INTERLEUKIN GENETICS INC
Form 10-K
April 17, 2017

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, 2016

.. **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," "smaller reporting company," and "emerging growth 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	Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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 $5,284,540.

As of April 13, 2017, there were 229,471,392 shares of the registrant's Common Stock issued and outstanding.

Documents Incorporated By Reference

Portions of the registrant's Definitive Proxy Statement for the 2017 Annual Meeting of Shareholders are incorporated by reference in Part III hereof.

INTERLEUKIN GENETICS, INC.

FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2016

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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 cardiovascular risk test and the ILUSTRA™ Inflammation Management Program (the "ILUSTRA Program"), which includes the ILUSTRA Genetic Risk Test (the "ILUSTRA Test", formerly referred to as the PerioPredict® Genetic Risk Test) that identifies individuals with a life-long predisposition to over-produce inflammation and our Inherent Health® line of genetic tests We continue to support the ILUSTRA Program deployments with customers and will advance new customer relationships that expand the evidence base of this program's effectiveness.

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 our cardiovascular risk test and the ILUSTRA Test, 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 technology has been shown to also be useful in assessing differential drug outcomes in clinical trials, and may have similar value in the future.

- 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. 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; Personalization, which path are you on; 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); University Hospital of Ioannina, (Greece); 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 secondary heart attacks, severe and progressive periodontitis, 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

Cardiovascular Disease

Use of IL-1 pro-inflammatory genetic variations to guide drug development and use to prevent recurrent cardiovascular disease ("CVD") events

During late 2016 and early 2017 we redefined our strategy to add emphasis to our CVD program based on confirming evidence from a second 4-year prospective clinical study and increased interest from potential collaborators working on next-generation CVD drugs.

Inflammation is well documented to contribute to 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 carried in the blood mostly by Lp(a), are at increased risk for coronary artery disease (Tsimikas et al. 2005). Following treatment for coronary artery disease the majority of individuals who developed recurrent CVD events in the subsequent four years were those who had elevated blood levels of Lp(a) and tested positive for our pro-inflammatory IL-1 genetic patterns (Tsimikas et al. 2014). 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 that amplify inflammation. These results were corroborated in a second study population at the University Hospital of Ioannina, Greece (presented at the Annual Meeting of the American College of Cardiology, March 2017), which further established that the role of Lp(a) in determining patients at elevated risk for recurrent CVD events is conditional on our IL-1 genetic patterns. This finding suggests a potential pharmacogenomic relationship that could be important to companies developing therapeutics and to clinicians managing certain high risk CVD patients.

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 trials to reduce Lp(a) levels as well as to use our genetic test in a new Phase 1 study. Additional companies are testing other drugs candidates to help treat high risk CVD patients by potentially lowering bad cholesterol such as LDL and Lp(a) or by blocking IL-1 production and are studying their impact on recurrent heart events. Amgen, Sanofi, Novartis and The Medicines Company have active development programs in this area. 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. We are currently seeking strategic interest in this program.

ILUSTRA™ Inflammation Management Program

On November 25, 2013 we announced the introduction of the PerioPredict Genetic Risk Test, and during 2016 our principal focus was on repositioning the test and commercializing the ILUSTRA Program. As part of our work force restructuring in March 2017, we are streamlining our commercial strategy for the ILUSTRA Program. We continue to support the ILUSTRA Program deployments with customers and will advance new customer relationships that expand the evidence base of this program's effectiveness. We will continue to refine our strategy for this program based on our financial resources and its commercial success.

Product Definition and Positioning

The ILUSTRA Test is a genetic risk test that analyzes genetic variations associated with inflammation and identifies individuals with a life-long predisposition to over-produce inflammation. The ILUSTRA Test 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 ILUSTRA Program/Test positive patients than in patients who were ILUSTRA Program/Test negative. ILUSTRA Program 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 the ILUSTRA Test has been validated for use in all major ethnic groups. The ILUSTRA Test 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 the ILUSTRA Program as a tool to drive medical value; empowering individuals and healthcare professionals with actionable genetics data. The ILUSTRA 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 ILUSTRA 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, the ILUSTRA Program 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) ILUSTRA 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 ILUSTRA 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 ILUSTRA Program/Test 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 ILUSTRA 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 ILUSTRA Program/Test 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%.

