754		25,340,107		23,702,967
					г			21		
		2000			Er	nded Decemb	er			2005
		2009		2008		2007		2006		2005

		I cai l		CI 51,	
	2009	2008	2007	2006	2005
Selected Balance Sheet Data:					
Cash and cash equivalents	\$ 906,248	\$ 4,952,481	\$ 7,646,468	\$10,082,919	\$ 3,415,174
Working Capital	\$ (518,100)	\$ 3,199,323	\$ 3,849,973	\$ 5,602,760	\$ 574,914
Total Assets	\$ 3,069,463	\$12,154,388	\$16,385,949	\$22,630,285	\$ 4,970,075
Long term debt and capital lease					
obligations, less current portion	\$ 7,000,000	\$ 4,000,000	-		-\$ 1,671,588
Stockholders' (deficit) equity	\$(5,764,628)	\$ 4,482,427	\$10,192,414	\$13,785,931	\$ 283,745

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

The following discussion of our financial condition and results of operations should be read in conjunction with our "Selected Consolidated Financial Data" and the audited Consolidated Financial Statements and the notes thereto included elsewhere in this Annual Report on Form 10-K.

General Overview and Trends

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Interleukin Genetics, Inc. is a personalized health company that develops condition-focused, unique genetic tests. Our overall mission is to provide test products that can help individuals improve or maintain their health through preventive measures. Our vision is to use the science of applied genetics to empower individuals and physicians to better understand the set of actions and steps necessary to guide the best lifestyle and treatment options. We believe that the science of applied genetics can help companies provide improved services to their consumers, and assist in improving outcomes in drug development and use.

2009 was a year of change and directional focus for our company. We initiated a product launch and closed three significant transactions that have impacted or we expect will impact our business. On June 8, 2009 we launched our new Inherent Health® brand of genetic tests and related programs including the first-of-its-kind test for weight management that identifies an individual's genetic tendencies for weight gain and metabolism. In addition, the brand launch offers customers a full suite of affordable, easy-to-use and meaningful genetic tests in heart health, nutritional needs, and bone health, which we launched in December 2009. In addition to the four Inherent Health® test products, we provide the PST® periodontal disease risk assessment test through a Licensing Agreement with OralDNA Labs, Inc. a Quest Diagnostics Inc. Company. To support the Inherent Health® brand launch, we implemented a fully functional web presence with e-commerce capabilities. Genetic tests may be purchased through our website. A nationwide advertising campaign consisting of television, print and internet media was started in the third quarter of 2009, which we anticipated would allow us to better understand the proper media mix for this brand. A third party support and call center was put in place in advance of the advertising campaign. The nationwide advertising campaign ran for two weeks and cost us approximately \$0.8 million. The media campaign provided strategic direction to our product marketing efforts. We learned from the campaign that television is not the primary media for our success and based on the experience gained from the campaign, we do not plan on utilizing significant media resources to market our products. Distribution of our tests and related technology in the short term will focus on:

- partnering with national and international companies for the sale and distribution of our genetic test products
  - partnering with biotechnology companies in the area of drug discovery
    - health care professional partnerships

In addition, we will continue to offer our products through our e-commerce web site.

On April 6, 2009, we entered into a licensing agreement with LABEC Pharma, S.L. to market and sell our Heart Health genetic test throughout Spain and Portugal. As part of the agreement, the test will be marketed by LABEC Pharma and the tests will be processed at our CLIA certified laboratory at our corporate headquarters in Waltham, Massachusetts. On January 19, 2010 we announced that LABEC Pharma has met European regulatory guidelines and will begin to sell our Heart Health genetic test in Spain and Portugal under the product name, Cardio Health<sup>TM</sup>.

Up to and including June 30, 2009, we had two primary business segments that included:

Personalized Health Segment – this segment conducts, researches, develops, markets and sells genetic tests panels primarily in inflammatory and metabolic areas to provide better insight into health, wellness and disease. Following the sale of substantially all of the Alan James Group business and assets prior to the opening of business on July 1, 2009, the Personalized Health segment became our only business segment.

•Consumer Products Segment – this segment was comprised of the Alan James Group business assets, which we sold prior to the opening of business on July 1, 2009, and was focused on developing, selling and marketing nutritional supplements and products into retail consumer channels. Following the sale of substantially all of the Alan James Group business and assets, the Consumer Products segment ceased to exist.

Prior to the opening of business on July 1, 2009 we sold substantially all of the Alan James Group business and assets of our wholly-owned subsidiary AJG Brands, Inc. to Pep Products, Inc., a subsidiary of Nutraceutical Corporation, for approximately \$4.6 million in cash. The proceeds consisted of a \$0.2 million holdback reflected in other assets and \$4.4 million cash which was received on July 1, 2009. The assets sold consisted primarily of accounts receivable, inventories, property and equipment and other assets related to the business. The buyer did not assume accounts payable and accrued liabilities. Subsequent to the closing, AJG Brands, Inc.'s name was changed to Interleukin Brands, Inc. ("IBI"). The non acquired assets remaining in IBI consist primarily of certain accounts receivable and inventory. IBI remained a wholly-owned subsidiary of Interleukin until December 29, 2009, when it was merged into Interleukin. We have fully reserved for all non-acquired inventory and accounts receivable in our financial statements. As a requirement of the transaction, we are prohibited from continuing to operate in a business competitive to the one previously conducted by AJG Brands, Inc., which primarily developed, marketed and sold nutritional supplements and related products into retail consumer channels. The sale of substantially all of the Alan James Group business and assets, which previously comprised the Consumer Products segment of our business, will allow us to focus our resources and attention exclusively on our genetic test business by developing new and selling our existing genetics tests to the growing personalized health market. From July 1, 2009 through December 31, 2009 we did not receive any revenue from the Alan James Group reflected in discontinued operations. We expect to continue to incur expenses until remaining liabilities primarily related to non acquired customer in store inventory is settled. We are working with these retailers to settle the remaining inventory which we believe is adequately reserved for in the financial statements. We are now focusing on genetic test development and commercialization which was formerly defined as our Personalized Health segment and is reflected as continuing operations.

