INTERLEUKIN GENETICS INC
Form 10-K
March 16, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2015

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

For the transition period from to

Commission File Number: 001-32715

INTERLEUKIN GENETICS, INC.

(Name of Registrant in its Charter)

Delaware	**94-3123681**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
135 Beaver Street, Waltham, MA	**02452**
(Address of principal executive offices)	(Zip Code)

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

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

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

Common Stock, $.001 par value per share

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

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

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

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

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

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

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

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

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of the last business day of the registrant's most recently completed second quarter was $5,267,683

As of March 16, 2016 there were 172,953,440 shares of the registrant's Common Stock issued and outstanding.

Documents Incorporated By Reference

Portions of the registrant's Definitive Proxy Statement for the 2016 Annual Meeting of Shareholders are incorporated by reference in Part III hereof.

INTERLEUKIN GENETICS, INC.

FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2015

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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. develops and markets proprietary genetic tests for chronic diseases and health-related conditions, and for informing lifestyle choices to facilitate wellness. Our tests provide information that is not otherwise available to empower individuals and their healthcare providers to manage their health and wellness through genetics-based insights and actionable guidance. We leverage our research, intellectual property, and genetic test development expertise in inflammation and metabolism to identify individuals whose risk for certain chronic diseases may be increased due to variants in one or more genes, which can enable a more personalized approach to the individual's healthcare. We market our tests through healthcare professionals, partnerships with health and wellness companies, and through other distribution channels. Our lead products are our proprietary PerioPredict® genetic test that identifies individuals with a life-long predisposition to over-produce inflammation and our Inherent Health® line of genetic tests.

Our Platform

We have developed a scientific and commercial platform that we believe offers unique approaches to improving outcomes for individuals at high risk for elevated systemic inflammation. Our platform is characterized by:

- Our expertise in IL-1 biology. We have been at the forefront of understanding the role of IL-1 genetic variation in the clinical expression of inflammation in humans.

- Proprietary assays and algorithms. Our existing tests, led by PerioPredict, are proprietary and provide unique insights that we believe enable individuals and their healthcare providers to better manage their health. We expect to develop and introduce more proprietary assays for specific inflammatory diseases.

- Unique test development approach. We identify and validate patterns of genetic variations with clinical utility for selected chronic inflammatory diseases. This approach uses our proprietary patterns of IL-1 gene variations or may use those proprietary variations to anchor a broader set of other, non-proprietary genetic factors that can be added to a test to capture risk for a specific health outcomes that are of high clinical value.

- Ability to support drug development. Our development platform may also useful in assessing differential drug outcomes that may be genetically influenced.

- Highly automated CLIA lab. All our tests use customized genetic arrays that allow processing of clinical samples in our CLIA approved clinical genetics laboratory, located in Waltham, MA.

- Value-added commercial approach. We partner with health and wellness companies, employers and others to leverage the unique information provided by our tests to drive greater patient engagement, more effective disease management and improved outcomes.

Market Conditions and Trends

Until recently, physicians and dentists treated patients with physical symptoms, such as pain or altered function, based on how early the diseases were discovered and the severity of damage produced. Management of chronic diseases has largely focused on identifying factors that "cause" the disease and ways to alter or reverse the disease after it has been diagnosed. Some causes, such as elevation of "bad" cholesterol in heart disease, are used for public health awareness and for patient testing to draw attention to early management. Common examples of altering or reversing initiating factors include calorie reduction in the case of being overweight, reducing levels of LDL cholesterol in the case of heart disease, reduction of bacteria with reduction of inflammation 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 severity of chronic diseases and their complications are mostly the result of modifying factors, such as smoking and genetics, that alter an individual's response to the disease initiator, and consequently the amount of damage produced.

The future of healthcare has been described as P4 medicine: Predictive, Preventive, Personalized, and Participatory. Personalization, which path are you on; Predictive, can we identify that you are on the disease path prior to development of severe disease; Prevention, if we can identify early which path you are on, what can we do to tilt the curve down to extend the years of wellness or prevent the disease complications entirely; and Participatory, to acknowledge the individual's responsibility in managing and preventing chronic diseases.

Many people have the mistaken impression that genetics dictates how an individual will look or feel and that there is nothing one can do to change that genetic destiny. 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 on one's phenotype can be modified. An active field of research in healthcare today is to better understand the interaction between our environment, behavior, and 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 aimed at improving 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 biological 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 that alter biology involved in inflammation or metabolic disease. We have worked with leading universities throughout the world to identify genetic variations that influence the body's inflammatory response. Our scientific advisory board includes Sir Gordon Duff, a pioneer in understanding the role that genetics plays in inflammatory disease pathways. In addition, we have conducted clinical studies for various indications throughout the world involving tens of thousands of individuals to demonstrate clinical value of our tests. To date, some of our clinical research collaborations include 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.

Inflammation is one of the body's most basic protective mechanisms, and the understanding of the role of inflammation in disease 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 the variation of disease progression among individuals who experience the same initiating events or conditions.

Chronic conditions that have traditionally been considered to be primarily 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 thought of as inflammatory diseases, including heart disease, diabetes 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, such as cardiovascular disease, osteoarthritis, and periodontal disease. There is growing evidence that genetic variants in IL-1 influence individual risk of developing these diseases and their severity and complications.

IL-1 is now recognized as a major driver of the inflammation involved in many of the chronic diseases, as evidenced by more than ten IL-1 blocking drugs now in active clinical development by pharmaceutical and biotechnology companies for major indications, including secondary cardiovascular events and type 2 diabetes mellitus.

Our proprietary IL-1 genetic patterns provide multiple access points to improve management of serious, highly prevalent conditions that are currently undermanaged. Our tests have shown significant value in predicting severe and progressive periodontitis, secondary heart attacks, and progression of knee osteoarthritis, and have the ability to differentiate clinical responses to IL-1 blocking drugs and preventive dental care. Since our IL-1 genetic tests identify individuals with a lifelong tendency to over produce IL-1, we are also engaged in projects to demonstrate how some of our tests may add value in the clinical management of the overall systemic inflammatory burden.

Our Product Focus

On November 25, 2013 we announced the introduction of the PerioPredict genetic test, and during 2015 our principal focus was on commercializing the test.

Product Definition and Positioning

PerioPredict is a genetic risk test that analyzes genetic variations associated with inflammation and identifies individuals with a life-long predisposition to over-produce inflammation. PerioPredict identifies specific polymorphisms (genetic variations) in genes that regulate the production of interleukin-1 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 PerioPredict positive patients than in patients who were PerioPredict negative. PerioPredict testing need only be done once in a lifetime and identifies “at

risk" patients early on, often before the onset of clinical symptoms, to enable targeted treatment. This objective information allows the dentist and hygienist to better guide treatment to reduce complications and costs associated with chronic inflammatory disease, such as severe periodontitis. The test may also help to establish long-term patient relationships based on the patient's prevention and care plan guided by the individual's genetic predisposition. Sample collection requires only a simple, easy-to-use cheek swab, and PerioPredict has been validated for use in all major ethnic groups. PerioPredict identifies adults at increased risk for severe periodontal disease who would not have otherwise been identified by a history of smoking or diabetes.

We position PerioPredict as a tool to drive medical value; empowering individuals and healthcare professionals with actionable genetics data. The test serves as the central component in a program to identify individuals at high risk for elevated systemic inflammation, enabling a risk stratification framework to personalize care interventions and patient outreach. The program creates value through early identification of risk, elevated professional surveillance for disease detection, and enhanced patient engagement and compliance.

Elevated systemic inflammation levels are implicated in the development and complications of numerous chronic diseases, such as heart attack, stroke, and type 2 diabetes. Severe periodontitis is one of the most common causes of increased systemic inflammation and is implicated as a risk factor for several other diseases. Studies demonstrate that preventive dental care can lower a patient's systemic inflammatory burden and is a practical, low-cost intervention access point to help manage systemic health. Additional health economic studies document that treatment of periodontitis is associated with substantial medical cost savings for patients with certain chronic diseases.

Leveraging this substantial clinical and health economics data, PerioPredict can be an essential element in an enhanced benefits design or employer-sponsored wellness initiative to identify individuals at high risk and to drive a risk stratification framework to personalize care interventions and patient outreach. The program integrates three components: 1) PerioPredict genetic test, 2) professional education to dental offices and 3) outreach to high risk members to enhance engagement and compliance. The overall goal of the program is to target high-risk individuals for more proactive dental care and to provide the education and support to ensure compliance with a modified care-plan designed to reduce systemic inflammation.

Clinical Utility and Health Economics

The clinical utility of the PerioPredict test is supported by the large validation study conducted by the University of Michigan and referred to as the Michigan Personalized Prevention Study, or MPPS. The objective of the MPPS was to improve dental care by identifying and using certain risk factors to set preventative treatment regimens. On August 6, 2012, we announced that we had received top line results from the MPPS, and on June 10, 2013, we announced the publication of the MPPS results in the *Journal of Dental Research.* The study examined data from 5,117 patients monitored for 16 consecutive years. These results indicated that in low risk patients (those with none of three risk factors: smoking, diabetes, and a PerioPredict result indicating the individual was at high risk of contracting periodontitis) 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 (those with any one of the three risk factors, with PerioPredict being the most common of the three), 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 the number of risk factors and the percentage of patients with extractions. For patients with two or three risk factors, and smoking plus PerioPredict positive represented approximately 67% of those patients, two cleanings annually did not appear to be sufficient to control risk for tooth loss.

IL-1 genetic information may be used to target more intensive periodontitis management and prevention to those patients more likely to have a level of disease that influences the systemic inflammatory burden. In a recent analysis of insurance claims data from more than 300,000 patients, treatment of periodontitis was associated with subsequent reduced cost of medical care for those with selected chronic diseases, including type 2 diabetes, coronary artery disease, stroke, and adverse pregnancy outcomes. The annual per patient decrease in medical costs over the three years following periodontitis treatment were: $2,840 for type 2 diabetes mellitus, $5,681 for stroke, and $1,090 for coronary artery disease (Jeffcoat et al. 2014).

The value of preventive dental care in reducing the cost of managing type 2 diabetes and its complications has been confirmed in a second study by United Healthcare and Optum, where claims data on more than 130,000 patients showed that regular preventive dental cleanings were associated with annual per patient cost decreases for diabetes management of $2,045, compared to irregular preventive dental care, an annual mean per patient cost reduction of 20%.

Business Strategy

We market PerioPredict to employers and insurance carriers as a central component to an enhanced benefit design or wellness initiative that is intended to lower medical costs through disease avoidance and reduced disease progression

and complications.

We target large employers, who are typically self-insured, that see value in the potential reduction of medical costs associated with the highly prevalent inflammatory diseases that our program can provide. Within this customer segment, initial targets tend to be progressive, wellness-minded companies that are engaged in other programs aimed at improving the overall health of their employees.

We also target insurance carriers, with a particular emphasis on companies with dental-medical integration (DMI) products, either in place or in development, and integrated delivery networks (IDNs), as these customers are best positioned to realize value from the reduction of medical costs associated with the highly prevalent inflammatory diseases that our program can provide.

This target customer segment represents a large market, as an estimated 170 million Americans have dental coverage through an insurance program. These customers are increasingly focused on DMI products, as the correlation between oral health and general health has become better understood. We believe the potential of our PerioPredict program to facilitate the realization of cost savings through reduced medical claims is well-aligned with this powerful trend in the insurance industry.

Our insurance carrier customers are also seeking differentiation, and the opportunity to be seen as adding value to their customers through novel product offerings, such as benefit plans that include PerioPredict genetic testing. For these customers, we typically establish demonstration projects aimed at providing evidence of the efficacy of our program in driving patient engagement, compliance and ultimately reduced costs. Once that demonstration is achieved, we believe the insurance carrier will be incentivized to incorporate our program broadly in their product offerings, thereby providing significant leverage to our commercialization efforts.

To create further leverage, we intend to partner with channel partners, primarily benefits consulting firms, to identify, and facilitate initial interactions with, potential customers. We have established one such relationship at this point, with Employee Benefit Consulting Group LLC, or EBCG, a firm with expertise in the U.S. insurance market and strong relationships with employers, insurance carriers, and health and wellness providers. We work with EBCG to build awareness of PerioPredict as a tool for personalizing patient care among insurance carriers, benefit plans and employer groups, and to potentially incorporate the test in the design of risk-based benefit plans.

PerioPredict is solely available through Interleukin Genetics. The web site for the PerioPredict test is *www.PerioPredict.com*. 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.

