

INTERLEUKIN GENETICS INC  
Form 10-K  
March 24, 2011

---

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

---

FORM 10-K

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES AND EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2010

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF 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  
(State or other jurisdiction of  
incorporation or organization)  
135 Beaver Street, Waltham, MA  
(Address of principal executive offices)

94-3123681  
(I.R.S. Employer  
Identification No.)  
02452  
(Zip Code)

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

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

Securities registered pursuant to Section 12(g) of the Exchange Act:  
Common Stock, \$.001 par value per share

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

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  NO

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  NO

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  NO

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

Edgar Filing: INTERLEUKIN GENETICS INC - Form 10-K

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

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

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 \$12,778,719.

As of March 7, 2011 there were 36,629,934 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 2011 Annual Meeting of Shareholders to be held on or about June 16, 2011, are incorporated by reference in Part III hereof.

---

---

---

INTERLEUKIN GENETICS, INC.

FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2010

## Table of Contents

<b>PART I</b>		
Item 1.	Business	3
Item 1A.	Risk Factors	13
Item 1B.	Unresolved Staff Comments	22
Item 2.	Properties	22
Item 3.	Legal Proceedings	22
Item 4.	[Removed and Reserved]	22
<b>PART II</b>		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	22
Item 6.	Selected Financial Data	23
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	23
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	29
Item 8.	Financial Statements and Supplementary Data	30
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	50
Item 9A.	Controls and Procedures	50
Item 9B.	Other Information	51
<b>PART III</b>		
Item 10.	Directors, Executive Officers and Corporate Governance	51
Item 11.	Executive Compensation	51
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	51
Item 13.	Certain Relationships and Related Transactions, and Director Independence	51
Item 14.	Principal Accountant Fees and Services	51
<b>PART IV</b>		
Item 15.	Exhibits, Financial Statement Schedules	52

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.

Smaller Reporting Company – Scaled Disclosure

Pursuant to Item 10(f) of Regulation S-K promulgated under the Securities Act of 1933, as amended, as indicated herein, we have elected to comply with the scaled disclosure requirements applicable to “smaller reporting companies,” including providing two years of audited financial statements.

Item 1. Business

Overview

Interleukin Genetics, Inc. is a personalized health company that develops unique genetic tests to provide information about health management and specific health risks. Our overall mission is to provide genetic testing services 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, dentists and physicians to better understand the set of actions necessary to guide lifestyle and treatment options. We believe that our tests can help companies provide improved services to their customers, empower individuals to personalize their health, and assist pharmaceutical companies to improve drug development and use by identifying subpopulations that are more responsive to a therapy. We currently have two primary focus areas to our business. Our personalized health business is focused on providing genetic tests with strong value. Our tests are made available via marketing partners or directly to end users. Our tests are developed with the goal of providing guidance to individuals interested in improved wellness. Research and development activities focused on developing genetic tests that are linked to a specific partner’s products in medical and dental channels is our second area of focus. Both areas of focus contribute toward our overall mission of providing services 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;

Edgar Filing: INTERLEUKIN GENETICS INC - Form 10-K

- receiving royalties from partners selling test services based on our intellectual property;
- performing genetic risk assessment tests in our laboratory, which is certified in accordance with the Clinical Laboratory Improvement Amendments of 1988, (CLIA);
- conducting research to develop new genetic risk assessment tests for us and partners.

3

---

We believe that by providing important genetic information combined with a set of actions and recommendations about possible interventions and therapies, we can help individuals improve their health outcomes. We have patents covering the use of certain gene variations in different ways 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 therapy. 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 increasing 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 Tests

Many people have the mistaken impression 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. 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 and commercialization efforts on identifying combinations of SNP variations for which there is biological understanding for certain uses associated with inflammation or metabolic disease. 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. Our scientific advisory board includes Sir Gordon Duff, one of the pioneers in the understanding of the role that genetics plays in inflammatory disease pathways. In addition, we have conducted clinical studies for various indications throughout the world involving over 22,000 individuals to demonstrate clinical utility. 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 School); University of California at San Francisco; University of California at San Diego; New York University Medical Center; University of Sheffield, (UK); Yonsei University Medical Center, (Korea); Tongji Medical College, (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 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/trajjectory of a disease for the same set of initiating events or conditions.

Typical inflammatory diseases include rheumatoid arthritis and periodontitis. In recent years, inflammation has been found to affect several other major diseases of aging that were not previously considered inflammatory diseases, including heart disease and osteoarthritis. Chronic inflammation can influence the process that leads to acute heart attacks. For example, an individual who 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 15 issued U.S. patents, which have expiration dates between 2015 and 2020, and have 24 additional U.S. patent applications pending, which are based on novel associations between particular gene sequences and certain metabolic and inflammatory conditions and disorders. The 15 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 tests that will benefit individuals wishing to understand ways to reduce risk of certain chronic conditions and illnesses or treatment guidance for their particular conditions. In order to do so, we believe a genetic test should be useful, understandable, credible and provide actionable guidance. The action resulting from the information we seek to provide through our genetic tests could be some form of medical treatment, dietary alteration, lifestyle change, or more careful monitoring of the person's condition. Before developing a genetic test, we make it a priority to understand both its market potential and our ability to launch and sell effectively.

Multiple genes and complex gene interactions along with environmental factors determine the probability for an individual contracting a common disease. We may develop a test based on our proprietary genetic markers or public 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) the genetic markers guide the development or use of lifestyle, preventive measures or therapeutic agents that modulate the specific actions of those genetic factors. The 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 one predictor of many for future heart attacks. Indeed, published studies indicate that chronic underlying inflammation is 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 inflammation-based risk for heart disease. Development efforts will 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 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 that we combined into novel patterns. 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;
- 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 to our tests.

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, now partnered with Henry Schein, sells the PST test directly to dentists throughout the United States. We earn a royalty from each sale of the PST test and can earn processing fees when samples are sent to our laboratory.

In April 2009, we entered into an exclusive license agreement with LABEC Pharma 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 Cardiohealth™. In January 2010, European regulatory authorities authorized LABEC Pharma to begin selling the CardioHealth product. Labec has begun delivering samples to us for processing.

In June 2009, we launched our own brand of consumer genetic tests under the name Inherent Health®. Our business strategy is to develop tests 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 tests through strategic alliances. We plan to continue to grow the Inherent Health® business and to continue to launch tests in new channels, including through distribution partners. In 2010 we added a number of commercial partners to distribute our weight management test. We are also interested in in-licensing products or intellectual property to create new products.

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 tests and developing additional genetic tests. Our plan is to commercialize and develop tests 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 2009, we created and launched our own brand of genetic tests under the Inherent Health® brand name, which consists of the following:

- 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 genetics. The test determines whether a low fat, low carbohydrate or balanced diet may be best and whether normal or vigorous exercise is needed to most efficiently lose existing body fat. The test provides new information beyond traditional assessments, so that nutritional intake and fitness routines can be tailored for improved, sustainable results. This test identifies five SNPs in four human genes; fatty acid binding protein 2 (FABP2), adrenergic receptor beta 2 (ADRB2 –two variations), adrenergic receptor beta 3 (ADRB3), peroxisome proliferator-activated receptor gamma (PPAR- ). These markers are involved in certain physiological pathways relating to body weight. Certain patterns of markers are associated with differential response to certain diet and exercise regimens. The test can be used to aid in the selection of diet and exercise regimens to improve weight loss and effectively manage body weight.

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. As reported by the Stanford researchers during an oral podium presentation at the March 2010 American Heart Meeting on prevention in San Francisco, 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 statistically significant in numerous categories and represents an approach to weight loss that has not been previously reported in the literature.” Following the Stanford presentation, we experienced extensive scientific and media attention relating to our Weight Management Genetic Test. Numerous national magazine and newspaper articles reported on the Stanford study as did several national television shows.

- Our Bone Health Genetic Test identifies whether an individual is 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. The test identifies a SNP in each of three genes involved in processes that affect bone; estrogen receptor alpha (ER1 Xba1), vitamin D receptor (VDR), and interleukin-1 (IL-1). Certain patterns of variations are associated with increased risk of spine fracture and/or low bone mineral density. The test can be used as an aid to making diet, exercise, and other lifestyle choices to maintain and improve bone health.
- Our Heart Health Genetic Test identifies 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 genetic risk will enable individuals to take specific actions to decrease overall risk. The test identifies three SNPs in two genes involved in inflammation, IL-1 alpha and IL-1 beta. Certain IL-1 variations are associated with increased inflammation, which is a risk factor for early heart attack. The test can be used as an aid to making diet, exercise, and other lifestyle choices to reduce inflammation-based 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. The test identifies the presence or absence of human genotypic markers methylenetetrahydrofolate reductase (MTHFR) and transcobalamin II (TCN2) involved in vitamin B metabolism and markers superoxide dismutase 2 (SOD2), glutathione S-transferase 1 deletions (GSTM1), paraoxonase 1 (PON1), X-ray repair cross complementing group 1 (XRCC1) in response to oxidative stress. Certain variations are associated with less efficient B-vitamin metabolism or reduced activity of endogenous anti-oxidant systems. The test can be used to aid individuals in deciding whether to supplement their diet with B vitamins and/or antioxidants.