Commercial Strategy for ILUSTRA

We market the ILUSTRA Inflammation Management Program 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 ILUSTRA 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 target 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 the ILUSTRA Program. 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 are creating partnerships with benefits consulting firms and employer benefits coalitions, to identify and facilitate initial interactions with potential customers.

The ILUSTRA Program is solely available through Interleukin Genetics. The web site for the ILUSTRA Program is *www.ILUSTRA.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.
- *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 Weight Management and Nutritional Needs 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. The Bone Health and Heart Health tests are ordered by physicians for their patients. 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 U.S. states that require a genetic test processing license and meet the regulatory requirements as needed for other countries.

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 2017 and 2032, five 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 2029 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 ensure 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 publicly 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 the 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 ILUSTRA 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 the ILUSTRA Test 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.

On April 5, 2016, we announced the results of discussions with the U.S. Food and Drug Administration ("FDA") in response to an Untitled Letter issued by the FDA on November 4, 2015 and a meeting on February 3, 2016 with personnel within FDA's Office of In Vitro Diagnostics and Radiological Health (OIR) to discuss Interleukin's written response to OIR with respect to the Untitled Letter. OIR personnel confirmed that the ILUSTRA Test is a laboratory developed test (LDT) currently subject to FDA enforcement discretion and may continue to be marketed without prior marketing authorization at this time. Our Bone Health and Heart Health tests, which are part of the Inherent Health line of tests, will be transitioned from a direct-to-consumer (DTC) distribution channel to a distribution model under which a licensed healthcare provider orders tests and oversees any resulting change in care. These two tests were available through Interleukin Genetics' DTC retail channels until May 22, 2016, at which time they were no longer available unless requested by an authorized healthcare provider.

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.ILUSTRA.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 or enter into a collaboration or strategic transaction by the second quarter of 2017, 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 through the second quarter of 2017. We need significant additional capital to fund our continued operations, including to capitalize on the opportunity in CVD testing, for the commercialization efforts for our ILUSTRA Program, continued research and development efforts, obtaining and protecting patents and administrative expenses. We 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. We have also been considering potential strategic alternatives. Such strategic alternatives include, but are not limited to, a sale of the company, a business combination or collaboration, and an orderly liquidation of the company. We do not know if we will be successful in pursuing any strategic alternative or that any transaction will occur. If we cannot obtain additional funding on acceptable terms or enter into a strategic transaction, 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. The financial statements do not include any adjustments that might result from the outcome of this uncertain realization. We expect to incur additional losses in 2017 and beyond and, accordingly, we are dependent on financings and potential revenue to fund our operations, to advance interest in our CVD program and support the market adoption of the ILUSTRA Program. The timing of any revenues that we may receive from the ILUSTRA Program is uncertain at this time, and is contingent upon a number of factors, including our ability to attract employer and insurance carriers as customers directly, to consummate arrangements with additional partners to promote the ILUSTRA Program, our partners' ability to attract customers for the ILUSTRA Program, and the timing of utilization of the ILUSTRA Program by customers, among other possible variables. We cannot assure you that we will ever receive substantial revenues from the ILUSTRA Program. We expect that our current cash will be sufficient to support our operations only through the second quarter of 2017.

Our ability to realize the carrying value of our fixed assets and intangible assets is especially dependent on management's ability to successfully execute on its plan. We need to generate additional funds in order to meet our financial obligations. If we are unsuccessful in doing so, we may not be able to realize the carrying value of its fixed assets and intangible assets.