Additional Products Marketed

We market additional genetic tests through our Inherent Heath brand:

- *Weight Management Genetic Test*: This test determines whether individuals will lose weight more predictably on a low fat, low carbohydrate or balanced diet and whether normal or vigorous exercise is needed to most efficiently lose existing body fat. The test results guide more effective long-term weight loss.
- *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.
- *Heart Health Genetic Test*: This test is designed to identify genetic predisposition to excess inflammation, which is a risk factor for heart attack.
- *Nutritional Needs Genetic Test*: This test is designed to identify DNA variations in genes crucial to B-vitamin metabolism and the ability to manage oxidative stress.

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

Weight Management Genetic Test

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, as well as 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 that 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.

Bone Health Genetic Test

Our Bone Health Genetic Test is designed to identify whether an individual is more likely to develop 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 Genetic 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 involved in vitamin B metabolism and markers 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.

Marketing and Distribution of Inherent Health Tests

We market our Inherent Health brand of genetic tests using our e-commerce website and under contract with Amway-affiliated companies, which are affiliates of Alticor, Inc., the parent of Pyxis Innovations Inc., a significant stockholder (“Pyxis”), and several regional weight management focused organizations. Amway sells the Inherent Health Weight Management test in the U.S. and fifteen countries in Europe. The European tests are processed through two European laboratories that have been validated for quality assurance purposes by Interleukin Genetics. We receive a royalty payment from each test processed in Europe but do not receive a test processing fee. We have developed a

complete e-commerce solution for our Inherent Health brand of genetic tests. 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.

Laboratory Testing Procedure

To conduct a genetic risk assessment test, the customer collects cells from inside the cheek using a buccal swab brush and submits it by mail to our laboratory. Samples are processed only with a requisition signed by either a customer's physician, one provided by an Interleukin Genetics physician or a patient's dentist and a customer consent for the genetic test. Our CLIA-certified clinical laboratory performs the ordered genetic test using stringent standard operating protocols. Following state and country regulations the test results are provided directly to the customer and/or the designated health care provider.

We process test samples in our CLIA-certified genetic testing laboratory. The regulatory requirements associated with a CLIA-certified 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 as well as updated protocols for all of the laboratory processes. We currently hold laboratory permits or licenses for all US states that require a genetic test processing license and meet the regulatory requirements as needed for other countries.

Platform Extensions and Genetic Test Pipeline

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

Cardiovascular Disease: Use of IL-1 pro-inflammatory genetic variations to guide drug development and use to prevent secondary CVD events

Inflammation is well documented to contribute to acute cardiovascular (CVD) events through biological effects on multiple components of the atherothrombotic cardiovascular disease process. Inflammatory biomarkers such as high-sensitivity C-reactive protein (hsCRP) identify individuals at high risk for both first and recurrent CVD events even in individuals without elevated lipid levels. We have previously reported that individuals with elevated oxidized phospholipids, as represented by Lp(a), are at increased risk for coronary artery atherosclerosis (Tsimikas et al. 2005), but the linear relationship was only present in individuals who tested positive for our pro-inflammatory IL-1 genetic patterns (Tsimikas et al. 2014). In addition, the combination of high Lp(a) levels and presence of the pro-inflammatory IL-1 genetic variations in one of our tests was predictive of which of those patients developed secondary CVD events in the next 4 years. The combination was significantly better than either factor alone and suggests that the bad lipids are working in part through the gene variations in our test.

In 2015, we announced a collaboration with Ionis Pharmaceuticals to use our IL-1 genetic test in a Phase 2 study of their anti-sense drug that has been shown in Phase 1 to reduce Lp(a) levels as well as to use our genetic test in a new Phase 1 study. Other companies are testing IL-1 blocking drugs for various indications, including Novartis, which is in current clinical trial of Canikinumab for secondary CVD events. We believe that our proprietary IL-1 genetic patterns that identify patients who over-produce IL-1 may have value in guiding development and use of drugs that directly or indirectly target IL-1 effects on CVD events.

Osteoarthritis

Osteoarthritis, or OA, is the most common adult joint disease, increasing in frequency and severity in all aging populations. Considerable data provide support for a central role of interleukins in the pathogenesis of OA and genetic variations in the interleukin-1 gene cluster have been previously determined to be associated with multiple clinical phenotypes in OA. Our OA program centers on 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.

We have published findings on the genetics of OA in the *Annals of Rheumatic Diseases*, where we reported that a novel, patent-pending 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 (NYU) Hospital for Joint Diseases, and 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. In 2015, we signed a license agreement with NYU School of Medicine related to the development and commercialization of the first genetic test of its kind to identify individuals at

increased risk for progression of OA and related complications.

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 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. Some of our tests may include our proprietary genetic variations plus other gene variations that may be publicly available or in-licensed by Interleukin Genetics.

We have and have been 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 nine issued U.S. patents that have expiration dates between 2016 and 2029, six U.S. patent applications and one U.S. Provisional patent application pending, that are based on novel associations between particular gene sequences and certain metabolic and inflammatory conditions and disorders. The nine issued U.S. patents relate to genetic tests for, 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, osteoarthritis and IL-1 blocking drug indications. If granted, we expect many of these patents are not likely to expire until between 2028 and 2037.

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

Federal and state governmental authorities regulate the testing services that we provide. Failure to comply with the applicable laws and regulations can subject us to civil and criminal penalties, loss of licensure, certification, or accreditation. We intend to comply with all applicable government regulations and believe that we are currently in compliance. 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. In particular, the FDA's approach to regulating laboratory developed tests is evolving, including such tests that are made available directly to the consumer, and we are in discussions with the FDA about how our tests, primarily certain of our Inherent Health tests, may be impacted, as discussed further in the "Government Regulation - Food and Drug Administration" section below.

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. Requirements 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 requirements. 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 September 2015 and no deficiencies or other 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.

In July 2010, FDA held a public meeting in which FDA officials including those from the Office of In Vitro Diagnostic Products (OIR), 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."

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 OIR 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 OIR planned to issue three guidance documents addressing oversight of laboratory-developed tests. However, he did not provide a timeframe for OIR'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."

On July 31, 2014 the FDA provided 60-day notice to Congress of its plan to issue draft guidance on the regulation of laboratory developed tests. On September 30, 2014, the FDA posted two draft guidances on its website, followed by notice in the Federal Register on October 3, 2014 announcing their release and the opening of a 120-day public comment period. This comment period lasted until February 2, 2015. FDA has not to date issued final versions of either of these guidance documents. In a footnote to one of these draft guidance documents, FDA stated that laboratory tests offered directly to consumers were not considered LDTs and would not be subject to FDA enforcement discretion.

The FDA issued a Draft Guidance for Industry and Food and Drug Administrative Staff on In Vitro Companion Diagnostic Devices on July 14, 2011, which, if finalized, is intended to assist companies developing in vitro companion diagnostics and companies developing therapeutic products that depend on the use of a specific in vitro companion diagnostic for the safe and effective use of the product. The FDA defined an in vitro companion diagnostic device, or IVD Companion Diagnostic Device, as a device that provides information that is essential for the safe and effective use of a corresponding therapeutic product. This definition is much narrower than the commonly used term "companion diagnostic," which refers generally to tests that may be useful, but are not necessarily a determining factor in the safe and effective use of the therapeutic product. The FDA expects that the therapeutic sponsor will address the need for an approved or cleared IVD Companion Diagnostic Device in its therapeutic product development plan. The sponsor of the therapeutic product can decide to develop its own IVD Companion Diagnostic Device, partner with a diagnostic device sponsor to develop the appropriate IVD Companion Diagnostic Device, or explore modification of an existing IVD diagnostic device (its own or another sponsor's) to accommodate the appropriate intended use. The FDA has approved a number of drug/diagnostic device companions in accordance with the Draft Guidance. However, this guidance will not apply to the LDTs that are used as companion diagnostics that merely provide useful information and are not linked to a specific drug indication.

On November 1, 2010, we met with the director and staff members of the OIR to present information on our tests. At FDA's request, we submitted a plan for how our tests would be submitted to FDA in December 2010 and requested a follow-up meeting to obtain feedback on the plan from OIR personnel. We did not receive any substantive feedback on this plan from FDA.

In October and November 2015 FDA sent a number of "Untitled Letters" to entities marketing genetic tests directly to consumers, including to us. Specifically, on November 2, we received an Untitled Letter from the FDA requesting information about whether certain specified tests had obtained FDA clearance. We submitted a written reply to this letter on December 16, 2015, in which we responded that (1) we do not currently offer an osteoarthritis test; (2) that the PerioPredict test is a LDT subject to FDA "enforcement discretion; and (3) that the Weight Management Genetic test is not a medical device subject to FDA's statutory jurisdiction or, if it is, should be subject to enforcement discretion because it is a low-risk wellness product. We requested a meeting with OIR to discuss the Inherent Health tests.

On February 3, 2016 we met with the director and staff members of OIR to further discuss our letter response. The FDA issued minutes of the meeting on February 16, 2016, which confirmed that we do not offer an Osteoarthritis test and that PerioPredict is currently offered only as an LDT and is therefore currently subject to FDA enforcement discretion. In addition, they confirmed their interest in obtaining further information on how we would come into compliance with respect to the Inherent Health tests, since those tests are offered DTC and therefore are not subject to FDA enforcement discretion. We are continuing to engage with OIR regarding the appropriate next steps for these tests.

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 be 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, including most medical devices, 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*, *www.inherenthealth.com* and *www.periopredict.com*. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to such reports are available to you free of charge through the Investor Relations Section of *www.ilgenetics.com* as soon as practicable after such materials have been electronically filed with, or furnished to, the Securities and Exchange Commission. The information contained on our websites are not incorporated by reference into this Form 10-K. We have included our website addresses only as an inactive textual reference and do not intend them to be active links to our websites.

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

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

If we fail to obtain additional capital by the second half of 2016, we may have to end our operations and seek protection under bankruptcy laws.

We expect that our current and anticipated financial resources will be adequate to maintain our current and planned operations only into the second half of 2016. We need significant additional capital to fund our continued operations, including for the commercialization efforts for our PerioPredict 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.

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 increasing revenue through new arrangements with commercial distribution partners and continuing to finance operations through the private or public placement of debt and/or equity securities. However, no assurance can be given at this time as to whether we will be able to achieve these objectives. The financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern. We can provide no assurance that we will be successful in increasing revenues, or that we will receive additional funding on reasonable terms, or at all.

The timing and amount of revenues, if any, that we may receive pursuant to any existing or future agreement we may enter into with insurance carriers or large employers is uncertain.

The timing of any revenues that we may receive under any agreement we have or may enter into with an insurance carrier, large employer or other customer is very uncertain at this time and is dependent on a number of variables that are or may be beyond our control. We continue to engage in discussions for the use of our PerioPredict test with insurance companies and large employers who might ultimately adopt enhanced benefits designs or employer-sponsored wellness initiatives that incorporate PerioPredict, or utilize PerioPredict through other arrangements, through the use of consultants, channel partners and our internal management team. The failure to enter into any agreement with other insurance carriers or large employers and to receive significant revenues under any such agreement would have a material adverse effect on our business.

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 operations of $6.3 million in 2014 and $7.3 million in 2015. As of December 31, 2015, our accumulated deficit was $129.0 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.

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 customers 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. We expect to expend significant funds and resources to educate patients, dentists and other providers, and payers on the benefits of our PerioPredict test. There is no assurance that we will be able to successfully do so. 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 PerioPredict test.

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, our business will be materially harmed. We expect competition to intensify in our industry as technical advances are made and become more widely known.

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 and genetic variants. 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 limited experience and capabilities with respect to distributing, marketing and selling genetic risk assessment tests on our own. In June 2009, we announced the launch of our new Inherent Health brand of genetic tests. On October 26, 2009, we entered into an agreement with Amway Global, an affiliate of Alticor, pursuant to which it sells our Inherent Health brand of genetics tests through its e-commerce Web site via a hyperlink to our e-commerce site. In 2015 and 2014, revenues from this agreement accounted for 45% and 44% of our revenues, respectively. In addition, beginning in September 2012 and again in 2013, Access Business Group LLC, an affiliate of Alticor, placed purchase orders totaling approximately $3.3 million consisting of weight management kits. The kits are included as part of a promotional bundle of products that Amway is now selling to their Individual Business Owners. In 2015 and 2014, revenues from this arrangement accounted for 13% and 32% of our revenues, respectively. We continue to engage in discussions for the use of our PerioPredict test with insurance companies and large employers who might ultimately adopt enhanced benefits designs or employer-sponsored wellness initiatives that incorporate PerioPredict, or utilize PerioPredict through other arrangements, through the use of consultants, channel partners and our internal management team. We have, to date, had very limited success in marketing and selling our genetic tests, including PerioPredict, 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.

