

INTERLEUKIN GENETICS INC  
Form 10-K  
March 28, 2013

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

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**FORM 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT  
X OF 1934**

**For the fiscal year ended December 31, 2012**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
O ACT OF 1934**

**For the transition period from                      to**

**Commission File Number: 001-32715**

**INTERLEUKIN GENETICS, INC.**

(Name of Registrant in its Charter)

|   |   |
|---|---|
| <b>Delaware</b>   | <b>94-3123681</b>                       |
| (State or other jurisdiction of<br>incorporation or organization) | (I.R.S. Employer<br>Identification No.) |

|  |              |
|--|--------------|
| <b>135 Beaver Street, Waltham, MA</b>    | <b>02452</b> |
| (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:

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Common Stock, \$.001 par value per share

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained 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 .

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):

Non-accelerated filer

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

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

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

registrant's most recently completed second quarter was \$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**

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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. 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 initiating 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*<sup>®</sup>: 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<sup>®</sup> brand of genetic tests either directly to end users or through partnerships such as the Amway Global channel;

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

· sales of our PST<sup>®</sup> 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<sup>®</sup> genetic test. In addition, we plan to continue to develop and sell tests for our own business needs under the Inherent Health<sup>®</sup> brand.

We market our Inherent Health<sup>®</sup> 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<sup>®</sup> brand of genetic tests via a hyperlink from the Amway Global website to the Inherent Health<sup>®</sup> 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<sup>®</sup> 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 TNF $\alpha$  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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> test and no history of diabetes. High Risk patients were defined as having one or more risk factors, PST<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> test. A new revised PST<sup>®</sup> 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<sup>®</sup> 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/m<sup>2</sup>), 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](http://www.inherenthealth.com). We have subcontracted with a fulfillment center to distribute tests to customers ordering via our online store. The e-commerce solution has provided a friendly and easy to use method for the purchase of our genetic tests. We are partnered with a number of websites that have established a link to our site in order to distribute tests. We pay these sites commissions for all orders made via a click through from their site to ours.

## **PST<sup>®</sup>**

During 2012 we marketed and distributed our PST<sup>®</sup> 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<sup>®</sup> 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 performing 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 it 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](http://www.ilgenetics.com) and [www.inherenthealth.com](http://www.inherenthealth.com). Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to such reports are available to you free of charge through the Investor Relations Section of [www.ilgenetics.com](http://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<sup>®</sup> 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.

*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.*

Although we have entered into a Preferred Participation Agreement with RHSC, for itself and on behalf of certain of its affiliates and subsidiaries, pursuant to which RHSC affiliates are expected to develop and offer dental benefit plans that provide for use of the PST® test and reimbursement of the test at an agreed upon price (each such plan, hereinafter referred to as a “Reimbursed Dental Plan”), the timing of any revenues that we may receive under this agreement is dependent upon the timing of the offering of such Reimbursed Dental Plans, which timing is very uncertain at this time. While our current intent is to market our PST® test through Reimbursed Dental Plans offered and sold by RHSC’s affiliates to employer groups for plan years starting in January 2014, 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, the earliest that we may receive any significant revenues under this agreement is in the first quarter of 2014, and the timing of any such revenues may be substantially later. The failure to begin receiving significant revenues under this agreement in 2014 would require us to obtain additional funding and would have a material adverse affect on our business.

*There is substantial doubt concerning our ability to continue as a going concern.*

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. Although we have retained a financial advisor and have had discussions with potential investors concerning funding, we can provide no assurance that we will receive additional funding on reasonable terms, or at all.

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

We have experienced significant operating losses since our inception and expect these losses to continue for some time. We incurred losses from continuing operations of \$5.2 million in 2011 and \$5.1 million in 2012. As of

December 31, 2012, our accumulated deficit was \$107.7 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.

*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 and more quickly and effectively develop and commercialize genetic tests than we or our partners are able to do. If we are not able to successfully market genetic tests, either alone or through collaborations such as our Preferred Participation Agreement with RHSc and its affiliates, our business will be materially harmed. 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 and materially harm our business.

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. For example, it may be difficult to convince the dental community and dental patients that one cleaning per year is sufficient for Low Risk patients, and we expect to expend significant funds and resources to educate dentists and patients with respect to the benefits of our PST<sup>®</sup> test. 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 successfully commercialize our products, including the PST<sup>®</sup> test.

*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 may 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 and will continue to depend substantially on third parties to commercialize our tests.*

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<sup>®</sup> 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<sup>®</sup> brand of genetics tests through its e-commerce Web site via a hyperlink to our e-commerce site. In 2012 and 2011, revenues from this agreement accounted for 65% and 66% of our revenues, respectively. During 2012 we marketed and distributed our PST<sup>®</sup> 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 PST<sup>®</sup> test from RHSC and its affiliates. Based on this agreement we will no longer sell the test through OralDNA Labs, and we are dependent on the timing of the offering of Reimbursed Dental Plans by RHSC affiliates, which timing is very uncertain at this time, and the ability of RHSC affiliates to successfully commercialize such Reimbursed Dental Plans. 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 Pyxis or Delta Dental of Michigan or any of their respective affiliates enters a business in competition with ours, certain of our directors might have a conflict of interest.*

We have entered into agreements with our stockholders, Pyxis and Delta Dental of Michigan (collectively, with their respective affiliates, the “Interested Parties”), allocating corporate opportunities as permitted under Section 122(17) of the Delaware General Corporation Law. These agreements, regulate and define the conduct of certain of our affairs as they may involve the Interested Parties, and our powers, rights, duties and liabilities and those of our officers and directors in connection with corporate opportunities. Except under certain circumstances, the Interested Parties 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 any Interested Parties or one of our directors appointed by an Interested Party acquire knowledge of a potential transaction or matter that may be a corporate opportunity for both the Interested Party and us, to the fullest extent permitted by law, the Interested Party will not have a duty to inform us about the corporate opportunity. In addition, the Interested Party will not be liable to us or to other stockholders 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 an Interested Party 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.

*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 of our net operating loss carryforwards. As of December 31, 2012, we had gross net operating loss and research tax credit carryforwards of approximately \$84.7 million and \$1.5 million, respectively, for federal income tax purposes, expiring in varying amounts through the year 2032. As of December 31, 2012, the Company had gross NOL and research tax credit carryforwards of approximately \$8.1 million and \$.9 million for state income tax purposes, expiring in varying amounts through the year 2032. 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 three such ownership changes in March 2003, June 1999 and June 2012. As a result, our net operating loss carryforwards that relate to periods prior these dates 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.

From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability and any such changes could have a negative impact on our business. There have been several cases involving “gene patents” and diagnostic claims that have been considered by the U.S. Supreme Court. A suit brought by multiple plaintiffs, including the American Civil Liberties Union, or ACLU, against Myriad Genetics, or Myriad, and the USPTO, could impact biotechnology and diagnostic patents. That case involves certain of Myriad’s U.S. patents related to the breast cancer susceptibility genes BRCA1 and BRCA2. The Federal Circuit issued a written decision on July 29, 2011 that reversed the decision of the U.S. District Court for the Southern District of New York that Myriad’s composition claims to “isolated” DNA molecules cover unpatentable subject matter. The Federal Circuit court instead held that the breast cancer genes are patentable subject matter. Subsequently, on March 20, 2012, the Supreme Court issued a decision in *Mayo Collaborative v. Prometheus Laboratories*, or Prometheus, a case involving patent claims directed to optimizing the amount of drug administered to a specific patient. According to that decision, Prometheus’ claims failed to add enough inventive content to the underlying correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws. The Supreme Court subsequently granted *certiorari* in the Myriad case, vacated the judgment, and remanded the case back to the Federal Circuit for further consideration in light of their decision in the Prometheus case. The Federal Circuit heard oral arguments on July 20, 2012, and issued a decision on August 16, 2012. The Federal Circuit reaffirmed its earlier decision and held that composition of matter claims directed to isolated nucleic acids are patent-eligible subject matter, but that method claims consisting of only abstract mental processes are not patent-eligible. On September 25, 2012, the ACLU filed a petition for a *writ of certiorari* asking the Supreme Court to review the Federal Circuit’s decision. On November 30, 2012, the Supreme Court granted the petition and agreed to review the case. Many companies, have submitted amicus briefs, or friend of the court briefs, in the case. The Supreme Court is scheduled to hear oral argument on April 15, 2013. A decision by the Supreme Court is expected by the end of June 2013. There can be no assurance that the Supreme Court’s decision in the Myriad case will not have a negative impact gene or diagnostic patents generally or the ability of biotechnology and diagnostic companies to obtain or enforce their patents in the future. Any such negative decision by the Supreme Court could have a material adverse affect on the Company’s existing patent portfolio and the Company’s ability to protect and enforce its intellectual property in the future.

On July 3, 2012, the USPTO issued a memorandum to patent examiners providing guidelines for examining process claims for patent eligibility in view of the Supreme Court decision in Prometheus. The guidance indicates that claims directed to a law of nature, a natural phenomenon, or an abstract idea that do not meet the eligibility requirements should be rejected as non-statutory subject matter. We cannot assure you that our patent portfolio will not be negatively impacted by the decision described above, rulings in other cases or changes in guidance or procedures issued by the USPTO.

Congress directed the USPTO to study effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist. This study will examine the impact that independent second opinion testing has on providing medical care to patients; the effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test; the impact of current practices on testing results and performance; and the role of insurance coverage on the provision of genetic diagnostic tests. The USPTO was directed to report the findings of the study to Congress and provide recommendations for establishing the availability of independent confirming genetic diagnostic test activity by June 16, 2012. On August 28, 2012, the Department of Commerce sent a letter to the House and Senate Judiciary Committee leadership updating them on the status of the genetic testing report. The letter stated in part: “Given the complexity and diversity of the opinions, comments, and suggestions provided by interested parties, and the

important policy considerations involved, we believe that further review, discussion, and analysis are required before a final report can be submitted to Congress.” The USPTO issued a Request for Comments and Notice of Public Hearing on Genetic Diagnostic Testing on January 25, 2012, and held additional public hearings in February and March 2013. It is unclear whether the results of this study will be acted upon by the USPTO or result in Congressional efforts to change the law or process in a manner that could negatively impact our present or future patent portfolio.

