INTERLEUKIN GENETICS INC
Form 10-K
March 29, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES AND EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2011
.. 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)	94-3123681 (I.R.S. Employer Identification No.)
135 Beaver Street, Waltham, MA (Address of principal executive offices)	02452 (Zip Code)

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

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

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 x

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x 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 xNO ¨

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

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

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

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

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of the last business day of the registrant's most recently completed second quarter was $12,778,719.

As of March 9, 2012 there were 36,756,236 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 2012 Annual Meeting of Shareholders are incorporated by reference in Part III hereof.

INTERLEUKIN GENETICS, INC.

FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2011

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PART I

Special Note Regarding Forward-Looking Statements

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

Smaller Reporting Company – Scaled Disclosure

Pursuant to Item 10(f) of Regulation S-K promulgated under the Securities Act of 1933, 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 to better manage health and specific health risks. Our overall mission is to provide genetic testing services to empower

individuals, physicians and dentists to better guide lifestyle and treatment options that can help individuals maintain or improve their health. We believe that our proprietary genetic tests can help our commercial distribution partners 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. Our business focuses on personalized health, by providing genetic tests with strong clinical value. Our tests are made available via marketing partners or directly to end users. The business focus contributes toward our overall mission of providing services that can help individuals maintain or improve their health through preventive or treatment measures.

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 and specific combinations of gene variations for a number of common chronic diseases and conditions.

We believe that one of the great challenges confronting healthcare today is to better understand why some people are more prone than others to develop various medical conditions and why some people respond to treatments for those conditions differently than do 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, it is now well established that while intiating factors are essential for disease, the mere presence of such factors does not necessarily determine whether a single individual will develop an illness, have mild or severe disease, or respond the same way as everyone else. Many common conditions arise in part as a result of how our bodies respond and interact with 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 some genetics have a permanent effect on a person's appearance or condition (referred to as a phenotype), the vast majority of genetic influences of one's phenotype can be modified. An active field of research in healthcare today is better to 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 inactivated 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 is often 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/trajectory 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.

Our patents are "use" patents that claim that a SNP, or set of SNPs in unique patterns can be used in a novel way to predict disease development or progression, predict responses to preventive or therapeutic interventions and identify specific actions that improve health outcomes. We currently own rights in 11 issued U.S. patents, that have expiration dates between 2015 and 2020, and have 21 additional U.S. patent applications pending, that are based on novel associations between particular gene sequences and certain metabolic and inflammatory conditions and disorders. The 11 issued U.S. patents relate to genetic tests for obesity, periodontal disease, osteoporosis, coronary artery disease, 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 not likely to expire until between 2027 and 2031.

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 many common diseases. 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 he or she ages or predicts a patient’s likelihood of severe complications from disease or response to specific treatment if the individual has already been diagnosed with disease.

For each targeted clinical area that meets our criteria, we may develop one or more 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. We have filed patent applications covering this product.

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 patent applications in this area as well.

Business Strategy

Our revenue model consists of:

- sales from our Inherent Health® brand of genetic tests either directly to end users or through partnerships such as the Amway Global channel;
- sales of our genetic tests to commercial distribution partners such as regional weight loss centers and insurance providers;
- 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., a division of Quest Diagnostics to market our PST genetic risk assessment test for the prediction of periodontal disease. Quest Diagnostics, 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 in Spain and Portugal our heart health genetic risk assessment test for the prediction of early heart attack. The test is 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.

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 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 develop and commercialize tests that (1) identify healthy individuals who have a higher probability of increased risk for early or more severe health risks, (2) allow for an individual to understand which lifestyles will be best suited for his or her 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

Weight Management Genetic Test

On any given day one in three adult women and one out of four adult men in the U.S. are dieting. This is a total of approximately 63 million individuals. The diet market can be broken down into four levels of dieters. The majority of individuals dieting are in do-it-yourself programs (55 million) with the remaining majority distributed through various national mass market retailers such as Jenny Craig, Weight Watchers, Nutrisystems, medifast (approximately 5 million). A small category of programs are led by regional, boutique groups or dieticians (1 to 2 million) such as the Canyon Ranch and finally the remainder those in most need are being medically treated (~200,000) with the majority undergoing bariatric surgery or lapbanding. Several estimates have been published for the total number of weight related services and specialty products being provided in the US. Estimated annual expenditures range from $40 to $50 billion in the U.S. with the majority of these costs being paid out of pocket by individuals.

Our *Weight Management Genetic Test* helps take 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.

We have conducted a number of studies that demonstrate a gene-diet interaction based on the multi-locus patterns noted above. The first study, completed in 2010, involved subjects who originally participated in Stanford University's A TO Z weight loss study. Individuals from the A TO Z study were contacted to participate in this retrospective genotype-diet interaction study. In the original study 311 free-living, overweight/obese (body mass index, 27-40 kg/m2), nondiabetic, premenopausal, generally healthy women were randomly assigned for 12 months to either the Atkins-like (very low carbohydrate), Zone-like (low carbohydrate), LEARN-like (balanced), or Ornish-like (low fat) diets for the primary purpose of losing weight. The extensive data collected in that study included dietary intake assessment (three unannounced 24-hour recalls for each time point administered by a dietitian and analyzed using NDS-R, University of Minnesota), anthropometric measures including weight, and related physiological variables, all collected at baseline, 2, 6, and 12 months.