#### Genetic Test for Risk of Periodontal Disease

PST® is a genetic test that analyzes genes for variations that identify an individual's predisposition for over-expression of inflammation and risk for more severe periodontal disease. The PST genetic test identifies specific polymorphisms (genetic variations) in genes that regulate the production of interleukin cytokines. Higher gingival levels of these proteins are associated with destruction of soft tissue attachment and bone, and increased severity of periodontitis in certain patient populations. The test is sold through a licensing agreement with OralDNA Labs, Inc., a Quest Diagnostics company. Quest has partnered with Henry Schein to add more sales representatives to the PST® test.

In August of 2010 we signed an agreement with the University of Michigan to conduct a clinical study on risk factors predictive of periodontal disease progression to tooth loss using a new version of Interleukin Genetics' PST genetic test. The clinical study using a large dental claims database will be conducted and led by Dr. William Giannobile, Director of the Michigan Center for Oral Health Research ("MCOHR") at the University of Michigan School of Dentistry and is designed to test whether risk factors, including genetic information, can guide more successful intervention and thus reduce the adverse outcomes of periodontal disease, such as tooth loss. The goal of the study is to enroll approximately 4,000 consenting individuals with more than 15 consecutive years of documented oral health history. Information on periodontitis risk factors and genetic information will be collected from participants to assess the frequency of preventive visits that is consistent with maintenance of proper periodontal health in patients classified as either low-risk or high-risk for periodontitis progression. This study is being funded by Renaissance Health Service Corporation, a nonprofit organization focused on the advancement of oral health.

Genetic Test 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; sold via physicians
- 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 proprietary 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.

Human obesity arises from the interactions of multiple genes, environmental factors and behaviors and renders management and prevention of obesity very challenging. According to The World Health Organization, 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 predict which obese patients are 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. 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-1 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.



In November 2009, we 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. In November 2010 the Company and the Thurston Arthritis Research Center at the University of North Carolina at Chapel Hill announced findings from a 1,154-patient longitudinal study to evaluate the role of genetic factors in osteoarthritis (OA) progression. The new data replicated the findings reported previously by Interleukin Genetics and showed that specific proprietary patterns of IL-1 receptor antagonist gene variations predicted knee OA progression. In addition, we reported that patients with radiographic signs of early knee osteoarthritis were genetically different from those without radiographic signs of the disease and progressed to moderate or severe OA at a much greater frequency. Of those individuals who were completely free of radiographic signs of knee osteoarthritis at the onset of the study, only 8.5 percent progressed to moderate or severe disease, whereas 33 percent of those with very early radiographic signs of disease exhibited progression. Those with early signs of OA were more likely than those who had no signs of disease to carry certain genetic factors, including variations in both the IL-1 receptor antagonist gene (IL1RA) and the DVWA gene that is involved in collagen formation. The combination of early radiographic signs of disease and carriage of gene variations associated with OA progression appears to identify individuals at increased risk for severe OA. We have filed patent applications on these findings.

We believe this information may allow pharmaceutical companies that are developing the first disease-modifying drugs (DMOADs) for OA 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 search for marketing and sales partners to introduce the tests into the medical channel.

On September 21, 2010, we and researchers from The Thurston Arthritis Research Center at the University of North Carolina at Chapel Hill announced findings from a large clinical study to evaluate the role of genetic factors in osteoarthritis progression which showed patients with radiographic evidence of knee osteoarthritis who inherited a specific pattern of genetic variations in the interleukin-1 receptor antagonist (IL-1Ra) gene were almost twice as likely to progress to severe disease as other patients. Results from the study, which followed 1,154 patients for up to 11 years, were presented at the World Congress on Osteoarthritis in Brussels, Belgium.

#### Periodontal Disease genetic Test (version 2.0)

For certain populations the frequency of the risk allele is low in the current PST test. The new PST product in development is predictive of severe disease and tooth loss for all ethnic populations. Results from several previous clinical studies indicate that certain inflammatory cytokine levels in the gingival crevicular fluid were significantly higher in PST positive patients than in patients who were PST negative. PST testing need only be done once in a lifetime and identifies “at risk” patients early on to enable targeted treatment. This objective information allows the dentist and hygienist to better guide treatment to reduce complications and costs associated with more severe periodontitis. The test also helps to establish long-term patient relationships based on the patient’s genetic predisposition.

#### 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 either a customer’s physician or one recommended by Interleukin Genetics. 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 a health care provider designated by the customer, of the results.

During 2004, we completed the construction of our genetic testing laboratory (for which we obtained CLIA certification 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, which is exempt from CLIA and maintains its own laboratory certification program, 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.

In July 2010, we received a letter from the FDA inquiring about our Inherent Health brand of genetic tests and stating that these tests appeared to meet the definition of a “device” under the Federal Food, Drug, and Cosmetic (FD&C) Act. The letter requested that the Company provide FDA with the clearance or approval number for the tests or with the basis for determination that the tests do not require FDA clearance or approval. In the letter, FDA offered to meet with

us, “to discuss whether there are tests you are promoting that do not require review by FDA and what information you would need to submit in order for your products to be legally marketed.” On November 1, 2010, we met with FDA personnel, including the director and staff members of the Office of In vitro Diagnostic Device Evaluation and Safety (OIVD), within FDA’s Center for Devices and Radiological Health (CDRH), to present information on our tests. At FDA’s request, we submitted a plan. We have requested a follow- up meeting with FDA to discuss the plan. The meeting has not yet been scheduled.

## Marketing and Distribution Strategy

We market our Inherent Health® brand of genetic tests using our e-commerce website and under contract with Amway and several regional weight management focused organizations. 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™. In Turkey we market our weight management test via the Turkish firm, eLabs. We intend to continue to partner with domestic and foreign distributors for the sale of our genetic tests. In addition, we intend to develop tests with partners in the pharmaceutical, biotechnology and other industries. Once tests are developed and launched, revenue may come from various sources including reimbursement from insurance companies and payments from 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](http://www.inherenthealth.com). 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. We are partnered with a number of websites that have established a link to our site in order to distribute tests. We pay these sites the commissions for all orders made via a click through from their site to ours.

## 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 large numbers of SNPs or 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 perceived benefit by the user, 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 clinical laboratories to ensure the accuracy and reliability of patient test results. The particular requirements for a clinical laboratory under CLIA depends on the level of complexity of the testing performed, with moderate and high complexity laboratories subject to more requirements than laboratories performing only low complexity testing. Genetic tests are considered high complexity under CLIA. Requirements for laboratories performing high complexity testing can include quality control and quality assurance requirements, personnel standards, and the requirement to perform proficiency testing. Laboratories must renew certification every two years, which typically includes an inspection of the laboratory.

In addition to CLIA certification, some states require clinical laboratories operating in those states or testing samples from those states to comply with state licensure requirements. In particular, New York State is exempt from the CLIA program and operates its own licensing program with more stringent standards than CLIA.

### Food and Drug Administration

Laboratory Developed Tests. FDA regulates components used by clinical laboratories to develop genetic and other laboratory tests, including general purpose reagents, analyte specific reagents and in vitro diagnostic test kits. Additionally, FDA historically has taken the position that tests developed in-house by a laboratory and used by that laboratory to provide testing services, so called “laboratory developed tests” or “LDTs”, are subject to FDA jurisdiction as medical devices. Notwithstanding its assertion of jurisdiction, FDA has also historically maintained that LDTs, with limited exceptions, are subject to “enforcement discretion” meaning that FDA generally would not subject LDTs to its regulatory requirements for medical devices. More recently, in July 2010, FDA held a public meeting in which officials from CDRH and OIVD announced their intention to develop a regulatory framework for LDTs that would be based on the risks posed by such tests. In particular, FDA officials stated that laboratory developed tests offered directly to consumers would no longer be subject to enforcement discretion. Concomitant with that meeting, FDA sent letters to more than a dozen companies offering direct-to-consumer genetic tests, including us, informing that their tests were subject to regulation as medical devices and requesting information on how the companies planned to come into compliance with FDA requirements. In March 2011, the FDA convened an expert advisory panel to review and make recommendations to the FDA regarding the regulation of direct-to-consumer medical genetic tests. We testified before the panel and also submitted written comments.

### 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 generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or the individual's family members, or using it for decisions regarding coverage, rates, or preexisting conditions. The law also prohibits most employers from using genetic information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment. Regulations implementing the nondiscrimination provisions of GINA were issued by the Equal Opportunity Employment Commission (EEOC) in November 2010 and took effect in January 2011.