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 direct-to-consumer (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 premarket submission, such as a 510k 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 more active regulation as medical devices by FDA, we would be required to comply with other regulatory requirements, 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 effect on our business. CLIA is a federal law that regulates clinical laboratories that perform testing on human specimens 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 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.

*Future therapeutic collaborators, if any, may be unable to obtain regulatory approval of any therapeutic product that they may develop.*

If, in the future, we enter into any collaborations relating to the use of our technology in the development of therapeutic products, any therapeutic products 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 were delisted from the NYSE Amex in 2010 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. 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, 2012, our stock price has fluctuated from a low of \$0.17 to a high of \$0.55. 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:

- the timing and commercial success of the launch of Reimbursed Dental Plans our PST® test;

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

As of March 15, 2013, there were 5,000,000 shares of our Series A-1 Convertible Preferred Stock (the “Series A-1 Preferred Stock”) outstanding, all of which were held by Pyxis, and 500,000 shares of our Series B Convertible Preferred Stock (the “Series B Preferred Stock” and, together with the Series A-1 Preferred Stock, the “Preferred Stock”) outstanding, all of which were held by Delta Dental of Michigan. Each share of Series A-1 Preferred Stock and Series B Preferred Stock is convertible at the option of the holder into such number of fully paid and nonassessable shares of common stock as is determined by dividing the applicable original purchase price (\$1.80 per share for the Series A-1 Preferred Stock and \$6.00 per share for the Series B Preferred Stock) by the Series A-1 Conversion Price or the Series B Conversion Price, as applicable. The “Series A-1 Conversion Price” is \$0.3196 and the “Series B Conversion Price” is \$0.2745, each as subject to adjustment pursuant to certain antidilution provisions set forth in the Certificate of Designation. The Series A-1 Preferred Stock is currently convertible into 28,160,200 shares of our common stock, and the Series B Preferred Stock is convertible into 10,928,961 shares of our common stock.

The holders of the Series A-1 Preferred Stock and Series B Preferred Stock are entitled to receive dividends at the rate of 8% of the applicable original purchase price per year. Such dividends shall be payable only when, as 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-1 Preferred Stock and the Series B Preferred Stock are entitled to a proportionate share of any such distribution as though the holders of the Series A-1 Preferred Stock and the Series B Preferred Stock were the holders of the number of shares of our common stock into which their respective shares are convertible as of the record date fixed for the determination of the holders of our common stock entitled to receive such distribution.

In the event of any liquidation, dissolution or winding up of the company, whether voluntary or involuntary, the holders of the Series A-1 Preferred Stock and Series B Preferred Stock shall be entitled to receive, on a *pari passu* basis, prior and in preference to any distribution of any of our assets or surplus funds to the holders of our common stock, the amount of two times the applicable original purchase price plus all declared but unpaid dividends on such share for each share of Series A-1 Preferred Stock and Series B Preferred Stock then held by them. If upon the occurrence of any liquidation, dissolution or winding up of the company, the assets and funds thus distributed among the holders of the Series A-1 Preferred Stock and the Series B Preferred Stock are insufficient to permit the payment to such holders of the full preferential amount, then the entire assets and funds shall be distributed ratably among the

holders of the Series A-1 Preferred Stock and Series B Preferred Stock in proportion to the preferential amount each such holder is otherwise entitled to receive. After receiving this amount, the holders of the Series A-1 Preferred Stock and Series B Preferred Stock shall participate on an as-converted basis with the holders of common stock in any of our remaining assets.

For all matters, including voting on matters where the holders of the Series A-1 Preferred Stock and the Series B Preferred Stock have a separate vote as a single class, each holder of shares of Series A-1 Preferred Stock or Series B Preferred Stock shall be entitled to the number of votes equal to the number of shares of common stock into which such shares of Series A-1 Preferred Stock or Series B Preferred Stock, as the case may be, could be converted and shall have voting rights and powers equal to the voting rights and powers of the common stock (except as otherwise expressly provided in the Certificate of Designation or as required by law, voting together with the common stock as a single class on an as-converted basis). In addition, so long as at least forty percent (40%) of the originally issued shares of Series A-1 Preferred Stock remain outstanding, the holders of Series A-1 Preferred Stock, voting together as a class, shall be entitled to nominate and elect three (3) members of our Board of Directors, and so long as at least forty percent (40%) of the originally issued shares of Series B Preferred Stock remain outstanding, the holders of Series B Preferred Stock, voting together as a class, shall be entitled to nominate and elect one (1) member of our Board of Directors. Any additional members of the Board of Directors will be nominated and elected or appointed in accordance with the provisions of our Certificate of Incorporation and Bylaws, and the holders of Series A-1 Preferred Stock and Series B Preferred Stock shall be entitled to vote in each election of directors with the common stock and on an as-converted basis.



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

As of March 15, 2013, Pyxis, was our largest stockholder, holding approximately 48% of the voting power of our capital stock. Accordingly, this stockholder may be able to determine the outcome of stockholder votes, including votes concerning the election of directors, the adoption or amendment of provisions in our Certificate of Incorporation or By-Laws and the approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets. This stockholder may make decisions that are adverse to other stockholders' interests. This ownership concentration may also adversely affect the market price of our common stock. Three of our seven directors are individuals chosen by this single stockholder. 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**

We lease approximately 19,000 square feet of office and laboratory space at 135 Beaver Street, Waltham, Massachusetts 02452, pursuant to a lease that expires March 31, 2014. In April 2010, we entered into a sublease for approximately 6,000 square feet of unused office and laboratory space. The sublease expires 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    |
|----------------|--------|--------|
| 2012:          |        |        |
| First Quarter  | \$0.35 | \$0.17 |
| Second Quarter | \$0.33 | \$0.23 |
| Third Quarter  | \$0.55 | \$0.28 |
| Fourth Quarter | \$0.46 | \$0.26 |

|                | 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 |

### **Stockholders**

As of March 15, 2013, there were approximately 112 stockholders of record and according to our 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, 2012, we continued to focus our resources on conducting, finalizing and commercializing our large PST® validation study (referred to herein as the "PDPS") with the University of Michigan and Renaissance Health Services Corporation (RHSC) and the sales of our Inherent Health® brand of genetic tests and related programs. The objective of the PDPS is to improve dental care by identifying and using certain risk factors to set preventative treatment regimens. 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%, respectively. 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%. There was also a positive relationship between number of risk factors and the percentage of patients with extractions. 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. We expect RHSC to begin offering dental plans that incorporate our genetic PST® test for plan years beginning January 1, 2014.

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.

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 Inherent Health® brand also offers customers a full suite of affordable, easy-to-use and meaningful genetic tests in 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 through our e-commerce web site decreased by \$677,000 during the year ended December 31, 2012, as compared to the prior year caused primarily by a decrease in the sales of our Weight Management Genetic Test through Amway Global. In September 2012, Access Business Group LLC, an Alticor Company, placed a purchase order totaling \$1.0 million consisting of weight management kits. The kits will be included as part of a promotional bundle of products that Amway will be offering to their Individual Business Owners (IBOs) in March 2013. The order was shipped in two shipments in December 2012 and February 2013. Cash received from the order will remain in deferred revenue until the tests are returned and processed. The program has an end date of December 31, 2013 and we expect to recognize revenue from the program throughout 2013.

Our research and development expenses are focused on our own development and commercialization efforts related primarily to a new version of our PST® test and Osteoarthritis genetic test. We are also focusing on seeking potential

commercial partners to validate our technology within their specific business model 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 2013 and beyond will be to develop the market for our other personalized health products, in particular our PST<sup>®</sup> test. We continue to allocate considerable resources to commercialization of our PST<sup>®</sup> and Inherent Health<sup>®</sup> brands of genetic tests. 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 Preferred Participation Agreement with RHSC and its affiliates and 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, 2012, we had cash and cash equivalents of \$1.2 million. We have no further borrowing capacity under our credit facility with Pyxis. The full amount of \$14.3 million becomes due on March 31, 2014.

Cash used in operations was \$4.5 million for each of the years ended December 31, 2012 and 2011. 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. In 2012 cash used in operations was primarily impacted by lower operating costs associated with our genetic testing laboratory and administrative operations and lower sales of our genetic tests. In 2012 we experienced a decrease in genetic test sales resulting from less media attention related to our Weight Management Genetic Test, decreased sales to commercial customers and decreased sales within the Amway Global channel. Deferred revenue from genetic test sales increased by \$0.8 million to \$1.6 million during the year ended December 31, 2012. In the deferred revenue balance and accounts receivable at December 31, 2012 is a balance of \$0.5 million relating to Weight Management Genetic Test kits shipped to Amway as part of a 2013 promotional sales program. The order payment was received on January 22, 2013.

Cash used in investing activities was \$5,000 for the year ended December 31, 2012, compared to cash provided of \$196,000 for the year ended December 31, 2011. Capital additions were \$5,000 for the year ended December 31, 2012 compared to \$4,000 for the year ended December 31, 2011. Capital additions primarily consisted of laboratory equipment in 2012 and computers and office equipment in 2011. 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 \$200,000 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 \$4.0 million for the year ended December 31, 2012 compared to \$2.0 million for the year ended December 31, 2011. In April 2012 we received \$1.3 million in proceeds from the issuance of notes payable under our existing credit facility with Pyxis as compared to \$2.0 million received in 2011. We have no financial covenants as part of our credit facility with Pyxis. The debt becomes due on March 31, 2014. We have borrowed the full amount of the credit facility. On June 29, 2012, we completed a financing with Delta Dental of Michigan, pursuant to which Delta Dental purchased 500,000 shares of our Series B Convertible Preferred Stock for gross proceeds of \$3,000,000. Net proceeds to the Company after fees and expenses were approximately \$2.7 million. We received approximately \$8,800 and \$33,000 from stock purchases through the employee stock purchase plan for the years ended December 31, 2012 and 2011, respectively.

