INTERLEUKIN GENETICS INC
Form 10-K
March 28, 2013

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

---

**FORM 10-K**

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the fiscal year ended December 31, 2012**
o **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** | **94-3123681** |
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **135 Beaver Street, Waltham, MA** | **02452** |
| (Address of principal executive offices) | (Zip Code) |

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

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

Securities registered pursuant to Section 12(g) of the 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 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 x NO ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein 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 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 $8,067,008.

As of March 8, 2013 there were 36,761,864 shares of the registrant's Common Stock and 5,500,000 shares of the registrant's Preferred Stock, issued and outstanding.

**Documents Incorporated By Reference**

Portions of the registrant's Definitive Proxy Statement for the 2013 Annual Meeting of Shareholders are incorporated by reference in Part III hereof.

**INTERLEUKIN GENETICS, INC.**

**FORM 10-K**

**FOR THE YEAR ENDED DECEMBER 31, 2012**

**Table of Contents**

**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. 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.

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.

**Our Products**

Our genetic tests that are currently being commercialized are:

- *PST*®: This genetic test analyzes genetic variations associated with inflammation and identifies individuals who are at increased risk for more severe periodontal disease.

- *Weight Management Genetic Test*: This 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. This test is marketed under our Inherent Health® brand.

- *Bone Health Genetic Test*: This 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. This test is marketed under our Inherent Health® brand.

- *Heart Health Genetic Test*: This test is designed to identify genetic predisposition to excess inflammation, which is a risk factor for heart attack. This test is marketed under our Inherent Health® brand.

- *Wellness Select Genetic Test:* This allows buyers to purchase any combination of Inherent Health® genetic tests at a discounted price. This is marketed under our Inherent Health® brand.

We recently entered into a Preferred Participation Agreement with Renaissance Health Services Corporation, or RHSC, the exclusive distributor of the Delta Dental brand in eight states, with respect to reimbursement of our PST® test. We market our Inherent Health® brand of genetic assessment tests primarily through our Merchant Network and Channel Partner Agreement with Alticor's Amway Global Company.

In addition to the genetic tests listed above that we are currently marketing, we are also focusing our genetic test development efforts on the development of an Osteoarthritis, or OA, genetic test to identify individuals at increased risk for severe OA.

**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 to better understand the interaction between our environment and our genes. The scientific community is learning more each day about the role and significance of genetic variations, such as single nucleotide polymorphisms, or SNPs, and haplotypes, on an individual’s health. SNP and haplotype analysis coupled with detailed knowledge of environmental factors now is an important area of study in order to improve human health. A SNP may cause a gene to make a different amount of a protein for a given condition, change the timing of protein synthesis or make a variant form of the protein; each of these changes may lead to a discernible physiological impact. However, certain lifestyle changes can influence significantly whether a set of genes are activated or 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.

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 periodontitis and rheumatoid arthritis. 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. 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, osteoporosis, osteoarthritis, and periodontal disease. Individuals' gene variations influence the severity of the risks and predispositions to these diseases.

**Our Approach to Test Development**

We seek to develop tests that may reduce the risk of certain chronic conditions and illnesses or offer 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 its market potential.

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, our osteoporosis risk assessment panel 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, our weight management genetic test panel 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 of our Inherent Health® brand of genetic tests either directly to end users or through partnerships such as the Amway Global channel;

- sales of our Inherent Health® brand of genetic tests to commercial distribution partners such as regional weight loss centers;

- sales of our PST® genetic tests to insurance providers; and

- license fees for intellectual property used in the sale of partner genetic tests.

Our primary business focus and strategy is to continue our commercialization efforts with our PST® genetic test. In addition, we plan to continue to develop and sell tests for our own business needs under the Inherent Health® brand.

We market our Inherent Health® brand of genetic assessment tests primarily through our Merchant Network and Channel Partner Agreement with Alticor's Amway Global Company. 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 IBOs' customers. Sales with Amway Global through this business arrangement began in December 2009.

**Our Products and Product Development Pipeline**

We are focused on commercializing our existing genetic tests, primarily PST® and less on 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.

***Genetic Test for Risk of Periodontal 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. 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 could need 3-4 preventive visits per year and many people could 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. Results from several 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.