In addition to completing the merger of the IBI subsidiary with Interleukin Genetics, Inc. our wholly owned inactive subsidiary, Interleukin Genetics Laboratory Services, Inc. was also merged into Interleukin Genetics, Inc. on December 29, 2009. The subsidiary had not conducted any business and had no assets or liabilities. As of December 29, 2009 we have no subsidiaries.

On October 26, 2009, we entered into a Merchant Network and Channel Partner Agreement with Amway Corp. d/b/a Amway Global ("Amway Global"), a subsidiary of Alticor Inc. Pursuant to this Agreement, Amway Global will sell the Company's Inherent Health® brand of genetic tests through its e-commerce Web site via a hyperlink to our e-commerce site. Amway Global will receive a commission equal to a percentage of net sales received by us from Amway Global customers. We anticipate the Merchant Network and Channel Partner Agreement in combination with the launch of our Inherent Health® brand of genetic tests and related programs in June 2009 will help us achieve the goal of increasing our genetic test sales.

Our genetic test business contributes toward our overall mission of developing tests and products that can help individuals improve and maintain their health through preventive measures. We plan to pursue this by:

• developing genetic risk assessment tests for use in multiple indications, countries and various demographics; and

• processing genetic risk assessment tests in our CLIA-certified lab or in those of sublicenses.

In 2006, sales of our genetic test products began under marketing and other business arrangements with Alticor. Alticor is a significant customer, representing virtually all of our genetic test revenues and contract research revenue for each of the years ended December 31, 2009, 2008 and 2007. Revenues from Alticor accounted for approximately 88%, 94% and 99% of continuing operations revenues in 2009, 2008 and 2007, respectively.

We have traditionally spent approximately \$3-4 million annually on research and development. We completed our research agreements with Alticor in 2009 and plan to dedicate more of our resources to our own product development efforts. We expect our research & development expenses to decrease as we focus more on our own development and commercialization efforts. This is different than in prior years our development focus was concentrated in research

and development to bring new test configurations to market. As a result of the launch of our Inherent Health® brand of genetic tests, we expect corporate selling, general, marketing and administrative expenses associated with our genetic test products to increase in 2010 and beyond. As of December 31, 2009, we had \$7.3 million of borrowings available under our credit line with Pyxis Innovations, Inc., an affiliate of Alticor, which permits borrowing any time prior to January 1, 2011. On February 1, 2010 the credit line was extended to permit borrowing any time prior to June 30, 2011. On February 1, 2010 we borrowed an additional \$2.0 million which leaves \$5.3 million available under our credit line.

On February 25, 2008, we entered into our most recent research agreement, known as RA8, with Access Business Group International LLC (ABG), a subsidiary of Alticor. RA8 encompasses four primary areas: osteoporosis, cardiovascular disease, nutrigenomics, and dermagenomics. On January 31, 2009, the Company entered into an amendment to RA8, which extends the term from a maximum of six months to eight months terminating on September 30, 2009. We received an additional \$200,316 on March 31, 2009 per the amendment to complete ongoing research. See financial statement footnote 6 for a discussion of our strategic alliance with Alticor. As of September 30, 2009, we had completed the clinical studies under RA8 which aim to correlate SNP gene variations to the risk of osteoporosis or cardiovascular disease in Asian populations. Other studies conducted in North American populations identified genetic factors that influence athletic performance (nutrigenomics) and skin health, such as wrinkles, elasticity, aging (dermagenomics), for the purpose of developing products to enhance healthy aging. Under the terms of RA8, ABG paid us \$1.2 million during 2008 for the research. In addition, we recognized approximately \$800,000 of revenue which was unused from prior research agreements with Alticor and its subsidiaries. No additional research agreements are planned with Alticor.

On September 23, 2009, we announced top line positive results from a retrospective clinical study on weight management using patients who participated in a diet study previously reported in the Journal of The American Medical Association. Our study demonstrated that individuals following diets matched to their genotype, as determined by our weight management genetic test, showed statistically significant greater weight loss (6.2% versus 2.4% p<0.013 at 12 months) and other benefits at all time points (2, 6 and 12 months) when compared to individuals on diets not matched to their genotype.