The amount of cash we generate from operations is not sufficient to continue to fund operations and grow our business. We expect that our current and anticipated financial resources, including the full amount drawn under our credit facility with Pyxis, 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<sup>®</sup> genetic test, continued research and development efforts, obtaining and protecting patents and administrative expenses. We believe our success depends on our ability to have sufficient capital and liquidity to fund operations at least until we begin to receive significant revenues under the Preferred Participation Agreement with RHSC and its affiliates. The timing of any revenues that we may receive under this agreement is dependent upon the timing of the offering of Reimbursed Dental Plans by RHSC affiliates, which timing is very uncertain at this time. While our current intent is to market our PST<sup>®</sup> test through Reimbursed Dental Plans offered and sold by RHSC's affiliates to employer groups for plan years starting in January 2014, 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 informed 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, the earliest that we may receive any significant revenues under this agreement is in the first quarter of 2014, and the timing of any such revenues may be substantially later.



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. 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. If we cannot obtain additional funding on acceptable terms, we may have to discontinue operations and seek protection under U.S. bankruptcy laws. See “Part I, Item 1A. Risk Factors. 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” and “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.”

We have taken and 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 focus on our PST® and osteoarthritis technologies. 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 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.

## **Results of Operations**

*Years Ended December 31, 2012 and 2011*

Total revenue from operations for the year ended December 31, 2012 was \$2.2 million, compared to \$2.9 million for the year ended December 31, 2011. The decrease of \$0.7 million, or 21.9%, is primarily attributable to decreased genetic testing revenue. Genetic testing revenue decreased to \$2.2 million in the year ended December 31, 2012, compared to \$2.7 million in the year ended December 31, 2011, a decrease of 21.7%. The decrease is primarily attributable to decreased sales of our Inherent Health® Brand of genetic tests through the Amway Global sales channel. In addition, in 2012 we experienced a decrease in sales of our Inherent Health® Weight Management Genetic Test to commercial customers and less media attention than in 2011 which increased sales in 2011. Genetic testing revenue is derived from tests sold and processed, which is driven by consumer demand.

During the years ended December 31, 2012 and 2011, we had one significant customer, Alticor, our principal shareholder, that accounted for approximately 66% and 68%, respectively, of our revenues from operations. During the years ended December 31, 2012 and 2011, approximately 65% and 66%, 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, 2012 was \$1.3 million, or 59.4% of revenue, compared to \$1.5 million, or 53.5% of revenue, for the year ended December 31, 2011. The increase in the cost of revenue as a percentage of revenue is primarily attributable to the higher absorption rate associated with fixed laboratory costs due to the decrease in revenues.

Research and development expenses were \$1.3 million for the year ended December 31, 2012, compared to \$1.4 million for the year ended December 31, 2011. The decrease of \$0.1 million, or 4.7%, is primarily attributable to decreased consulting costs offset by increased compensation expenses as compared to the year ended December 31, 2011.

Selling, general and administrative expenses were \$4.2 million for the year ended December 31, 2012, compared to \$4.7 million for the year ended December 31, 2011. The decrease of \$0.5 million, or 11.0%, is primarily attributable to decreases in sales commissions paid to Amway Global as part of our Merchant Channel and Partner Store Agreement, compensation expenses and depreciation, partially offset by increased professional fees and employee separation costs attributable to the resignation of our former Chief Executive Officer on August 23, 2012.

Interest expense was \$454,000 for the year ended December 31, 2012, as compared to \$367,000 for the year ended December 31, 2011. The increase in interest expense of \$87,000 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.

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

**INTERLEUKIN GENETICS, INC.**

**INDEX TO FINANCIAL STATEMENTS**

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## Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

Interleukin Genetics, Inc.

We have audited the accompanying balance sheets of Interleukin Genetics, Inc. (a Delaware corporation) (the “Company”) as of December 31, 2012 and 2011, 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 audits 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, 2012 and 2011, 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 that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company incurred a net loss of \$5,120,084 during the year ended December 31, 2012, and as of that date, the Company’s total liabilities exceeded its total assets by \$13,623,800. 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 28, 2013

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**INTERLEUKIN GENETICS, INC.****BALANCE SHEETS**

|   | December 31,  |               |
|---|---------------|---------------|
|   | 2012          | 2011          |
| <b>ASSETS</b>   |               |               |
| Current assets:   |               |               |
| Cash and cash equivalents   | \$1,225,426   | \$1,728,222   |
| Accounts receivable from related party  | 552,572       | 2,662         |
| Trade accounts receivable   | 47,560        | 55,892        |
| Inventory   | 158,238       | 107,758       |
| Prepaid expenses  | 417,772       | 217,387       |
| Total current assets  | 2,401,568     | 2,111,921     |
| Fixed assets, net   | 126,946       | 289,011       |
| Intangible assets, net  | 399,131       | 514,584       |
| Other assets  | 38,001        | 38,001        |
| Total assets  | \$2,965,646   | \$2,953,517   |
| <b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>  |               |               |
| Current liabilities:  |               |               |
| Accounts payable  | \$479,182     | \$369,306     |
| Accrued expenses  | 165,745       | 182,597       |
| Deferred revenue  | 1,628,264     | 824,845       |
| Current portion of convertible long-term debt   | —             | 13,000,000    |
| Total current liabilities   | 2,273,191     | 14,376,748    |
| Convertible long-term debt  | 14,316,255    | —             |
| Total liabilities   | 16,589,446    | 14,376,748    |
| Stockholders' deficit:  |               |               |
| Convertible preferred stock, \$0.001 par value — 6,000,000 shares authorized;<br>5,500,000 and 5,000,000 shares issued and outstanding at December 31, 2012 and<br>2011, respectively; aggregate liquidation preference of \$24,000,000 and<br>\$18,000,000 at December 31, 2012 and 2011, respectively | 5,500         | 5,000         |
| Common stock, \$0.001 par value — 150,000,000 and 100,000,000 shares authorized;<br>36,761,864 and 36,709,706 shares issued and outstanding at December 31, 2012 and<br>2011, respectively  | 36,762        | 36,710        |
| Additional paid-in capital  | 94,030,603    | 91,111,640    |
| Accumulated deficit   | (107,696,665) | (102,576,581) |
| Total stockholders' deficit   | (13,623,800)  | (11,423,231)  |
| Total liabilities and stockholders' deficit   | \$2,965,646   | \$2,953,517   |

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





**INTERLEUKIN GENETICS, INC.****STATEMENTS OF OPERATIONS**

|   | For The Year Ended December 31, |                 |
|---|---------------------------------|-----------------|
|   | 2012                            | 2011            |
| Genetic testing   | \$ 2,154,785                    | \$ 2,757,355    |
| Other   | 81,602                          | 99,750          |
| Total revenue   | 2,236,387                       | 2,857,105       |
| Cost of revenue   | 1,328,538                       | 1,527,201       |
| Gross profit  | 907,849                         | 1,329,904       |
| Operating expenses:   |                                 |                 |
| Research and development  | 1,311,877                       | 1,376,394       |
| Selling, general and administrative                             | 4,150,607                       | 4,665,360       |
| Amortization of intangibles                                     | 115,453                         | 115,453         |
| Total operating expenses  | 5,577,937                       | 6,157,207       |
| Loss from operations  | (4,670,088 )                    | (4,827,303 )    |
| Other income (expense):   |                                 |                 |
| Interest income   | 4,485                           | 6,419           |
| Interest expense  | (454,481 )                      | (366,938 )      |
| Other income  | —                               | 4,274           |
| Total other income (expense)                                    | (449,996 )                      | (356,245 )      |
| Loss from continuing operations before benefit for income taxes | (5,120,084 )                    | (5,183,548 )    |
| Benefit for income taxes  | —                               | —               |
| Loss from continuing operations                                 | (5,120,084 )                    | (5,183,548 )    |
| Income from discontinued operations, net of tax                 | —                               | 158,366         |
| Net loss  | \$ (5,120,084 )                 | \$ (5,025,182 ) |
| Basic and diluted net loss per common share from:               |                                 |                 |
| Continuing operations   | \$ (0.14 )                      | \$ (0.14 )      |
| Discontinued operations   | —                               | 0.00            |
| Net loss  | \$ (0.14 )                      | \$ (0.14 )      |
| Weighted average common shares outstanding, basic and diluted   | 36,754,679                      | 36,661,290      |

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

**INTERLEUKIN GENETICS, INC.****STATEMENTS OF STOCKHOLDERS' DEFICIT****For the Years Ended December 31, 2012 and 2011**

|  | Convertible Preferred Stock |           | Common Stock |           | Additional Paid-in Capital | Accumulated Deficit | Total           |
|--|-----------------------------|-----------|--------------|-----------|----------------------------|---------------------|-----------------|
|  | Shares                      | Par Value | Shares       | Par Value |                            |                     |                 |
| 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 ) |
| Net loss   | —                           | —         | —            | —         | —                          | (5,120,084 )        | (5,120,084 )    |
| Private placement of preferred stock, net of offering costs of \$386,030 | 500,000                     | 500       | —            | —         | 2,613,470                  | —                   | 2,613,970       |
| Warrants issued in connection with private placement of preferred stock  | —                           | —         | —            | —         | 104,907                    | —                   | 104,907         |
| Common stock issued:   |                             |           |              |           |                            |                     |                 |
| Employee stock purchase plan   | —                           | —         | 52,158       | 52        | 8,758                      | —                   | 8,810           |
| Stock-based compensation expense   | —                           | —         | —            | —         | 191,828                    | —                   | 191,828         |
| Balance as of December 31, 2012  | 5,500,000                   | \$ 5,500  | 36,761,864   | \$ 36,762 | \$ 94,030,603              | \$(107,696,665 )    | \$(13,623,800 ) |