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, rating downgrades of certain investments and declining valuations of others. We believe 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.

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 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 any of its affiliates enters a business in competition with ours, certain of our directors might have a conflict of interest.

We have entered into an agreement with our stockholder, Pyxis (collectively, with its affiliates, the "Interested Parties"), allocating corporate opportunities as permitted under Section 122(17) of the Delaware General Corporation Law. This agreement regulates and defines the conduct of certain of our affairs as they may involve 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, 2015, we had gross net operating loss (NOL) and research tax credit carryforwards of approximately $88.2 million and $1.6 million, respectively for federal income tax purposes, and of approximately $11.0 million and $1.0 million for state income tax purposes, expiring in varying amounts through the year 2035. Our ability to use these NOLs 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. On March 5, 2003, we had such a change. As a result, all of our 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. In addition, our equity offerings, including those in 2013 and 2014, may have resulted in qualifying changes in ownership. A formal study, which we have not undertaken, is required to determine applicability of restrictions and might indicate that our NOL carryforwards are subject to additional limitations on 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 9 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 with respect to the composition of matter claims. On November 30, 2012, the Supreme Court granted the petition and agreed to review the case. On June 13, 2013, the Supreme Court issued a decision in the Myriad case. According to the decision, claims directed to genomic DNA cover unpatentable subject matter. However, claims directed to cDNA are patent eligible subject matter.

On March 4, 2014, 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. . On December 16, 2014 an interim guidance was issued that supersedes the March 4, 2014 memorandum but essentially followed the same direction for patent eligibility. 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.

There can be no assurance that the Supreme Court’s decision in either the Myriad or Prometheus 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. Such negative decisions by the Supreme Court could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

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 also be performed at our CLIA-certified laboratory. Although FDA believes that tests such as ours fall within its jurisdiction as medical devices, it has historically exercised enforcement discretion with respect to LDTs, meaning that such tests generally have not been subject to FDA regulatory requirements. However, the Agency’s regulatory approach to LDTs is uncertain, and whether or when FDA will issue final guidance documents implementing the agency’s proposed regulatory framework is unclear. It is also unclear how a final regulatory framework will affect our current and future tests, as the level of regulation will depend on FDA’s evaluation of the risk posed by the specific test. With respect to our LDTs that are not offered DTC, such as PerioPredict, if FDA issues final guidance implementing a risk-based regulatory framework for LDTs, we intend to comply fully and acknowledge that non-compliance may result in enforcement actions, which could affect our ability to market and sell our tests and may harm our reputation. 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.

With respect to our Inherent Health tests, which have historically been offered DTC, FDA has informed us that these tests are not LDTs and are not subject to enforcement discretion. We and FDA are in the midst of discussing appropriate next steps for these tests. It is unclear which, if any, of these tests will be permitted to continue to be offered DTC, or for how long. We cannot provide any assurance that FDA regulation, including pre-market review or approval, will not be required for these tests in the future.

If the FDA requires us to obtain clearance through its 510k premarket notification process or obtain approval through its premarket approval, or PMA process, either as a condition of continuing to market our tests or bringing future tests to market, our business could be negatively impacted. Requiring FDA clearance or approval could be lengthy, costly and burdensome. In addition, depending upon the 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 the FDA, we would be required to comply with requirements including establishment 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 all states. Failure to comply with state regulations or changes in state regulatory requirements, 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. In addition, if the use of any test that we develop is necessary for the safe use of a collaborator's therapeutic product, we might be required to obtain clearance or approval of our test.

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;
- 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.

Changes in healthcare policy could impact commercialization of our tests.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the ACA, became law. This law substantially changes the way health care is financed by both governmental and private insurers. The ACA contains a number of provisions that may impact our business and operations in ways we cannot currently predict. In particular, we believe that the ACA may impact adoption of Reimbursed Dental Plans and other reimbursed insurance plans that include our PerioPredict® test because there is uncertainty in the cost of compliance with the ACA and how that may impact employer coverage for adult dental care in their overall benefits plan.

In addition to the ACA, there will likely continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our tests or the amounts of reimbursement available for our tests from governmental agencies or third-party payors. While in general it is too early to predict specifically what effect the ACA or any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

Risks Related to Our Common Stock

Our common stock is listed on the OTCQB, which could result in a limited market for our common stock.

Our common stock was listed on the NYSE Amex until August 16, 2010, when it was suspended for failure to comply with the NYSE Amex continued listing standards. Our common stock then began trading on the OTCQB™ under the symbol ILIU. This delisting 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 three years ended December 31, 2015, our stock price has fluctuated from a low of $0.01 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 commercial success of the PerioPredict 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 management and their affiliates own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of March 1, 2016, our executive officers, directors and their respective affiliates, beneficially owned approximately 43.9% of our outstanding common stock. Accordingly, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. This concentration of ownership could have the effect of entrenching our management and/or the board of directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

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. 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. In addition, our ability to pay cash dividends is currently prohibited by the terms of the Loan Agreement with Horizon Technology Finance Corporation, and any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. 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 13,000 square feet of office and laboratory space in Waltham, Massachusetts under a non-cancelable operating lease which expires on March 31, 2017.

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™. The following table sets forth, for the periods indicated, the high and low sales prices for our common stock, as reported by the OTCQB™.

	High	Low
2015:		
First Quarter	$0.46	$0.11
Second Quarter	$0.18	$0.09
Third Quarter	$0.16	$0.08
Fourth Quarter	$0.12	$0.01

	High	Low
2014:		
First Quarter	$0.38	$0.25
Second Quarter	$0.35	$0.25
Third Quarter	$0.29	$0.11
Fourth Quarter	$0.17	$0.05

Stockholders

As of March 11, 2016, there were approximately 122 stockholders of record and according to our estimate, approximately 2,421 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. In addition, our ability to pay cash dividends is currently prohibited by the terms of the Loan Agreement with Horizon Technology Finance Corporation, and any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock.

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. develops and markets proprietary genetic tests for chronic diseases and health-related conditions. Our products provide information that is not otherwise available to empower individuals and their healthcare providers to manage their health and wellness through genetics-based insights and actionable guidance. We leverage our research, intellectual property, and genetic test development expertise in inflammation and metabolism to identify an individual's risk for severe and progressive chronic inflammatory diseases, thereby enabling personalized healthcare. We market our tests through healthcare professionals, partnerships with health and wellness companies, and other distribution channels. We have patents covering the use of specific patterns of gene variations for a number of common chronic diseases. Our lead products are our proprietary PerioPredict genetic test that identifies individuals with a life-long predisposition to over-produce inflammation and our Inherent Health line of genetic tests.

During the year ended December 31, 2015, our principal focus has been on commercializing our PerioPredict test, and on the sales of our Inherent Health brand of genetic tests and related programs.

PerioPredict serves as a central component to an enhanced benefit design or wellness initiative directed to lower medical costs through disease avoidance and reduced disease progression and complications. We position PerioPredict as a tool to drive medical value; empowering individuals and healthcare professionals with actionable genetics data. The test identifies individuals at high risk for elevated systemic inflammation, enabling a risk stratification framework to personalize care interventions and patient outreach. The program creates value through early identification of risk, elevated professional surveillance for disease detection, and enhanced patient engagement and compliance

We market PerioPredict to large employers, who are typically self-insured, and to insurance carriers. Our employer customers see value in the potential reduction of medical costs associated with the highly prevalent inflammatory diseases that our program can provide. Within this customer segment, initial targets tend to be progressive, wellness-minded companies that are engaged in other programs aimed at improving the overall health of their employees.

Within the insurance carrier segment, we place particular emphasis on carriers with dental-medical integration (DMI) products, either in place or in development, and integrated delivery networks (IDNs), as these customers are best positioned to realize value from the reduction of medical costs associated with the highly prevalent inflammatory diseases that our program can provide. This insurance carrier segment represents a large market, as an estimated 170 million Americans have dental coverage through an insurance program. These customers are increasingly focused on DMI products, as the correlation between oral health and general health has become better understood. We believe the potential of our PerioPredict program to facilitate the realization of cost savings through reduced medical claims is well-aligned with this powerful trend in the insurance industry.

We pursue these customers through our internal team, and through consultants and other third parties, including channel partners, primarily benefits consulting firms, who may be helpful to identify, and facilitate initial interactions with, potential customers. We have established one such relationship at this point, with Employee Benefit Consulting Group LLC (EBCG), a firm with expertise in the U.S. insurance market and strong relationships with employers, insurance carriers, and health and wellness providers. We work with EBCG to build awareness of PerioPredict as a tool for personalizing patient care among insurance carriers, benefit plans and employer groups, and to potentially incorporate the test in the design of risk-based benefit plans.

The timing of any revenues that we may receive from our marketing efforts is very uncertain at this time and is dependent on a number of variables, many of which we may have a limited ability to influence. We may never receive significant revenues for the PerioPredict test.

On April 11, 2014, we announced the pre-print online publication of our research study titled “Association of interleukin-1 gene variations with moderate to severe chronic periodontitis in multiple ethnicities” in the *Journal of Periodontal Research*. The study results from multiple ethnic groups further validated the association between periodontitis and the interleukin-1 beta (IL1B) composite genotype pattern, a specific genetic profile that can be elucidated by our PerioPredict genetic risk test. In addition, the study results demonstrated that detection of the IL1B variations tested provided added value in the prediction of moderate to severe periodontitis above and beyond the risk attributable to smoking and diabetes alone.

On April 22, 2014, we announced receipt of conditional approval from the New York State Department of Health to offer, process and report the results of the PerioPredict test for periodontal disease. The State of New York is the only U.S. state that requires an independent regulatory review process including technical validation with clinical utility for laboratory developed tests run within a CLIA certified laboratory. Conditional status will be removed on successful completion of a future additional review, the timing of which is determined solely by the State of New York. As a result of New York State conditional approval, the PerioPredict test is now available to dental providers and their patients in all 50 U.S. states.

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.

We market our Inherent Health brand of genetic assessment tests primarily through our commercial relationships with Alticor Inc. affiliated companies. Alticor is a related party. On October 26, 2009, we entered into a Merchant Network and Channel Partner Agreement with Amway Corp., d/b/a/ Amway Global (Amway Global), a subsidiary of Alticor. Pursuant to this agreement, Amway Global sells our Inherent Health brand of genetic tests through its e-commerce website via a hyperlink to our e-commerce site. In 2015 and 2014, revenues from this agreement accounted for approximately 45% and 44% of our revenues, respectively.

Beginning in September 2012 and again in 2013, Access Business Group LLC (ABG), an affiliate of Alticor, placed purchase orders totaling approximately $3.3 million consisting of weight management kits. The kits are included as part of a promotional bundle of products that Amway is now selling to their Individual Business Owners (IBOs). Of the $3.3 million in orders received in 2013, $1.8 million was related to the 2014 program and $1.5 million was related to the 2013 program. Cash for the kits purchased for the 2013 program was received in the first quarter of 2013 and cash for the kits purchased for the 2014 program was received by December 31, 2013. As a component of the 2013 promotional program, and not reflective of actual product expiry, the kits were required to be redeemed before December 31, 2013. In February 2014, we removed the redemption date requirement for the 2013 promotional program, for which ABG paid us $519,000 as a retrospective increase in the product purchase price. All revenues related to the 2013 promotional program, including the $519,000, will remain deferred until the kits are redeemed or the breakage analysis determines the probability of eventual redemption is remote. In October 2014, we received $250,000 as a retrospective increase in the product purchase price for unsold kits as consideration for extending the required redemption date of the 2014 promotional program to December 31, 2017. Cash received for these kits will be treated as deferred revenues until specific kits are returned for processing or on the final allowed redemption date of December 31, 2017. For the years ended December 31, 2015 and 2014, approximately 13% and 32%, respectively, of our revenue came from sales through ABG's promotional product bundle program.

On September 21, 2012, we entered into a License Agreement (the License Agreement) with Access Business Group International LLC (ABGI), an affiliate of Alticor. Pursuant to this License Agreement, we granted ABGI and its affiliates (the Licensees) a non-exclusive license to use the technology related to our Weight Management genetic test and to sell the Weight Management test in Europe, Russia and South Africa. ABGI, or a laboratory designated by ABGI, is responsible for processing the tests, and we receive a royalty for each test sold. 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. For the years ended December 31, 2015 and December 31, 2014, $191,000 and $150,000, respectively, in license fees have been received pursuant to the License Agreement. The increase in license fees is due primarily to higher per-unit royalties resulting from the issuance of patents in the European Union and Russia, and additional unit volume from new Eastern European markets.