Stanford University had retained plasma samples from the original A TO Z study. However, the Institutional Review Board (IRB) reviewing the project first requested that we recruit and collect DNA under informed consent. Recruitment first began in August 2008 and ended in February 2009. A TO Z study participants eligible for inclusion in the study were those who provided both consent for the current study as well as a sufficient sample of DNA for genotyping (N=138). Those who completed the full 12-month protocol of the original A TO Z study totaled 121. The first set of analysis (N=138) showed a diet-gene interaction as determined by the test's pattern assignments. As a result of promising preliminary results from the genetic analysis of this subset of subjects who participated in the A TO Z study, our research collaborators at Stanford University received IRB approval in 2011 to extract DNA from retained plasma samples from all subjects who participated in the study. We successfully obtained DNA and genotyped 291 of the 311 subjects. Preliminary analysis conducted solely by the Company in March 2012, demonstrated that subjects with three different genetic test patterns had different weight loss responses at 12 months depending on the diets to which they were assigned. The analysis from the larger dataset showed that further improved weight loss could be achieved if certain of the test's original diet assignments were modified. As a result, in March 2012, we updated our laboratory information management system's reporting and generated new diet recommendations for each pattern to provide customers the latest information from the new research.

Another study was conducted on the Weight Management Genetic Test with MetroWest Medical Center Hospital (MWM) as a prospective, real world setting trial. Thirty-four overweight mail & female hospital employees were enrolled in a corporate wellness program. All study participants were counseled on diet and exercise by dietitians and exercise physiologists employed by MWM for the wellness program. Diet guidance included the American Heart Association diet and 500kcal reduction in caloric intake. Fourteen names were drawn from box and given the Weight Management Genetic Test and diet guidance based on test results 2 weeks after baseline. Weight measurements and blood samples were taken at baseline, 24, 49, 86 and 100 days. The results of the study showed that those subjects who had taken the test lost statistically significantly more weight during the period than those who had not taken the test.

Bone Health Genetic Test

Our *Bone Health Genetic Test* is designed to identify whether an individual is more likely to be susceptible to spine fractures and low bone mineral density associated with osteoporosis. Although it typically starts later in life, early intervention can help prevent osteoporosis. Preventive 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.

Heart Health Genetic Test

Our *Heart Health Genetic Test* is designed to identify genetic predisposition to excess inflammation, which is a risk factor for heart attack. 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 may 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 may be used as an aid to making diet, exercise, and other lifestyle choices to reduce inflammation-based risk.

Nutritional Needs Genetics Test

Our *Nutritional Needs Genetics Test* is designed to identify DNA variations in genes crucial to B-vitamin metabolism and the ability to manage oxidative stress. Individuals with certain variations in these genes may 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 may be used to aid individuals in deciding whether to supplement their diet with B vitamins and/or antioxidants.

Wellness Select Genetic Test

Our *Wellness Select Genetic Test* allows buyers to purchase any combination of Inherent Health genetic tests at a discounted price.

Genetic Test for Risk of Periodontal Disease

The Centers for Disease Control reports that 25% of adults over 60 are missing all their natural teeth, and 5% of adults between 40 and 59 years of age have lost all their teeth. Dental service costs amounted to nearly $108 billion in 2010. The majority of tooth loss can be attributed to periodontal (gum) disease. Periodontitis is a chronic inflammatory disease initiated by specific bacteria that activate host mechanisms destroying the bone and connective tissues that support the teeth. Between 8% and 13% of the worldwide adult population exhibit severe generalized periodontitis, with many more having clinical signs of moderate disease. In the U.S., as noted above, the vast majority of the disease is segregated into 25% of the population. Twin studies indicate that heritability is high, with approximately half of the variation in clinical expression of disease explainable by genetic factors. Indeed, even in the absence of conventional oral hygiene to control the bacterial challenge, the progression of periodontitis can vary significantly. Substantial data support the current concept that specific bacteria are essential to initiation and progression of chronic periodontitis, but host modifiers such as smoking, diabetes, and genetic influences determine the rate of progression and disease severity. Interleukin-1 (IL-1) is well-established as one of the critical regulators of periodontal disease, and studies in non-human primates have shown that drugs specifically blocking IL-1 alone or IL-1 plus TNFa dramatically and significantly reduce tissue destruction even when the bacterial challenge is not reduced. Current preventative treatments for gum disease are more routine cleanings and good oral hygiene.

There are nearly 175 million individuals covered by dental insurance in the U.S. Most typical insurance plans now reimburse for two cleanings per year per individual. Many plans cover more cleanings for individuals already diagnosed with severe periodontal disease. However the current system of prevention is a “one size fits all model,” and there is little evidence to support two visits per year for everyone. Some individuals will need 3-4 preventive visits per year and many people will need only one or potentially fewer cleanings. Our belief is that there is a need for a greater optimization or preventative dental care to improve outcomes and reduce long term oral healthcare expenses.