In the genetic test business, competition is in flux and the markets and customer base are not well established. Adoption of new technologies by consumers requires substantial market development and customer education. Historically, we have focused on our relationship with our primary customer, Alticor, a significant direct marketing company, in order to assist us in developing the market for our products and educating our potential customers. Our challenge in 2010 and beyond will be to develop the market for our own personalized health products. We have begun to allocate considerable resources to our own brand of consumer products, including the June 2009 launch of our new Inherent Health® brand of genetic tests and related programs. Due to the early stage of these initiatives, we cannot predict with certainty fluctuations we may experience in our test revenues or whether revenues derived from the Merchant Network and Channel Partner Agreement with Amway Global will ever be material or if material, will be sustained in future periods.

#### Liquidity and Capital Resources

As of December 31, 2009, we had cash and cash equivalents of \$0.9 million and borrowings available under our credit facility of \$7.3 million, which permits borrowing at any time prior to June 30, 2011. On February 1, 2010 we borrowed an additional \$2.0 million leaving \$5.3 million of available credit. In connection with the closing of the sale of substantially all of the Alan James Group business and assets of AJG Brands, Inc., prior to the opening of business on July 1, 2009, we received \$4.4 million of cash proceeds on July 1, 2009.

Cash used in continuing operations was \$6.5 million for the year ended December 31, 2009, as compared to \$5.6 million for the year ended December 31, 2008. Cash used in operations is primarily impacted by operating results and changes in working capital, particularly the timing of the collection of receivables, inventory levels and the timing of payments to suppliers.

Prior to the sale of substantially all of the Alan James Group business and assets, we received positive operating cash flow from the retail sale of supplements. The sale of assets provided cash of approximately \$4.4 million on July 1, 2009. The combination of positive operating cash flow from the operations of The Alan James Group in the years 2006-2009 and sale proceeds reduced our need for borrowings from our credit line with Alticor. As we build our genetic test business the need for capital may increase due to the sale of the supplement business. Beyond our credit

line we have no assurance we will be able to raise sufficient capital from the public markets or other financing alternatives. On December 23, 2009, we filed a shelf registration statement with the SEC for the issuance of common stock, preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, with a total value of up to \$75 million, from time to time at prices and on terms to be determined at the time of such offerings. The filing was declared effective on January 5, 2010. On March 5, 2010, we entered into a definitive agreement with certain institutional investors to sell \$5.3 million of securities in a registered direct offering. The investors purchased an aggregate of 4,375,002 units for \$1.20 per unit, with each unit consisting of a share of common stock and a warrant to purchase 0.40 of a share of common stock. The warrants are exerciseable at \$1.30 per share and expire in five years. Net proceeds to us after fees and expenses were approximately \$4.9 million.

A significant use of cash in the year ended December 31, 2008 was a payment of \$1.2 million, relating to the settlement of purchase obligations with the Alan James Group, \$0.6 million of which had been accrued prior to 2008 and is reflected as being paid in net cash used in continuing operation activities in the year ended December 31, 2008. The remaining \$0.6 million is reflected in net cash used in investing activities of our continuing operations as described below. The increase of \$0.9 million of cash used in continuing operations is primarily attributable to the closing costs related to the sale of substantially all of the Alan James Group business and assets, as well as costs of advertising, media and product development costs related to the launch of our Inherent Health® brand of genetic tests.

Cash used in investing activities of our continuing operations was \$0.6 million for the year ended December 31, 2009, compared to \$1.1 million for the year ended December 31, 2008. The most significant use of cash in investing activities during the year ended December 31, 2008 was the settlement of claims related to the acquisition of the assets and business of the Alan James Group as described above. As a result of the settlement, we paid additional consideration of \$0.6 million. Capital additions were \$0.7 million for the twelve months ended December 31, 2009, compared to \$0.2 million for the twelve months ended December 31, 2008. The increase in capital additions primarily consists of new commercial laboratory equipment installed and validated during 2009, which allows for high volume processing of genetic test samples.

Cash provided by financing activities of our continuing operations was \$3.1 million for the year ended December 31, 2009, compared to \$4.0 million for the year ended December 31, 2008. On May 29, 2009 we received proceeds from the issuance of a note payable in the amount of \$1.0 million under our existing credit facility with Pyxis. On November 9, 2009 we received an additional \$2.0 million under the credit facility. On June 10, 2008 we received \$4.0 million under the same credit facility. We received approximately \$73,000 and \$18,000, respectively from the exercise of stock options and stock purchases through the employee stock purchase plan for the years ended December 31, 2009 and 2008.

On December 23, 2008, we were notified of our failure to comply with the NYSE Amex, hereinafter referred to as the Exchange, continued listing standards under section 1003 of the Exchange's Company Guide. Specifically, the Exchange noted our failure to comply with section 1003(a) (iii) of the Company Guide because our stockholders' equity was less than \$6,000,000 and we had losses from continuing operations and net losses in our five most recent fiscal years. The notice was based on a review by the Exchange of publicly available information, including our Ouarterly Report on Form 10-O for the quarter ended September 30, 2008. As of December 31, 2008, our stockholders equity was \$4.5 million, and as of December 31, 2009 we had a stockholders' deficit of \$5.8 million. On January 27, 2009, we submitted a plan to the exchange to meet the continued listing requirements. The plan consists of several elements, but is primarily focused on increasing the sales of our products and services and raising additional equity capital. On March 27, 2009, we were notified that the Exchange found our plan to regain compliance with the continued listing standards to be unacceptable. We filed an appeal for an oral hearing and submitted a revised plan to the Exchange. On May 11, 2009, the Exchange notified us that the Exchange accepted our redrafted plan of compliance, without a hearing, and granted us an extension until December 31, 2009 to regain compliance with the continued listing standards. In December 2009 we provided more information to the Exchange and requested an extension. The Exchange continued to review our progress toward regaining compliance and on March 17, 2010 granted us an extension until June 23, 2010 to regain compliance. Failure to make progress consistent with the plan or to regain compliance with the continued listing standards could result in delisting from the Exchange, which could significantly impact our ability to raise additional capital.