Our research and development expenses are focused on our own development efforts related primarily to our PerioPredict and cardiovascular disease genetic tests. 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.

We recognize revenue from genetic testing services 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. During the fourth quarter of 2013, we concluded that sufficient historical customer genetic test redemption patterns existed to determine the period of time after which the likelihood of test redemption was remote for Inherent Health tests purchased. Based on our analysis of the redemption data, we estimate that period of time to be three years after the sale of a genetic test kit. Prior to making this determination, revenue was recognized only on test kits returned and processed. Beginning in the fourth quarter of 2013, we began to recognize breakage revenue based on the likelihood of test redemption becoming remote. The term remote requires statistical analysis of customer redemption patterns for all tests sold and returned. We analyzed redemption patterns from 2009 through 2015. Included in genetic test revenue in the years ended December 31, 2015 and December 31, 2014 is $218,000 and $309,000, respectively, of breakage revenue related to unredeemed genetic test kits from 2012 and 2011. We expect to continue to recognize breakage revenue and the corresponding deferred cost of goods as well as analyze the data on a quarterly basis based on the historical analysis.

On May 17, 2013, we entered into a Common Stock Purchase Agreement (the 2013 Purchase Agreement) with various accredited investors (the 2013 Investors), pursuant to which we sold securities to the 2013 Investors in a private placement transaction (the May 2013 Private Placement). In the May 2013 Private Placement, we sold an aggregate of 43,715,847 shares of our common stock at a price of $0.2745 per share for gross proceeds of $12,000,000. The 2013 Investors also received warrants to purchase up to an aggregate of 32,786,885 shares of common stock at an exercise price of $0.2745 per share (the 2013 Warrants). The 2013 Warrants are all currently exercisable and have a term of seven years from the date they became exercisable.

In addition, pursuant to the 2013 Purchase Agreement, each 2013 Investor had the right, at any time on or before June 30, 2014 (the Expiration Date), to purchase at one or more subsequent closings its pro rata share of up to an aggregate of 18,214,936 additional shares of common stock at a purchase price of $0.2745 per share and warrants to purchase up to an aggregate of 13,661,201 shares of common stock at an exercise price of $0.2745 per share. The Expiration Date was extended until December 31, 2014, and this right expired unexercised.

On December 23, 2014, we entered into a Securities Purchase Agreement (the 2014 Purchase Agreement) with various accredited investors (the 2014 Investors), pursuant to which we sold to the 2014 Investors in a private placement transaction (the December 2014 Private Placement) an aggregate of 50,099,700 shares of our common stock at a price of $0.1003 per share for gross proceeds of approximately $5.025 million. The 2014 Investors also received warrants to purchase up to an aggregate of 50,099,700 shares of common stock at an exercise price of $0.1003 per share (the 2014 Warrants). The 2014 Warrants are all currently exercisable and have a term of seven years.

On December 23, 2014, we also entered into a venture loan and security agreement (the Loan Agreement) with Horizon Technology Finance Corporation (the Lender) under which we have borrowed $5.0 million (the December

2014 Debt Transaction). The loan bears interest at a floating rate equal to the One Month LIBOR Rate (with a floor of 0.50%) plus 8.50%. In the event that the One Month LIBOR Rate, as reported in the Wall Street Journal, exceeds 0.50%, the interest rate will be adjusted by an amount equal to the difference between such rates at the end of that particular month. At December 31, 2015, the rate was 9.0% per annum. The loan is to be repaid in forty-five (45) monthly payments consisting of fifteen (15) monthly payments of only interest followed by thirty (30) equal monthly payments of principal and interest. In addition, at the end of the repayment term (or at early termination of the loan) a final payment equal to 4.5% of the loan will be due and payable. Our obligations under the Loan Agreement are secured by a first priority security interest in substantially all of our assets other than our intellectual property. We have also agreed not to pledge or otherwise encumber our intellectual property assets, subject to certain exceptions. In connection with the Loan Agreement, we issued to the Lender and its affiliates warrants to purchase a total of 2,492,523 shares of common stock at an exercise price of $0.1003 per share, which we refer to herein as the Lender Warrants. The Lender Warrants have a term of ten (10) years.

In the genetic test business, competition is in flux and the markets and customer base are not well established. Adoption of new technologies by customers 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 2016 and beyond will be to develop the market for our personalized health products, in particular our PerioPredict® test, and we will allocate considerable resources to commercialization of our PerioPredict® genetic test. Due to the early stage of this initiative, we cannot predict with certainty fluctuations we may experience in our genetic test revenues or whether such revenues will ever be material, or if material, will be sustained in future periods.

Liquidity and Capital Resources

As of December 31, 2015, we had cash and cash equivalents of $4.7 million.

Cash used in operations was $6.7 million for the year ended December 31, 2015 compared to $5.7 million for the year ended December 31, 2014. Cash used in operations is primarily impacted by operating results and changes in working capital, particularly the timing of prepaid expenses, reduced payments from related party receivables, inventory levels, receipt of orders and the timing of payments to suppliers.

Cash used in investing activities was $82,000 for the year ended December 31, 2015, compared to $98,000 for the year ended December 31, 2014. Capital additions were $82,000 for the year ended December 31, 2015, of which approximately $11,000 related to internal use software, $50,000 related to the addition of laboratory equipment and $21,000 related to the addition of new servers. Capital additions were $98,000 for the year ended December 31, 2014, partially offset by a $10,000 refund from our landlord related to the surrender of the approximately 6,000 square feet of subleased office and laboratory space as of March 31, 2014, which included approximately $28,000 related to internal use software, $5,000 related to the addition of laboratory equipment, $16,000 related to the addition of a new server, and $49,000 related to software enhancements to our laboratory access server.

Cash provided by financing activities was $13,000 for the year ended December 31, 2015 compared to $9.7 million for the year ended December 31, 2014. The Company received $21,000 from stock purchases through the employee stock purchase plan during the year ended December 31, 2015 compared to $32,000 for the year ended December 31, 2014. The $21,000 received through the employee stock purchase plan for the year ended December 31, 2015 was offset in part by $8,000 in additional fees related to the December 2014 Private Placement. The aggregate net cash proceeds from the December 2014 Private Placement and the December 2014 Debt Transaction accounted for the $9.7 million in cash provided by financing activities in 2014.

The amount of cash we generate from operations is currently not sufficient to continue to fund operations and grow our business. We expect that our current financial resources will be adequate to maintain our current and planned operations into the second half of 2016. We believe our success depends on our ability to generate significant revenues for the PerioPredict® test through potential partners. The timing of any revenues that we may receive for the PerioPredict® test is uncertain at this time, and is contingent upon a number of factors, including our ability to consummate arrangements with other partners to promote the PerioPredict test, our partners' ability to develop reimbursed insurance plans and to develop a viable market for such plans, and the timing of utilization of the PerioPredict test pursuant to insured plans, or other possible arrangements. We do not expect to receive any material revenues from the PerioPredict test until mid to late 2016, at the earliest, and the timing of any such revenues may be substantially later. We may never receive significant revenues from the PerioPredict test.

Until such time, if ever, that we generate revenues sufficient to fund operations, we may fund our operations by issuing common stock, debt or other securities in one or more public or private offerings, as market conditions permit, or through the incurrence of debt from commercial lenders. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends. There can be no assurance that additional funds will be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or cease activities or operations or enter into licenses or other arrangements with third parties on terms that may be unfavorable to us or sell, license or relinquish rights to develop or commercialize our products, technologies or intellectual property. 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, 2015 and 2014

Total revenue was $1.44 million for the year ended December 31, 2015 compared to $1.81 million for the year ended December 31, 2014. The change in total revenue is largely attributable to a decrease in the number of kits returned for processing related to our sales through ABG’s promotional product bundle program. Breakage revenue recognized in the year ended December 31, 2015 was $218,000, compared to $309,000 of breakage revenue recognized in the year ended December 31, 2014, also contributing to the change in revenue. Royalty revenue from our license agreement with ABGI was $191,000 for the year ended December 31, 2015, compared to $151,000 of royalties earned in the year ended December 31, 2014, partially offsetting the decrease in total revenue.

During the year ended December 31, 2015, 45% of our sales revenue came through our Merchant Network and Channel Partner Agreement with Amway Global compared to 44% during the year ended December 31, 2014. During the same periods, 13% and 32%, respectively, of our revenue came from sales through ABG's promotional product bundle program.

Cost of revenue for the year ended December 31, 2015 was $1.41 million, or 98.1% of revenue, compared to $1.44 million, or 79.3% of revenue, for the year ended December 31, 2014. The increase in the cost of revenue as a percentage of revenue in the year ended December 31, 2015 compared to the year ended December 31, 2014 is primarily attributable to the fixed laboratory costs being applied to a lower volume of genetic tests being processed in the period. Deferred cost of revenue related to breakage revenue was $10,000 for the year ended December 31, 2015 compared to $13,200 for the year ended December 31, 2014. Also included in cost of revenue for the year ended December 31, 2015 is a charge of $27,000 from the write off of obsolete raw materials and kits related to ABG's 2013 promotional program.

Research and development expenses were $1.3 million for the year ended December 31, 2015, compared to $843,000 for the year ended December 31, 2014. The increase of $456,000, or 54.1%, is primarily attributable to expenses related to Dr. Kornman moving back to the R&D department in April 2015 as President and Chief Scientific Officer from his previous position as CEO. While he served as CEO, expenses generated by Dr. Kornman were recorded as selling, general and administrative expenses. The increase in research and development expenses was also partially due to increased compensation expense related to annual salary increases for existing staff.

Selling, general and administrative expenses were $5.9 million for the year ended December 31, 2015, compared to $5.8 million for the year ended December 31, 2014. The 1.7% increase is primarily attributable to severance expenses for the former chief marketing officer and recruiting fees for the new chief executive officer and search for a new chief commercial officer.

Interest expense was $609,000 for the year ended December 31, 2015, as compared to $11,000 for the year ended December 31, 2014. Interest expense related to the venture loan and security agreement entered into with Horizon Technology Finance Corporation on December 23, 2014 was $456,000 and $11,000 for the years ended December 31, 2015 and 2014, respectively. Also included in interest expense for the year ended December 31, 2015 is $153,000 attributable to non-cash interest expense related to venture loan issuance costs, final payment obligations of the venture loan and fair value of the 2014 Warrants.

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 3 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.

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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, 2015 and 2014, and the related statements of operations, stockholders' equity, 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's 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, 2015 and 2014, 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 has incurred recurring losses from operations and has an accumulated deficit that 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 16, 2016

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INTERLEUKIN GENETICS, INC.

BALANCE SHEETS

	December 31, 2015	2014
ASSETS		
Current assets:		
Cash and cash equivalents	$4,706,018	$11,466,807
Accounts receivable from related party	39,989	23,544
Trade accounts receivable	45,973	14,013
Inventory	124,583	171,575
Prepaid expenses	778,970	504,719
Total prepaid expenses and other current assets	5,695,533	12,180,658
Fixed assets, net	643,900	773,779
Intangible assets, net	58,879	195,765
Other assets	93,208	116,919
Total assets	$6,491,520	$13,267,121
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$408,374	$513,927
Accrued expenses	497,688	343,225
Deferred revenue	3,238,541	3,154,498
Short term debt	1,333,333	—
Total current liabilities	5,477,936	4,011,650
Long term debt	3,474,984	4,738,614
Total liabilities	8,952,920	8,750,264
Stockholders' equity:		
Convertible preferred stock, $0.001 par value — 6,000,000 shares authorized; 0 shares issued and outstanding at December 31, 2015 and 2014, respectively	—	—
Common stock, $0.001 par value — 450,000,000 and 300,000,000 shares authorized; 172,887,221 and 172,683,342 shares issued and outstanding at December 31, 2015 and 2014, respectively	172,889	172,686
Additional paid-in capital	126,354,036	125,434,483
Accumulated deficit	(128,988,325)	(121,090,312)
Total stockholders' equity(deficit)	(2,461,400)	4,516,857
Total liabilities and stockholders' equity (deficit)	$6,491,520	$13,267,121

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

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INTERLEUKIN GENETICS, INC.