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, |                 |
|--|---------------------------------|-----------------|
|  | 2012                            | 2011            |
| <b>CASH FLOW FROM OPERATING ACTIVITIES:</b>  |                                 |                 |
| Net loss   | \$ (5,120,084 )                 | \$ (5,025,182 ) |
| Income from discontinued operations  | —                               | 158,366         |
| Loss from continuing operations  | (5,120,084 )                    | (5,183,548 )    |
| Adjustments to reconcile loss from continuing operations to net cash used in operating activities: |                                 |                 |
| Depreciation and amortization  | 282,518                         | 385,031         |
| Stock-based compensation expense   | 191,828                         | 227,091         |
| Changes in operating assets and liabilities:   |                                 |                 |
| Accounts receivable from related party   | (549,910 )                      | 11,995          |
| Trade accounts receivable  | 8,332                           | (18,932 )       |
| Federal grant receivable   | —                               | 117,946         |
| Inventory  | (50,480 )                       | 10,091          |
| Prepaid expenses and other current assets  | (200,385 )                      | 48,962          |
| Accounts payable   | 109,876                         | (140,341 )      |
| Accrued expenses   | (16,852 )                       | (260,658 )      |
| Deferred revenue   | 803,419                         | 308,892         |
| Net cash used in operating activities of discontinued operations                                   | —                               | (5,873 )        |
| Net cash used in operating activities  | (4,541,738 )                    | (4,499,344 )    |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>   |                                 |                 |
| Capital additions  | (5,000 )                        | (4,418 )        |
| Net cash provided by investing activities of discontinued operations                               | —                               | 200,000         |
| Net cash (used in) provided by investing activities  | (5,000 )                        | 195,582         |
| <b>CASH FLOW FROM FINANCING ACTIVITIES:</b>  |                                 |                 |
| Proceeds from issuance of convertible notes  | 1,316,255                       | 2,000,000       |
| Private placement of preferred stock   | 3,000,000                       | —               |
| Private placement offering costs   | (281,123 )                      | —               |
| Proceeds from employee stock purchase plan   | 8,810                           | 32,955          |
| Net cash provided by financing activities  | 4,043,942                       | 2,032,955       |
| Net decrease in cash and equivalents   | (502,796 )                      | (2,270,807 )    |
| Cash and cash equivalents, beginning of period   | 1,728,222                       | 3,999,029       |
| Cash and cash equivalents, end of period   | \$ 1,225,426                    | \$ 1,728,222    |
| <b>Supplemental disclosures of cash flow information:</b>  |                                 |                 |
| Cash paid for interest   | \$ 436,754                      | \$ 357,500      |
| <b>Supplemental disclosures of non-cash investing and financing activities:</b>                    |                                 |                 |
| Warrants issued in connection with preferred stock financing                                       | \$ 104,907                      | \$ —            |

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

**INTERLEUKIN GENETICS, INC.**

**NOTES TO FINANCIAL STATEMENTS**

**December 31, 2012**

**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 focus is on commercializing its periodontal genetic risk assessment test and its Inherent Health® brand of genetic tests which includes the Company’s Weight Management genetic test.

**Note 2—Operating Matters, Liquidity and Going Concern**

The Company has experienced net operating losses since its inception through December 31, 2012. During the last two fiscal years such losses totaled \$10.1 million contributing to an accumulated deficit of \$107.7 million as of December 31, 2012. During this same period, the Company has increased its borrowings to \$14.3 million under its line of credit with Pyxis Innovations, Inc. (“Pyxis”). All outstanding amounts under this line of credit are due on March 31, 2014. Management expects that its current financial resources are adequate to maintain current and planned operations through April 2013.

The Company took steps in 2012 and 2011 to reduce operating costs, including genetic test processing costs as well as general and administrative expenses. Cost savings were achieved through test process improvements, 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 2013 and, accordingly, is dependent on finding additional sources of liquidity to

fund its operations. We are currently in discussions with potential investors to fund the Company through the commercial launch of the PST<sup>®</sup> test with Renaissance Health Services Corporation, an affiliation of eight Delta Dental corporations (RHSC). This funding will not occur prior to the acceptance of the PST<sup>®</sup> study results in a peer reviewed publication. If this funding is completed, we believe that RHSC will be in a position to begin selling new insurance policies to employer groups that utilize our PST<sup>®</sup> test beginning in 2014. Management's plans include identifying sources of debt and/or equity financing. 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 doing so it will not be able to fund operations beyond April 30, 2013. These uncertainties raise substantial doubt about the Company's ability to continue as a going concern and to realize its assets and satisfy its liabilities in the normal course of business. 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 April 30, 2013. 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**

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. The proceeds consisted of a \$200,000 holdback reflected in other current assets at December 31, 2010 which was received on July 1, 2011.

In 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. 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. Actual returns since then have been insignificant and 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, 2012 and December 31, 2011, the Company has deferred genetic test revenue of \$1,628,264 and \$824,845, respectively. Included in deferred revenue at December 31, 2012 are \$576,191 in customer payments in excess of one year old. Management is currently in the process of evaluating steps it may take in resolving these older payments.

##### *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 \$726,000 and \$951,000 for the years ended December 31, 2012 and 2011, 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. No accounts receivable reserve is required at December 31, 2012 as all accounts receivable are expected to be collected.

*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, 2012 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, 2012 and 2011:

|                      | 2012       | 2011       |
|----------------------|------------|------------|
| Raw materials        | \$ 154,485 | \$ 100,432 |
| Finished goods       | 3,753      | 7,325      |
| Total inventory, net | \$ 158,238 | \$ 107,758 |

### *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 within 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 \$30.9 million as of December 31, 2012, 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 began filing 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 combined 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 significantly reduced through this required computation. Due to a change in common ownership, the Company is no longer qualified to join in a combined filing of the unitary group as of June 29, 2012. Accordingly, the Company ceased filing combined Massachusetts tax returns with the unitary group in 2012. The combined and

separate filings had no impact on the Company's payment of state income taxes or state portion of the provision.

On January 2, 2013, President Obama signed The American Taxpayer Relief Act of 2012 (H.R. 8) legislation which extended many of the tax provisions that expired in 2011 or 2012. For financial reporting purposes, the tax impact of this legislation is taken into account in the quarter in which the legislation is enacted by Congress and signed into law by the President. Since President Obama signed the bill on January 2, 2013, the financial reporting for these legislative changes will occur in the first quarter of 2013. Therefore, for 2012, no deferred tax asset with respect to the federal R&D tax credit was recorded. In the first quarter of 2013, the full deferred tax asset for the 2012 federal R&D tax credit will be recorded however, due to the uncertainty of its realization, this legislation is not expected to have any impact on the Company's results of operations.

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, 2012 and 2011. However, if the Company incurred interest and penalties they would be recorded in general and administrative expenses.

*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, 2012 and 2011, advertising expense was \$18,000 and \$33,000, 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, |            |
|-----------------------------|--------------------|------------|
|                             | 2012               | 2011       |
| Stock options               | 2,302,000          | 2,228,067  |
| Warrants                    | 2,187,158          | 2,150,000  |
| Convertible preferred stock | 39,089,161         | 28,160,200 |
| Convertible debt            | 2,521,222          | 2,289,418  |
| Total                       | 46,099,541         | 34,827,685 |

*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, 2012 and 2011, 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, 2012, 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, 2012 and 2011.

*Segment Reporting*

As of December 31, 2012 and 2011, 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.

*Recent Accounting Pronouncements*

No recently issued updates or other guidance issued by the FASB through the issuance of these financial statements are expected to have a material impact on the Company's financial reporting.

**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 \$726,000 and \$951,000 in commissions for the years ended December 31, 2012 and 2011, 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.

On September 14, 2012, the Company received a purchase order from Access Business Group, LLC (“ABG”), an affiliate of Pyxis, the Company’s largest stockholder. The order consists of kits of the Company’s Weight Management genetic test to be included in a promotional product bundle to be offered by ABG to the Amway sales channel in 2013. The total amount of the order is \$1.0 million. The Company shipped \$0.5 million in December 2012 and expects to ship the balance in the first quarter of 2013. The Company reflected \$0.5 million in accounts receivable with a corresponding offset to deferred revenue in the December 31, 2012 financial statements. The Company received payment of \$0.5 million in January 22, 2013. No tests have been processed from the order at December 31, 2012.

On September 21, 2012, the Company entered into a License Agreement with Access Business Group International LLC (“ABGI”), an affiliate of Pyxis. Pursuant to the License Agreement, the Company has granted ABGI and its affiliates a non-exclusive license to use the technology related to Interleukin’s Weight Management genetic test and to sell the Weight Management test in Europe, Russia and South Africa (the “Territories”). ABGI, or a laboratory designated by ABGI, will be responsible for processing the tests, and the Company will receive a royalty for each test sold, which royalty will increase if certain pending patent applications are issued. The License Agreement has an initial term of five years from the date of first commercial sale of the Weight Management test under the agreement. Thereafter, the term will automatically renew for additional one-year periods unless at least 60 days prior notice is delivered by either party. At December 31, 2012 no license fees have been earned from this agreement.

In connection with the execution of the License Agreement, the Company and ABGI also entered into a Professional Services Agreement (the “PSA”) pursuant to which the Company has agreed to provide services to ABGI in connection with its sale and processing of the tests within the Territories. Services will be provided pursuant to a statement of work to be entered into from time to time between the parties. Such statements of work will also specify the fees to be paid by ABGI to Interleukin for such services. The PSA has no set term and may be terminated by either party, subject to certain conditions. At December 31, 2012, \$3,450 had been earned from this 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 2,521,222 shares of common stock, reflecting a conversion price of \$5.6783 per share.

On April 13, 2012, the Company borrowed the remaining \$1,316,255 of available credit. This credit facility has been modified several times, including on November 29, 2012, to extend the due date to March 31, 2014.

The fair value of convertible debt is estimated to be approximately \$0.7 million at December 31, 2012.

#### Note 7—Fixed Assets

The useful lives and balances of fixed assets at December 31, 2012 and 2011 consisted of the following:

|  | Useful Life  | 2012        | 2011        |
|--|--------------|-------------|-------------|
| Computer software, computer equipment and office equipment | 3 years      | \$314,717   | \$314,717   |
| Laboratory equipment                                       | 5 years      | 1,225,770   | 1,220,770   |
| 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      |
|  |              | 2,177,692   | 2,172,692   |
| Less — Accumulated depreciation and amortization           |              | (2,050,746) | (1,883,681) |
| Total  |              | \$126,946   | \$289,011   |



Depreciation and amortization expense was \$167,065 and \$269,578, for the years ended December 31, 2012 and 2011, respectively.

**Note 8—Intangible Assets**

Intangible assets at December 31, 2012 and 2011 consisted of the following:

|  | 2012        | 2011        |
|--|-------------|-------------|
| Patent costs                               | \$1,154,523 | \$1,154,523 |
| Less — Accumulated amortization (755,392 ) | (639,939 )  | (639,939 )  |
| Total                                      | \$399,131   | \$514,584   |

Patent amortization expense was \$115,453 for the years ended December 31, 2012 and 2011, respectively.