## Federal Trade Commission

The Federal Trade Commission (FTC) has jurisdiction to prohibit unfair or deceptive trade practices, including false or misleading advertising. Advertising for our tests, including statements made on our website, is subject to FTC requirements. In recent years, the FTC instituted enforcement actions against several dietary supplement companies for false and misleading marketing practices and advertising of certain products, including those intended for weight loss. 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](http://www.ilgenetics.com) and [www.inherenthealth.com](http://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 \$9.2 million in 2009 and \$6.5 million in 2010. As of December 31, 2010, our accumulated deficit was \$97.6 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 field of personalized health. We have not yet demonstrated an ability to successfully commercialize our genetic tests. 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 Innovations, Inc., an affiliate of our majority stockholder, Alticor, Inc., will be adequate to maintain our current and planned operations through June 2012. We expect that we will 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.

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. 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 can have a negative impact on the industry overall as well as on sales of the challenged 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. In order to develop customers and markets for our genetic risk assessment tests, we will be required to invest substantial additional capital and other resources.

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 sells our 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 diagnostic tests 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 acquire knowledge of a potential transaction or matter that may be a corporate opportunity for both Alticor, 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, 2010, we had gross net operating loss and research tax credit carryforwards of approximately \$79.5 million and \$1.5 million, respectively, for federal income tax purposes, expiring in varying amounts through the year 2030. As of December 31, 2010, we had a research tax credit carryforward of approximately \$0.8 million for state income tax purposes, expiring in varying amounts through the year 2025. 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.

16

---

### 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 15 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.



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

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

Our currently marketed tests were launched as laboratory developed tests, or LDTs, performed in 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. Although FDA has historically exercised enforcement discretion with respect to LDTs, meaning that such tests generally have not been subject to FDA regulatory requirements for in vitro diagnostic devices, the Agency's regulatory approach to LDTs is in a period of transition and FDA officials have stated that DTC genetic tests will no longer be subject to enforcement discretion. FDA's letter to the Company in July 2010 is consistent with this change in Agency position. However, FDA has not stated what specific requirements will apply to LDTs sold DTC and we have not received any feedback from FDA regarding the plan we submitted in January 2011. FDA convened an advisory panel in March 2011 to make recommendations regarding oversight of DTC genetic tests. We are uncertain as to what, if any, regulatory requirements may apply to our tests in the future. We cannot provide any assurance that FDA regulation, including pre-market review or approval, will not be required in the future.

If FDA requires us to make a marketing submission (a 510(k) premarket notification or a premarket approval application) either as a condition of continuing to market our tests or bringing future tests to market, our business could be negatively impacted. Requiring prior FDA clearance or approval could be lengthy, costly and burdensome. In addition, depending upon FDA's response to a submission we may be required to stop selling our tests, revise our tests significantly, or delay introduction of new tests. Additionally, if our tests become subject to regulation as medical devices by FDA, we would be required to comply with other regulatory provisions, including facility registration, device listing, adverse event reporting, and good manufacturing practices. We would also be subject to penalties, including seizure and injunction, for noncompliance with FDA requirements. Complying with FDA requirements could add additional costs and burdens to our operations.

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 federal and state legal requirements including CLIA, the FD&C Act, state clinical laboratory licensure laws and implementing 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 is 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 comply with state regulations 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 affect 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.

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 could include:

- warning letters;
- recalls, public notification or medical device 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;
- product seizures;
- injunctions;
- civil penalties, including monetary fines; and
- criminal penalties.

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 have been delisted from the NYSE Amex resulting in a more limited market for our common stock.

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. On January 27, 2009, we submitted a plan to the Exchange to meet the continued listing requirements and 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 they 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. On June 24, 2010, we received notification from the Corporate Compliance Staff of the Exchange that the Exchange intended to initiate proceedings to delist our common stock because we did not regain compliance with Section 1003(a)(iii) of the Exchange's Company Guide. We requested a hearing before a Listing Qualifications Panel (the "Panel") to appeal the Exchange Staffs delisting determination. Despite our continued attempts to regain compliance and after exhausting the grace period allowances extended by the Exchange, we did not regain compliance and withdrew our appeal. As a result, our common stock was suspended from the Exchange effective with the open of business on August 16, 2010 and began trading on the OTCQB™ under the symbol ILIU. The delisting by the NYSE Amex could hurt our investors by reducing the liquidity and market price of our common stock. Additionally, the 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, 2010, our stock price has fluctuated from a low of \$0.17 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;
- 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.

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, 2010, 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, 2010, Alticor was our largest stockholder and owned, or had rights to acquire, approximately 55% of our outstanding common stock. Accordingly, this stockholder will be able to determine the outcome of stockholder votes, including votes concerning the election of directors, the adoption or amendment of provisions in our Certificate of Incorporation or By-Laws and the approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets. This stockholder may make decisions that are adverse to other stockholders' 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 1B. Unresolved Staff Comments

Not applicable.

## 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. On April 12, 2010 we entered into a sublease for approximately 6,000 square feet of unused office and laboratory space. The sublease expires March 31, 2013 unless extended through March 31, 2014 when the master lease expires. Our current office and genetic testing facilities are not impacted by the sublease. We believe that within our current facility we have the capacity to have our operations grow in the future.

## Item 3. Legal Proceedings

Not applicable.

## Item 4. [Removed and 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 "ILIU" on the OTCQB™. Prior to August 16, 2010, our common stock was traded 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 OTCQB™ and NYSE Amex.

	High	Low
<b>2010:</b>		
First Quarter	\$ 1.50	\$ 0.72
Second Quarter	\$ 0.80	\$ 0.35
Third Quarter	\$ 0.44	\$ 0.25
Fourth Quarter	\$ 0.43	\$ 0.30
	High	Low
<b>2009:</b>		
First Quarter	\$ 0.50	\$ 0.17
Second Quarter	\$ 0.85	\$ 0.21
Third Quarter	\$ 3.00	\$ 0.36
Fourth Quarter	\$ 1.31	\$ 0.60

## Stockholders

As of March 7, 2011, 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

Not applicable.

#### Issuer Purchases of Equity Securities

Not applicable.

#### Item 6. Selected Financial Data

As a smaller reporting company, we have elected scaled disclosure reporting obligations and therefore are not required to provide the information required by this item 6.

#### 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. As a smaller reporting company, we have elected scaled disclosure reporting obligations and therefore are required to provide the information requested by this item 7 for only the last two most recent fiscal years.

##### General Overview and Trends

Interleukin Genetics, Inc. is a personalized health company that develops specific, health area 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.

During the year ended December 31, 2010, we continued to focus our resources on sales of our Inherent Health® brand of genetic tests and related programs, which began in the second quarter of 2009, including the first-of-its-kind test for weight management that identifies an individual's genetic tendencies for weight gain related to either fat or carbohydrates in the diet. The brand offers customers a full suite of affordable, easy-to-use and meaningful genetic tests in weight management, heart health, bone health and nutritional needs. On June 30, 2010, we launched an additional product under the name Wellness Select that allows our e-commerce customers to purchase any combination of our Inherent Health® genetic tests at a discounted price. Customer orders have indicated that selling multiple tests in one package has the potential to be a valuable addition to our Inherent Health® brand. In addition to our Inherent Health® test products we offer PST®, the periodontal disease risk assessment test sold through a licensing agreement with OralDNA Labs, Inc. a Quest Diagnostics Inc. company.

We experienced extensive scientific and media attention relating to our Weight Management Genetic Test. 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, based on our test, 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." This announcement followed our release of top line positive results from the study on September 29, 2009.

Sales of our genetic tests increased significantly during the year ended December 31, 2010, as compared to the same period in the prior year driven primarily by media attention after the findings announced at the American Heart Association's conference related to our Weight Management Genetic Test. The findings were reported in multiple

national print publications as well as on television. What we have experienced is a better understanding of the importance of our genetic test in the field of personalized health when public awareness is gained. We plan to explore further media opportunities in the future. We did not incur any significant expenses relating to this media.

During the year ended December 31, 2010, we experienced a significant increase in sales of our genetic test kits to commercial distribution partners. Regional weight loss centers have incorporated our weight management genetic test into their weight loss programs. These companies purchase genetic tests in bulk from us and obtain discounted pricing at significant volumes. We plan on continuing to support this sales channel. In addition, we continue to see increased sales of genetic tests through our Merchant Network and Channel Partner Agreement with Amway Global. We continue to work with Alticor to promote our products in its sales channel.

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. In 2010 we continued to pay ongoing amounts owed on the accrued liabilities primarily related to retail inventory returns. During the quarter ended June 30, 2010, we reversed \$0.5 million of the accrual for returns after considering the settlement with one retailer and the pattern of returns with others over the past year. We expect to continue to settle these accounts within the amounts accrued for at the date of the transaction. During 2010 we paid \$0.4 million to former customers, including \$0.3 million paid as a final settlement with a retailer.

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.

Up to and including September 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.