STATEMENTS OF OPERATIONS

	For The Year Ended December 31,	
	2015	2014
Genetic testing	$1,155,980	$1,641,490
Other	284,930	168,828
Total revenue	1,440,910	1,810,318
Cost of revenue	1,414,113	1,435,377
Gross profit	26,797	374,941
Operating expenses:		
Research and development	1,299,542	843,102
Selling, general and administrative	5,878,940	5,767,138
Amortization of intangibles	136,886	94,100
Total operating expenses	7,315,368	6,704,340
Loss from operations	(7,288,571)	(6,329,399)
Other income (expense):		
Interest income	222	4,935
Interest expense	(609,664)	(11,250)
Total other expense	(609,442)	(6,315)
Loss before income taxes	(7,898,013)	(6,335,714)
Net loss	$(7,898,013)	$(6,335,714)
Basic and diluted net loss per common share	$(0.05)	$(0.05)
Weighted average common shares outstanding, basic and diluted	172,813,224	123,768,139

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

INTERLEUKIN GENETICS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY

For the Years Ended December 31, 2015 and 2014

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Shares	Par Value	Capital	Deficit	Total
Balance as of December 31, 2013	—	—	122,448,707	$122,449	$119,885,371	$ (114,754,598)	$5,253,222
Net loss	—	—	—	—	—	(6,335,714)	(6,335,714)
Private placement of preferred stock, net of offering costs of $218,127	—	—	50,099,700	50,100	4,756,774	—	4,806,874
Warrants issued in connection with long term debt	—	—	—	—	261,386		261,386
Employee stock purchase plan	—	—	134,935	137	32,017	—	32,154
Stock-based compensation expense	—	—	—	—	498,935	—	498,935
Balance as of December 31, 2014	—	—	172,683,342	$172,686	$125,434,483	$ (121,090,312)	$4,516,857
Net loss	—	—	—	—	—	(7,898,013)	(7,898,013)
Common stock issued:							
Private placement	—	—	—	—	(8,095)		(8,095)
Horizon warrant	—	—	—	—	14,810	—	14,810
Employee stock purchase plan	—	—	203,879	203	20,751	—	20,954
Stock-based compensation expense	—	—	—	—	892,087	—	892,087
Balance as of December 31, 2015	—	—	172,887,221	$172,889	$126,354,036	$ (128,988,325)	$(2,461,400)

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

INTERLEUKIN GENETICS, INC.

STATEMENTS OF CASH FLOWS

	For the Year Ended December 31,	
	2015	2014
CASH FLOW FROM OPERATING ACTIVITIES:		
Net loss	$ (7,898,013)	$ (6,335,714)
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	349,254	262,961
Amortization of loan issuance costs and FV of warrants	108,224	—
Stock-based compensation expense	892,087	498,935
Changes in operating assets and liabilities:		
Receivable from related party	(16,445)	511,159
Trade accounts receivable	(31,960)	(5,196)
Inventory	46,992	18,849
Prepaid expenses and other assets	(274,251)	171,639
Accounts payable	(105,553)	(321,512)
Accrued expenses	154,463	90,272
Other Assets (lease deposit refund)	—	10,000
Deferred revenue	84,043	(628,943)
Net cash used in operating activities	(6,691,159)	(5,727,550)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Capital additions	(82,489)	(98,033)
Net cash used in investing activities	(82,489)	(98,033)
CASH FLOW FROM FINANCING ACTIVITIES:		
Proceeds from issuance of notes payable	—	5,000,000
Loan origination costs	—	(88,918)
Proceeds from private placement of common stock and warrants	—	5,025,000
Private placement offering costs	(8,095)	(218,127)
Proceeds from employee stock purchase plan	20,954	32,154
Net cash provided by financing activities	12,859	9,750,109
Net increase (decrease) in cash and equivalents	(6,760,789)	3,924,526
Cash and cash equivalents, beginning of period	11,466,807	7,542,281
Cash and cash equivalents, end of period	$ 4,706,018	$ 11,466,807
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 467,500	$ —
Supplemental disclosures of non-cash investing and financing activities:		
Warrants issued in connection with long term debt	$ —	$ 261,386

The accompanying notes are an integral part of these financial statements

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INTERLEUKIN GENETICS, INC.

NOTES TO FINANCIAL STATEMENTS

December 31, 2015

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 and Liquidity

The Company has experienced net operating losses since its inception through December 31, 2015. The Company had net losses of $7.9 million and $6.3 million for the years ended December 31, 2015 and 2014, respectively, contributing to an accumulated deficit of $129.0 million as of December 31, 2015.

The Company continues to take steps to reduce genetic test processing costs. Cost savings are primarily achieved through test process improvements. Management believes that the current laboratory space is adequate to process high volumes of genetic tests.

On May 17, 2013, the Company entered into a Common Stock Purchase Agreement (the "2013 Purchase Agreement") with various accredited investors (the "2013 Investors"), pursuant to which the Company sold securities to the 2013 Investors in a private placement transaction (the "May 2013 Private Placement"). In the May 2013 Private Placement, the Company sold an aggregate of 43,715,847 shares of our common stock at a price of $0.2745 per share for gross proceeds of $12,000,000. The 2013 Investors also received warrants to purchase up to an aggregate of 32,786,885 shares of common stock an exercise price of $0.2745 per share (the "2013 Warrants"). The 2013 Warrants are all

currently exercisable and have a term of seven years from the date they became exercisable.

On December 23, 2014, the Company entered into a Securities Purchase Agreement (the "2014 Purchase Agreement") with various accredited investors (the "2014 Investors"), pursuant to which the Company sold to the 2014 Investors in a private placement transaction (the "December 2014 Private Placement") an aggregate of 50,099,700 shares of common stock at a price of $0.1003 per share for gross proceeds of approximately $5.025 million. The 2014 Investors also received warrants (the "2014 Warrants") to purchase up to an aggregate of 50,099,700 shares of common stock an exercise price of $0.1003 per share. The 2014 Warrants are all currently exercisable and have a term of seven years.

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 financial statements do not include any adjustments that might result from the outcome of this uncertain realization. The Company expects to incur additional losses in 2016 and, accordingly, is dependent on financings and potential revenue to fund its operations and support the market adoption of the PerioPredict® test. The timing of any revenues that the Company may receive from the PerioPredict® test is uncertain at this time, and is contingent upon a number of factors, including the Company's ability to consummate arrangements with partners to promote the PerioPredict® test, the Company's partners' ability to develop insurance plans that provide for use and reimbursement of the PerioPredict® test and to develop a viable market for such plans, and the timing of utilization of the PerioPredict® test pursuant to such plans, or other possible arrangements. The Company expects to have the cash resources necessary to support the further commercialization of the PerioPredict® test at least into the second half of 2016.

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. The Company needs to generate additional funds in order to meet its financial obligations. 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—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, 2015 and December 31, 2014, the Company had deferred genetic test revenue of $3.2 million and $3.2 million, respectively. Included in deferred revenue at December 31, 2015 is $2.6 million for kits that are still outstanding one year or longer after initial kit sale, of which $0.3 million was sold directly to consumers (credit card payments) and $2.3 million was sold to distributors for the promotional bundle. Beginning in September 2012 and again in 2013, Access Business Group LLC ("ABG"), an affiliate of Alticor, placed purchase orders totaling approximately $3.3 million consisting of Weight Management test kits. The kits are included as part of a promotional bundle of products that Amway sold to their Individual Business Owners (IBOs).

The Company recognizes breakage revenue related to genetic test kits utilizing the remote method. Under the remote method, breakage revenue should be recognized when the likelihood of the customer exercising rights of redemption becomes remote. The term remote requires statistical analysis of customer redemption patterns for all tests sold and returned. The Company analyzed redemption patterns from 2009 through 2015 and determined the period of time after which the likelihood of test redemption was remote was three years after the sale of a genetic test kit. Included in genetic test revenue in the years ended December 31, 2015 and 2014 is $218,000 and $309,000, respectively, of breakage revenue related to unredeemed genetic test kits sold in 2012 and 2011, respectively. The Company expects to continue to recognize breakage revenue on a quarterly basis based on the historical analysis.

Sales Commission

On October 26, 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. ("Alticor"). 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. The Company accounts for sales commissions due to Amway Global under the Merchant Network and Channel Partner Agreement in accordance with SEC Staff Accounting Bulletin ("SAB") 104. Commissions are recorded as an expense at the time they become due which is at the point of sale. The cost of commissions was $302,000 and $218,000 for the years ended December 31, 2015 and 2014, 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 10 days of the invoice date. No accounts receivable reserve is required at December 31, 2015 as all accounts receivable are expected to be collected.

Inventory

Inventory is carried at lower of cost (first-in, first-out method) or market and no inventory reserve is deemed necessary at December 31, 2015. As the Company does not manufacture any products, no overhead costs are included in inventory. The Company has contracted with a fulfillment provider to supply its PerioPredict® genetic tests kits to dental offices. The agreement with the fulfillment provider requires them to purchase and fulfill all materials related to the PerioPredict® test and Body Key™ genetic test kits, with the Company's approval. The Company reimburses the fulfillment provider for materials and pays fulfillment charges when the product is shipped. During the year ended December 31, 2015, the Company made a one-time purchase of $33,000 of inventory related to its PerioPredict® test from our fulfillment provider, which is held at our fulfillment center. The balance of our inventory is related to our Inherent Health® brand and is stored at a separate facility. When a kit is sold, the corresponding cost of the kit is recorded as deferred cost of goods sold and removed from inventory. Any kit components remaining at the fulfillment center are reflected in inventory with a corresponding offset to accounts payable.

Inventory consisted of the following at December 31, 2015 and 2014:

	December 31, 2015	December 31, 2014
Raw materials	$ 112,372	$ 163,239
Finished goods	12,211	8,336
Total inventory, net	$ 124,583	$ 171,575

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. The Company expenses 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 $33.5 million as of December 31, 2015, 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.

As a result of the Company's change in its capital structure during the quarters ended June 30, 2013 and December 31, 2014, the Company may have undergone IRC section 382 ownership changes which would limit its ability to realize the benefit of its tax attributes (i.e., federal/state net operating losses and research and development credits) during their respective carry forward periods. Furthermore, pursuant to the change in capital structure in the quarter ended June 30, 2013, the Company realized cancellation of indebtedness income under IRC section 108(e)(8), which reduced the Company's federal net operating loss carry-forward pursuant to IRC section 108(b)(2)(A), due to the fact that the Company's liabilities exceeded the fair market value of its assets. Accordingly, the Company had a reduction in its deferred tax asset and a corresponding reduction in its valuation allowance for the quarter ending June 30, 2013. The cancellation of indebtedness income resulted from a shareholder's conversion of debt of approximately $14.3 million into common stock of the Company prior to an additional investment by an unrelated investor.

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 year ended December 31, 2015. 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.

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 are as follows:

	As of December 31,	
	2015	2014
Options outstanding	21,657,776	4,523,900
Warrants outstanding	88,301,079	89,951,079
Total	109,958,855	94,474,979

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, 2015 and 2014, 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 short term nature of these instruments. The fair value of warrants is calculated using the Black-Scholes pricing model.

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, 2015, its concentration of credit risk related to cash and cash equivalents was not significant. Cash and cash equivalents are available on demand and are generally 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 shorter of the estimated useful life of the asset or the remaining term of the lease.

Assets that have not yet been placed in service, have the costs incurred presented as part of Projects in Progress. Once the asset has been placed in service, the related costs are transferred to the appropriate category and depreciation commences. There are no items in Projects in Process for the year ended December 31, 2015.

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. For the year ended December 31, 2015, the Company recorded a write down of $66,000 associated with the patents that no longer were needed to support the Company’s business. The Company determined that no impairment existed related to the Company’s long-lived assets at December 31, 2015.

Segment Reporting

As of December 31, 2015 and 2014, 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

FASB ASU 2015-03 - Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs.

In April 2015, the FASB issued ASU No. 2015-03, which requires that debt issuance costs be reported in the balance sheet as a direct deduction from the face amount of the related liability, consistent with the presentation of debt discounts. Prior to the amendments, debt issuance costs were presented as a deferred charge (i.e., an asset) on the balance sheet. Further, the amendments require the amortization of debt issuance costs to be reported as interest expense. Similarly, debt issuance costs and any discount or premium are considered in the aggregate when determining the effective interest rate on the debt. The amendments are effective for public business entities for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The amendments must be applied retrospectively. All entities have the option of adopting the new requirements as of an earlier date for financial statements that have not been previously issued. The Company does not expect this ASU to have a material impact on its consolidated financial statements.

FASB ASC 606 ASU 2014-09 - Revenue from contracts with customers.

In May 2014, the FASB issued amended guidance on contracts with customers to transfer goods or services or contracts for the transfer of nonfinancial assets, unless those contracts are within the scope of other standards (e.g., insurance contracts or lease contracts). The guidance requires an entity to recognize revenue on contracts with customers to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The guidance requires that an entity depict the consideration by applying the following five steps:

- Identify the contract(s) with a customer.