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

Year ending December 31,

|      |           |
|------|-----------|
| 2013 | 109,266   |
| 2014 | 94,100    |
| 2015 | 77,656    |
| 2016 | 61,119    |
| 2017 | 42,229    |
| 2018 | 14,761    |
|      | \$399,131 |

**Note 9—Accrued Expenses**

Accrued expenses at December 31, 2012 and 2011 consisted of the following:

|                        | 2012      | 2011      |
|------------------------|-----------|-----------|
| Payroll and vacation   | \$121,362 | \$112,121 |
| Other                  | 44,383    | 70,437    |
| Total accrued expenses | \$165,745 | \$182,597 |

**Note 10—Commitments and Contingencies**

*Off-Balance Sheet Arrangements*

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

*Employment Agreements*

On February 14, 2011, the Company entered into an employment agreement with Lewis H. Bender, its then Chief Executive Officer. The agreement replaced and superseded the employment agreement between the Company and Mr. Bender that expired by its terms on January 22, 2011. The agreement automatically renewed for a one year period on February 14, 2012. The agreement also provided that Mr. Bender would serve as a member of the Company's Board of Directors for as long as he served as the Company's Chief Executive Officer, subject to any required approval of the Company's shareholders.

On August 23, 2012, Mr. Bender notified the Board of Directors of the Company of his intention to resign as the Chief Executive Officer and as a member of the Board of Directors effective immediately. In connection with his resignation, on September 14, 2012, the Company entered into a Separation Agreement with Mr. Bender. Pursuant to the terms and conditions of the Separation Agreement, Mr. Bender will receive seven months of base salary, continuation of health insurance benefits through February 28, 2013 and extension of the date through which vested options at the date of his resignation can be exercised to September 14, 2013. The costs associated with Mr. Bender's resignation, including costs associated with the modification of stock options, are reflected in the accompanying 2012 financial statements.

On April 25, 2012, the Company executed an amendment, effective as of March 31, 2012, to the Employment Agreement dated as of November 12, 2008 by and between the Company and Kenneth S. Kornman, its then President and Chief Scientific Officer to extend the term through November 30, 2012. In connection with Mr. Bender's resignation on August 23, 2012, the Board of Directors appointed Dr. Kornman as Chief Executive Officer in addition to his role as President and Chief Scientific Officer. The Board of Directors also appointed Dr. Kornman as a director to fill the vacancy created by Mr. Bender's resignation. On November 29, 2012, the Company entered into a second amendment to Dr. Kornman's employment agreement to extend the term through November 30, 2015.

On December 21, 2012, The Compensation Committee of the Board of Directors of the Company approved a Bonus Plan the “Bonus Plan”) for the Company’s executives. Under the terms of the Bonus Plan:

1. Executives are not entitled to a non-discretionary bonus for the year ending December 31, 2013.

Provided the Company meets certain earnings and revenue targets for the six months ending June 30, 2014 and

2. Executive is employed by the Company as of June 30, 2014, Executive shall receive a bonus equal to 30% of such Executive’s base salary.

Provided the Company meets certain earnings and revenue targets for the year ending December 31, 2014 and

3. Executive is employed by the Company as of December 31, 2014, Executive shall receive a bonus equal to 15% of such Executive’s base salary.

On December 21, 2012, Dr. Kornman was granted an option to purchase 300,000 shares of the Company’s common stock at an exercise price of \$0.34, the fair value of the Company’s stock on the grant date of the option. The option will vest in three installments of 75,000, 100,000 and 125,000 shares on each of the first three anniversaries of the grant date. Also on December 21, 2012, the Company’s Chief Financial Officer, Eliot M. Lurier, was granted an option to purchase 200,000 shares of the Company’s common stock at an exercise price of \$0.34, the fair value of the Company’s stock on the grant date of the option. The option will vest in three installments of 50,000, 66,000 and 84,000 shares on each of the first three anniversaries of the grant date.

On December 26, 2012, the Company entered into an employment agreement with Scott Snyder for the position of Chief Marketing Officer beginning on January 2, 2013. The agreement provides for a minimum annual base salary of \$265,000, and for 2013 and 2014 he is eligible for a bonus pursuant to the Bonus Plan as set forth above. For 2015 and any subsequent year in which he is employed, he is eligible for a bonus of up to 30% of his base salary, based on factors such as the Company’s evaluation of individual performance, the Company’s financial performance, economic conditions generally, and the policy terms applicable to such bonus. Mr. Snyder is entitled to a maximum of \$34,000 in expense reimbursement in calendar year 2013, and an additional \$16,000 for the six months ending June 30, 2014, for travel and housing expenses from his residence to the Company’s offices. Upon hire, Mr. Snyder was granted an option to purchase 200,000 shares of the Company’s common stock at an exercise price of \$0.29 on January 2, 2013, the grant date of the option. The option will vest in three installments of 50,000, 66,000 and 84,000 shares on each of the first three anniversaries of the grant date.

Mr. Snyder’s agreement is terminable at will by the Company or Mr. Snyder. If the Company terminates Mr. Snyder without cause, then the Company will pay Mr. Snyder, in addition to any accrued, but unpaid compensation prior to termination, an amount equal to six months of his base salary in effect at the time of the termination.

#### *Operating Leases*

The Company leases its office and laboratory space under a non-cancelable operating lease expiring on March 31, 2014. On May 24, 2010, the Company completed a sublease of approximately 6,000 square feet of office and laboratory space which also expires on March 31, 2014.

Future minimum lease commitments under non-cancelable lease agreements with initial or remaining terms of one year or more at December 31, 2012, are as follows:

| <b>Year Ending<br/>December 31,</b> | Master Space<br>Lease | Sublease    | Net Master<br>Space Lease | Office<br>Equipment | Total<br>Payments, Net |
|-------------------------------------|-----------------------|-------------|---------------------------|---------------------|------------------------|
| 2013                                | 472,623               | (145,768)   | 326,855                   | 6,336               | 333,191                |
| 2014                                | 118,749               | (37,569 )   | 81,180                    | 6,336               | 87,516                 |
| Thereafter                          | —                     | —           | —                         | 1,056               | 1,056                  |
|                                     | \$ 591,372            | \$(188,337) | \$ 408,035                | \$ 13,728           | \$ 421,763             |

Rent expense was \$338,221 and \$324,900 for the years ended December 31, 2012 and 2011, respectively.

## **Note 11—Capital Stock**

### *Authorized Preferred and Common Stock*

At December 31, 2012, the Company had authorized 6,000,000 shares of \$0.001 par value preferred stock, of which 5,000,000 shares, designated as Series A-1 Convertible Preferred Stock, were issued and outstanding and 500,000 shares, designated as Series B Convertible Preferred Stock, were issued and outstanding (collectively, the “Preferred Stock”). At December 31, 2012, the Company had authorized 150,000,000 shares of \$0.001 par value common stock of which 85,644,185 shares were outstanding or reserved for issuance. Of those, 36,761,864 shares were outstanding; 39,089,161 shares were reserved for the conversion of the outstanding Preferred Stock to common stock; 2,521,222 shares were reserved for the conversion of the \$14,316,255 of debt outstanding under the credit facility with Pyxis; 4,334,780 shares were reserved for the potential exercise of outstanding stock options and for shares of common stock available for future grants under our stock plan; 750,000 shares were reserved for the potential exercise of rights held under the Employee Stock Purchase Plan; 1,750,000 shares were reserved for the exercise of outstanding warrants to purchase common stock at an exercise price of \$1.30 per share which are exercisable currently until the expiration date of March 5, 2015; and 437,158 shares were reserved for the exercise of outstanding warrants to purchase common stock at an exercise price of \$0.2745 per share which are exercisable currently until the expiration date of June 29, 2017.

On August 7, 2012, at the Company’s 2012 annual meeting, the Company’s shareholders approved an amendment to the Company’s Charter affecting an increase in authorized shares of common stock from 100,000,000 to 150,000,000 shares. The Company believes that the availability of additional shares for issuance from time to time in the Board of Directors’ discretion in connection with future financings, investment opportunities, stock splits or dividends, possible acquisitions or for other corporate purposes is desirable in order to avoid repeated separate amendments to the Company’s Charter and the delay and expense incurred in holding special meetings of the stockholders to approve such amendments. The Company currently has no specific understandings, arrangements, or agreements with respect to any financings, investment opportunities, stock splits or dividends, or acquisitions or for any other corporate purposes that would require the Company to issue a material amount of new shares of common stock.

On June 29, 2012, the Company entered into an agreement with Pyxis to exchange the 5,000,000 shares of Series A Convertible Preferred Stock held by Pyxis for 5,000,000 shares of Series A-1 Convertible Preferred Stock (the “Series A-1 Preferred Stock”) and filed a new Certificate of Designation, Preferences and Rights of Preferred Stock with the State of Delaware for the Series A-1 Preferred Stock and Series B Convertible Preferred Stock (the “Series B Preferred Stock” and, with the Series A-1 Preferred Stock, the “Preferred Stock”). Concurrently therewith, the Company completed a financing with Delta Dental pursuant to which Delta Dental purchased 500,000 shares of Series B Preferred Stock for gross proceeds of \$3,000,000. Each share of Series B Preferred Stock is convertible into approximately 21.86

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shares of common stock reflecting a conversion price of \$0.2745 per share. Net proceeds to the Company after fees and expenses were approximately \$2.7 million. In addition, fully vested warrants to purchase 437,158 shares of common stock at an exercise price of \$0.2745 per share were issued to the placement agent in the transaction. These warrants expire in five years. For purposes of determining the fair value of the warrants issued in the Preferred Stock transaction, the Black-Scholes pricing model was used with the following assumptions:

|                         |        |       |
|-------------------------|--------|-------|
| Risk-free interest rate | 1      | %     |
| Expected life           | 5      | years |
| Expected volatility     | 142.36 | %     |
| Dividend yield          | 0      | %     |

Using these assumptions, the fair value of the warrants is \$104,907.