We have traditionally spent approximately \$3-4 million annually on research and development. We completed our research agreements with Alticor in 2009 and are now dedicating our resources to our own product development efforts. Our research and development expenses have significantly decreased to \$1.9 million in 2010, as we focus more on our own development and commercialization efforts. Our focus is now on working with potential commercial partners to validate our technology within their specific business model often as a collaboration with little or no cost to us. This is different than in prior years when 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 2011 and beyond.

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 2011 and beyond will be to develop the market for our own personalized health products. We continue to allocate considerable resources to our 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 genetic 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, 2010, we had cash and cash equivalents of \$4.0 million and borrowing capacity of approximately \$3.3 million under our credit facility which permits borrowing at any time prior to June 30, 2012.

Cash used in operations was \$5.7 million for the year ended December 31, 2010, as compared to \$6.5 million for the year ended December 31, 2009. 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. A use of cash in the year ended December 31, 2010 were total payments of \$0.4 million, relating to the settlement of our obligations with former customers of the Alan James Group in connection with their rights of return of purchased product which included a final settlement reached with a major customer for inventory yet to be returned in accordance with the contractual terms of the retail relationship. This use of cash was partially offset by a significant increase in genetic test sales resulting from the media attention related to our Weight Management Genetic Test and increased sales to commercial customers. Cash received from genetic test sales which is reflected in deferred revenue until the test report is issued, increased by \$0.4 million to \$0.5 million during the year ended December 31, 2010. As we build our genetic test business the need for capital may increase.

Cash used in investing activities was \$0.1 million for the year ended December 31, 2010, compared to \$0.6 million for the year ended December 31, 2009. Capital additions were \$95,000 for the year ended December 31, 2010 compared to \$0.7 million for the year ended December 31, 2009. During the year ended December 31, 2009, capital additions primarily consisted of new commercial laboratory equipment that was purchased and installed which allows for high volume processing of genetic test samples. We believe that based on current and projected volumes, our laboratory equipment is sufficient to process genetic tests and no additional material capital purchases will be needed in the foreseeable future.

Cash provided by financing activities was \$8.9 million for the year ended December 31, 2010 compared to \$3.1 million for the year ended December 31, 2009. On February 1, 2010, we received \$2.0 million and on September 30, 2010 we received an additional \$2.0 million in proceeds from the issuance of notes payable for a total of \$4.0 million under our existing credit facility with Pyxis. We have no financial covenants as part of our credit facility with Pyxis. As of December 31, 2010, we had \$11.0 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 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 exercisable at \$1.30 per share and expire on March 10, 2015. Net proceeds to us after fees and expenses were approximately \$4.9 million. We received approximately \$44,000 and \$38,000, respectively, from the exercise of stock options and stock purchases through the employee stock purchase plan for the years ended December 31, 2010 and 2009.

In addition, our liquidity was enhanced on November 1, 2010 when we were awarded two grants totaling \$473,000 by the United States Government under the Qualifying Therapeutic Discovery Project (QTDP) Program to advance the development of our osteoarthritis and obesity genetic test programs. The grants reimburse us for expenditures made in 2009 and 2010 for these programs according to the QTDP guidelines. On November 18, 2010 we received \$355,448 in grant funding for 2009 expenditures. The balance for expenditures made in 2010 was paid during the first quarter of 2011. Grant revenue was recognized in the fourth quarter of 2010 for the full amount of the grants.

The amount of cash we generate from operations is not currently sufficient to continue to fund and grow our business. 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 currently believe we will be required to raise additional capital. Even though we are experiencing significant sales increases in our genetic testing business we continue to explore additional steps to reduce our operating costs. In 2009 and 2010, we reduced our headcount in non-essential areas. We were successful in the second quarter of 2010 in completing a sublease of approximately 6,000 square feet, or one-third of our total office space. The space includes offices and a laboratory that was being underutilized. Our remaining office and laboratory space is adequate for our current business needs. We are able to process high volumes of genetic tests in our current laboratory. 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 lower cost. While we expect that our current and anticipated financial resources, including the amount available under our credit facility with Pyxis, are adequate to maintain our current and planned operations through June 2012, we anticipate we will need substantial additional funds in the future. We intend to obtain such funds from operations, through strategic alliances or through the sale of equity or debt securities, but such funding may not be available on terms acceptable to us, or at all. On August 16, 2010, our common stock was delisted from the NYSE Amex and began trading on the OTCQB™ under the symbol ILIU. As a result, our access to capital through the public markets may be more limited.





## Results of Operations

### Years Ended December 31, 2010 and 2009

Total revenue from our continuing operations for the year ended December 31, 2010 was \$2.0 million, compared to \$1.1 million for the year ended December 31, 2009. The increase of \$0.9 million, or 85.2%, is primarily attributable to increased genetic testing and royalty revenue offset by a decrease in contract research revenue. Genetic testing revenue increased to \$1.9 million, or 283.5%, in the year ended December 31, 2010, compared to \$0.5 million in the year ended December 31, 2009. The increase is primarily attributable to sales of our Inherent Health® Brand of genetic tests, which benefited from media attention surrounding the March 2010 announcement of successful study results with Stanford University on our Weight Management Genetic Test. In addition, we have experienced an increase in sales of our Inherent Health® Weight Management Genetic Test to commercial customers, both foreign and domestic, who have incorporated the test into their business as well as increased sales of our new Wellness Select multi test genetic test kit. Genetic testing revenue is derived from tests sold and processed, which is driven by consumer demand. We had no contract research revenue in the year ended December 31, 2010, compared to \$0.5 million in the year ended December 31, 2009. The decrease of \$0.5 million is primarily attributable to the completion in 2009 of our reimbursable research projects with Alticor.

During the years ended December 31, 2010 and 2009, we had one significant customer, Alticor, our principal shareholder, that accounted for approximately 37% and 88%, respectively, of our revenues from continuing operations. During the years ended December 31, 2010 and 2009, approximately 32% and 0.2%, respectively, of our revenue came from sales through our Merchant Network and Channel Partner Agreement with Amway Global, an affiliate of Alticor.

Cost of revenue for the year ended December 31, 2010 was \$1.6 million, or 81.1% of revenue, compared to \$1.2 million, or 111.6% of revenue, for the year ended December 31, 2009. The significant decrease in the cost of revenue as a percentage of revenue is primarily attributable to increased genetic test revenue which absorbed fixed costs associated with our genetic testing laboratory. Fixed costs of the laboratory primarily relate to high volume genetic testing equipment installed during the first nine months of 2009. In addition, variable costs, such as laboratory supplies, increased due to the higher volume of genetic tests processed in 2010 compared to 2009. We can provide no assurance that we will be able to maintain or increase the volume of tests performed in subsequent periods.

Gross margin for the year ended December 31, 2010, was a profit of \$0.4 million, or 18.9%, compared to a loss of \$0.1 million, or 11.6%, for the year ended December 31, 2009. The increase in gross margin is primarily attributable to genetic test revenue offset by a decrease in contract research revenue.

Research and development expenses were \$1.9 million for the year ended December 31, 2010, compared to \$3.2 million for the year ended December 31, 2009. The decrease of \$1.3 million, or 40.1% is primarily attributable to decreased clinical trial expenses related to our research agreements with Alticor and decreased compensation, consulting and patent related expenses as compared to the year ended December 31, 2009.

In the fourth quarter of 2010, we were awarded two grants totaling \$473,000 by the United States Government under the Qualifying Therapeutic Discovery Project (QTDP) Program. The grant reimburses us for expenditures made in 2009 and 2010 for these programs according to the QTDP guidelines. In November 2010, \$355,448 in grant funding was received for 2009 expenditures. The balance for expenditures made in 2010 was paid during the first quarter of 2011.

Selling, general and administrative expenses were \$5.0 million for the nine months ended December 31, 2010, compared to \$5.6 million for the year ended December 31, 2009. The decrease of \$0.6 million, or 10.1% is primarily

attributable to decreases in compensation, product development, promotion and consulting expenses. Sales commissions paid to Amway Global as part of our Merchant Channel and Partner Store Agreement increased in 2010 as we paid commissions throughout 2010 versus 2009 where commissions were only paid in the fourth quarter.

Interest expense was \$303,000 for the year ended December 31, 2010, as compared to \$159,000 for the year ended December 31, 2009. The increase in interest expense of \$144,000 is primarily attributable to increased borrowings on our credit facility with Pyxis.

### Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our 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, 2010 and December 31, 2009, we had deferred revenue of \$506,000 and \$108,000, respectively, for tests that have been prepaid but results have not yet been reported.

#### Sales Commissions:

We account for sales commissions due to Amway Global under our Merchant Channel and Partner Agreement in accordance with Staff Accounting Bulletin (“SAB”) 104. Commissions are recorded as an expense at the time they become due which is at the point of sale. The cost of commissions was \$370,000 and \$26,000 for the years ended December 31, 2010 and 2009, respectively.