PST® is a genetic test that analyzes genetic variations associated with inflammation and identifies individuals who are at increased 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, using a large dental claims database, on risk factors predictive of periodontal disease progression to tooth loss using a new version of our PST genetic test. The study is led by Dr. William Giannobile, Director of the Michigan Center for Oral Health Research ("MCOHR") at the University of Michigan School of Dentistry. The study will evaluate whether a second annual cleaning is necessary for the prevention of tooth loss and periodontal disease in low risk individuals, defined as nonsmoking, PST negative and without diabetes. The study is also designed to determine if high risk individuals need more prevention. The goal of the study is to enroll at least 4,000 individuals from whom consent has been obtained with more than 15 consecutive years of documented oral health history. The individuals will come from the same age and socio-economic cohort. Enrollment began in November 2010. Information on periodontitis risk factors and genetic information is being 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. The study's primary efficacy outcome is tooth loss at 15 years for individuals with 1 versus 2 visits per year at low risk (PST negative, non-smokers, non-diabetics). Additional endpoints in the high risk population are included in the trial design. This study is being funded by Renaissance Health Service Corporation, a nonprofit organization focused on the advancement of oral health. Renaissance is the exclusive distributor of the Delta Dental brand in seven states with approximately 8 million covered lives. Patient enrollment was completed in March 2012 and we expect all study samples to be processed by April 2012. The University of Michigan is solely responsible for the data analysis and we expect top line results within a few months of when they begin the analysis.

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:

- Osteoarthritis Genetic Test — North America populations; Medical channel

- Periodontal Disease Genetic Test (version 2.0) — North America and International populations; Medical and Dental channel

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 new findings on the genetics of OA in the Annals of Rheumatic Diseases.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 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 OA 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.

On September 21, 2010, we and researchers from The Thurston Arthritis Research Center 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.

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.

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 genetic test 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. On November 1, 2011 we initiated two clinical studies to demonstrate the utility of the test in the ethnic Chinese population. The programs are being conducted in collaboration with Kaohsiung Medical University and Shanghai Stomatological Disease Center.

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 processed only with a requisition signed by either a customer’s physician or one provided by Interleukin Genetics. Our clinical laboratory then performs the test using our protocols. Depending on the regulations in the particular state or (in Canada) province, test results are provided to the customer and/or designated health care provider.

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. **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. Our partners are responsible for regulatory compliance in the foreign territories in which they sell.

If the clinical study with the University of Michigan has positive results, we believe we would be able to obtain reimbursement coverage for the test from Renaissance Health Services Corporation and other Delta Dental companies. In December 2011 we entered in to an agreement with Renaissance Health Services Corporation to initiate a pilot program to determine the feasibility of marketing the PST genetic test to employees through their dental benefit plans. Beginning on January 1, 2012, the test was offered to select dental group employees affiliated with Renaissance. Employees are able to obtain the test through a secure website at no cost to the employee. The processing of the tests is billed to Renaissance. We intend to continue to partner with domestic and foreign distributors for the sale of our genetic tests. Additionally, we are in discussions with large organizations with large dental sales forces. These organizations have expressed interest in “detailing” the test to dentists.

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. 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 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

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.

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 (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. Our laboratory was most recently inspected in October 2011 and no deficiencies or issues were noted and our CLIA license was renewed.

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. The Food and Drug Administration *(*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 FDA officials including those from the Office of In Vitro Diagnostic Products (OIVD), within the Center for Devices and Radiological Health (CDRH) 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, stating that their tests appeared to be 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.

The FDA letter inquired 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 the director and staff members of the OIVD to present information on our tests. At FDA's request, we submitted a plan in December 2010 and requested a follow-up meeting to obtain feedback on the plan from OIVD personnel. We have had no further communications with the FDA.

In March 2011, FDA convened an expert advisory panel to discuss and make recommendations on scientific issues concerning direct-to-consumer (DTC) genetic tests that make medical claims. The panel expressed a variety of concerns regarding DTC genetic testing and recommended that certain tests not be permitted DTC. We submitted a position paper to the FDA in advance of the meeting and presented testimony to the panel at a public meeting on March 8, 2011.

After the March meeting, the OIVD director publically stated that FDA will likely take a case-by-case approach with respect to which types of genetic tests may be offered DTC. He also stated that OIVD plans to issue three guidance

documents addressing oversight of laboratory developed tests. He did not provide a timeframe for OIVD's release of these documents, but they are listed on CDRH's 2012 regulatory agenda.

In March 2012, an FDA spokesperson stated that FDA's plan to adjust its enforcement discretion policy for LDT's is currently under "administrative review."

HIPAA and Other Privacy Laws

The Administrative Simplification provisions of 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 Health Information Technology for Economic and Clinical Health Act (HITECH), part of the American Recovery and Reinvestment Act of 2009, significantly expanded the scope of HIPAA and increased penalties for violating HIPAA. 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. They also apply to vendors of Covered Entities called "Business Associates" that access protected health information to provide services to or perform functions on behalf of Covered Entities. Covered Entities and Business Associates must have in place administrative, physical and technical standards to guard against the misuse of individually identifiable health information. 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, which include health care providers. Even though we are not directly subject to HIPAA, we could be subject to penalties, lawsuits and experience other adverse consequences if we aid and abet a HIPAA violation by a customer or, under a broad reading of the HIPAA criminal provisions, we obtain or disclose protected health information maintained by a Covered Entity without authorization in violation of HIPAA. In addition, some lawsuits have been pursued at the state level against entities that are not directly subject to HIPAA for breach of confidentiality under the theory that HIPAA establishes a standard of care relative to health information, the breach of which constitutes negligence.