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 technology for CVD testing and the ILUSTRA Program with insurance companies and large employers who might ultimately adopt enhanced benefits designs or employer-sponsored wellness initiatives that incorporate the ILUSTRA Test, or utilize the ILUSTRA Program through other arrangements, through the use of consultants, channel partners and our internal management team. However, we cannot assure you that we will be able to successfully enter into any such agreements or arrangements, or that if entered into, such agreements or arrangements will provide significant revenue. 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 $7.3 million in 2015 and $6.7 million in 2016. As of December 31, 2016, our accumulated deficit was $136.4 million. Our losses result primarily from research and development expenses, 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 ILUSTRA Program. 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 ILUSTRA Program.

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 2016 and 2015, revenues from this agreement accounted for 24% and 45% 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 sold to their Individual Business Owners. In 2016 and 2015, revenues from this arrangement accounted for 4% and 13% of our revenues, respectively. We continue to engage in discussions with potential partners for the use of our IL-1 technology for CVD testing and with insurance companies and large employers for the use of our ILUSTRA Program, 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 the CVD and ILUSTRA Tests, and we can provide no assurance that our current or planned commercialization efforts will be successful.

If we are unsuccessful in establishing additional strategic alliances, our ability to develop and market products and services may be damaged.

Entering into additional strategic alliances for the development and commercialization of products and services based on our discoveries is an important element of our business strategy. We face significant competition in seeking appropriate collaborators. If we fail to maintain our existing alliances or to establish additional 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, 2016, we had gross net operating loss (NOL) and research tax credit carryforwards of approximately $94.9 million and $1.7 million, respectively for federal income tax purposes, and of approximately $17.6 million and $1.1 million for state income tax purposes, expiring in varying amounts through the year 2036. 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, 2014 and 2016 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 the decision described above, rulings in other cases or changes in guidance or procedures issued by the USPTO will not negatively impact our patent portfolio.

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 the ILUSTRA Test, 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, we have been working with the FDA to address concerns and bring our tests into compliance for DTC. At this time two of our tests are still offered DTC, Weight Management and Nutritional Needs and we are in the midst of finalizing changes in marketing materials required for these tests. 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 ILUSTRA 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, 2016, our stock price has fluctuated from a low of $0.01 to a high of $0.46. 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:

- our ability to enter into a partnership or partnerships for the CVD test;
- the commercial success of the ILUSTRA Program;
- 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.

Members or our Board of Directors and their affiliates and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of April 13, 2017, our executive officers, directors and their respective affiliates, beneficially owned approximately 46.5% 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. In September 2016, we entered into the Third Amendment to extend the lease from April 1, 2017 through March 31, 2019. The Third Amendment includes an initial base rent beginning in April 2017 with an escalation of 2.88% of the base rent in year two.

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
2016:		
First Quarter	$0.11	$0.04
Second Quarter	$0.41	$0.08
Third Quarter	$0.25	$0.08
Fourth Quarter	$0.20	$0.04

	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

Stockholders

As of April 13, 2017, there were approximately 122 stockholders of record and according to our estimate, approximately 2,402 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 cardiovascular risk test and the ILUSTRA Test that identifies individuals with a life-long predisposition to over-produce inflammation, and our Inherent Health line of genetic tests.

Recent Developments

On April 17, 2017, we entered into a Subscription Agreement (the "Subscription Agreement"), with funds affiliated with Bay City Capital ("Bay City Capital") and Horizon Technology Finance Corporation ("Horizon") under which we issued and sold $500,000 of Subordinated Convertible Promissory Notes (the "2017 Notes") to each of Bay City Capital and Horizon (the "Note Holders"), for a total of $1,000,000 in aggregate principal amount. The 2017 Notes will convert in common shares:

(a) Upon the closing of a Qualified Financing (defined as our next common stock financing, whether in a single transaction or series of related transactions, whether a public or private financing, yielding aggregate cash proceeds to us (inclusive of amounts converted under the 2017 Notes or other outstanding indebtedness) of at least $5.0 million on or before January 1, 2022. The unpaid principal amount and accrued interest outstanding under the 2017 Notes shall automatically convert in whole into fully paid and nonassessable shares of our common stock. The total number of shares of common stock issuable upon conversion of the 2017 Notes in this circumstance shall be determined by dividing (i) the then outstanding principal amount and accrued interest under the 2017 Notes by (ii) a conversion price equal to (A) eighty percent (80%) multiplied by (B) the lowest price per share of the common

stock paid by investors in such Qualified Financing;