We currently do not have any commitments for any additional material capital purchases.

Prior to June 30, 2009, we generated operating cash by sales of consumer products and subsequent to that date we continue to generate cash from the sale of genetic tests, royalties, and reimbursements for funded research. Subsequent to June 30, 2009, pursuant to the asset purchase agreement with the Alan James Group, we are prohibited from continuing to operate in a business competitive to the one previously conducted by AJG Brands, Inc., which primarily

developed, marketed and sold nutritional supplements and related products into retail consumer channel. The amount of operating cash we generate is not currently sufficient to continue to fund and grow our operations. In addition to funds generated by our operations, we have a \$14.3 million credit facility with Pyxis, under which we had \$7.3 million in borrowings available as of December 31, 2009. On February 1, 2010 we borrowed an additional \$2.0 million leaving borrowings available of \$5.3 million under the credit facility. Clinical studies and other research and development activities may require cash outflows that depend on the timing of activities.

We believe our success depends on our ability to have sufficient capital and liquidity to achieve our objectives of closing negotiations with partners and creating additional distribution channels for our genetic testing products and technology. In addition to our current operating line of credit we will have to raise additional capital. At the current time we are unable to cover our operating expenses. Even though we are experiencing sales increases in our genetic testing business we must take additional steps to reduce our operating costs. In 2009 we reduced our headcount in non essential areas. We are currently attempting to sublease approximately one-third of our 19,000 square feet of office space. The space includes offices and a laboratory that is not being used. We have significantly reduced our research and development programs to only those that focus on technology related to deals with potential commercial partners. We have taken steps to reduce our corporate administrative expenses by working with or seeking new vendors who offer the same service for a better cost. While we expect that our current and anticipated financial resources, including the amount available under our credit facility with Pyxis and the \$4.9 million in net proceeds we received from our March 2010 registered direct offering, are adequate to maintain our current and planned operations for at least the next 18 months, we anticipate we will need substantial additional funds in the future which we intend to obtain from operations, alliances or raising additional capital, but such funding may not be available on terms acceptable to us, or at all. After taking into account the 4,375,002 shares of common stock and warrants to purchase 1,750,000 shares of common stock we issued in the March 2010 registered direct offering, we have approximately \$65.5 million of securities available for sale under our effective shelf registration statement, although we may be limited by the rules and regulations of the SEC and the NYSE Amex in the amount of securities we may offer under this registration statement. Even if we are unsuccessful in raising addition capital we may not be able to raise enough capital to cover our ongoing operating expenses and may be forced to seek other strategic alternatives.

We have no financial covenants as part of our credit facility with Pyxis. As of December 31, 2009, we had \$7.0 million outstanding under the credit facility, which is reflected as long term debt on our balance sheet and is convertible, at the option of Pyxis into shares of our common stock at a price of \$5.6783 per share. On February 1, 2010, we drew down an additional \$2.0 million under the credit facility with Pyxis and issued a convertible promissory note to Pyxis in that amount. We currently have \$9.0 million outstanding under the credit facility, and we have \$5.3 million available to us to borrow under the credit facility.

A summary of our contractual obligations as of December 31, 2009 is included in the table below:

	Payments Due By Period (000's)									
			Les	s than					More	than
Contractual Obligations		Total	1	Year	1-3	3 Years	3-5	Years	5 Ye	ears
Long-Term Debt Obligations	\$	7,000	\$		\$	7,000	\$		- \$	
Operating Lease Obligations		1,966		452		1,395		119		
TOTAL	\$	8.966	\$	452	\$	8.395	\$	119	\$	

**Results of Operations** 

	Year Ended December 31,							
		2009		2008		2007		
Personalized health – continuing operations								
Genetic testing	\$	505,913	\$	409,452	\$	779,238		
Contract research & development		545,847		2,061,149		2,028,030		
Other		26,670		150,086		20,016		
Total revenue from continuing operations		1,078,430		2,620,687		2,827,284		
Cost of revenue		1,203,647		940,241		975,770		
Gross margin		(125,217)		1,680,446		1,851,514		
Expenses:								
Research & development		3,213,115		3,560,002		2,928,249		

Selling, general & administrative	5,575,911	5,012,345	3,970,869
Amortization of intangibles	115,453	100,693	73,223
Other (income) expense	148,577	(28,520)	273,722
Total expenses	9,053,056	8,644,520	7,246,063
Net loss from continuing operations before income			
taxes	(9,178,273)	(6,964,074)	(5,394,549)
Benefit for income taxes		31,000	(31,000)
Net loss from continuing operations	\$ (9,178,273)	\$ (6,933,074)	\$ (5,425,549)