The Preferred Stock accrues dividends at the rate of 8% of the original purchase price per year, payable only when, as and if declared by the Board of Directors and are non-cumulative. To date, no dividends have been declared on these shares. If the Company declares a distribution, with certain exceptions, payable in securities of other persons, evidences of indebtedness issued by the Company or other persons, assets (excluding cash dividends) or options or rights to purchase any such securities or evidences of indebtedness, then, in each such case the holders of the Preferred Stock shall be entitled to a proportionate share of any such distribution as though the holders of the Preferred Stock were the holders of the number of shares of common stock into which their respective shares of Preferred Stock are convertible as of the record date fixed for the determination of the holders of common stock entitled to receive such distribution.

In the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of the Preferred Stock shall be entitled to receive on a *pari passu* basis, prior and in preference to any distribution of any of the Company's assets or surplus funds to the holders of its common stock by reason of their ownership thereof, the amount of two times the then-effective purchase price per share, as adjusted for any stock dividends, combinations or splits with respect to such shares, plus all declared but unpaid dividends on such shares for each share of Preferred Stock then held by them. The liquidation preference for the Preferred Stock at December 31, 2012 was \$24,000,000 in the aggregate, reflecting a liquidation preference of \$18,000,000 for the Series A-1 Preferred Stock and \$6,000,000 for the Series B Preferred Stock. After receiving this amount, the holders of the Preferred Stock are entitled to participate on an as-converted basis with the holders of common stock in any of the remaining assets.

Each share of Series A-1 Preferred Stock is convertible at any time at the option of the holder into a number of shares of the Company's common stock determined by dividing the then-effective purchase price (\$1.80, and subject to further adjustment) by the conversion price in effect on the date the certificate is surrendered for conversion. As of December 31, 2012, the Series A-1 Preferred Stock was convertible into 28,160,200 shares of common stock reflecting a current conversion price of \$0.3196 per share. Each share of Series B Preferred Stock is convertible at any time at the option of the holder into a number of shares of the Company's common stock determined by dividing the then-effective purchase price (\$6.00, and subject to further adjustment) by the conversion price in effect on the date the certificate is surrendered for conversion. As of December 31, 2012, the Series B Preferred Stock was convertible into 10,928,961 shares of common stock reflecting a current conversion price of \$0.2745 per share.

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

#### **Note 12—Stock-Based Compensation Arrangements**

In June 2004, the Company's shareholders approved the adoption of the 2004 Employee Stock Compensation Plan (the 2004 Plan). The 2004 Plan provides for the award of nonqualified and incentive stock options, restricted stock, and stock awards to employees, directors, officers, and consultants of the Company. A total of 4,000,000 shares of the Company's common stock had been reserved for award under the 2004 Plan. At the Company's 2011 annual meeting stockholders approved an amendment to the 2004 Employee, Director and Consultant Stock Plan increasing the aggregate number of shares of common stock which may be offered under the plan by an additional 2,000,000 shares. At December 31, 2012, 2,032,780 shares were available for future issuance under the 2004 plan. At the Company's 2012 annual meeting the stockholders approved a new Employee Stock Purchase Plan, pursuant to which 750,000 shares of common stock are authorized to be issued. During the year ended December 31, 2012, the Company granted 581,000 stock options under the 2004 Plan.



*Stock option grants*

It is the Company's policy to grant stock options with an exercise price equal to the fair market value of the Company's common stock at the grant date. Historically, the majority of the Company's stock options have been granted in connection with the employee's start date with the Company. In addition, the Company may grant stock options in recognition of promotion and/or performance.

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

For purposes of determining the stock-based compensation expense for stock option awards in 2012 and 2011, the Black-Scholes option-pricing model was used with the following weighted-average assumptions:

|                         |            |   |            |   |
|-------------------------|------------|---|------------|---|
|                         | 2012       |   | 2011       |   |
| Risk-free interest rate | 0.66       | % | 2.04       | % |
| Expected life           | 5.73 years |   | 5.73 years |   |
| Expected volatility     | 140.32     | % | 123.40     | % |
| Dividend yield          | 0          | % | 0          | % |

Using these assumptions, the weighted average grant date fair value of options granted in 2012 and 2011 was \$0.33 and \$0.30, respectively.

#### *Restricted Stock Awards*

Holders of restricted stock awards participate fully in the rewards of stock ownership of the Company, including voting and dividend rights. Recipients of restricted stock awards are generally not required to pay any consideration to the Company for these restricted stock awards. The Company measures the fair value of the shares based on the last reported price at which the Company's common stock traded on the date of the grant and compensation cost is recognized over the remaining service period. During each of the years ended December 31, 2012 and 2011 the Company granted no restricted stock awards.

#### *Employee Stock Purchase Plan*

Purchases made under the Company's Employee Stock Purchase Plan are deemed to be compensatory because employees may purchase stock at a price equal to 85% of the fair market value of the Company's common stock on either the first day or the last day of a calendar quarter, whichever is lower. During the three months ended June 30, 2012, the remaining shares were cancelled with the termination of the plan. At the Company's 2012 annual meeting the stockholders approved a new Employee Stock Purchase Plan, pursuant to which 750,000 shares of common stock are authorized to be issued. During the years ended December 31, 2012 and 2011, employees purchased 52,158 and 114,907 shares of common stock at a weighted-average purchase price of \$0.17 and \$0.29, while the weighted-average fair value was \$0.20 and \$0.34 per share, resulting in compensation expense of \$1,332 and \$5,647, respectively.

The following table details stock option and restricted stock activity for the years ended December 31, 2012 and 2011.

|  |        |                           |        |                           |
|--|--------|---------------------------|--------|---------------------------|
|  | 2012   |                           | 2011   |                           |
|  | Shares | Weighted Avg.<br>Exercise | Shares | Weighted Avg.<br>Exercise |

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|                                  |            | Price   |            | Price   |
|----------------------------------|------------|---------|------------|---------|
| Outstanding, beginning of period | 2,228,067  | \$ 1.14 | 1,611,267  | \$ 1.54 |
| Granted                          | 581,000    | 0.36    | 810,000    | 0.34    |
| Exercised                        | (2,500 )   | 0.00    | (2,500 )   | 0.00    |
| Forfeited/Expired                | (504,567 ) | 0.60    | (190,700 ) | 1.21    |
| Outstanding, end of period       | 2,302,000  | \$ 1.06 | 2,228,067  | \$ 1.14 |
| Exercisable, end of period       | 1,376,950  | \$ 1.49 | 1,099,817  | \$ 1.72 |

The following table details further information regarding stock options and restricted stock outstanding and exercisable at December 31, 2012:

| Range of Exercise Price:  | Stock Options/Restricted Stock Outstanding |  |                              | Stock Options/Restricted Stock Exercisable |                              |
|---------------------------|--|--|------------------------------|--|------------------------------|
|                           | Shares                                     | Weighted Avg. remaining contractual life (years) | Weighted Avg. Exercise Price | Shares                                     | Weighted Avg. Exercise Price |
| \$0.01–\$1.00             | 1,497,000                                  | 8.52   | \$ 0.44                      | 593,050                                    | \$ 0.49                      |
| \$1.01–\$2.00             | 547,500                                    | 4.86   | 1.17                         | 526,400                                    | 1.16                         |
| \$2.01–\$3.00             | —  | —  | —                            | —  | —                            |
| \$3.01–\$4.00             | 45,000                                     | 2.04   | 3.67                         | 45,000                                     | 3.67                         |
| \$4.01–\$5.00             | 212,500                                    | 1.03   | 4.61                         | 212,500                                    | 4.61                         |
|                           | 2,302,000                                  | 6.83   | \$ 1.06                      | 1,376,950                                  | \$ 1.49                      |
| Aggregate intrinsic value | \$ 5,075                                   |  |                              | \$ 0                                       |                              |

The aggregate intrinsic value in the preceding table is based on the last reported price at which the Company's common stock traded on December 31, 2012, of \$0.31.

The following table summarizes the status of the Company's non-vested options for the years ended December 31, 2012 and 2011:

|                                       | 2012       |                             | 2011       |                             |
|---------------------------------------|------------|-----------------------------|------------|-----------------------------|
|                                       | Shares     | Weighted Avg Exercise Price | Shares     | Weighted Avg Exercise Price |
| Non-vested options, beginning of year | 1,128,250  | \$ 0.57                     | 671,500    | \$ 0.89                     |
| Granted                               | 581,000    | 0.36                        | 810,000    | 0.34                        |
| Vested                                | (367,600 ) | 0.65                        | (330,050 ) | 0.69                        |
| Forfeited                             | (416,600 ) | 0.52                        | (23,200 )  | 1.21                        |
| Non-vested options, end of year       | 925,050    | \$ 0.42                     | 1,128,250  | \$ 0.57                     |

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

Year Ended December 31,

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|   | 2012       | 2011       |
|---|------------|------------|
| Stock option grants beginning of period     | \$ 182,064 | \$ 139,272 |
| Stock-based arrangements during the period: |            |            |
| Stock option grants                         | 6,188      | 79,897     |
| Restricted stock issued:                    |            |            |
| Employee stock purchase plan                | 1,332      | 5,647      |
| Director agreements                         | 2,244      | 2,275      |
|   | \$ 191,828 | \$ 227,091 |

As of December 31, 2012 and 2011, there was approximately \$266,718 and \$251,187, respectively, of total unrecognized compensation related to non-vested share-based compensation arrangements granted under the Company's stock plans. That cost is expected to be recognized over a weighted average period of approximately 1.5 years.

In connection with the resignation of the Company's former Chief Executive Officer, the Company as part of the Separation Agreement agreed to extend the expiration date of vested options until September 14, 2013. This change resulted in a modification of stock option terms per ASC 718 resulting in an additional stock compensation cost of \$102,307, reflected in the December 31, 2012 financial statements. See Note 10.

**Note 13—Employee Benefit Plan**

The Company sponsors a profit sharing plan covering substantially all of its employees. The profit sharing plan allows for pre-tax employee contributions. The Company may, at the discretion of the Board of Directors, match a portion of the participant contributions. The Company currently contributes 25% of any amount employees contribute, up to a maximum of \$1,500 per participant per calendar year. Company contributions vest over a period of five years based on the participant's initial service date with the Company. During the years ended December 31, 2012 and 2011, \$10,663 and \$13,653, respectively, was contributed by the Company to the plan.