- Identify the performance obligations in the contract.
- Determine the transaction price.
- Allocate the transaction price to the performance obligations in the contract.
- Recognize revenue when (or as) the entity satisfies a performance obligation.

The amendments in this ASU are effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early application is not permitted. This amendment is to be either retrospectively adopted to each prior reporting period presented or retrospectively with the cumulative effect of initially applying this ASU recognized at the date of initial application. The Company is evaluating the impact of the adoption of this guidance to determine whether or not it has a material impact on the Company's financial statements.

In April 2015, the FASB voted to defer the required implementation date of ASU 2014-09 to December 2017. Public companies may elect to adopt the standard along the original timeline. We are evaluating the impact of the adoption of this guidance to determine whether or not it has a material impact on the Company's financial statements.

FASB ASC 606 ASU 2014-15 - Presentation of Financial Statements—Going Concern (Subtopic 205-40); Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.

In August 2014, the FASB issued ASU No. 2014-15, which applies should a company be facing probable liquidation within one year of the issuance of the financial statements, but is not actually in liquidation at the time of issuance. The applicable basis for presentation remains as a going concern, but if liquidation within one year is probable, then certain disclosures must be included in the financial statement presentation. ASU 2014-15 is effective for annual and interim periods beginning after December 15, 2016, with early adoption permitted. The Company is not electing to adopt early and is evaluating the impact of ASU 2014-15 on the Company's financial disclosures.

Note 4—Related Party Transactions

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

On October 26, 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 $302,000 and $218,000 in commissions for the years ended December 31, 2015 and 2014, 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.

Beginning in September 2012 and again in 2013, Access Business Group LLC ("ABG"), an affiliate of Alticor, placed purchase orders totaling approximately $3.3 million consisting of Weight Management test kits. The kits are included as part of a promotional bundle of products that Amway sold to their Individual Business Owners (IBOs). Of the $3.3 million in orders, $1.5 million was received for the 2013 program and $1.8 million for the 2014 program. As a component of the 2013 promotional program, and not reflective of actual product expiry, the kits were required to be redeemed by December 31, 2013. In February 2014, the Company removed the redemption date requirement for the 2013 promotional program, for which ABG paid the Company $519,000 as a retrospective increase in the product purchase price. All cash received related to the 2013 promotional program, including the $519,000, will be treated as deferred revenue until specific kits are returned for processing or the breakage analysis determines the probability of eventual redemption is remote. In October 2014, the Company received $250,000 as a retrospective increase in the product purchase price for unsold kits as consideration for extending the required redemption date of the 2014 promotional program to December 31, 2017. All cash received for these kits will be treated as deferred revenue until

specific kits are returned for processing or on the final allowed redemption date of December 31, 2017.

On September 21, 2012, the Company entered into a License Agreement with Access Business Group International LLC ("ABGI"), an affiliate of Alticor. 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 which was June 2013. Thereafter, the term will automatically renew for additional one-year periods unless notice is delivered by either party at least 60 days prior to the anniversary date. During the years ended December 31, 2015 and 2014, $191,000 and $150,000, respectively, of revenue was earned.

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. No fees were earned in the years ended December 31, 2015 and 2014 under the PSA.

For years ended December 31, 2015 and 2014, approximately 45% and 44%, respectively, of our revenue came from sales through our Merchant Network and Channel Partner Agreement with Amway Global, a subsidiary of Alticor, and 13% and 32%, respectively, of our revenue came from sales through ABG's promotional product bundle program.

On February 25, 2013, the Company entered into a Preferred Participation Agreement with Renaissance Health Services Corporation ("RHSC"), for itself and on behalf of certain of its affiliates and subsidiaries. This agreement was amended and restated on November 1, 2013. RHSC is a related party through its affiliation with Delta Dental of Michigan, Inc. ("DDMI"), a stockholder of the Company. Pursuant to this agreement, as amended, affiliates of RHSC agreed to reimburse the Company a fixed price for each PerioPredict® genetic test that the Company processed for a customer of affiliates of RHSC. This amended agreement had a term of three years beginning February 25, 2013, unless 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 amended agreement by either party. This agreement terminated on February 25, 2016.

Note 5—Debt Instruments

Venture Loan and Security Agreement

On December 23, 2014, the Company entered into the Loan Agreement with Horizon Technology Finance Corporation (the "Lender") under which the Company borrowed $5.0 million. The loan bears interest at a floating rate equal to the One Month LIBOR Rate (with a floor of 0.50%) plus 8.50%. In the event that the One Month LIBOR Rate, as reported in the Wall Street Journal, exceeds 0.50%, the interest rate will be adjusted by an amount equal to the difference between such rates at the end of that particular month. At December 31, 2015, the rate was 9.0% per annum. The loan is to be repaid in forty-five (45) monthly payments consisting of fifteen (15) monthly payments of only interest followed by thirty (30) equal monthly payments of principal and interest. In addition, at the end of the repayment term (or at early termination of the loan) a final payment equal to 4.5% of the loan, or $225,000, will be due and payable. The Company's obligations under the Loan Agreement are secured by a first priority security interest in substantially all of its assets other than its intellectual property. The Company has also agreed not to pledge or otherwise encumber its intellectual property assets, subject to certain exceptions. In connection with the Loan Agreement, the Company issued to the Lender and its affiliates warrants to purchase a total of 2,492,523 shares of common stock at an exercise price of $0.1003 per share, which the Company refers to herein as the Lender Warrants. The Lender Warrants have a term of ten (10) years.

Additionally, $89,000 in cash fees paid to the Lender and $261,000, the intrinsic value of the Lender Warrants, were recorded as a discount on the loan and amortized over the term of the loan. The final non-principal payment of $225,000 will be accrued as additional interest expense, using the effective interest method, over the term of the loan. As of December 31, 2015, the unamortized discount associated with the loan was $257,000. Cash interest expense for the years ended December 31, 2015 and 2014 was $456,000 and $11,000, respectively. Non-cash interest expense for the years ended December 31, 2015 and 2014 was $153,000 and $0, respectively.

Note 6—Fixed Assets

The useful lives and balances of fixed assets at December 31, 2015 and 2014 consisted of the following:

	Useful Life	2015	2014
Computer software, computer equipment and office equipment	3 years	$ 516,511	$ 477,222
Laboratory equipment	5 years	1,887,454	1,837,504
Furniture and fixtures	5 years	40,349	40,349

Leasehold improvements	5 years	309,618	309,618
Website development	3 years	298,553	298,553
Projects in Progress		—	6,750
		3,052,485	2,969,996
Less — Accumulated depreciation and amortization		(2,408,585)	(2,196,217)
Total		$ 643,900	$ 773,779

Depreciation and amortization expense was $212,000 and $169,000, for the years ended December 31, 2015 and 2014, respectively.

Note 7—Intangible Assets

Intangible assets at December 31, 2015 and 2014 consisted of the following:

	2015	2014
Patent costs	$1,154,523	$1,154,523
Less — Accumulated amortization	(1,029,497)	(958,758)
Less — Write off related to patents no longer in use	(66,147)	—
Total	$58,879	$195,765

Patent amortization expense was $136,900 and $94,100 for the years ended December 31, 2015 and 2014, respectively.

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

Year ended December 31,	
2016	33,450
2017	19,117
2018	6,312
	$58,879

Note 8—Accrued Expenses

Accrued expenses at December 31, 2015 and 2014 consisted of the following:

	2015	2014
Payroll and vacation	$412,674	$328,972
Other	85,014	14,253
Total accrued expenses	$497,688	$343,225

Note 9—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

Mark B. Carbeau

On April 6, 2015 the Company entered into an Executive Employment Agreement (the "Agreement"), pursuant to which Mark B. Carbeau was appointed as the Company's Chief Executive Officer and a member of the Company's Board of Directors. Effective upon Mr. Carbeau's appointment, Dr. Kenneth S. Kornman resigned as Chief Executive Officer and remained as the Company's President and Chief Scientific Officer.

Pursuant to the Agreement, Mr. Carbeau will receive an initial annual base salary of $365,000 per year and is eligible to receive an annual target bonus of 35% of his base salary, with a stretch bonus opportunity of 150% of the target bonus. Under the terms of the Agreement, Mr. Carbeau has been granted options to purchase up to 14,245,227 shares of Interleukin's common stock (the "Options") at an exercise price of $0.1525 per share (the closing price of the common stock on April 6, 2015). The Options will vest as to 25% of the shares on April 6, 2016, and as to an additional 2.083% of the shares on the last day of each successive month thereafter, provided that he remains employed by Company on the vesting date.

The Agreement provides that if Mr. Carbeau's employment with the Company is terminated for any reason other than Cause (as defined in the Agreement) and on execution of a release of claims agreement, he will be entitled to (i) severance payments equal to 12 months of base salary and (ii) continuation of medical benefits for up to 12 months. In addition to the above, if termination is within one year following a Change of Control event and is for any reason other than Cause, all outstanding unvested equity awards held by Mr. Carbeau will immediately vest and be exercisable.

Kenneth S. Kornman, DDS, Ph.D.

On November 12, 2008, the Company entered into an employment agreement with Dr. Kornman, its President and Chief Scientific Officer, for a three-year term, commencing on March 31, 2009, the date his previous employment agreement expired. Effective March 31, 2012, this agreement was extended through November 30, 2012, and was extended again on November 20, 2012 through November 30, 2015. Under this agreement, Dr. Kornman received an initial annual salary of $360,000 and is eligible to receive annual bonuses solely at the discretion of the Board of Directors. Under the agreement, on November 12, 2008 Dr. Kornman received a stock option to purchase 75,000 shares of common stock at an exercise price of $0.48 per share (the closing price of the common stock on the grant date). The option is fully vested.

The Company entered into a new employment agreement with Dr. Kornman on December 1, 2015 (the “Agreement”), pursuant to which Dr. Kornman will receive an initial annual salary of $360,000, is eligible to receive annual bonuses solely at the discretion of the Board of Directors, and received a stock option to purchase 400,000 shares of common stock at an exercise price of $0.07 per share (the closing price of the common stock on the grant date), which option will vest over a four year period in 48 equal monthly installments on the first day of each month beginning January 1, 2016. If at any time within the 90 days prior to or 12 months following the effective date of a Change in Control, Dr. Kornman is terminated without Cause (as such terms are defined in the Agreement), this option shall become fully vested and exercisable as of the date of termination, and the Company will pay him an amount equal to his base pay in effect at the time of such termination for a period commencing on the effective date of a release agreement and ending on the six moth anniversary of such effective date. The agreement can be terminated by Dr. Kornman or the Company at any time for any reason, with or without advance notice. Under the Agreement, Dr. Kornman is entitled to participate in employee benefit plans that the Company provides or may establish for the benefit of its executive management generally. In addition, while Dr. Kornman remains employed by the Company, it will reimburse him $3,296 annually for payment of life insurance premiums.

On March 31, 2010, Dr. Kornman was issued 12,500 shares of restricted stock under a restricted stock agreement dated April 30, 2008. In April 2010, as part of the year-end compensation process, the Compensation Committee granted Dr. Kornman an option to purchase 30,000 shares of the Company’s common stock. This option is exercisable at $0.745 per share and vests as to 20% of the shares on each of the first five anniversaries of the date of grant.

In May 2011, the Compensation Committee granted Dr. Kornman an option to purchase 100,000 shares of the Company’s common stock. This option is exercisable at $0.46 per share and vests as to 25% of the shares on each of the first four anniversaries of the date of grant.

In December 2012, the Compensation Committee granted Dr. Kornman an option to purchase 300,000 shares of the Company’s common stock. This option is exercisable at $0.34 per share and vests as to 25%, 33% and 42% of the

shares on each of the first three anniversaries of the date of grant.

In October 2013, Dr. Kornman was granted an option to purchase 2,250,000 shares of the Company's common stock. This option has an exercise price of $0.3799, the fair value of the Company's common stock on the grant date of the option, and will vest as to 1/4 of the shares on the first anniversary of the grant date, and as to 1/36 of the remaining shares at the end of each month thereafter beginning on October 31, 2014.

In January 2015, Dr. Kornman was granted an option to purchase 2,030,000 shares of the Company's common stock. This option has an exercise price of $0.26 per share. The option vests as to 1/48 of the shares at the beginning of each month beginning on February 1, 2015.

Scott Snyder

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 was eligible for a bonus pursuant to the Bonus Plan as described below under "Employee Bonus Plan." Mr. Snyder's employment with the Company terminated effective November 13, 2015.

The Company will pay Mr. Snyder any compensation that is earned but unpaid prior to termination, and an amount equal to six months of his base salary in effect at the time of the termination with such payment made in equal installments on the Company's regularly-scheduled payroll dates. All stock options granted to Mr. Snyder expired unexercised as of February 11, 2016.