Our activities must also comply with other applicable privacy laws. There are international privacy laws, such as the European Data Directive, that impose restrictions on the access, use, and disclosure of health information. Additionally, some state laws that protect the confidentially of medical information impose privacy protections more stringent than those of HIPAA and are not preempted by HIPAA. There are genetic information privacy laws at the state level. Our failure to comply with these privacy laws could significant impact our business and our future business plans. In addition, legislation is being considered at the federal and state level that could impose stricter requirements regarding the confidentiality of medical information, including genetic information and could impact our operations.

GINA Legislation

In 2008, the Congress passed and the President signed into law, the Genetic Information Non-discrimination Act or GINA. GINA prohibits certain entities from discriminating using genetic information, which includes information from genetic tests, genetic tests of family members and family medical history. It also includes information about an individual's or family member's request for or receipt of genetic services. This law generally prohibits health insurers or health benefit plans from:

- increasing the group premium or contribution amounts (such as co-payments) based on genetic information;
- requesting or requiring an individual or family member to undergo a genetic test; or
- requesting, requiring or purchasing genetic information prior to or in connection with enrollment, or at any time for underwriting purposes.

The law also prohibits employers and certain other entities, including employment agencies, from using genetic information in employment decision-making and from requesting, requiring, or purchasing genetic information. It also strictly limits such entities from disclosing genetic information.

In October 2009, the Department of Health and Human Services issued a proposed rule to modify the HIPAA Privacy Rule to implement Title I of GINA. Among other things, this rule would revise the definition of health information under HIPAA to include genetic information.

GINA applies to some of our customers and to us as an employer. We could be subject to penalties, lawsuits or experience other adverse consequences if our operations violate GINA or cause another entity to violate GINA.

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.

Other Information

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

Item 1A. ***Risk Factors***

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

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. Our financial statements have been prepared assuming that we will continue as a going concern which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We expect to incur further losses in the development of our business and have been dependent on funding operations through the issuance of convertible debt and the sale of equity securities. These conditions raise substantial doubt about our ability to continue as a going concern. Management's plans include continuing to finance operations through the private or public placement of debt and/or equity securities, increasing revenue through new arrangements with commercial distribution partners and the reduction of expenditures. However, no assurance can be given at this time as to whether we will be able to achieve these objectives. The financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

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 $6.5 million in 2010 and $5.2 million in 2011. As of December 31, 2011, our accumulated deficit was $102.6 million. Our losses result primarily from research and development, selling, general and administrative expenses and amortization of intangible assets. Although we

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 generate substantial revenue from the commercializion of 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.

Current economic conditions 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 tests on our own.

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, an affiliate of Alticor, 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 2011 and 2010, revenues from this agreement accounted for 66% and 31% of our revenues, respectively. 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.

Because our products are based on emerging science, if we make changes to our tests based on new scientific findings, market acceptance of our products may decrease and we may be exposed to liability in excess of our product liability insurance coverage.

Our genetic test products are based on emerging science, and we continue to conduct studies to further enhance the usefulness and scientific credibility of our products. If we make changes to our tests based on new data, it could harm our credibility, decrease market acceptance of our products or expose us to liability claims. 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, 2011, we had gross net operating loss and research tax credit carryforwards of approximately $84.3 million and $1.5 million, respectively, for federal income tax purposes, expiring in varying amounts through the year 2031. As of December 31, 2011, we had a research tax credit carryforward of approximately $0.9 million for state income tax purposes, expiring in varying amounts through the year 2026. Our ability to use these net operating loss and credit carryforwards is subject to restrictions contained in the Internal Revenue Code which provide for limitations on our utilization of our net operating loss and credit carryforwards following a greater than 50% ownership change during the prescribed testing period. We have experienced two such ownership changes. One change arose in March 2003 and the other was in June 1999. As a result, our net operating loss carryforwards that relate to periods prior to March 2003 and June 1999 are limited in utilization. The annual limitation may result in the expiration of the carryforwards prior to utilization. In addition, in order to realize the future tax benefits of our net operating loss and tax credit carryforwards, we must generate taxable income, of which there is no assurance.

Risks Related to Our Intellectual Property

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

Our success will depend on our ability to obtain patent protection in the United States and in other countries for our products and services. In addition, our success will also depend upon our ability to preserve our trade secrets and to operate without infringing upon the proprietary rights of third parties. We own rights to 11 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. 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. FDA officials have stated that DTC genetic tests that make medical claims 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. Following the meeting, the director of OIVD stated that FDA would likely need to take a case-by-case approach with respect to which types of genetic tests could be offered by DTC. 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, or that our tests will be permitted to be offered DTC.