In August of 2010, we signed an agreement with the University of Michigan and Renaissance Health Services Corporation, or RHSC, to conduct a clinical study, using a large dental claims database, on risk factors predictive of periodontal disease progression to tooth loss using our PST® genetic test. This study, which we refer to herein as the PDPS, was led by Dr. William Giannobile, Director of the Michigan Center for Oral Health Research, or MCOHR, at the University of Michigan School of Dentistry. The PDPS was funded by RHSC, which is the exclusive distributor of the Delta Dental brand in eight states with approximately 8 million covered lives. The PDPS evaluated 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 PDPS was also designed to determine if high risk individuals need more prevention. On March 28, 2012, we jointly announced with the University of Michigan that the PDPS had been fully enrolled with approximately 5,400 consenting adults and on August 6, 2012, we announced that we had received top line results from the PDPS. These results indicate that in Low Risk patients, there was no significant difference between two dental preventive visits per year and one preventive visit per year in the percentage of patients who had tooth extractions over the 16 year monitoring period; 13.8% versus 16.4% (p=.092 n.s.). In addition, these results indicate that in High Risk patients, two preventive visits per year significantly reduced the percentage of patients who had extractions over a 16 year monitoring period compared to one preventive visit per year; 16.9% vs. 22.1% (p=0.002). There was also a positive relationship between number of risk factors and the percentage of patients with extractions (p<0.001). Low Risk patients (47% of the study population) were defined as non-smokers, genetically negative per our PST® test and no history of diabetes. High Risk patients were defined as having one or more risk factors, PST® positive, diabetes or smoking. The University of Michigan was solely responsible for the study data analysis.

On February 25, 2013, we entered into a Preferred Participation Agreement with RHSC, for itself and on behalf of certain of its affiliates and subsidiaries. Pursuant to this agreement, affiliates of RHSC have agreed to reimburse us a fixed price for each PST® genetic test that we process for a customer of affiliates of RHSC. In addition, if during the term of the agreement we offer the PST® test to any other person or party for a lower price, such lower price shall then be applicable to tests processed for a customer of such affiliates of RHSC for the remainder of the term of the agreement. The pricing arrangement is subject to the satisfaction of certain milestones, including that (1) within a specified timeframe, RHSC affiliates must develop and offer dental benefit plans for which a significant portion of such affiliate's clients are eligible that provides for use of the PST® test and reimbursement of the test at the agreed upon price (each such plan, hereinafter referred to as a “Reimbursed Dental Plan”) and (2) prior to a specified date, RHSC affiliates shall have sold policies for Reimbursed Dental Plans for the year beginning January 1, 2014. We have agreed that for a one year period beginning on the date on which RHSC affiliates first offer a Reimbursed Dental Plan, we will make the PST® test available solely to RHSC affiliates and not to any other third party or person. This agreement has a term of three years beginning on February 25, 2013, but may be terminated earlier (1) upon the mutual written agreement of us and RHSC, (2) if either party becomes the subject of bankruptcy, insolvency, liquidation or other similar proceedings, or (3) in the event of an uncured breach of the Agreement by either party.

The timing of any revenues that we may receive under this agreement is dependent upon the timing of the offering of Reimbursed Dental Plans, which timing is very uncertain at this time. We do not expect to receive any significant revenues under this agreement until the first quarter of 2014 at the earliest, and the timing of any such revenues may be substantially later. See “Part I, Item 1A. Risk Factors - The timing and amount of revenues, if any, that we may receive pursuant to our Preferred Participation Agreement with RHSC and its affiliates is uncertain” for a discussion of the risks associated with the timing and amount of any revenues we may receive under this agreement.

For certain ethnic populations the frequency of the risk allele is low in the current PST® test. A new revised PST® genetic test is predictive of severe disease and tooth loss for all ethnic populations. 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.

***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 U.S. 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); and 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 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, two, six, and 12 months.

Although Stanford University had retained plasma samples from the original A TO Z study, 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 Interleukin 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 male & 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 subjects were randomly 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 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 program:

*Osteoarthritis Genetic Test*

Osteoarthritis, or 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 five 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 multi-joint 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, we 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 us 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 OA drugs (DMOADs) to screen patients and include in their clinical trials only those patients who have progressive disease. There is currently no mechanism for selecting high risk patients, and multiple clinical DMOAD studies have failed due to excessive numbers of patients with no progression of disease. The results may be useful for setting the dose of hyaluronic acids in the treatment of osteoarthritis pain. The genetic test could help identify those patients who need increased frequency dosing regimens or higher doses of the compound. This genetic information may also assist the rheumatologist in managing the medical and surgical options of individual patients. Additional studies identified a different set of genetic markers that were predictive of which patients started with knee OA and subsequently developed hand problems. We intend to search for marketing and sales partners to introduce the tests into the medical channel.