Bonus Plan

On February 26, 2014, the Compensation Committee approved an Employee Bonus Plan (the "Employee Bonus Plan") that replaces the Bonus Plan approved on December 21, 2012. Under the Employee Bonus Plan, bonuses may be awarded upon the achievement of corporate goals, however, the Compensation Committee has absolute discretion as to whether bonuses will be awarded and the size of any bonus, notwithstanding whether any such corporate goals are met. Bonus accruals totaling $166,000 were recorded in 2015 in accrued expenses on the balance sheet. In January 2016, the Board of Directors approved the 2015 bonus disbursement, which occurred in February 2016.

Operating Leases

The Company leases its office and laboratory space under a non-cancelable operating lease which was originally scheduled to expire on March 31, 2014. In May 2010, the Company completed a sublease of 6,011 square feet of underutilized office and laboratory space and on March 31, 2014, the sublease expired. On February 7, 2014, the Company entered into the Second Amendment to Commercial Lease which, among other things a) extended the term of the lease from March 31, 2014 to March 31, 2017; b) reduced the 19,000 square feet, the amount of space under the master lease, by approximately 6,011 square feet, to approximately 13,000 square feet, which is the amount of space the Company currently occupies; and, c) set an initial base rent with an escalation of 2.06% of base rent in year two and another 2.06% in year three.

Future minimum lease commitments under non-cancelable lease agreements with initial or remaining terms of one year or more at December 31, 2015, are as follows:

Year Ended December 31,	Office Lease	Copier Lease	Net Lease	Office Equipment	Total Payments, Net
2016	326,349	6,624	332,973	2,226	335,199
2017	81,993	6,624	88,617	2,226	90,843
2018	—	1,104	1,104	1,484	2,588
	$ 408,342	14,352	$422,694	$ 5,936	$ 428,630

Rent expense, net of the benefit of the sublease in 2014, was $352,682 and $309,891 for the years ended December 31, 2015 and 2014, respectively. The February 2014 lease amendment states an initial base rent with an escalation of 2.06% of base rent in year two and another 2.06% in year three.

Note 10—Capital Stock

Authorized Preferred and Common Stock

As of December 31, 2015, the Company has 6,000,000 shares of preferred stock, par value $0.001 authorized and 450,000,000 shares of common stock, par value $0.001 authorized. As of December 31, 2015 the Company has 172,887,221 shares of common stock outstanding and the following shares of common stock are reserved for issuance:

	Reserved for issuance	Strike Price	**Expiry**
Shares reserved under outstanding stock options and options available for grant	52,307,279		
Shares reserved for future issuance under the Employee Stock Purchase Plan	300,073		
Warrants to purchase common stock associated with December 2014 private placement	50,189,431	$0.1003	December 23, 2021
Warrants to purchase common stock associated with December 2014 venture loan and security agreement	2,492,523	$0.1003	December 23, 2024
Warrants to purchase common stock associated with September 2014 consulting agreement with Danforth Advisors	100,000	$0.2500	September 8, 2024
Outstanding warrants issued in June 2012	437,158	$0.2745	June 29, 2017
Outstanding warrants issued in May 2013, vesting May 2013	20,655,737	$0.2745	May 17, 2020
Outstanding warrants issued in May 2013, vesting August 2013	14,426,230	$0.2745	August 9, 2020
Total common shares reserved for issuance at December 31, 2015	140,908,431		
Total common shares issued and outstanding at December 31, 2015	172,887,221		
Total common shares outstanding and reserved for issuance at December 31, 2015	313,795,652		

On May 17, 2013, the Company entered into the 2013 Purchase Agreement with the 2013 Investors, pursuant to which the Company sold securities to the 2013 Investors in the May 2013 Private Placement. In the May 2013 Private Placement, the Company sold an aggregate of 43,715,847 shares of its common stock at a price of $0.2745 per share for gross proceeds of $12,000,000. The 2013 Investors also received the 2013 Warrants to purchase up to an aggregate of 32,786,885 shares of common stock an exercise price of $0.2745 per share. The 2013 Warrants were immediately exercisable as to 63% of the shares issuable thereunder. The remaining 37% of the shares issuable under the 2013 Warrants were to become exercisable upon an increase in the number of authorized shares of common stock. On August 9, 2013, the Company's shareholders' approved an amendment to the Company's Certificate of Incorporation to increase the number of authorized shares of common stock from 150,000,000 to 300,000,000 shares, which provided for adequate authorized shares for all potential common stock equivalents issued pursuant to the May 2013 Private Placement. The 2013 Warrants are all currently exercisable and have a term of seven years from the date they became exercisable.

For its services in this transaction, the placement agent received cash compensation in the amount of approximately $780,000 and the placement agent and an affiliate received warrants to purchase an aggregate of 2,295,082 shares of common stock, at an exercise price of $0.2745 per share (the "2013 Placement Agent Warrants"). The 2013 Placement Agent Warrants became exercisable on August 9, 2013, following shareholder approval of an increase in the Company's authorized shares of common stock and expire August 9, 2020. The cash compensation and the fair value of the warrants were recorded as issuance costs resulting in a reduction to shareholders' equity.

In connection with this private placement, all preferred stockholders converted their shares of Preferred Stock to common stock resulting in the issuance of 39,089,161 shares of common stock.

In addition, pursuant to the 2013 Purchase Agreement, each Investor had the right, at any time on or before June 30, 2014 (the "Exercise Date"), to purchase at one or more subsequent closings its pro rata share of up to an aggregate of 18,214,936 additional shares of common stock at a purchase price of $0.2745 per share and 2013 Warrants to purchase up to an aggregate of 13,661,201 shares of common stock at an exercise price of $0.2745 per share. The Exercise Date was extended until December 31, 2014, and this right expired unexercised.

In September, 2014, the Company issued warrants to the Company's financial consultant, Danforth Advisors, to purchase up to 100,000 shares of common stock at a price of $0.25 per share. The warrants have a ten year term and vest on a monthly basis over two years, provided that, if the Company terminates the agreement without cause before the one year anniversary, 50% of the warrants immediately vest, and the remaining 50% of the warrants immediately vest if the Company terminates the agreement without cause after the extension of the agreement after one year. The warrant will also become exercisable in full upon a change of control of the Company if the agreement is still in effect. The fair value of the warrants at issuance was recorded as equity totaling $24,000 and will be amortized to consulting fees over the remaining service requirement. The non-cash compensation expense for the years ended December 31, 2015 and 2014 was $12,000 and $3,000 respectively.

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On December 23, 2014, the Company entered into the 2014 Purchase Agreement with the 2014 Investors, pursuant to which it sold to the 2014 Investors in the December 2014 Private Placement an aggregate of 50,099,700 shares of common stock at a price of $0.1003 per share for gross proceeds of approximately $5.025 million. The 2014 Investors also received 2014 Warrants to purchase up to an aggregate of 50,099,700 shares of common stock at an exercise price of $0.1003 per share. The 2014 Warrants are all currently exercisable and have a term of seven years.

For services related to this transaction, the placement agent and legal counsel received an aggregate of $218,000 in cash fees and the placement agent and an affiliate received warrants to purchase an aggregate of 89,731 shares of common stock (the “2014 Placement Agent Warrants”). The cash fees and the fair value of the 2014 Placement Agent Warrants were recorded as equity issuance costs resulting in a reduction to shareholders’ equity.

The 2014 Warrants were recorded as equity at fair value on the date of issuance. Fair value of the 2014 Warrants was calculated using the following inputs in a Black-Scholes model:

	December 23, 2014	
Risk-free interest rate	1.98	%
Expected life	O years	
Expected volatility	138.4	%
Dividend yield	0	%

On the closing date of the December 2014 Private Placement, the fair value of the 2014 Warrants was $5.2 million, and the fair value of the 2014 Placement Agent Warrants was $9,000.

Registration Rights Agreements

In connection with the December 2014 Private Placement, on December 23, 2014, the Company also entered into a Registration Rights Agreement with the 2014 Investors and the placement agent, pursuant to which the Company was required to file a registration statement on Form S-1 within 45 days of December 23, 2014 to cover the resale of (i) the shares of common stock sold to the 2014 Investors and the shares of common stock underlying the 2014 Warrants and (ii) the shares of common stock underlying the 2014 Placement Agent Warrants. The Company filed the registration statement on February 6, 2015, and it was declared effective on March 31, 2015.

Venture Loan and Security Agreement

On December 23, 2014, the Company entered into the Loan Agreement with Horizon Technology Finance Corporation (the “Lender”) under which the Company has borrowed $5.0 million. In connection with the Loan Agreement, the Company issued to the Lender and its affiliates Lender Warrants to purchase a total of 2,492,523 shares of common stock at an exercise price of $0.1003 per share. The Lender Warrants have a term of ten (10) years.

The Lender Warrants were recorded as equity at fair value on the date of issuance. Fair value of the Lender Warrants was calculated using the following inputs in a Black-Scholes model:

	December 23, 2014	
Risk-free interest rate	2.17	%
Expected life	10 years	
Expected volatility	121.6	%
Dividend yield	0	%

The fair value of the Lender Warrants at issuance was $261,000. Cash interest paid during the years ended December 31, 2015 and 2014 totaled $467,500 and $0, respectively. Non-cash interest related to debt discounts recorded during the years ended December 31, 2015 and 2014 totaled was $153,000 and $0, respectively, with a remaining debt discount balance of $257,000 as of December 31, 2015.

Principal payments due under the terms of the Loan Agreement are as follows:

2016	1,333,333
2017	2,000,000
2018	1,666,667
	$5,000,000

Note 11—Stock-Based Compensation Arrangements

On August 9, 2013, the Company's shareholders' approved the 2013 Employee, Director and Consultant Equity Incentive Plan (the "2013 Plan"). The 2013 Plan allows for the issuance of up to 8,860,000 additional shares of our common stock pursuant to awards granted under the 2013 Plan. Additionally, the 2013 plan allows for the issuance of up to a maximum of 2,435,500 additional shares of our common stock, pursuant to the cancellation, forfeiture, or expiry, of awards granted under the 2004 Plan and terminated on or after the 2013 plan approval on August 9, 2013. During the year ended December 31, 2015, the Company granted 6,570,748 stock options under the 2013 Plan. On July 21, 2015, the Company's stockholders approved an amendment to the 2013 Plan to increase the number of shares of common stock available for issuance thereunder by 30,000,000 shares. At December, 2015, the Company had an aggregate of 30,649,503 shares of common stock available for grant under the 2013 Plan.

Pursuant to his Employment Agreement on April 6, 2015, Mr. Carbeau was granted options to purchase up to 14,245,227 shares of Interleukin's common stock at an exercise price of $0.1525 per share (the closing price of the common stock on April 6, 2015). Of those options, 2,622,948 were granted under the 2013 Plan and 11,622,279 were granted outside of the 2013 Plan. The options will vest as to 25% of the shares on April 6, 2016, and as to an additional 2.083% of the shares on the last day of each successive month thereafter, provided that he remains employed by Company on the vesting date.

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 2015 and 2014, the Black-Scholes option-pricing model was used with the following weighted-average assumptions:

	2015		2014	
Risk-free interest rate	1.54	%	1.53	%
Expected life	5.73 years		5.73 years	
Expected volatility	138.80	%	144.74	%
Dividend yield	0	%	0	%

Using these assumptions, the weighted average grant date fair value of options granted in 2015 and 2014 was $0.16 and $0.32, 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, 2015 and 2014, 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 years ended December 31, 2015 and 2014, employees purchased 203,879 and 134,935 shares, respectively, of common stock at a weighted-average purchase price of $0.10 and $0.24, respectively, while the weighted-average market value was $0.12 and $0.28 per share, respectively, resulting in compensation expense of $4,053 and $5,437, respectively.

The following table details stock option and restricted stock activity for the years ended December 31, 2015 and 2014.