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 being found in violation of these laws. Our risk of being found in violation of these laws and regulations is further increased by the fact that the technologies at issue are new and the applicability of statutory and regulatory provisions to these technologies has not been fully developed, implemented, or subjected to judicial review, and the statutory and regulatory provisions themselves 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 unannounced 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 LDT's, we may be required to perform clinical trials prior to submitting a marketing application. If we are required to conduct pre-market clinical trials, whether using prospectively acquired tissue 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 June 24, 2010, we received notification from the Corporate Compliance Staff of the NYSE Amex, hereafter referred to as 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 Exchange 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, 2011, our stock price has fluctuated from a low of $0.19 to a high of $1.50. Furthermore, the stock market has 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 Pyxis, an affiliate of 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, 2011, 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, 2011, Pyxis, was our largest stockholder, holding approximately 56% of the voting power of our capital 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. ***Mine Safety Disclosures***

Not applicable.

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
2011:		
First Quarter	$0.41	$0.27
Second Quarter	$0.47	$0.31
Third Quarter	$0.49	$0.20
Fourth Quarter	$0.35	$0.17

	High	Low
2010:		
First Quarter	$1.50	$0.72
Second Quarter	$0.80	$0.35
Third Quarter	$0.44	$0.25
Fourth Quarter	$0.43	$0.30

Stockholders

As of March 9, 2012, there were approximately 132 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 audited 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 or lifestyle changes. 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, 2011, we continued to focus our resources on conducting our large PST® validation study with the University of Michigan and Renaissance Health Services Corporation and the sales of our Inherent Health® brand of genetic tests and related programs. The objective of the PST validation study is to improve dental care by identifying and using certain risk factors to set preventative treatment regimens. We offer our periodontal disease risk assessment test through a licensing agreement with OralDNA Labs, Inc. a Quest Diagnostics Inc. company. In December 2011 we entered into an agreement with Renaissance Health Services Corporation to initiate a pilot program to determine the feasibility of marketing the PST genetic test to employees through their dental benefit package. On January 1, 2012, the test was offered to select dental group employees affiliated with Renaissance.

Our Inherent Health brand of genetic tests includes 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. In addition, we launched additional products 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.

Sales of our genetic tests increased by $817,000 during the year ended December 31, 2011, as compared to the prior year driven primarily by the marketing efforts of Amway Global, related to our Weight Management Genetic Test. In addition, during the year ended December 31, 2011, we experienced an 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 $483,000 of the accrual for returns after considering the settlement with one retailer and the pattern of returns with others over the past year. During 2010, we paid $414,000 to former customers, including $259,000 paid as a final settlement with a retailer. During 2011, we paid $15,201 to former customers and determined that the remaining accrual of $158,000 should be reversed as any remaining returns are expected to be minimal.

Our research and development expenses have significantly decreased from $3-4 million per year prior to 2010 to $1.4 million in 2010 and 2011, 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.

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 2012 and beyond will be to develop the market for our other personalized health products, such as PST. We continue to allocate considerable resources to our PST and Inherent Health® brands of genetic tests and their 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, 2011, we had cash and cash equivalents of $1.7 million and borrowing capacity of approximately $1.3 million under our credit facility which permits borrowing at any time prior to June 30, 2012.

Cash used in operations was $4.5 million for the year ended December 31, 2011, as compared to $5.7 million for the year ended December 31, 2010. 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 in 2010 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. In 2011 cash used in operations decreased by $1.2 million as compared to 2010 primarily due to increased sales within the Amway Global channel. Cash received from genetic test sales which is reflected in deferred revenue until the test report is issued, increased by $0.3 million to $0.8 million during the year ended December 31, 2011. As we build our genetic test business the need for capital may increase.

Cash provided by investing activities was $0.2 million for the year ended December 31, 2011, compared to cash used of $0.1 million for the year ended December 31, 2010. Capital additions were $4,000 for the year ended December 31, 2011 compared to $95,000 for the year ended December 31, 2010. Capital additions primarily consisted of computers and commercial laboratory support equipment that was purchased to allow 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. In addition, the $0.2 million in other current assets at December 31, 2010 representing a receivable from Nutraceutical Corporation in connection with the sale of the Alan James Group business and assets in July 2009 was received on July 1, 2011.

Cash provided by financing activities was $2.0 million for the year ended December 31, 2011 compared to $8.9 million for the year ended December 31, 2010. In November 2011 we received $2.0 million in proceeds from the issuance of notes payable under our existing credit facility with Pyxis as compared to $4.0 million received in 2010. We have no financial covenants as part of our credit facility with Pyxis. As of December 31, 2011, we had $13.0 million outstanding under the credit facility, which is reflected as current 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. The debt becomes due on June 30, 2012. 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 $33,000 and $44,000 from the exercise of stock options and stock purchases through the employee stock purchase plan for the years ended December 31, 2011 and 2010, respectively.

On November 1, 2010 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 of $118,000 for expenditures made in 2010 was received on March 2, 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 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 extending our current operating line of credit we will need to raise additional capital. Even though we are experiencing sales increases in our genetic testing business we continue to explore additional steps to reduce our operating costs. In 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. During 2011, we reduced our cost of processing samples in our laboratory by working with our raw material vendors to make our genetic testing process more efficient resulting in lower processing costs. We have significantly reduced our research and development programs to only those that focus on technology related to agreements 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. Our common stock was delisted from the NYSE Amex in 2010 and is currently trading on the OTCQB™. As a result, our access to capital through the public markets may be more limited.