#### 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.

We have continued to reserve for estimated sales returns, discontinued items and trade promotions applicable to the non-acquired accounts resulting from our sale of substantially all of the assets of the Alan James Group business. The remaining balance of \$0.2 million at December 31, 2010 represents management’s best estimate of the cost of future returns. Payments of approximately \$0.4 million were made that directly related to product returns from non acquired accounts during the year ended December 31, 2010.

#### Accounts Receivable

Trade accounts receivable is stated at their estimated net realizable value, which is generally the invoiced amount less any estimated discount related to payment terms. Payment is due within 30 days of the invoice date.

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.

Inventory:

We value our inventory at the lower of cost (first-in, first out method) 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. We provide an allowance against that portion of inventory that we believe is unlikely to be sold or used. 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. Common stock purchased pursuant to our employee stock purchase plan is expensed based upon the fair market value in excess of purchase price.

Intangible Assets:

At least annually, we evaluate our intangible assets, consisting solely of patent rights, for possible 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. Management identified our continuing losses from operations as a triggering event as of December 31, 2010. Based on our analysis of future undiscounted cash flows the carrying value of patents is not deemed to be impaired at December 31, 2010.

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.

Income taxes:

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 approximately \$28.5 million as of December 31, 2010, 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 would 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 changes in Massachusetts corporate income tax regulations which became effective in 2009, we file a combined tax return with certain Alticor affiliated entities, referred to herein as "the unitary group". The law requires corporations with net operating loss carryforwards to go back to each year in which the loss was generated and

recompute the loss as if it occurred on a consolidated basis. We are required to include data from the newly formed unitary group as if the unitary group was in place during the loss years. As a result, the losses generated by us were eliminated through this required computation. The combined filing had no impact on our financial statements in 2010 and 2009.

In addition, FASB ASC 740 prescribes how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that a company has taken or expects to take on a tax return. At December 31, 2010, we reviewed all material tax positions for all years open to statute for all tax jurisdictions in which the Company is subject to tax to determine whether it was more likely than not that the positions taken would be sustained based upon the technical merits of those positions. We have no uncertain tax positions at December 31, 2010 and 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 Disclosures About Market Risk

As a smaller reporting company, we have elected scaled disclosure reporting obligations and therefore are not required to provide the information required by this item 7A.



Item 8. Financial Statements and Supplementary Data

INTERLEUKIN GENETICS, INC.  
INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm	31
Balance Sheets	32
Statements of Operations	33
Statements of Stockholders' Deficit	34
Statements of Cash Flows	35
Notes to Financial Statements	36

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, 2010 and 2009, and the related statements of operations, stockholders' deficit and cash flows for the years then ended. 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, 2010 and 2009, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ Grant Thornton LLP

Boston, Massachusetts  
March 24, 2011

## INTERLEUKIN GENETICS, INC.

## BALANCE SHEETS

	December 31,	
	2010	2009
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$3,999,029	\$906,248
Accounts receivable from related party	14,657	24,594
Trade accounts receivable	36,960	9,285
Federal grant receivable	117,946	—
Inventory	117,849	118,430
Prepaid expenses	251,383	225,493
Other current assets	200,000	—
Current assets of discontinued operations	14,966	31,941
<b>Total current assets</b>	<b>4,752,790</b>	<b>1,315,991</b>
Fixed assets, net	554,172	769,981
Intangible assets, net	630,037	745,490
Other assets	38,001	238,001
<b>Total assets</b>	<b>\$5,975,000</b>	<b>\$3,069,463</b>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$509,647	\$321,444
Accrued expenses	443,255	281,806
Deferred revenue	515,953	107,792
Liabilities of discontinued operations	164,241	1,123,049
<b>Total current liabilities</b>	<b>1,633,096</b>	<b>1,834,091</b>
Convertible long term debt	11,000,000	7,000,000
<b>Total liabilities</b>	<b>12,633,096</b>	<b>8,834,091</b>
Stockholders' deficit:		
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, 2010 and 2009; aggregate liquidation preference of \$18,000,000 at December 31, 2010	5,000	5,000
Common stock, \$0.001 par value — 100,000,000 shares authorized; 36,594,799 and 32,102,435 shares issued and outstanding at December 31, 2010 and 2009, respectively	36,594	32,102
Additional paid-in capital	90,851,709	85,763,379
Accumulated deficit	(97,551,399)	(91,565,109)
<b>Total stockholders' deficit</b>	<b>(6,658,096 )</b>	<b>(5,764,628 )</b>
<b>Total liabilities and stockholders' deficit</b>	<b>\$5,975,000</b>	<b>\$3,069,463</b>

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

## INTERLEUKIN GENETICS, INC.

## STATEMENTS OF OPERATIONS

	For The Year Ended December 31,	
	2010	2009
Genetic testing	\$ 1,940,190	\$ 505,914
Contract research and development	—	545,847
Other	56,983	26,669
Total revenue	1,997,173	1,078,430
Cost of revenue	1,618,841	1,203,647
Gross profit (loss)	378,332	(125,217 )
Operating expenses:		
Research and development	1,925,975	3,213,115
Research and development reimbursement grant	(473,394 )	—
Selling, general and administrative	5,013,903	5,575,911
Amortization of intangibles	115,453	115,453
Total operating expenses	6,581,937	8,904,479
Loss from operations	(6,203,605 )	(9,029,696 )
Other income (expense):		
Interest income	4,989	10,183
Interest expense	(303,363 )	(158,760 )
Other income (expense)	33,159	—
Total other income (expense)	(265,215 )	(148,577 )
Loss from continuing operations before provision for income taxes	(6,468,820 )	(9,178,273 )
Provision for income taxes	—	—
Loss from continuing operations	(6,468,820 )	(9,178,273 )
Income (loss) from discontinued operations, net of income taxes	482,530	(27,928 )
Loss on sale of discontinued operations including impairment charge of \$3,251,838 in 2009	—	(1,346,202 )
Income (loss) from discontinued operations, net of tax	482,530	(1,374,130 )
Net loss	\$ (5,986,290 )	\$ (10,552,403 )
Basic and diluted net income (loss) per common share from:		
Continuing operations	\$ (0.18 )	\$ (0.29 )
Discontinued operations	0.01	(0.04 )
Net loss	\$ (0.17 )	\$ (0.33 )
Weighted average common shares outstanding, basic and diluted	35,706,271	32,007,826

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

## INTERLEUKIN GENETICS, INC.

## STATEMENTS OF STOCKHOLDERS' DEFICIT

For the Years Ended December 31, 2010 and 2009

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Par Value	Shares	Par Value			
Balance as of December 31, 2008	5,000,000	\$ 5,000	31,799,381	\$ 31,799	\$ 85,458,334	\$ (81,012,706)	\$ 4,482,427
Net loss	—	—	—	—	—	(10,552,403)	(10,552,403)
Common stock issued:							
Employee stock purchase	—	—	126,500	127	34,028	—	34,155
Exercise of employee stock options	—	—	15,000	15	3,885	—	3,900
Employee stock purchase plan	—	—	149,054	149	34,455	—	34,604
Restricted stock awards	—	—	12,500	12	(12 )	—	—
Stock-based compensation expense	—	—	—	—	232,689	—	232,689
Balance as of December 31, 2009	5,000,000	\$ 5,000	32,102,435	\$ 32,102	\$ 85,763,379	\$ (91,565,109)	\$ (5,764,628 )
Net loss	—	—	—	—	—	(5,986,290 )	(5,986,290 )
Common stock issued:							
Private placement, net of offering costs of \$365,328	—	—	4,375,002	4,375	4,880,299	—	4,884,674
Exercise of employee stock options	—	—	1,300	2	336	—	338
Employee stock purchase plan	—	—	106,062	105	43,334	—	43,439
Restricted stock awards	—	—	10,000	10	(10 )	—	—
Stock-based compensation expense	—	—	—	—	164,371	—	164,371
	5,000,000	\$ 5,000	36,594,799	\$ 36,594	\$ 90,851,709	\$ (97,551,399)	\$ (6,658,096 )