**Note 14—Income Taxes**

For the years ended December 31, 2012 and 2011, the Company recorded no tax provision or benefit. While the Company has incurred losses from operations it has not recorded an income tax benefit for 2012 or 2011 as it has recorded a valuation allowance against net operating losses and other net deferred tax assets due to uncertainties related to the realizability of these tax assets.

Deferred tax assets and liabilities are determined based on the difference between financial statement and tax bases using enacted federal and state tax rates in effect for the year in which the differences are expected to reverse. As of December 31, 2012 and 2011, the approximate income tax effect of the Company's deferred tax assets (liabilities) consisted of the following:

|  | 2012         | 2011         |
|--|--------------|--------------|
| Deferred tax asset:  |              |              |
| Tax effect of:   |              |              |
| Net operating loss carryforwards                                   | \$27,926,000 | \$27,804,000 |
| Accrued expenses   | 21,000       | 25,000       |
| Amortization of definite lived intangible assets                   | 16,000       | 16,000       |
| Non-qualified stock option compensation                            | 248,000      | 193,000      |
| Depreciation   | 121,000      | 108,000      |
| Other  | 227,000      | 82,000       |
| Patents  | (158,000 )   | (175,000 )   |
| State net operating loss carryforwards, net of federal tax benefit | 428,000      | —            |
| Research tax credit carryforwards                                  | 2,080,000    | 2,121,000    |
| Total deferred tax assets  | 30,909,000   | 30,174,000   |
| Valuation allowance  | (30,909,000) | (30,174,000) |
| Net deferred tax assets  | \$—          | \$—          |

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As of December 31, 2012, the Company had gross net operating loss (NOL) and research tax credit carryforwards of approximately \$84.7 million and \$1.5 million, respectively, for federal income tax purposes, expiring in varying amounts through the year 2032. Of the \$84.7 million NOL carryforward, \$2.5 million relates to stock-based compensation and has not been reflected in the deferred taxes and when the benefit of these losses, if any, is realized, the Company will credit additional paid in capital.

As of December 31, 2012, the Company had gross NOL and research tax credit carryforwards of approximately \$8.1 million and \$.9 million for state income tax purposes, expiring in varying amounts through the year 2032.

The Company's ability to use its NOL and tax credit carryforwards to reduce future taxes is subject to the restrictions provided by Section 382 of the Internal Revenue Code of 1986. These restrictions provide for limitations on the Company's utilization of its NOL and tax credit carryforwards following a greater than 50% ownership change during the prescribed testing period. On March 5, 2003, the Company had such a change. As a result, all of the Company's NOL carryforwards as of that date are limited as to utilization. The annual limitation may result in the expiration of certain of the carryforwards prior to utilization.

The benefit for income taxes differs from the federal statutory rate due to the following:

|  | 2012    | 2011    |
|--|---------|---------|
| Tax at statutory rate  | (34.0)% | (34.0)% |
| State taxes, net of federal benefit  | 0.0     | 0.1     |
| Research and development credit  | 0.1     | (2.6 )  |
| Share based payment expense  | 0.9     | 0.8     |
| Other  | 1.4     | (1.8 )  |
| Removal of deferred tax asset on federal net operating losses  | 26.9    | 0.0     |
| Establishment of deferred tax asset on state net operating losses and state deferred taxes, net of federal income tax benefits | (9.6 )  | 0.0     |
| Change in valuation allowance  | 14.3    | 37.5    |
| Effective tax rate   | 0.0 %   | 0.0 %   |

#### Note 15—Risks and Uncertainties

The Company develops genetic risk assessment tests and performs research for its own benefit. As of December 31, 2012, the Company has introduced four genetic risk assessment tests commercially. Commercial success of the Company's genetic risk assessment tests will depend on their success as scientifically credible and cost-effective by consumers and the marketing success of the Company and its collaborative partner.

Research in the field of disease predisposing genes and genetic markers is intense and highly competitive. The Company has many competitors in the United States and abroad that have considerably greater financial, technical, marketing, and other resources available. If the Company does not discover disease predisposing genes or genetic markers and develop risk assessment tests and launch such services or products before its competitors, then the potential for significant revenues may be reduced or eliminated. During the years ended December 31, 2012 and 2011, we had one significant customer, Alticor, an affiliate of our principal shareholder, that accounted for approximately 66% and 68%, respectively of our revenues from operations. In addition, in the same years, approximately 65% and 66%, respectively, of the Company's revenue came from sales through the Merchant Network and Channel Partner Agreement with Amway Global, a subsidiary of Alticor.

As disclosed in Note 2, the Company has continued to experience operating losses and its debt agreement with Pyxis is scheduled to mature on March 31, 2014 at which time the loan balance becomes due. Management has taken steps to address its liquidity needs and to improve operating results; however, there can be no assurance that these steps will be sufficient to permit the Company to continue in existence through 2013. The ability of the Company to realize the carrying value of its fixed assets and intangible assets depends on management being successful in executing on its plans to raise funds through either the issuance of debt or equity, defer the due date of existing debt, generate additional revenue and reduce expenses. No assurance can be given that the Company will be able to achieve these



plans.

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

None

**Item 9A. *Controls and Procedures***

**Evaluation of Disclosure Controls and Procedures**

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Annual Report on Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to give reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

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## **Management's Report on Internal Control over Financial Reporting**

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2012. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on our assessment, management believes that, as of December 31, 2012, the Company's internal control over financial reporting is effective based on those criteria.

This Annual Report on Form 10-K does not include an attestation report of the Company's registered public accounting firm regarding the Company's internal control over financial reporting. Management's report on internal control over financial reporting was not subject to attestation by the Company's registered public accounting firm.

## **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting identified in connection with the evaluation of such internal control that occurred during the fourth quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **Item 9B. Other Information**

None

## **PART III**

## **Item 10. Directors, Executive Officers and Corporate Governance**

Information responsive to this item is incorporated by reference from the relevant discussions in our Proxy Statement for the 2013 Annual Meeting of Stockholders under the captions “Management and Corporation Governance, “Compliance with Section 16(a) of the Securities Exchange Act of 1934” and “Code of Conduct and Ethics.”

**Item 11. *Executive Compensation***

Information responsive to this item is incorporated by reference from the relevant discussions in our Proxy Statement for the 2013 Annual Meeting of Stockholders under the caption “Executive Compensation.”

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

Information responsive to this item is incorporated by reference from the relevant discussions in our Proxy Statement for the 2013 Annual Meeting of Stockholders under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information.”

**Item 13. *Certain Relationships and Related Transactions, and Director Independence***

Information responsive to this item is incorporated by reference from the relevant discussions in our Proxy Statement for the 2013 Annual Meeting of Stockholders under the captions “Certain Relationships and Related Transactions” and “Management and Corporate Governance.”

**Item 14. *Principal Accountant Fees and Services***

Information responsive to this item is incorporated by reference from the relevant discussions in our Proxy Statement for the 2013 Annual Meeting of Stockholders under the proposal entitled “Ratification of Appointment of Independent Public Accountants.”

**PART IV**

**Item 15. *Exhibits***

**Item 15(a).** The following documents are filed as part of this Annual Report on Form 10-K:

**Item 15(a)(1) and (2).** See “Index to Financial Statements” at Item 8 to this Annual Report on Form 10-K. Other financial statement schedules have not been included because they are not applicable or the information is included in the financial statements or notes thereto.

**Item 15(a)(3)** Exhibits:

The exhibits listed below are filed as part of or incorporated by reference into this Annual Report. Where certain exhibits are incorporated by reference from a previous filing, the exhibit numbers and previous filings are identified in parentheses. The SEC file number for each Form 10-K, Form 10-Q and Form 8-K identified below is File No. 001-32715.

**Exhibit No. Identification of Exhibit**

- 3.1.1 Certificate of Incorporation of the Company, as filed with the Delaware Secretary of State on March 28, 2000 (incorporated herein by reference to Exhibit 3.1 of the Company’s Quarterly Report on Form 10-Q filed August 14, 2000)
- 3.1.2 Certificate of Designations, Preferences and Rights of Series A Preferred Stock, as filed with the Delaware Secretary of State on March 5, 2003 (incorporated herein by reference to Exhibit 3.1 of the Company’s Current Report on Form 8-K filed on March 5, 2003)
- 3.1.3 Certificate of Amendment to Certificate of Incorporation, as filed with the Delaware Secretary of State on August 5, 2003 (incorporated herein by reference to Exhibit 3.1 of the Company’s Quarterly Report on Form 10-Q filed on November 12, 2003)
- 3.1.4 Certificate of Amendment to Certificate of Incorporation, as filed with the Delaware Secretary of State on June 21, 2007 (incorporated herein by reference to Exhibit 3.1 of the Company’s Quarterly Report on Form 10-Q filed on August 9, 2007)
- 3.1.5

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- Corrected Certificate of Amendment filed with the Delaware Secretary of State on June 29, 2012 (incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K filed on July 2, 2012)
- 3.1.6 Certificate of Elimination of the Series A Preferred Stock filed with the Delaware Secretary of State on June 29, 2012 (incorporated by reference to Exhibit 3.2 of the Current Report on Form 8-K filed on July 2, 2012)
- 3.1.7 Certificate of Designations, Preferences, and Rights of Series A-1 Preferred Stock and Series B Preferred Stock filed with the Delaware Secretary of State on June 29, 2012 (incorporated by reference to Exhibit 3.3 of the Current Report on Form 8-K filed on July 2, 2012)
- 3.1.8 Certificate of Amendment filed with the Delaware Secretary of State on August 9, 2012 (incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K filed on August 9, 2012)
- 3.2 Amended and Restated Bylaws of the Company dated July 24, 2008 (incorporated by reference to the Current Report on Form 8-K filed on July 28, 2008)
- 4.1 Form of Stock Certificate representing Common Stock, \$0.001 par value, of the Company (incorporated herein by reference to Exhibit 4.1 of the Company's Quarterly Report on Form 10-Q filed August 14, 2000)
- 4.2 Form of Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q filed on November 7, 2002)
- 4.3 Form of Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on March 5, 2010)