Consumer products – discontinued operations			
Consumer product revenue	3,580,169	7,394,293	6,873,209
Cost of revenue	1,892,815	3,797,677	3,723,676
Gross margin	1,687,354	3,596,616	3,149,533
Expenses:			
Selling, general & administrative	1,206,714	2,022,023	2,397,104
Amortization of intangibles	4,010	1,234,745	1,578,021
Other (Income)expenses	451,558	1,057	(16,856)
Loss on discontinued operations	1,346,202		_
Net (Income)expenses	3,008,484	3,257,825	3,958,269
Net income(loss) from discontinued operations before			
income taxes	(1,321,130)	338,791	(808,736)
Provision for income taxes	(53,000)	(57,102)	15,500
Net income(loss) from discontinued operations	\$ (1,374,130) \$	281,689 \$	(793,236)
Combined continuing and discontinued operations			
Total revenue	4,658,599	10,014,980	9,700,493
Cost of revenue	3,096,462	4,737,918	4,699,446
Gross margin	1,562,137	5,277,062	5,001,047
Expenses:			
Research & development	3,213,115	3,560,002	2,928,249
Selling, general & administrative	6,782,625	7,034,368	6,367,973
Amortization of intangibles	119,463	1,335,438	1,651,244
Other (income) expense	600,135	(27,463)	256,866
Loss on discontinued operations	1,346,202	—	_
Total expenses	12,061,540	11,902,345	11,204,332
Net loss before income taxes	(10,499,403)	(6,625,283)	(6,203,285)
Provision for income taxes	(53,000)	(26,102)	(15,500)
Net loss	\$ (10,552,403) \$	(6,651,385) \$	(6,218,785)
Basic and diluted net profit (loss) per common share from:			
Continuing operations	\$ (0.29) \$	(0.22) \$	(0.20)
Discontinued operations	\$ (0.04) \$	0.01 \$	(0.02)
Net loss	\$ (0.33) \$	(0.21) \$	(0.22)
Weighted average common shares outstanding	32,007,826	31,354,198	27,723,754

Years Ended December 31, 2009 and 2008

#### **Continuing Operations**

Total revenue from our continuing operations for the year ended December 31, 2009 was \$1.1 million, compared to \$2.6 million for the year ended December 31, 2008. The decrease of \$1.5 million or 58.8% is primarily attributable to a decrease in contract research revenue and royalty revenue offset by an increase in genetic test revenue. Contract research revenue decreased \$1.5 million primarily due to the completion in 2009 of sponsored projects with reimbursable research expenses. Genetic testing revenue was \$0.5 million in the year ended December 31, 2009, compared to \$0.4 million in the year ended December 31, 2008, the increase of \$0.1 million or 23.6% is primarily attributable to the launch of our Inherent Health® brand of genetic tests, which commenced in June 2009.

Revenues from Alticor represented approximately 87.7% and 93.9%, respectively of our revenues from continuing operations for the years ended December 31, 2009 and 2008.

Cost of revenue from continuing operations for the year ended December 31, 2009 was \$1.2 million, or 111.6% of its revenue, compared to \$0.9 million, or 35.9% of its revenue, for the year ended December 31, 2008. The significant increase in the cost of revenue as a percentage of revenue is primarily attributable to increased fixed costs associated with our genetic testing laboratory notwithstanding decreases in our revenue. Increased fixed costs include supplies and depreciation related to the installation of new high volume genetic testing equipment. In addition lab personnel are spending significantly more of their time processing tests as no further research agreements with Alticor are in place.

Gross margin from continuing operations for the year ended December 31, 2009 was a loss of \$125,000, or 11.6% of its revenue, compared to a profit of \$1.7 million, or 64.1% of its revenue for the year ended December 31, 2008. The decrease in gross margin of \$1.8 million, or 107.5%, is primarily attributable to a reduction in contract research revenue and royalty revenue offset by an increase in genetic testing revenue for the year ended December 31, 2009, compared to the year ended December 31, 2008. Fixed costs increased during the year ended December 31, 2009 due to the purchase and installation of new high volume genetic testing equipment, which we expect to be absorbed with changes in volume of tests performed. The equipment will allow for higher volume processing. No such costs were recognized in the twelve months ended December 31, 2008.

Research and development expenses from continuing operations were \$3.2 million for the year ended December 31, 2009, compared to \$3.6 million for the year ended December 31, 2008. The decrease of \$0.4 million, or 9.7%, is primarily attributable to decreases in clinical trial expenses related to our research agreements with Alticor and lower consulting expenses offset by increased separation costs and increased expenses related to our patent portfolio

Selling, general and administrative expenses from continuing operations were \$5.6 million for the year ended December 31, 2009 compared to \$5.0 million for the year ended December 31, 2008. The increase of \$0.6 million, or 11.2%, is primarily attributable to increased product development and advertising expenses for our Inherent Health® brand of genetic test and increased headcount, offset by decreased expenses relating to administrative support consultants.

Interest expense from continuing operations was \$159,000 for the year ended December 31, 2009, as compared to \$130,000 for the year ended December 31, 2008. The increase in interest expense of \$29,000 is primarily attributable to interest expense associated with borrowings on our credit facility with Pyxis.