Balance as of  
December 31,  
2010

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

34

---

## INTERLEUKIN GENETICS, INC.

## STATEMENTS OF CASH FLOWS

	For the Year Ended December 31,	
	2010	2009
<b>CASH FLOW FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (5,986,290 )	\$ (10,552,403 )
Loss on sale of discontinued operations	—	1,346,202
Loss (income) from discontinued operations	(482,530 )	27,928
Loss from continuing operations	(6,468,820 )	(9,178,273 )
Adjustments to reconcile loss from continuing operations to net cash used in operating activities:		
Depreciation and Amortization	426,670	494,956
Stock-based compensation expense	164,371	193,912
Changes in operating assets and liabilities:		
Account receivable, net	(17,738 )	9,507
Federal grant receivable	(117,946 )	—
Inventory	581	(118,430 )
Prepaid expenses and other current assets	(8,915 )	(62,659 )
Accounts payable	188,206	(562,977 )
Accrued expenses	161,447	84,783
Deferred revenue	408,161	(295,683 )
Commitments for funded R&D	—	(22,056 )
Net cash (used) provided by operating activities of discontinued operations	(476,278 )	2,908,588
Net cash used in operating activities	(5,740,261 )	(6,548,332 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Capital additions	(95,409 )	(714,003 )
Decrease (Increase) in intangibles	—	28,998
Net cash provided by investing activities of discontinued operations	—	114,445
Net cash used in investing activities	(95,409 )	(570,560 )
<b>CASH FLOW FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of notes payable	4,000,000	3,000,000
Proceeds from registered direct offering of common stock	5,250,002	—
Registered direct offering costs	(365,328 )	—
Proceeds from issuance of common stock	—	34,155
Proceeds from exercises of employee stock options	338	3,900
Proceeds from employee stock purchase plan	43,439	34,604
Net cash provided by financing activities	8,928,451	3,072,659
Net increase (decrease) in cash and equivalents	3,092,781	(4,046,233 )
Cash and cash equivalents, beginning of period	906,248	4,952,481
Cash and cash equivalents, end of period	\$ 3,999,029	\$ 906,248
Supplemental disclosures of cash flow information:		
Cash paid for income taxes	\$ —	\$ 41,941
Cash paid for interest	\$ 263,651	\$ 158,774

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





INTERLEUKIN GENETICS, INC.  
NOTES TO FINANCIAL STATEMENTS  
December 31, 2010

Note 1—Company Overview

Interleukin Genetics, Inc. (Interleukin or the Company) is focused on developing and commercializing personalized health products that can help individuals improve and maintain their health through preventive measures. It uses functional genomics to help in the development of risk assessment tests based on the genetic variations in people. Interleukin has commercialized genetic tests for periodontal disease risk assessment, cardiovascular risk assessment, general nutrition assessment, weight management and bone health.

Through its former Alan James Group subsidiary, which it acquired in August 2006 and divested in June 2009, Interleukin sold its nutritional product brands, including Ginsana®, Ginkoba™, and Venastat®, through the nation's largest food, drug and mass retailers. See Note 3 for further discussion.

The Company's current development programs focus on commercializing its weight management and periodontal genetic risk assessment tests.

Note 2—Operating Matters and Liquidity

The Company has experienced net operating losses since its inception through December 31, 2010. During the last two fiscal years such losses totaled \$16.5 million contributing to an accumulated deficit of \$97.6 million as of December 31, 2010. During this same period, the Company has increased its borrowings to \$11.0 million under its line of credit with Pyxis.

In March 2010, the Company entered into a definitive agreement with institutional investors to sell \$5.3 million of securities in a registered direct offering. Net proceeds of approximately \$4.9 million were received on March 10, 2010.

Throughout 2009 and 2010, the Company took steps to control expenses and further enhance its liquidity and cash flow. Prior to the opening of business on July 1, 2009 the Company sold substantially all of the Alan James Group business of its subsidiary AJG Brands, Inc. for \$4.6 million consisting of \$4.4 million in cash and a \$0.2 million holdback. The Company decided to sell these non-core assets as a way to concentrate on its genetic test business. The Company no longer has the positive cash flow of this business but has lower administration and operating costs as a result of the focus on the genetic test business.

The Company also took steps in 2009 and 2010 to further reduce operating costs such as consulting, research and personnel expenses to focus on our product development efforts. In May 2010, the Company completed a sublease of approximately 6,000 square feet of underutilized office and laboratory space. The sublease represents approximately one-third of the total space leased by the Company and will not adversely affect current operations. The Company's current laboratory space is deemed to be adequate and able to process high volumes of genetic tests.

We expect that our current and anticipated financial resources, including \$3.3 million available under our credit facility with Pyxis, are adequate to maintain our current and planned operations through June 2012.

Note 3—Discontinued Operations

In August 2006, the Company acquired the assets and business of the Alan James Group, LLC (the Alan James Group). The Alan James Group was a provider of products and services in the consumer healthcare marketplace and the acquired business primarily developed, marketed and sold nutritional products and engaged in related activities.

Prior to the opening of business on July 1, 2009, the Company and its wholly-owned subsidiary, AJG Brands, Inc. entered into an asset purchase agreement with Nutraceutical Corporation and Pep Products, Inc., a wholly-owned subsidiary of Nutraceutical Corporation, pursuant to which substantially all of the Alan James Group business and assets of AJG Brands, Inc. were sold to Pep Products, Inc. for an aggregate price of \$4,572,292. The proceeds consisted of a \$200,000 holdback reflected in other current assets at December 31, 2010 and \$4,372,292 of cash received on July 1, 2009. The holdback is available to satisfy potential amounts owed to the buyer pursuant to the agreement and is payable to the Company on July 1, 2011. The assets sold consisted primarily of accounts receivable, inventories, property and equipment and other assets related to the business, which primarily develops, markets and sells nutritional supplements and related products into retail consumer channels. 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"). On December 29, 2009, IBI was merged with Interleukin Genetics, Inc. At December 31, 2010 remaining assets of the former subsidiary consisted primarily of prepaid expenses and liabilities consisted of accruals for inventory remaining in the retail channel where the customer has the right of return.

The Company recognized a loss on the sale of discontinued operations of \$1,346,202 in the quarter ended June 30, 2009 including direct costs of the disposition of \$674,243.

AJG Brands, Inc.'s sales reported in discontinued operations for the year ended December 31, 2009 was \$3,580,169.

The following is a summary of the net assets sold at the close of business on June 30, 2009.

Accounts receivable	\$ 1,114,835
Inventories	783,512
Property and equipment, net.	21,073
Other assets	72,993
	\$ 1,992,413

We have continued to reserve for estimated sales returns, discontinued items and trade promotions applicable to the non-acquired accounts resulting from our sale of substantially all of the assets of the Alan James Group business. During the quarter ended June 30, 2010 we completed an analysis of all payments made for these items since the sale occurred on July 1, 2009, including the final settlement with a large customer and determined that the reserve should be reduced by approximately \$0.5 million. The remaining balance of \$0.2 million at December 31, 2010 represented management's best estimate of the cost of future returns. The adjustment is reflected in income from discontinued operations in the statement of operations.

#### Note 4—Significant Accounting Policies

Prior to December 29, 2009, the consolidated financial statements included the accounts of Interleukin Genetics, Inc., and its wholly-owned subsidiaries, Interleukin Genetics Laboratory Services, Inc. and Interleukin Brands, Inc., formerly AJG Brands, Inc. doing business as the Alan James Group. On December 29, 2009, the two wholly-owned subsidiaries were merged into Interleukin Genetics, Inc. and the consolidated financial statements remained unchanged with this transaction. All intercompany accounts and transactions have been eliminated.

#### Management Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenue and expenses during the reported periods. Actual results could differ from those estimates. The Company's most critical accounting policies are more fully discussed in these notes to the financial statements.

#### 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, 2010 and December 31, 2009, the Company has deferred genetic test revenue of \$505,935 and \$107,792, respectively.

Revenue from contract research and development is recognized over the term of the contract as the Company performs its obligations under that contract (including revenue from Alticor, a related party).

In November 2010 the Company was awarded two grants totaling \$473,000 by the United States Government under the Qualifying Therapeutic Discovery Project (QTDP) Program to advance the development its osteoarthritis and obesity genetic test programs. The grants reimburse the Company for expenditures made in 2009 and 2010 for these programs according to the QTDP guidelines. The Company recognized the full amount awarded under the grants as a reimbursement of research and development expenses reducing operating expenses in the 2010 statement of operations.

## Sales Commissions:

The Company account for sales commissions due to Amway Global under the Merchant Channel and Partner Agreement in accordance with Staff Accounting Bulletin (“SAB”) 104. Commissions are recorded as an expense at the time they become due which is at the point of sale. The cost of commissions was \$370,000 and \$26,000 for the years ended December 31, 2010 and 2009, respectively.

## Allowance for Sales Return

Prior to the sale of the Alan James Group, the Company analyzed sales returns in accordance with the provisions of FASB ASC 605, Revenue Recognition. The Company estimated the allowance for sales returns based on the buying patterns of the end-users of its products based on sales data received.

## Accounts Receivable

Accounts receivable is stated at estimated net realizable value, which is generally the invoiced amount less any estimated discount related to payment terms. The Company offers its commercial genetic test customers a 2% cash discount if payment is made by bank wire transfer within ten days of the invoice date.

## Inventory

Inventory is stated at the lower of cost (first-in, first-out method) or market. As the Company does not manufacture any products, no overhead costs are included in inventory. No inventory reserve is required at December 31, 2010 as all test kits are available for sale and are expected to be sold. When a kit is sold, the corresponding cost of the kit is recorded as cost of goods sold and removed from inventory.

As part of the Company’s subsequent sale of substantially all of the Alan James Group business and assets all non-acquired inventory amounting to approximately \$129,000 was scrapped and written off in the fourth quarter of 2009.