Our financial statements have been prepared assuming that we will continue as a going concern which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We expect to incur further losses in the development of our business and have been dependent on funding operations through the issuance of convertible debt and the sale of equity securities. These conditions raise substantial doubt about our ability to continue as a going concern. Management's plans include continuing to finance operations through the private or public placement of debt and/or equity securities, increasing revenue through new arrangements with commercial distribution partners and the reduction of expenditures. However, no assurance can be given at this time as to whether we will be able to achieve these objectives. The financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

We expect that our current and anticipated financial resources, including the $1.3 million available as of December 31, 2011 under our credit facility with Pyxis, are adequate to maintain current and planned operations through June 30, 2012, however, if we are not successful in capital raising efforts, partnering negotiations, extending the due date of our debt or in generating additional revenues, we will not be able to fund operations beyond June 30, 2012. We continue to attempt to raise additional capital, seek additional streams of revenue, extend the due date of our debt and improve sales with new and existing channels.

Results of Operations

Years Ended December 31, 2011 and 2010

Total revenue from our continuing operations for the year ended December 31, 2011 was $2.9 million, compared to $2.0 million for the year ended December 31, 2010. The increase of $0.9 million, or 43.1%, is primarily attributable to increased genetic testing revenue. Genetic testing revenue increased to $2.8 million, or 42.1%, in the year ended December 31, 2011, compared to $1.9 million in the year ended December 31, 2010. The increase is primarily attributable to sales of our Inherent Health® Brand of genetic tests through the Amway Global sales channel. 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.

During the years ended December 31, 2011 and 2010, we had one significant customer, Alticor, our principal shareholder, that accounted for approximately 68% and 37%, respectively, of our revenues from continuing operations. During the years ended December 31, 2011 and 2010, approximately 66% and 32%, 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, 2011 was $1.5 million, or 53.5% of revenue, compared to $1.6 million, or 81.1% of revenue, for the year ended December 31, 2010. The significant decrease in the cost of revenue as a percentage of revenue is primarily attributable to increased revenue, which absorbed fixed costs associated with our genetic testing laboratory and more efficient processing of genetic tests. During 2011, we worked with our genetic testing supply vendors to provide more efficient materials that result in a lower cost of production. 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, 2011, was a profit of $1.3 million, or 46.5%, compared to $0.4 million, or 18.9%, for the year ended December 31, 2010. The increase in gross margin is primarily attributable to genetic test revenue and cost savings realized by the more efficient processing of genetic tests.

Research and development expenses were $1.4 million for each of the years ended December 31, 2011 and 2010. The small decrease is primarily attributable to decreased compensation and facility operating costs offset by increased consulting expenses as compared to the year ended December 31, 2010.

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 $4.7 million for the year ended December 31, 2011, compared to $5.5 million for the year ended December 31, 2010. The decrease of $0.8 million, or 15.5% is primarily attributable to decreases in compensation, product development, promotion and consulting expenses, partially offset by increased sales commissions paid to Amway Global as part of our Merchant Channel and Partner Store Agreement.

Interest expense was $367,000 for the year ended December 31, 2011, as compared to $303,000 for the year ended December 31, 2010. The increase in interest expense of $64,000 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 set forth in Note 4 to our financial statements included in Item 8 presented elsewhere herein.

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.

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

INTERLEUKIN GENETICS, INC.

INDEX TO FINANCIAL STATEMENTS

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, 2011 and 2010, 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, 2011 and 2010, 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.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company incurred a net loss of $5,025,182 during the year ended December 31, 2011 and, as of that date, the Company's current liabilities exceeded its current assets by $12,264,827 and its total liabilities exceeded total assets by $11,423,231. These conditions, along with other matters as set forth in Note 2, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Grant Thornton LLP

Boston, Massachusetts

March 29, 2012

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INTERLEUKIN GENETICS, INC.

BALANCE SHEETS

	December 31, 2011	2010
ASSETS		
Current assets:		
Cash and cash equivalents	$1,728,222	$3,999,029
Accounts receivable from related party	2,662	14,657
Trade accounts receivable	55,892	36,960
Federal grant receivable	—	117,946
Inventory	107,758	117,849
Prepaid expenses	217,387	251,383
Other current assets	—	200,000
Current assets of discontinued operations	—	14,966
Total current assets	2,111,921	4,752,790
Fixed assets, net	289,011	554,172
Intangible assets, net	514,584	630,037
Other assets	38,001	38,001
Total assets	$2,953,517	$5,975,000
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$369,306	$509,647
Accrued expenses	182,597	443,255
Deferred revenue	824,845	515,953
Current portion of long-term debt	13,000,000	—
Liabilities of discontinued operations	—	164,241
Total current liabilities	14,376,748	1,633,096
Convertible long-term debt	—	11,000,000
Total liabilities	14,376,748	12,633,096
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, 2011 and 2010; aggregate liquidation preference of $18,000,000 at December 31, 2011	5,000	5,000
Common stock, $0.001 par value — 100,000,000 shares authorized; 36,709,706 and 36,594,799 shares issued and outstanding at December 31, 2011 and 2010, respectively	36,710	36,594
Additional paid-in capital	91,111,640	90,851,709
Accumulated deficit	(102,576,581)	(97,551,399)
Total stockholders' deficit	(11,423,231)	(6,658,096)
Total liabilities and stockholders' deficit	$2,953,517	$5,975,000

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

INTERLEUKIN GENETICS, INC.