Interest income from continuing operations was \$10,000 for the year ended December 31, 2009, as compared to \$159,000 for the year ended December 31, 2008. The decrease in interest income of \$149,000 is primarily attributable to the decrease in our cash balance in combination with lower interest being earned on available cash balances. The current financial market conditions have significantly reduced the interest rate we are able to earn on our cash and cash equivalent balances.

Years Ended December 31, 2008 and 2007

Total revenue from our continuing operations for the year ended December 31, 2008 was \$2.6 million, compared to \$2.8 million for the year ended December 31, 2007. The decrease of \$0.2 million or 7.3% is attributable to a decrease in genetic test revenue offset by an increase in royalty revenue. Contract research revenue increased slightly due to sponsored projects with reimbursable research expenses. Genetic testing revenue was \$0.4 million in the year ended December 31, 2008, compared to \$0.8 million in the year ended December 31, 2007 or a decrease of \$0.4 million or 47.5% is primarily attributable to a decrease in customer demand which was higher during the products' initial launch in 2007.

Revenues from Alticor represented approximately 93.9% and 98.8%, respectively of our revenues from continuing operations for the years ended December 31, 2008 and 2007.

Cost of revenue from continuing operations for the year ended December 31, 2008 was \$0.9 million, or 35.9% of its revenue, compared to \$1.0 million, or 34.5% of its revenue, for the year ended December 31, 2007. The decrease of \$0.1 million is attributable to increased laboratory operating costs and rent offset by lower labor and lab supply costs.

Gross margin from continuing operations for the year ended December 31, 2008 was \$1.7 million, or 64.1% of its revenue, compared to \$1.9 million, or 65.5% of its revenue, for the year ended December 31, 2007. The decrease in gross margin of \$0.2 million, or 9.2%, is attributable to a reduction in revenue and offset by an increase in royalty revenue for the year ended December 31, 2008.

Research and development expenses from continuing operations were \$3.6 million for the year ended December 31, 2008 compared to \$2.9 million for the year ended December 21, 2007. The increase of \$0.7 million, or 21.6%, is primarily attributable to an increase in expenses relating to our sponsored research agreement with Yonsei University, combined with increased costs related to our patent portfolio, partially offset by a reduction in research consulting expenses.

Selling, general and administrative expenses from continuing operations were \$5.0 million for the year ended December 31, 2008 compared to \$4.0 million for the year ended December 31, 2007. The increase of \$1.0 million, or 26.2%, is primarily attributable to increased promotional and advertising expenses plus additional compensation expenses due to our increased headcount. These expense increases were partially offset by a reduction in settlement expenses relating to the acquisition of The Alan James Group, of which \$.6 million was accrued in 2007 and no such expenses were accrued in 2008.

Interest expense from continuing operations was \$130,000 for the year ended December 31, 2008, as compared to \$232,000 for the year ended December 31, 2007. The decrease in interest expense of \$102,000 is primarily attributable to decreased interest expense associated with borrowings under our credit facility with Pyxis, as Pyxis converted a portion of the borrowings into shares of our common stock in 2008.

Interest income from continuing operations was \$159,000 for the year ended December 31, 2008, as compared to \$415,000 for the year ended December 31, 2007. The decrease in interest income of \$256,000 is primarily attributable to the decrease in cash balance with lower interest being earned on available cash balances. Current financial market conditions in 2008 significantly reduced the interest rate we were able to earn on our cash and cash equivalent balances.

#### Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements. The preparation of these financial statements and related disclosures in conformity with accounting principles generally accepted in the United States of America requires us to (i) make judgments, assumptions and estimates that affect the reported amounts of assets, liabilities, revenue and expenses; and (ii) disclose contingent assets and liabilities. A critical accounting estimate is an assumption that could have a material effect on our consolidated financial statements if another, also reasonable, amount were used or a change in the estimates is reasonably likely from period to period. We base our accounting estimates on historical experience and other factors that we consider reasonable under the circumstances. However, actual results may differ from these estimates. To the extent there are material differences between our estimates and the actual results, our future financial condition and results of operations will be affected. Our most critical accounting policies and estimates upon which our financial condition depends, and which involve the most complex or subjective decisions or assessments are the following:

#### Revenue Recognition:

Revenue from genetic testing services is recognized when there is persuasive evidence of an arrangement, service has been rendered, the sales price is determinable and collectability is reasonably assured. Service is deemed to be rendered when the results have been reported to the individual who ordered the test. To the extent that tests have been prepaid but results have not yet been reported, recognition of all related revenue is deferred. As of December 31, 2009 and December 31, 2008, we had deferred revenue of \$108,000 and \$80,000, respectively, for tests that have been prepaid but results have not yet been reported.

Revenue from product sales is recognized when there is persuasive evidence of an arrangement, delivery has occurred and title and risk of loss have transferred to the customer, the sales price is determinable and collectability is reasonably assured. The Company has no consignment sales. Product revenue is reduced for allowances and adjustments, including returns, discontinued items, discounts, trade promotions and slotting fees.

Revenue from contract research and development is recognized over the term of the contract as we perform our obligations under that contract (including revenue from Alticor, or related party).