**Exhibit No. Identification of Exhibit**

Leases

- 10.1 Commercial Lease Agreement between the Company and Clematis LLC dated February 13, 2004 (incorporated herein by reference to Exhibit 10.44 of the Company's Annual Report on Form 10-K filed on March 29, 2004)
- 10.2 Sublease Agreement between the Company and Kala Pharmaceuticals, Inc. dated April 12, 2010 (incorporated herein by reference to Exhibit 10.2 of the Company's Annual Report on Form 10-K filed on March 24, 2011)

Equity Compensation Plans

- 10.3.1@ 2000 Employee Stock Compensation Plan for the Company (incorporated herein by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q filed August 14, 2000)
- 10.3.2@ Form of Nonqualified Stock Option Agreement under the 2000 Employee Stock Compensation Plan (incorporated herein by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q filed August 14, 2000)
- 10.3.3@ Form of Incentive Stock Option Agreement under the 2000 Employee Stock Compensation Plan (incorporated herein by reference to Exhibit 10.5 of the Company's Quarterly Report on Form 10-Q filed August 14, 2000)
- 10.4.1@ Interleukin Genetics, Inc. 2004 Employee, Director and Consultant Stock Plan (incorporated by reference to Appendix A of the Company's Definitive Proxy Statement filed on April 29, 2011)
- 10.4.2@ Form of Nonqualified Stock Option Agreement under the 2004 Employee, Director and Consultant Stock Plan (incorporated by reference to Exhibit 10.5.1 of the Company's Annual Report on Form 10-K filed March 25, 2010)
- 10.4.3@ Form of Incentive Stock Option Agreement under the 2004 Employee, Director and Consultant Stock Plan (incorporated by reference to Exhibit 10.5.2 of the Company's Annual Report on Form 10-K filed March 25, 2010)

Agreements with Executive Officers and Directors

- 10.5.1@ Employment Agreement dated November 12, 2008 between the Company and Kenneth S. Kornman (incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q filed on November 13, 2008)
- 10.5.2 First Amendment, effective as of March 31, 2012, to the Employment Agreement, dated as of November 12, 2008, by and between Interleukin Genetics, Inc. and Kenneth S. Kornman (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed on April 26, 2012)
- 10.5.3 Second Amendment, dated November 29, 2012, to the Employment Agreement, dated as of November 12, 2008, by and between Interleukin Genetics, Inc. and Kenneth S. Kornman (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed on November 30, 2012)
- 10.6@ Employment Agreement dated February 14, 2011 between the Company and Lewis H. Bender (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on February 16, 2011)
- 10.6.1 Separation Agreement, dated September 14, 2012, between Interleukin Genetics, Inc. and Lewis H. Bender (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on September 30, 2012)
- 10.7@ Employment agreement dated April 30, 2008 between the Company and Eliot M. Lurier (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on August 13, 2008)
- 10.8@ Form of Director Indemnity Agreement dated March 5, 2003 (incorporated herein by reference to Exhibit 10.13 of the Company's Current Report on Form 8-K filed on March 5, 2003)
- 10.9@

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Director Compensation Policy dated April 29, 2010 (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed August 12, 2010)

10.10@\* Employment agreement dated December 26, 2012 between the Company and Scott Snyder

Agreements with respect to Financings and Rights of Stockholders

10.11 Registration Rights Agreement dated August 9, 2002 (incorporated herein by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q filed on November 7, 2002)

10.12.1 Security Agreement between the Company and Pyxis Innovations Inc., dated October 23, 2002 (incorporated herein by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed on October 28, 2002)

10.12..2 Amendment No. 2 to the Security Agreement between the Company and Pyxis Innovations Inc., dated March 5, 2003 (incorporated herein by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed on March 5, 2003)

**Exhibit No. Identification of Exhibit**

- 10.13 Registration Rights Agreement between the Company and Pyxis Innovations Inc. dated March 5, 2003 (incorporated herein by reference to Exhibit 10.8 of the Company's Current Report on Form 8-K filed on March 5, 2003)
- 10.14.1 Stock Purchase Agreement between the Company and Pyxis Innovations Inc. dated March 5, 2003 (incorporated herein by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on March 5, 2003)
- 10.14.2 Amendment No. 1 to Stock Purchase Agreement between the Company and Pyxis Innovations Inc. dated May 20, 2003 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on May 30, 2003)
- 10.14.3 Second Amendment to Stock Purchase Agreement between the Company and Pyxis Innovations Inc. dated February 28, 2005 (incorporated by reference to Exhibit 10.41 of the Company's Annual Report on Form 10-K filed on April 26, 2005)
- 10.14.4 Third Amendment, dated June 29, 2012, to the Stock Purchase Agreement, dated March 3, 2003, between Interleukin and Pyxis Innovations Inc. (incorporated by reference to Exhibit 10.5 of the Current Report on Form 8-K filed on July 2, 2012)
- 10.15 Stock Purchase Agreement Between the Company and Pyxis Innovations Inc. dated August 17, 2006 (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K/A filed on October 31, 2006)
- 10.16 Form of Amended and Restated Promissory Note under credit facility with Pyxis Innovations Inc. (incorporated by reference to Exhibit 4.1 of the Current Report on Form 8-K filed on November 30, 2012)
- 10.17.1 Amended and Restated Note Purchase Agreement between the Company and Pyxis Innovations Inc. dated March 10, 2009 (incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K filed on March 13, 2009)
- 10.17.2 First Amendment, dated August 10, 2009, to Amended and Restated Note Purchase Agreement dated March 10, 2009, by and between the Company and Pyxis Innovations Inc. (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on August 13, 2009)
- 10.17.3 Second Amendment, dated February 1, 2010, to Amended and Restated Note Purchase Agreement by and between the Company and Pyxis Innovations Inc. (incorporated by reference to Exhibit 10.1 of the Company's current Report on Form 8-K filed on February 2, 2010)
- 10.17.4 Third Amendment, dated September 30, 2010, to Amended and Restated Note Purchase Agreement by and between the Company and Pyxis Innovations Inc. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on October 4, 2010)
- 10.17.5 Fourth Amendment, dated June 29, 2012, to the Amended and Restated Note Purchase Agreement, dated March 11, 2009, between Interleukin and Pyxis Innovations Inc. (incorporated by reference to Exhibit 10.4 of the Current Report on Form 8-K filed on July 2, 2012)
- 10.17.6 Fifth Amendment, dated November 30, 2012, to the Amended and Restated Note Purchase Agreement, dated March 11, 2009, between Interleukin and Pyxis Innovations Inc. (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed on November 30, 2012)
- 10.18 Exchange Agreement, dated June 29, 2012, between Interleukin and Pyxis Innovations Inc. (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed on July 2, 2012)
- 10.19 Stock Purchase Agreement, dated June 29, between Interleukin and Delta Dental Plan of Michigan, Inc. (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K filed on July 2, 2012)
- 10.20 Registration Rights Agreement, dated June 29, between Interleukin and Delta Dental Plan of Michigan, Inc. (incorporated by reference to Exhibit 10.3 of the Current Report on Form 8-K filed on July 2, 2012)

Agreements with respect to Collaborations, Licenses and Research and Development



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- 10.21.1 Exclusive License Agreement between the Company and Access Business Group dated March 5, 2003 (incorporated herein by reference to Exhibit 10.7 of the Company's Current Report on Form 8-K filed on March 5, 2003)
- 10.21.2 First Amendment to License Agreement by and between the Company and Access Business Group International, LLC, dated September 1, 2008 (incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed on November 13, 2008)
- 10.22 Merchant Network and Channel Partner Agreement dated October 26, 2009 by and between the Company and Amway Corp. (incorporated by reference to Exhibit 10.23 of the Company's Annual Report on Form 10-K filed on March 25, 2010)

**Exhibit No. Identification of Exhibit**

- 10.23+ License Agreement, dated September 21, 2012, between Access Business Group International LLC and Interleukin Genetics, Inc. (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on November 14, 2012)
- 10.24 Professional Services Agreement, dated September 21, 2012, between Access Business Group International LLC and Interleukin Genetics, Inc. (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on November 14, 2012)

Consents, Certifications and Other Exhibits

- 23.1\* Consent of Grant Thornton LLP
- 31.1\* Certification of Chief Executive Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002
- 31.2\* Certification of Principal Financial Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002
- 32.1\* Certification pursuant to Section 906 of Sarbanes-Oxley Act of 2002
- 101\*\* The following materials from Interleukin Genetics Inc.'s Annual Report on Form 10-K for the year ended December 31, 2011, formatted in XBRL (eXtensible Business Reporting Language): (i) the Balance Sheets, (ii) the Statements of Operations, (iii) the Statements of Stockholders' Deficit, (iv) the Statements of Cash Flows, and (v) Notes to Financial Statements.

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Filed herewith.

<sup>+</sup> The Securities and Exchange Commission with respect to certain portions of this exhibit has previously granted confidential treatment. Omitted portions have been filed separately with the Securities and Exchange Commission.

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Management contract or compensatory plan, contract or arrangement.

Users of XBRL data are advised pursuant to Rule 406T of Regulation S-T that this interactive data file is deemed <sup>\*\*</sup>not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INTERLEUKIN  
 GENETICS, INC.  
 By: /s/ Kenneth S. Kornman  
 Kenneth S. Kornman  
*Chief Executive Officer*

Date: March 28, 2013

Pursuant to the requirements of with the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated below.

| <b>Signatures</b>                                | <b>Title</b>  | <b>Date Signed</b> |
|--|---|--------------------|
| /s/ Kenneth S. Kornman<br>Kenneth s. Kornman     | Chief Executive Officer, Director<br>(Principal Executive Officer)      | March 28, 2013     |
| /s/ Eliot M. Lurier<br>Eliot M. Lurier           | Chief Financial Officer<br>(Principal Financial and Accounting Officer) | March 28, 2013     |
| /s/ James Weaver<br>James Weaver                 | Chairman of the Board of Directors                                      | March 28, 2013     |
| /s/ Mary E. Chowning<br>Mary E. Chowning         | Director  | March 28, 2013     |
| /s/ Roger c. colman<br>Roger C. Colman           | Director  | March 28, 2013     |
| /s/ Thomas R. Curran Jr.<br>Thomas R. Curran Jr. | Director  | March 28, 2013     |
| /s/ Goran Jurcovic<br>Goran Jurcovic             | Director  | March 28, 2013     |

/s/ William C. Mills III    Director  
William C. Mills III

March 28, 2013