STATEMENTS OF OPERATIONS

	For The Year Ended December 31,	
	2011	2010
Genetic testing	$ 2,757,355	$ 1,940,190
Other	99,750	56,983
Total revenue	2,857,105	1,997,173
Cost of revenue	1,527,201	1,618,841
Gross profit	1,329,904	378,332
Operating expenses:		
Research and development	1,376,394	1,413,501
Research and development reimbursement grant	—	(473,394)
Selling, general and administrative	4,665,360	5,526,377
Amortization of intangibles	115,453	115,453
Total operating expenses	6,157,207	6,581,937
Loss from operations	(4,827,303)	(6,203,605)
Other income (expense):		
Interest income	6,419	4,989
Interest expense	(366,938)	(303,363)
Other income	4,274	33,159
Total other income (expense)	(356,245)	(265,215)
Loss from continuing operations before benefit for income taxes	(5,183,548)	(6,468,820)
Benefit for income taxes	—	—
Loss from continuing operations	(5,183,548)	(6,468,820)
Income from discontinued operations, net of tax	158,366	482,530
Net loss	$ (5,025,182)	$ (5,986,290)
Basic and diluted net loss per common share from:		
Continuing operations	$ (0.14)	$ (0.18)
Discontinued operations	0.00	(0.01)
Net loss	$ (0.14)	$ (0.17)
Weighted average common shares outstanding, basic and diluted	36,661,290	35,706,271

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

INTERLEUKIN GENETICS, INC.

STATEMENTS OF STOCKHOLDERS' DEFICIT

For the Years Ended December 31, 2011 and 2010

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Shares	Par Value	Capital	Deficit	Total
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
Balance as of December 31, 2010	5,000,000	$ 5,000	36,594,799	$ 36,594	$90,851,709	$(97,551,399)	$(6,658,096)
Net loss	—	—	—	—	—	(5,025,182)	(5,025,182)
Common stock issued:							
Employee stock purchase plan	—	—	114,907	116	32,839	—	32,955
Stock-based compensation expense	—	—	—	—	227,091	—	227,091
Balance as of December 31, 2011	5,000,000	$ 5,000	36,709,706	$ 36,710	$91,111,640	$(102,576,581)	$(11,423,231)

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

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INTERLEUKIN GENETICS, INC.

STATEMENTS OF CASH FLOWS

	For the Year Ended December 31,	
	2011	2010
CASH FLOW FROM OPERATING ACTIVITIES:		
Net loss	$ (5,025,182)	$ (5,986,290)
Income from discontinued operations	158,366	482,530
Loss from continuing operations	(5,183,548)	(6,468,820)
Adjustments to reconcile loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	385,031	426,670
Stock-based compensation expense	227,091	164,371
Changes in operating assets and liabilities:		
Account receivable, net	(6,937)	(17,738)
Federal grant receivable	117,946	(117,946)
Inventory	10,091	581
Prepaid expenses and other current assets	48,962	(8,915)
Accounts payable	(140,341)	188,206
Accrued expenses	(260,658)	161,447
Deferred revenue	308,892	408,161
Net cash used in operating activities of discontinued operations	(5,873)	(476,278)
Net cash used in operating activities	(4,499,344)	(5,740,261)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Capital additions	(4,418)	(95,409)
Net cash provided by investing activities of discontinued operations	200,000	—
Net cash provided by (used in) investing activities	195,582	(95,409)
CASH FLOW FROM FINANCING ACTIVITIES:		
Proceeds from issuance of notes payable	2,000,000	4,000,000
Proceeds from registered direct offering of common stock	—	5,250,002
Registered direct offering costs	—	(365,328)
Proceeds from exercises of employee stock options	—	338
Proceeds from employee stock purchase plan	32,955	43,439
Net cash provided by financing activities	2,032,955	8,928,451
Net increase (decrease) in cash and equivalents	(2,270,807)	3,092,781
Cash and cash equivalents, beginning of period	3,999,029	906,248
Cash and cash equivalents, end of period	$ 1,728,222	$ 3,999,029
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 357,500	$ 263,651

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

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INTERLEUKIN GENETICS, INC.

NOTES TO FINANCIAL STATEMENTS

December 31, 2011

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.

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

Note 2—Operating Matters, Liquidity and Going Concern

The Company has experienced net operating losses since its inception through December 31, 2011. During the last two fiscal years such losses totaled $11.0 million contributing to an accumulated deficit of $102.6 million as of December 31, 2011. During this same period, the Company has increased its borrowings to $13.0 million under its line of credit with Pyxis Innovations, Inc. ("Pyxis"). Management expects that its current financial resources, including $1.3 million available under its credit facility with Pyxis, are adequate to maintain current and planned operations through June 2012. All outstanding amounts under this line of credit become due on June 30, 2012.

The Company took steps in 2010 and 2011 to reduce operating costs, including manufacturing costs as well as general and administrative expenses. Cost savings were achieved through process improvements in manufacturing, reductions in personnel and the subleasing of underutilized rental space. Management believes that the current laboratory space is adequate to process high volumes of genetic tests.