**Laboratory Testing Procedure**

To conduct a genetic risk assessment test, the end-user collects cells from inside the cheek on a brush and submits it by mail to our laboratory. Samples are 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 in which the customer resides, we provide the test results 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.” We have upgraded the systems and processes for the laboratory with the addition of high volume analytical equipment. We currently are licensed in the seven states that require a genetic test processing license.

**Marketing and Distribution Strategy**

***Inherent Health®***

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 have developed 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.

***PST®***

During 2012 we marketed and distributed our PST® test directly to dentists and periodontists via Quest Diagnostic's subsidiary, OralDNA Labs in the U.S. With the PDPS yielding positive results, we executed a Preferred Participation Agreement obtaining reimbursement coverage for the test from RHSC and its affiliates. Based on this agreement we will no longer sell the test through OralDNA Labs. However, the timing of any revenues that we may receive under this agreement is dependent upon the timing of the offering of Reimbursed Dental Plans, which timing is very uncertain at this time. Our current intent is to market our PST® test through Reimbursed Dental Plans sold by RHSC's affiliates to employer groups for plan years starting in January 2014. However, RHSC affiliates will not begin marketing Reimbursed Dental Plans until positive results of the PDPS are published in a peer review journal. While an article has been submitted to a peer reviewed journal, there is no assurance that the article will be accepted for publication, or, even if accepted, when the article will be published. RHSC has told us that in order for its affiliates to begin marketing Reimbursed Dental Plans for plan years beginning in January 2014, the article must be accepted for publication in a peer review journal by May 31, 2013. Accordingly, we do not expect to receive any significant revenues under this agreement until the first quarter of 2014 at the earliest, and the timing of any such revenues may be substantially later. See "Part I, Item 1A. Risk Factors - The timing and amount of revenues, if any, that we may receive pursuant to our Preferred Participation Agreement with RHSC and its affiliates is uncertain" for a discussion of the risks associated with the timing and amount of any revenues we may receive under this agreement.

**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 granted patents and pending applications directed to 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 2027, and have 10 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 “Risk Factors” below in Part I, Item 1A of this Form 10-K. Our commercial success will 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.

**Competition**

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**

The services that we provide are regulated by federal and state governmental authorities. Failure to comply with the applicable laws and regulations can subject us to civil and criminal penalties, loss of licensure, certification, or accreditation. 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*

Our clinical laboratory must hold certain licenses, certifications, and permits to conduct our business. Laboratories that perform testing on human specimens for the purpose of providing information for the diagnosis, prevention or treatment of disease or assessment of health are subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). CLIA requires such a laboratory to be certified by the federal government and mandates compliance with various operational, personnel, facilities, administration, quality and proficiency testing requirements intended to insure that testing services are accurate, reliable and timely. Standards for testing under CLIA vary based on the level of complexity of the testing performed. Laboratories performing high complexity tests, such as genetic tests, must comply with more stringent requirements than laboratories perfoming moderate or waived testing.

As a condition of CLIA certification, our laboratory is subject to survey and inspection every other year, in addition to being subject to additional random inspections. The biennial survey is conducted by the Centers for Medicare & Medicaid Services, or CMS, a CMS agent (typically a state agency), or, if the laboratory is accredited, a CMS-approved accreditation organization.

CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law. In some cases, state licensure programs actually substitute for the federal CLIA program. In other instances, the state's regulations may be in addition to the CLIA program. In addition, our laboratory holds multiple state licenses to the extent that we accept specimens from one or more of these states, each of which require out-of-state laboratories to obtain licensure. If a laboratory is out of compliance with state laws or regulations governing licensed laboratories, penalties for violation vary from state to state but may include suspension, limitation, revocation or annulment of the license, assessment of financial penalties or fines, or imprisonment. We believe that we are in material compliance with all applicable licensing laws and regulations.

We may become aware from time to time of other states that require out-of-state laboratories to obtain licensure to accept specimens from the state, and other states may impose such requirements in the future. If we identify any other state with such requirements, or if we are contacted by any other state advising us of such requirements, we intend to follow all instructions from the state regulators regarding compliance with such requirements.

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.

*Food and Drug Administration*

Although the Food and Drug Administration (FDA) has consistently claimed that it has the authority to regulate laboratory-developed tests, or LDTs, that are validated by the developing laboratory and performed only by that laboratory, it has generally exercised enforcement discretion in not otherwise regulating most tests developed and performed by high complexity CLIA-certified laboratories. However, for the past few years, the FDA indicated that it was reviewing the regulatory requirements that will apply to LDTs.

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, or DTC, 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. The FDA letter inquired about our Inherent Health brand of DTC genetic tests and stated 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 regarding our products with the FDA. We have received no communication from the FDA relative to our periodontal disease test which is only available through licensed health practitioners.