#### Allowance for Sales Returns:

We analyze sales returns in accordance with the provisions of FASB ASC 605, Revenue Recognition. We are able to make reasonable and reliable estimates based on the buying patterns of the end-users of its products based on sales data received. We believe we have sufficient interaction with and knowledge of our customers, industry trends and industry conditions to adjust the accrual for returns when necessary.

At December 31, 2009, we have fully reserved for any potential sales returns and discontinued items applicable to balance in the non-acquired accounts resulting from our sale of substantially all of the assets of the Alan James Group business. The reserve of approximately \$1.0 million is deemed to be adequate and no additional amounts were added at December 31, 2009. Payments of approximately \$0.3 million were made that directly related to the product returns from non acquired accounts as of December 31, 2009.

#### Trade Promotions

Pursuant to the asset purchase agreement in connection with the sale of substantially all of the Alan James Group business and assets, we fully accrued for the approximately \$150,000 of agreed upon trade promotions implemented prior to June 30, 2009. At December 31, 2009 the balance of trade promotions estimated to be due in the future was \$70,859.

#### Accounts Receivable

Pursuant to the asset purchase agreement in connection with the sale of substantially all of the Alan James Group business and assets we retained non acquired accounts receivable in the amount of \$180,605 which was fully reserved for as uncollectible at June 30, 2009. At December 31, 2009, the balance in non acquired accounts receivable was \$0 as all remaining accounts amounting to \$107,000 were deemed uncollectable and were applied to the reserve. Prior to the acquisition trade accounts receivable were stated at their estimated net realizable value, which is generally the invoiced amount less any estimated discount related to payment terms. We offered our Consumer Product customers a 2% cash discount if payment is made within 30 days of the invoice date, however, most customers take the discount regardless of when payment occurs.

#### Inventory:

We value our inventory at the lower of cost or market. We monitor our inventory and analyze it on a regular basis. Cycle counts are taken periodically to verify inventory levels. In addition, we analyze the movement of items within our inventory in an effort to determine the likelihood that inventory will be sold or used before expiration dates are reached. We provide an allowance against that portion of inventory that we believe is unlikely to be sold or used before expiration dates are reached. An adverse change in any of these factors may result in the need for additional inventory allowance.

#### Stock-based compensation:

We account for our stock-based compensation expense in accordance with FASB ASC 718, Compensation – Stock Compensation. The standard addresses all forms of share-based payment (SBP) awards, including shares issued under employee stock purchase plans, stock options, restricted stock and stock appreciation rights. We expense SBP awards with compensation cost for SBP transactions measured at fair value. Compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the effective date shall be recognized as the requisite service is rendered on or after the effective date. The compensation cost for that portion of awards shall be based on the grant-date fair value of those awards as calculated from the pro forma disclosures. Common stock purchased pursuant to our employee stock purchase plan will be expensed based upon the fair market value in excess

of purchase price.

Intangible Assets:

Purchase accounting requires extensive use of accounting estimates and judgments to allocate the purchase price to the fair market value of the assets purchased and liabilities assumed. We have accounted for our acquisitions using the purchase method of accounting. Values were assigned to intangible assets based on third-party independent valuations, as well as management's forecasts and projections that include assumptions related to future revenue and cash flows generated from the acquired assets. We determined that due to the sale of substantially all of the Alan James Group business and assets prior to the opening of business on July 1, 2009, \$3,251,838 of intangible assets became permanently impaired and were expensed.

During the annual fiscal year end close process, we evaluate our intangible assets for impairment. We first must investigate if there was a triggering event that would cause us to evaluate the value of the intangible assets as outlined in the accounting standard for intangible assets. We determined that there was a triggering event during the fiscal year 2009, relating to the \$0.9 million of intangible assets related to capitalized patent costs. The triggering event was the result of a current period operating loss as well as our history of operating losses. We performed the step one evaluation of undiscounted cash flow which resulted in \$1.5 million of free cash flow which is greater than the carrying value of \$0.7 million therefore no impairment write-down was required.

#### Income taxes:

The preparation of our consolidated financial statements requires us to estimate our income taxes in each of the jurisdictions in which we operate, including those outside the United States, which may be subject to certain risks that ordinarily would not be expected in the United States. We account for income taxes in accordance with FASB ASC 740, 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 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. We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized.

Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against deferred tax assets. We have recorded a full valuation allowance against our deferred tax assets of \$26.3 million as of December 31, 2009, due to uncertainties related to our ability to utilize these assets. The valuation allowance is based on management's estimates of taxable income by jurisdiction in which we operate and the period over which the deferred tax assets will be recoverable. In the event that actual results differ from these estimates or management adjusts these estimates in future periods, we may need to adjust our valuation allowance, which could materially impact our financial position and results of operations.

Due to recent changes in Massachusetts corporate income tax regulations, we will be filing on a combined basis with Alticor affiliated entities on a go-forward basis and, as a result, our net operating losses will be fully utilized at December 31, 2009. The combined filing will have no impact on our financial statements due to the full valuation allowance that offsets any deferred tax assets.

Due to the sale of the majority of the assets of Interleukin Brands Inc. and the subsequent dissolution of Interleukin Brands Inc. during the year ended December 31, 2009, a full valuation allowance was recorded for the net operating loss experienced in 2009 and for other deferred tax assets for state income tax purposes.