The Company's financial statements have been prepared assuming that it will continue as a going concern which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company expects to incur additional losses in 2012 and, accordingly, is dependent on finding additional sources of liquidity to

fund its operations. Management's plans include identifying sources of debt and/or equity financing, extending the due date of its existing debt, growing its sources of revenue and further reducing expenditures. However, no assurance can be given at this time as to whether management will be able to achieve these plans. If the Company is not successful in raising additional debt or equity funding, extending the due date of its existing debt, completing negotiations with commercial distribution partners or reducing expenditures, it will not be able to fund operations beyond June 30, 2012. The financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue its existence.

The ability of the Company to realize the carrying value of its fixed assets and intangible assets is especially dependent on management's ability to successfully execute on its plan. As noted in the preceding paragraph, the Company needs to generate additional funds in order to meet its financial obligations beyond June 30, 2012. If it is unsuccessful in doing so, the Company may not be able to realize the carrying value of its fixed assets and intangible assets.

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, which was received on July 1, 2011, was available to satisfy potential amounts owed to the buyer pursuant to the agreement. 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. At December 31, 2010, the 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.

In 2010 and 2011 we 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. In June 2011, after completing an analysis of all return activity since the time of the sale, the remaining reserve of $0.2 million was reversed. Any future amounts that may be applicable to the non-acquired accounts are expected to be minimal.

Note 4—Summary of Significant Accounting Policies

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, 2011 and December 31, 2010, the Company has deferred genetic test revenue of $824,845 and $505,935, 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 which precedes the recognition of revenue. The cost of commissions was $951,000 and $370,000 for the years ended December 31, 2011 and 2010, respectively.

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, 2011 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.

Inventory consisted of the following at December, 2011 and 2010:

	2011	2010
Raw materials	$100,432	$110,347
Finished goods	7,325	7,502
Total inventory, net	$107,758	$117,849

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 under the Black-Scholes option pricing model. 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 $30.2 million as of December 31, 2011, 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 changes in Massachusetts corporate income tax regulations enacted in 2009, the Company files 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 Company estimates that the combined filing will have no impact on the Company's financial condition, results of operations and cash flows.

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, 2011 and 2010.

Research and Development

Research and development costs are expensed as incurred.

Advertising Expense

Advertising costs are expensed as incurred. During the years ended December 31, 2011 and 2010 advertising expense was $33,000 and $19,000, 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,	
	2011	2010
Stock options	2,228,067	1,611,267
Warrants	2,150,000	2,150,000
Convertible preferred stock	28,160,200	28,160,200
Convertible debt	2,289,418	1,937,200
Total	34,827,685	33,858,667

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, 2011 and 2010, 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 (see Note 6).

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, 2011, 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, 2011 and 2010.

Segment Reporting

As of December 31, 2011 and 2010, the Company has one segment, 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.

Reclassifications

Certain prior period amounts have been reclassified to conform to the current period presentation. In 2011, the Company concluded that patent related legal costs, which had previously been classified with research and development expenses, should be classified as selling, general and administrative expenses. For the year ended December 31, 2010, these costs amounted to $512,000. Such reclassification had no impact on the Company’s reported results of operations.

Recent Accounting Pronouncements

No new updates or other guidance issued to date by the FASB in 2011 are expected to have a material impact on the Company's financial statements.

Note 5—Strategic Alliance with Alticor Inc. (A Related Party)

Since March 2003, the Company has maintained a broad strategic alliance with several affiliates of the Alticor family of companies, a related party through its role as both significant shareholder and lender to the Company, 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 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 $951,000 and $370,000 in commissions for the years ended December 31, 2011 and 2010, respectively, representing a percentage of net sales to their customers. The Company expenses commissions owed to Amway Global at the point of sale with the customer.

On April 15, 2011, the Company entered into a contract services agreement with Alticor Corporate Enterprises Inc. and Amway International Inc. (collectively, "Alticor"). Pursuant to this agreement, the Company provided marketing, promotional and training services to Alticor in connection with its marketing of the Company's weight management genetic test. Upon execution of the agreement on April 15, 2011, the agreement received retroactive effect as of October 15, 2010 and expired on October 14, 2011 and has not been renewed. The Company received approximately $143,000 for its services under the agreement.

Note 6—Convertible Debt

On August 17, 2006, our existing credit facility with Pyxis was amended to provide the Company with access to approximately $14.3 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 modified 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, 2011, there was $13,000,000 in principal outstanding under the credit facility leaving $1,316,255 of available credit.

The fair value of convertible debt is estimated to be approximately $1.6 million at December 31, 2011.

Note 7—Fixed Assets

The useful lives and balances of fixed assets at December 31, 2011 and 2010 consisted of the following:

	Useful Life	2011	2010
Computer software, computer equipment and office equipment	3 years	$314,717	$350,822
Laboratory equipment	5 years	1,220,770	1,370,641
Furniture and fixtures	5 years	40,349	40,349
Leasehold improvements	5 years	303,258	303,258
Website development	3 years	270,678	270,678
Equipment under capital leases	3 to 5 years	22,920	22,920
		2,172,692	2,358,668
Less — Accumulated depreciation and amortization		(1,883,681)	(1,804,496)
Total		$289,011	$554,172