	2015		2014	
	Shares	Weighted Avg. Exercise Price	Shares	Weighted Avg. Exercise Price
Outstanding, beginning of period	4,523,900	$ 0.39	5,884,050	$ 0.43
Granted	18,193,027	0.17	137,000	0.35
Stock options exercised	—	0.00	—	0.00
Restricted stock exercised	—	0.00	—	0.00
Forfeited/Expired	(1,059,151)	0.17	(1,497,150)	0.53
Outstanding, end of period	21,657,776	$ 0.21	4,523,900	$ 0.39
Exercisable, end of period	3,665,124	$ 0.32	1,645,161	$ 0.43

The following table details further information regarding stock options and restricted stock outstanding and exercisable at December 31, 2015:

	Stock Options/Restricted Stock Outstanding			Stock Options/Restricted Stock Exercisable	
Range of Exercise Price:	Shares	Weighted Avg. remaining contractual life (years)	Weighted Avg. Exercise Price	Shares	Weighted Avg. Exercise Price
$0.01–$1.00	21,612,776	8.92	$ 0.21	3,620,124	$ 0.35
$1.01–$2.00	45,000	2.25	1.40	45,000	1.40
$2.01–$3.00	—	—	—	—	—
$3.01–$4.00	—	—	—	—	—

$4.01–$5.00	—	—	—	—	—
	21,657,776	8.90	$ 0.21	3,665,124	$ 0.37
Aggregate intrinsic value	$ 0			$ 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, 2015, of $0.0585.

The following table summarizes the status of the Company's non-vested options for the years ended December 31, 2015 and 2014:

	2015		2014	
	Shares	Weighted Avg. Exercise Price	Shares	Weighted Avg. Exercise Price
Non-vested options, beginning of year	2,878,739	$ 0.37	5,295,300	$ 0.38
Granted	18,193,027	0.17	137,000	0.35
Vested	(2,038,435)	0.33	(1,360,436)	0.38
Forfeited	(1,040,679)	0.17	(1,193,125)	0.38
Non-vested options, end of year	17,992,652	$ 0.18	2,878,739	$ 0.37

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

	Year Ended December 31,	
	2015	2014
Stock option grants beginning of period	$ 730,102	$ 492,332
Stock-based arrangements during the period:		
Stock option grants	157,932	1,166
Restricted stock issued:		
Employee stock purchase plan	4,053	5,437
Director agreements	—	—
	$ 892,087	$ 498,935

As of December 31, 2015 and 2014, there was approximately $2,248,591 and $835,551 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 3.11 and 2.6 years, respectively.

Note 12—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, 2015 and 2014, $2,239 and $7,105, respectively, was contributed by the Company to the plan.

Note 13—Income Taxes

For the years ended December 31, 2015 and 2014, 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 2015 or 2014 as it has recorded a valuation allowance against net operating losses and other net deferred tax assets due to uncertainties related to the ability of these tax assets to be realized.

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, 2015 and 2014, the expected income tax effect of the Company's deferred tax assets (liabilities) consisted of the following:

	2015	2014
Deferred tax asset:		
Tax effect of:		
Net operating loss carryforwards	$29,122,000	$26,754,000
Accrued expenses	87,000	105,000
Amortization of definite lived intangible assets	10,000	12,000
Non-qualified stock option compensation	315,000	113,000
Depreciation	72,000	97,000
Deferred revenue	880,000	930,000
Other	139,000	146,000
Patents	(23,000)	(77,000)
State net operating loss carryforwards, net of federal tax benefit	579,000	214,000
Research tax credit carryforwards	2,274,000	2,169,000
Total deferred tax assets	33,455,000	30,463,000
Valuation allowance	(33,455,000)	(30,463,000)
Net deferred tax assets	$-	$-

As of December 31, 2015, the Company had gross net operating loss (NOL) and research tax credit carryforwards of approximately $88.2 million and $1.6 million, respectively, for federal income tax purposes, expiring in varying amounts through the year 2035. Of the $88.2 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, 2015, the Company had gross NOL and research tax credit carryforwards of approximately $11.0 million and $1.0 million for state income tax purposes, expiring in varying amounts through the year 2035.

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. In addition, the Company's equity offerings, including those in 2013 and 2014, may have resulted in qualifying changes in ownership. A formal study, which the Company has not undertaken, is required to determine applicability of restrictions, and might indicate that the Company's NOL carryforwards are subject to additional limitations on utilization.

The Company is subject to taxation in the United States and the Commonwealth of Massachusetts. As of December 31, 2015, tax years for 2012, 2013 and 2014 are subject to examination by the tax authorities. As of December 31, 2015 we are no longer subject to U.S. federal and state examinations by tax authorities for years before 2012.

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

	2015	2014
Tax at statutory rate	(34.0)%	(34.0)%
State taxes, net of federal benefit	0.0	0.0
Research and development credit	(1.3)	(1.4)
Share based payment expense	1.6	1.8
Other	0.7	1.5
Removal of deferred tax asset on federal net operating losses	0.0	0.0
Establishment of deferred tax asset on state net operating losses and state deferred taxes, net of federal income tax benefits	(4.9)	(3.8)
Change in valuation allowance	37.9	36.0
Effective tax rate	0.0 %	0.0 %

Note 14—Risks and Uncertainties

The Company develops genetic risk assessment tests and performs research for its own benefit. As of December 31, 2015, 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 being deemed to be scientifically credible and cost-effective by consumers and the marketing success of the Company and its collaborative partners.

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, 2015 and 2014, approximately 45% and 44%, respectively, of the Company's revenue came from sales through our Merchant Network and Channel Partner Agreement with Amway Global, a subsidiary of Alticor, and 13% and 32%, respectively, of our revenue came from sales through ABG's promotional product bundle program.

Note 15—Subsequent Event

Effective February 1, 2016, the Company entered into an agreement with Metagenics, Inc., pursuant to which the Company will provide genetic testing and patient education to Metagenics employees, as well as dental professional support to their dental providers.

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 the Company 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**.**

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, 2015. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 revised guidelines. Based on our assessment and an independent review performed in 2015, management believes that, as of December 31, 2015, 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 2016 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 2016 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 2016 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 2016 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 2016 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	Restated Certificate of Incorporation of the Company, as filed with the Delaware Secretary of State on October 23, 2013 (incorporated herein by reference to Exhibit 3.1 of the Company’s Quarterly Report on Form 10-Q filed November 14, 2013)
3.1.2	Certificate of Amendment of Restated Certificate of Incorporation of the Company, as filed with the Delaware Secretary of State on July 21, 2015 (incorporated herein by reference to Exhibit 3.1 of the Company’s Current Report on Form 8-K filed July 23, 2015)

Exhibit No.	Identification of Exhibit
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 4.1 of the Company's Current Report on Form 8-K filed on March 5, 2010)
4.3	Form of Warrant issued to Investors in the May 2013 Private Placement (incorporated herein by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on May 20, 2013)
4.4	Form of Warrant issued to the Placement Agent in the May 2013 Private Placement (incorporated herein by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed on May 20, 2013)
4.5	Form of Warrant issued to the Investors and the Placement Agent in the December 2014 Private Placement (incorporated herein by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on December 23, 2014)
4.6	Form of Warrant issued to Horizon Technology Finance Corporation and its affiliates in the December 2014 Debt Transaction (incorporated herein by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed on December 23, 2014)
4.7	Common Stock Purchase Warrant, dated September 8, 2014, issued to Danforth Advisors, LLC (incorporated herein by reference to Exhibit 4.5 of the Company's Registration Statement on Form S-1 filed on February 6, 2015 (File No.: 333-201908))
	Leases
10.1.1	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)
10.1.2	Second Amendment to Commercial Lease, dated as of February 7, 2014, by and between the Company and Clematis, LLC (incorporated herein by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on February 12, 2014)
	Equity Compensation Plans
10.2.1@	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)
10.2.2@	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)
10.2.3@	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)
10.3.1@	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)
10.3.2@	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)
10.3.3@	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)
10.4.1@	2013 Employee, Director and Consultant Equity Incentive Plan, as amended (incorporated herein by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on July 23, 2015)
10.4.2@	Form of Nonqualified Stock Option Agreement under the 2013 Employee, Director and Consultant Equity Incentive Plan (incorporated by reference to Exhibit 10.6.2 of the Company's Annual Report on Form 10-K filed on March 20, 2014)
10.4.3@	Form of Incentive Stock Option Agreement under the 2013 Employee, Director and Consultant Equity Incentive Plan (incorporated by reference to Exhibit 10.6.3 of the Company's Annual Report on Form 10-K filed on March 20, 2014)
	Agreements with Executive Officers and Directors
10.5@	Employment Letter Agreement, dated December 14, 2015, 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 December 15, 2015)

Exhibit No.	Identification of Exhibit
10.6.1@	Executive Employment Agreement, dated April 6, 2015, between Interleukin Genetics, Inc. and Mark B. Carbeau (incorporated herein by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on April 9, 2015 (File No. 001-32715)).
10.6.2@	Non-Qualified Stock Option Agreement, dated April 6, 2015, by and between Interleukin Genetics, Inc. and Mark Carbeau (incorporated herein by reference to Exhibit 99.2 of the Company's Registration Statement on Form S-8 (File No. 333-208094) filed on November 18, 2015).
10.7@	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)
10.8@	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)
10.9@	Employment agreement dated December 26, 2012 between the Company and Scott Snyder (incorporated by reference to Exhibit 10.10 of the Company's Annual Report on Form 10-K filed March 28, 2013)
10.10@	Offer Letter, dated March 31, 2014, between Interleukin Genetics, Inc. and James M. Weaver (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed March 31, 2014)
10.11@	Consulting Agreement, dated September 8, 2014, by and between Interleukin Genetics, Inc. and Danforth Advisors, LLC. (incorporated herein by reference to Exhibit 10.13 of the Company's Registration Statement on Form S-1 filed on February 6, 2015)
10.12.1	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)
10.12.2	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)
10.12.3	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)
10.12.4	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)
10.13	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)
10.14.1	Common Stock Purchase Agreement, dated May 17, 2013, by and among Interleukin and the Investors in the May 2013 Private Placement (incorporated herein by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on May 20, 2013)
10.14.2	First Amendment, dated March 31, 2014, to Common Stock Purchase Agreement, dated May 17, 2013 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed March 31, 2014)
10.14.3	Second Amendment, dated May 30, 2014, to Common Stock Purchase Agreement, dated May 17, 2013 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed June 2, 2014)
10.14.4	Third Amendment, dated April 9, 2015, to Common Stock Purchase Agreement, dated May 17, 2013 (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed April 9, 2015)
10.15	

	Registration Rights Agreement, dated May 17, 2013, by and among Interleukin and the Investors in the May 2013 Private Placement, Pyxis Innovations Inc., Delta Dental Plan of Michigan, Inc. and BTIG, LLC (incorporated herein by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed on May 20, 2013)
10.16.1	Securities Purchase Agreement, dated December 23, 2014, by and among Interleukin and the Investors in the December 2014 Private Placement (incorporated herein by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on December 23, 2014)
10.16.2	First Amendment, dated April 6, 2015, to Securities Purchase Agreement dated December 23, 2014, by and among Interleukin and the Investors in the December Private Placement (incorporated herein by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed on April 9, 2015)
10.17	Registration Rights Agreement, dated December 23, 2014, by and among Interleukin and the Investors in the December 2014 Private Placement and BTIG, LLC (incorporated herein by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed on December 23, 2014)
10.18	Venture Loan and Security Agreement, dated December 23, 2014, by and between Interleukin and Horizon Technology Finance Corporation (incorporated herein by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed on December 23, 2014)

Exhibit No.	Identification of Exhibit
	Agreements with respect to Collaborations, Licenses and Research and Development
10.19.1	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)
10.19.2	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)
10.20	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)
10.21+	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)
10.22	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)
10.23++*	Services Agreement, effective as of February 1, 2016, by and between Interleukin Genetics, Inc. and Metagenics, Inc.
	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, 2015, 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.

* Filed herewith.

\+ 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.

++ Confidential treatment with respect to certain portions of this exhibit has been requested from the Securities and Exchange Commission. Omitted portions have been filed separately with the Securities and Exchange Commission.

@ Management contract or compensatory plan, contract or arrangement.

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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/ Mark B. Carbeau
Mark B. Carbeau

Chief Executive Officer

Date: March 16, 2016

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.

Signatures	**Title**	**Date Signed**
/s/ Mark B. Carbeau Mark B. Carbeau	Chief Executive Officer, Director (Principal Executive Officer)	March 16, 2016
/s/ Stephen J. DiPalma Stephen J. DiPalma	Interim Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2016
/s/ James M. Weaver James M. Weaver	Chairman of the Board	March 16, 2016
/s/ Lionel Carnot Lionel Carnot	Director	March 16, 2016

/s/ Roger C. Colman Roger C. Colman	Director	March 16, 2016
/s/ Joseph M. Landstra Joseph M. Landstra	Director	March 16, 2016
/s/ Kenneth S. Kornman Kenneth S. Kornman	Director	March 16, 2016
/s/ William C. Mills III William C. Mills III	Director	March 16, 2016
/s/ Dayton Misfeldt Dayton Misfeldt	Director	March 16, 2016