Inventory consisted of the following at December, 2010 and 2009:

	2010	2009
Raw materials	\$ 110,347	\$ 103,479
Finished goods	7,502	14,951
Total inventory, net	\$ 117,849	\$ 118,430

## Stock-Based Compensation

The Company accounts for 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.

Income Taxes

The Company accounts 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. The Company records a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized.

Significant management judgment is required in determining the Company's provision (benefit) for income taxes, its deferred tax assets and liabilities and any valuation allowance recorded against deferred tax assets. The Company has recorded a full valuation allowance against its deferred tax assets of approximately \$28.5 million as of December 31, 2010, due to uncertainties related to its ability to utilize these assets. The valuation allowance is based on management's estimates of taxable income by jurisdiction in which the Company operates 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, the Company may need to adjust its valuation allowance, which could materially impact its financial position and results of operations.

Due to recent changes in Massachusetts corporate income tax regulations, the Company filed a combined tax return with certain Alticor affiliated entities, referred to herein as "the unitary group". The law requires corporations with net operating loss carryforwards to go back to each year in which the loss was generated and recompute the loss as if it occurred on a consolidated basis. The Company was required to include data from the newly formed unitary group as if the unitary group was in place during the loss years. As a result, the losses generated by the Company were eliminated through this required computation. The combined filing will have no impact on the Company's financial statements.

The Company reviews its recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. The Company reviews 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. The Company did not recognize any adjustments for uncertain tax positions as of and during the years ended December 31, 2010 and 2009.

#### Research and Development

Research and development costs are expensed as incurred. Included in research and development expenses are legal expenses incurred to protect the Company's patents which amounted to \$0.5 million in 2010 and \$0.6 million in 2009.

#### Advertising Expense

Advertising costs are expensed as incurred. During the years ended December 31, 2010 and 2009 advertising expense was \$19,000 and \$580,000, respectively.

#### Basic and Diluted Net Loss per Common Share

The Company applies the provisions of FASB ASC 260, Earnings per Share, which establishes standards for computing and presenting earnings per share. Basic and diluted net loss per share was determined by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is the same as basic net loss per share for all the periods presented, as the effect of the potential common stock equivalents is anti-dilutive due to the loss in each period. Potential common stock equivalents excluded from the calculation of diluted net loss per share consists of stock options, warrants, convertible preferred stock and convertible debt as set forth in the table below:

	As of December 31,	
	2010	2009
Options outstanding	1,611,267	1,578,917
Warrants outstanding	2,150,000	400,000
Convertible preferred stock	28,160,200	28,160,200
Convertible debt	1,937,200	1,232,763

Total	33,858,667	31,371,880
-------	------------	------------



### Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. During the years ended December 31, 2010, and 2009, there were no items other than net loss included in the determination of comprehensive loss.

### Fair Value of Financial Instruments

The Company, using available market information, has determined the estimated fair values of financial instruments. The stated values of cash and cash equivalents, accounts receivable and accounts payable approximate fair value due to the nature of these instruments. The fair value of our convertible debt is inherently difficult to determine as a result of the Company's financial condition and history of operating losses. For financial reporting purposes, the Company has estimated the fair value of its debt as the difference between the book value of its assets less liabilities to third parties other than the debt holder.

### Cash and Cash Equivalents

The Company maintains its cash and cash equivalents with domestic financial institutions that the Company believes to be of high credit standing. The Company believes that, as of December 31, 2010, its concentration of credit risk related to cash and cash equivalents was not significant. Cash and cash equivalents are available on demand and at times may be in excess of FDIC insurance limits.

### Fixed Assets

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

### Impairment of Long-Lived Assets

The Company evaluates its long-lived assets, including intangible assets, for impairment whenever events or changes in circumstances indicate that carrying amounts of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. Any write-downs, based on fair value, are to be treated as permanent reductions in the carrying amount of the assets. The Company determined that no impairment existed related to the Company's long-lived assets at December 31, 2010 and 2009.

The Company determined that due to the sale of substantially all of the Alan James Group business and assets of its wholly-owned subsidiary, AJG Brands, Inc., prior to the opening of business on July 1, 2009, the remaining \$3,251,838 of intangible assets became permanently impaired and were expensed.

### Recent Accounting Pronouncements

Effective January 1, 2009, The Company has applied the provisions of FASB ASC 810, Consolidation. The standard establishes new accounting and reporting standards for noncontrolling interests in a subsidiary and for the deconsolidation of a subsidiary and required entities to classify noncontrolling interests as a component of stockholders' equity as well as require subsequent changes in ownership interest in a subsidiary to be accounted for as an equity transaction. Additionally, the standard requires entities to recognize a gain or loss upon the loss of control of a subsidiary and to remeasure any ownership interest retained at fair value on that date. This statement requires

expanded disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. The adoption of ASC 810 did not have a material effect on the Company's financial position or results of operations.

Effective January 1, 2009, the Company has applied the provisions of FASB ASC 808, Collaborative Arrangements. The guidance defines collaborative arrangements and established presentation and disclosure requirements for transactions within a collaborative arrangement (both with third parties and between participants in the arrangement) and required retrospective application to all collaborative arrangements existing as of the effective date, unless retrospective application was impracticable. The impracticability evaluation and exception should be performed on an arrangement-by-arrangement basis. This adoption did not have a significant effect on the Company's financial statements.

In April 2010, the FASB issued ASU 2010-17, Revenue Recognition—Milestone Method (Topic 605), (ASU 2010-17), which provides guidance on applying the milestone method to milestone payments for achieving specified performance measures when those payments are related to uncertain future events. ASU 2010-17 is effective for fiscal years and interim periods within those years beginning on or after June 15, 2010 with early adoption permitted. ASU 2010-17 is effective for the Company on January 1, 2011. The adoption of ASU 2010-17 is not expected to have a significant impact on the Company's financial statements.

In January 2010, the FASB issued ASU 2010-6, Fair Value Measurements and Disclosures (Topic 820), Improving Disclosures about Fair Value Measurements (ASU 2010-6), which requires additional information in the roll-forward of Level 3 assets and liabilities, including the presentation of purchases, sales, issuances and settlements on a gross basis. This ASU impacts disclosures only. The adoption of ASU 2010-6 is not expected to have a significant impact on the Company's financial statements.

### Segment Reporting

The Company applies the provisions of FASB ASC 280, Segment Reporting, which established standards for reporting information about operating segments in annual and interim financial statements, and requires that companies report financial and descriptive information about their reportable segments based on management's approach. The standard also established related disclosures about products and services, geographic areas and major customers.

As of December 31, 2010 and 2009 the Company has one segment remaining, the genetic test business. The Company develops genetic tests for sale into the emerging personalized health market and performs testing services that can help individuals improve and maintain their health through preventive measures. The Company's principal operations and markets are located in the United States.

### Note 5—Strategic Alliance with Alticor Inc.

Since March 2003, the Company has maintained a broad strategic alliance with several affiliates of the Alticor family of companies, a related party, to develop and market novel nutritional and skin care products. The alliance initially included an equity investment, a multi-year research and development agreement, a licensing agreement with royalties on marketed products, the deferment of outstanding loan repayment and the refinancing of bridge financing obligations.

On January 31, 2009, the Company entered into an amendment to its research agreement (RA8) with Alticor. The amendment extended the term from a maximum of six months to eight months, terminating on September 30, 2009. The Company received an additional \$200,316 on March 31, 2009 under the terms of the amendment to complete ongoing research which was recognized as revenue as of December 31, 2009 when all research agreements with Alticor were complete.

On October 20, 2009, the Company 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 sells the Company's Inherent Health® brand of genetic tests through its e-commerce website via a hyperlink to our e-commerce site. We paid Amway Global \$370,000 and \$26,000 in commissions for the years ended December 31, 2010 and 2009, respectively, representing a percentage of net sales to their customers. The Company expenses commissions owed to Amway Global when the sale is made to the customer.

### Note 6—Convertible Debt

On August 17, 2006, our existing credit facility with Pyxis was amended to provide the Company with access to approximately \$14.4 million of additional working capital borrowings at any time prior to August 17, 2008. Any amounts borrowed thereunder bear interest at the prime rate and require quarterly interest payments. The principal amount of any borrowing under this credit facility is convertible at Pyxis' election into a maximum of 2,533,234 shares of common stock, reflecting a conversion price of \$5.6783 per share.

This credit facility has been extended several times, most recently on September 30, 2010, to extend the availability of borrowings until June 30, 2012. In addition, the due date was extended from August 16, 2011 to June 30, 2012. As of December 31, 2010, there was \$11,000,000 in principal outstanding under the credit facility leaving \$3,316,255 of available credit.

The fair value of convertible debt is estimated to be approximately \$4.3 million at December 31, 2010.