In March 2011, FDA convened an expert advisory panel to discuss and make recommendations on scientific issues concerning 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 to be sold 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 that meeting, the OIVD director publically stated that FDA would likely take a case-by-case approach with respect to which types of genetic tests may be offered DTC. He also stated that OIVD planned to issue three guidance documents addressing oversight of laboratory developed tests. However, he did not provide a timeframe for OIVD’s release of these documents.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.”

As of now, the FDA has not issued the promised additional guidance, but we expect that is will do so in the future. Before any draft or final guidance is issued, however, the FDA will be required, for the next five years, to give at least sixty days prior notice to Congress in accordance with the recently enacted Food and Drug Administration Safety and Innovation Act, or FDASIA. The notice must include anticipated details of the action.

*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, such as health care providers and health plans. Even though we are not directly subject to HIPAA, we could be subject to penalties, lawsuits and experience other adverse consequences if we wrongfully acquire protected health information, aid and abet a HIPAA violation by a customer or if we obtain or disclose protected health information maintained by a Covered Entity without authorization in violation of HIPAA. In addition, some lawsuits, including class action lawsuits, have been pursued at the state level against both covered entities and entities that are not directly subject to HIPAA for breach of confidentiality and security violations.

Our activities must also comply with other applicable privacy laws, including state data security laws that apply to personal data of our employees as well as our customers. “Personal data” includes information such as name coupled with social security number, state issued identification number, or financial account number. State data security laws impose specific security measures for the protection of personal data and require notification to affected individuals and government authorities in the event of breach. Non compliance may result in government investigations, fines and significant negative publicity for our company.

Many states protect health information with confidentiality laws that are more stringent than HIPAA and that are not preempted by HIPAA. Most states protect certain categories of sensitive health information, such as infectious disease status or behavioral health history. Genetic information, including genetic test results, is often a protected category of health information. We must comply with all of these state-imposed laws. There are also international privacy laws, such as the European Data Directive, that impose restrictions on the access, use, and disclosure of health information and personal data across national lines.

In addition to health care privacy and data security laws, many states have adopted laws governing genetic testing and the use and disclosure of genetic test results. These laws typically require a specific form of written consent in advance of genetic testing and require special protections for test results. Given the complexity of genetic testing and the variety of techniques available for evaluating similar clinical conditions, these laws can be difficult to apply, making compliance more complex and potentially delaying implementation of a testing program when parties disagree on interpretation. Our failure to comply with these laws may result in fines, government enforcement, privacy litigation and adverse publicity for our company.

If we become subject to HIPAA or other state or federal privacy and security laws, we will have to establish and maintain an active compliance program. We will subject to audit and investigation and may also be audited in connection with a complaint. We would also be subject to prosecution and/or administrative enforcement and increased civil and criminal penalties for non-compliance, including a new, four-tiered system of monetary penalties adopted under HITECH. We would also subject to enforcement by state attorneys general who were given authority to enforce HIPAA under HITECH.

We are subject to laws and regulations related to the protection of the environment, the health and safety of employees and the handling, transportation and disposal of medical specimens, infectious and hazardous waste and radioactive materials. For example, the U.S. Occupational Safety and Health Administration, or OSHA, has established extensive requirements relating specifically to workplace safety for healthcare employers in the U.S. This includes requirements to develop and implement multi-faceted programs to protect workers from exposure to blood-borne pathogens, such as HIV and hepatitis B and C, including preventing or minimizing any exposure through needle stick injuries. For purposes of transportation, some biological materials and laboratory supplies are classified as hazardous materials and are subject to regulation by one or more of the following agencies: the U.S. Department of Transportation, the U.S. Public Health Service, the United States Postal Service and the International Air Transport Association. We generally use third-party vendors to dispose of regulated medical waste, hazardous waste and radioactive materials and contractually require them to comply with applicable laws and regulations.

*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. Final regulations were adopted in January, 2013.Among other things, this rule revises 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 over the advertisements of many types of products and prohibits unfair or deceptive trade practices. 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 *www.ilgenetics.com* 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 by the end of April 2013, then we may have to end our operations and seek protection under bankruptcy laws.*

We expect that our current and anticipated financial resources, including the full amount drawn 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 only through April 2013. We need significant additional capital to fund our continued operations, including for the commercial launch of our PST® genetic test, continued research and development efforts, obtaining and protecting patents and administrative expenses. We have retained a financial advisor and are actively seeking additional funding, however, based on current economic conditions, additional financing may not be available, 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 will 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, we may have to discontinue operations and seek protection under U.S. bankruptcy laws.