We review our recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. We review all material tax positions for all years open to statute to determine whether it is more likely than not that the positions taken would be sustained based on the technical merits of those positions. We did not recognize any adjustments for uncertain tax positions during the twelve months ended December 31, 2009.

#### Contingencies:

Estimated losses from contingencies are accrued by management based upon the likelihood of a loss and the ability to reasonably estimate the amount of the loss. Estimating potential losses, or even a range of losses, is difficult and involves a great deal of judgment. Management relies primarily on assessments made by its external legal counsel to make our determination as to whether a loss contingency arising from litigation should be recorded or disclosed. Should the resolution of a contingency result in a loss that we did not accrue because management did not believe a loss was probable or capable of being reasonably estimated, then this loss would result in a charge to income in the

period the contingency was resolved.

Recent Accounting Pronouncements:

Please see our discussion of "recent accounting pronouncements" in Note 4, significant accounting policies contained in the Notes to Consolidated Financial Statements elsewhere in this Annual Report on Form 10K.

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

As of December 31, 2009 the only financial instruments we carried were cash and cash equivalents denominated in U.S. Dollars. We believe the market risk arising from holding these financial instruments is not material. While we recognize that the interest rates these instruments bear are currently at historically low levels, we believe it is most prudent to maintain these relatively low risk positions during this time of unprecedented volatility and uncertainty across the global financial markets.

Some of our sales and some of our costs occur outside the United States and are transacted in foreign currencies. Accordingly, we may be 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

#### INTERLEUKIN GENETICS, INC. INDEX TO FINANCIAL STATEMENTS

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#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

#### Board of Directors and Shareholders of Interleukin Genetics, Inc.

We have audited the accompanying balance sheets of Interleukin Genetics, Inc. (a Delaware corporation) (the "Company") as of December 31, 2009 and 2008, and the related statements of operations, stockholders' (deficit) equity, and cash flows for each of the three years in the period ended December 31, 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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. as of December 31, 2009 and 2008, and the results of their operations and their cash flows for the each of the three years in the period ended December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

/s/ Grant Thornton LLP

Boston, Massachusetts March 25, 2010

# INTERLEUKIN GENETICS, INC.

## BALANCE SHEETS

		December 31,		
		2009		2008
ASSETS			( <i>F</i>	As Adjusted)
Current assets:				
Cash and cash equivalents	\$	906,248	\$	4,952,481
Accounts receivable from related party	Ψ	24,594	Ψ	35,167
Trade accounts receivable		9,285		8,219
Inventory		118,430		
Prepaid expenses and other current assets		225,493		162,834
Current assets of discontinued operations		31,941		1,707,583
Total current assets		1,315,991		6,866,284
Fixed assets, net		769,981		435,480
Intangible assets, net		745,490		889,941
Other assets		238,001		38,001
Other assets of discontinued operations		_	_	3,924,682
Total assets	\$	3,069,463	\$	12,154,388
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	321,444	\$	884,421
Accrued expenses		281,806		197,023
Deferred revenue		107,792		403,475
Accrued expenses related to funded research and development projects		-	_	22,056
Liabilities of discontinued operations		1,123,049		2,159,986
Total current liabilities		1,834,091		3,666,961
Convertible long term debt		7,000,000		4,000,000
Deferred tax liability of discontinued operations		_		5,000
Total liabilities		8,834,091		7,671,961
Stockholders' (deficit) equity:				
Convertible preferred stock, \$0.001 par value — 6,000,000 shares authorized;				
5,000,000 shares of Series A issued and outstanding at December 31, 2009 and				
December 31, 2008; aggregate liquidation preference of \$18,000,000 at December				
31, 2009		5,000		5,000
Common stock, \$0.001 par value — 100,000,000 shares authorized; 32,102,435 and				
31,799,381 shares issued and outstanding at December 31, 2009 and December 31,				
2008, respectively		32,102		31,799
Additional paid-in capital		85,763,379		85,458,334
Accumulated deficit	(	(91,565,109)		(81,012,706)
Total stockholders' (deficit) equity		(5,764,628)		4,482,427
Total liabilities and stockholders' equity	\$	3,069,463	\$	12,154,388

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

# INTERLEUKIN GENETICS, INC.

# STATEMENTS OF OPERATIONS

	Year Ended December 31,				
	2009	2008	2007		
		(As Adjusted)	(As Adjusted)		
Continuing Operations					
Total revenue	\$ 1,078,430	\$ 2,620,687	\$ 2,827,284		
Cost of revenue	1,203,647	940,241	975,770		
Gross profit (loss)	(125,217)	1,680,446	1,851,514		
Operating expenses:					
Research & development	3,213,115	3,560,002	2,928,249		
Selling, general & administrative	5,575,911	5,012,345	3,970,869		
Amortization of intangibles	115,453	100,693	73,223		
Total operating expenses	8,904,479	8,673,040	6,972,341		
Loss from continuing operations	(9,029,696)	(6,992,594)	(5,120,827)		
Other expense:					
Interest Income	10,183	158,773	414,493		
Interest Expense	(158,760)	(130,253)	(231,992)		
Other expense:			- (456,223)		
Total other income (expense)	(148,577)	28,520	(273,722)		
Net loss from continuing operations before income taxes	(9,178,273)	(6,964,074)	(5,394,549)		
Provision (benefit) for income taxes					