#### Note 7—Fixed Assets

Fixed assets useful lives and balances at December 31, 2010 and 2009 consisted of the following:

	Useful Life	2010	2009
Computer software, computer equipment and office equipment	3 years	\$ 350,822	\$ 344,557
Laboratory equipment	5 years	1,370,641	1,581,276
Furniture and fixtures	5 years	40,349	40,349
Leasehold improvements	5 years	303,258	265,563
Website Development	3 years	270,678	270,678
Equipment under capital leases	3 to 5 years	22,920	22,920
		2,358,668	2,525,343
Less — Accumulated depreciation and amortization		(1,804,496)	(1,755,362)
<b>Total</b>		<b>\$ 554,172</b>	<b>\$ 769,981</b>

Depreciation and amortization expense was \$311,217 and \$379,503, for the years ended December 31, 2010 and 2009, respectively.

#### Note 8—Intangible Assets

Intangible assets at December 31, 2010 and 2009 consisted of the following:

	2010	2009
Patent costs	\$ 1,154,523	\$ 1,154,523
Less — Accumulated amortization	(524,486 )	(409,033 )
<b>Total</b>	<b>\$ 630,037</b>	<b>\$ 745,490</b>

Patent amortization expense was \$115,453 for the years ended December 31, 2010 and 2009, respectively.

Patent costs which are amortized on a straight-line basis over a 10-year life, are scheduled to amortize as follows:

Year ended December 31,

2011	\$ 115,453
2012	115,453
2013	109,266
2014	94,100
2015	77,656
2016	61,119
2017	42,229
2018	14,761

\$630,037

## Note 9—Accrued Expenses

Accrued expenses consist of the following:

	December 31	
	2010	2009
Payroll and vacation	\$ 113,597	\$ 123,217
Other	329,658	158,589
Total accrued expenses of continuing operations	443,255	281,806
Total accrued expenses of discontinued operations	164,241	1,123,049
Total accrued expenses	\$ 607,496	\$ 1,404,855

## Note 10—Commitments and Contingencies

## Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material effect on its financial condition, results of operations or cash flows.

## Legal Proceedings

On February 11, 2010, Genetic Technologies Limited, or GTL, filed a complaint naming the Company and eight other corporations as defendants in an alleged patent infringement lawsuit. The complaint alleged that the defendants make, use or sell products or services that infringe one or more claims of the patent owned by GTL. The complaint did not seek specified damages. While, the Company believed it was not in violation of the named patent, based on a review of the options to efficiently resolve the matter, on September 25, 2010, the Company and GTL entered into an agreement, pursuant to which GTL dismissed its claims against the Company. The terms of the agreement did not have a material adverse effect on the Company's financial condition, results of operations and cash flows.

## Employment Agreements

On February 14, 2011, the Company entered into an employment agreement with Lewis H. Bender, its Chief Executive Officer. The agreement replaced and superseded the employment agreement between the Company and Mr. Bender that expired by its terms on January 22, 2011. The agreement has an initial term of one year and is automatically renewable for successive one year periods unless at least 90 days prior notice is given by either the Company or Mr. Bender. The agreement also provides that Mr. Bender will serve as a member of the Company's Board of Directors for as long as he serves as the Company's Chief Executive Officer, subject to any required approval of the Company's shareholders.

The agreement is terminable by the Company for cause or upon thirty days prior written notice without cause and by Mr. Bender upon thirty days prior written notice for "good reason" (as defined in the agreement) or upon ninety days prior written notice without good reason. If the Company terminates Mr. Bender without cause or Mr. Bender terminates his employment for good reason, then the Company will pay Mr. Bender, in addition to any accrued, but unpaid compensation prior to the termination, an amount equal to six months of his base salary. If the Company terminates Mr. Bender without cause or Mr. Bender terminates his employment with good reason within six months after a "change of control" (as defined in the agreement), then the Company will pay Mr. Bender, in addition to any accrued, but unpaid compensation prior to the termination, an amount equal to twelve months of his base salary, and all unvested stock options will automatically vest.

The agreement also includes non-compete and non-solicitation provisions for a period of six months following the termination of Mr. Bender's employment with the Company.

#### Operating Leases

The Company leases its office and laboratory space under a non-cancelable operating lease expiring on March 31, 2014. On May 24, 2010, the Company completed a sublease of approximately 6,000 square feet of underutilized office and laboratory space which successfully reduced our total space operating costs. The sublease expires on March 31, 2013 and has a one year renewal option. The loss on the sublease of \$51,044 was recognized in 2010.



Future minimum lease commitments under lease agreements with initial or remaining terms of one year or more at December 31, 2010, are as follows:

Year Ending December 31,	Master Space Lease	Sublease Income	Net
2011	\$ 453,624	\$ (105,954 )	\$ 347,670
2012	463,128	(114,971 )	348,157
2013	472,623	(29,355 )	443,268
2014	118,749	—	118,749
Thereafter	—	—	—
	\$ 1,508,124	\$ (250,280 )	\$ 1,257,844

Rent expense was \$412,740 and \$519,536 for the years ended December 31, 2010 and 2009, respectively.

#### Note 11—Capital Stock

##### Authorized Preferred and Common Stock

At December 31, 2010, the Company had authorized 6,000,000 shares of \$0.001 par value Series A Preferred Stock, of which 5,000,000 were issued and outstanding. At December 31, 2010, the Company had authorized 100,000,000 shares of \$0.001 par value common stock of which 72,243,670 shares were outstanding or reserved for issuance. Of those, 36,594,799 shares were outstanding; 28,160,200 shares were reserved for the conversion of Series A Preferred to common stock; 1,937,200 shares were reserved for the conversion of the \$11,000,000 of debt outstanding under the credit facility with Pyxis; 2,650,380 shares were reserved for the potential exercise of authorized and outstanding stock options; 400,000 shares were reserved for the exercise of outstanding warrants to purchase common stock at an exercise price of \$2.50 per share which are exercisable currently until the expiration date of August 9, 2012; 1,750,000 shares were reserved for the exercise of outstanding warrants to purchase common stock at an exercise price of \$1.30 per share which are exercisable currently until the expiration date of March 5, 2015; 167,068 shares were reserved for the potential exercise of rights held under the Employee Stock Purchase Plan; and 584,023 shares were reserved for the issuance upon the conversion of convertible notes that may be issued to Pyxis under the existing credit facility.

On March 5, 2010, the Company entered into a definitive agreement with 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 exercisable at \$1.30 per share and expire in five years. No warrants had been exercised as of December 31, 2010. Net proceeds to the Company after fees and expenses were approximately \$4.9 million.

##### Series A Preferred Stock

On March 5, 2003, the Company entered into a Stock Purchase Agreement with Pyxis, pursuant to which Pyxis purchased from the Company 5,000,000 shares of Series A Preferred Stock for \$7,000,000 in cash on that date, and an additional \$2,000,000 in cash that was paid, as a result of the Company achieving a certain milestone, on March 11, 2004.

The Series A Preferred Stock accrues dividends at the rate of 8% of the original purchase price per year, payable only when, as and if declared by the Board of Directors and are non-cumulative. To date, no dividends have been declared on these shares. If the Company declares a distribution, with certain exceptions, payable in securities of other persons, evidences of indebtedness issued by the Company or other persons, assets (excluding cash dividends) or options or

rights to purchase any such securities or evidences of indebtedness, then, in each such case the holders of the Series A Preferred Stock shall be entitled to a proportionate share of any such distribution as though the holders of the Series A Preferred Stock were the holders of the number of shares of our Common Stock into which their respective shares of Series A Preferred Stock are convertible as of the record date fixed for the determination of the holders of our Common Stock entitled to receive such distribution.

In the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of the Series A Preferred Stock shall be entitled to receive, prior and in preference to any distribution of any of the Company's assets or surplus funds to the holders of its 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. The liquidation preference at December 31, 2010 was \$18,000,000. After receiving this amount, the holders of the Series A Preferred Stock shall participate on an as-converted basis with the holders of common stock in any of the remaining assets.

Each share of Series A Preferred Stock is convertible at any time at the option of the holder into a number of shares of the Company's common stock determined by dividing the then-effective purchase price (\$1.80, and subject to further adjustment) by the conversion price in effect on the date the certificate is surrendered for conversion. As of December 31, 2010, the Series A Preferred Stock was convertible into 28,160,200 shares of Common Stock reflecting a current conversion price of \$0.3196 per share.

Each holder of Series A Preferred Stock is entitled to vote its shares of Series A Preferred Stock on an as-converted basis with the holders of Common Stock as a single class on all matters submitted to a vote of the stockholders, except as otherwise required by applicable law. This means that each share of Series A Preferred Stock will be entitled to a number of votes equal to the number of shares of Common Stock into which it is convertible on the applicable record date.

Note 12—Stock-Based Compensation Arrangements

Total cost for stock-based compensation arrangements is as follows:

	Year Ended December 31,	
	2010	2009
Stock option grants beginning of period	\$ 59,036	\$ 179,571
Stock-based arrangements during the period:		
Stock option grants	96,014	6,800
Restricted stock issued:		
Employee stock purchase plan	7,539	5,916
Employment agreements	—	