(b) In the event that a change of control occurs before the closing of a Qualified Financing and on or before January 1, 2022, then upon the written election of the holders of 2017 Notes representing at least fifty percent (50%) of the aggregate principal amount of all 2017 Notes, the unpaid principal amount and accrued interest outstanding under the 2017 Notes shall convert in whole into fully paid and nonassessable shares of common stock immediately before the closing of the change of control. The total number of shares of common stock issuable upon conversion of the 2017 Notes in this circumstance shall be determined by dividing (i) the then outstanding principal amount and accrued interest under the 2017 Notes by (ii) a conversion price equal to (A) eighty percent (80%) multiplied by (B) the price per share of our common stock in such change of control; or

(c) At the option of the individual Note Holder at any time before the Maturity Date, the unpaid principal amount and accrued interest outstanding under the 2017 Note may be converted in whole or in part into fully paid and nonassessable shares of common stock. The total number of shares of common stock issuable upon conversion of the particular 2017 Note in this circumstance shall be determined by dividing (i) the then outstanding principal amount and accrued interest under the 2017 Note by (ii) a conversion price equal to $0.125256.

The 2017 Notes are secured by a security interest in all of our assets and are subordinated to our existing venture loan with Horizon.

In addition, under the Subscription Agreement, each Note Holder received a Warrant to purchase our common stock (the "2017 Note Warrants"). The 2017 Note Warrants have an exercise price per share of $0.10438 and are exercisable for that number of shares of common stock equal to the original principal amount of the corresponding 2017 Note divided by such exercise price, or an aggregate of approximately 9,580,379 shares. The 2017 Note Warrants are exercisable on a net issuance basis and have a 5-year term.

Amendment to Venture Loan and Security Agreement

Also on April 17, 2017, we entered into a series of agreements, including the Second Amendment of Venture Loan and Security Agreement and a warrant to purchase common stock, to restructure our existing debt with Horizon, which resulted in the deferral of the principal amount due to Horizon on April 1, May 1, and June 1, 2017, and the potential deferral of the principal amount due to Horizon on July 1, August 1 and September 1, 2017, such potential deferral of principal is dependent upon whether, as of June 15, 2017, we provide evidence reasonably satisfactory to Horizon that we are actively negotiating a clinical services or similar agreement, the terms of which are satisfactory to Horizon, which we believe, in good faith, we will enter into no later than September 1, 2017. In exchange for agreeing to defer principal payments, Horizon was granted a warrant to purchase our common stock. The number of shares of common stock issuable upon exercise of the warrant is determined by dividing the amount of principal payments deferred by the exercise price of the warrant, which could result in the warrant being exercisable for between approximately 5,519,604 and 11,039,209 shares. The warrant has an exercise prices of $0.10438 per share, is exercisable on a net basis and has a 10-year term.

In March 2017, we implemented a work force restructuring to better utilize our resources, to align our organization to support our emerging cardiovascular testing program, for which we are seeking strategic interest, and to streamline our commercial strategy for the ILUSTRA Program. As a consequence of the restructuring, we reduced our workforce in our commercial organization and administrative functions by eight persons. We continue to support the ILUSTRA Program deployments with customers and will advance new customer relationships that expand the evidence base of this program's effectiveness. We expect that the restructuring will result in approximately $948,000 in reduced annualized operating expenses when fully implemented.

During late 2016 and early 2017 we redefined our strategy to add emphasis to our CVD program based on confirming evidence from a second clinical study and increased interest from potential collaborators working on next-generation CVD drugs. 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 trials to reduce Lp(a) levels as well as to use our genetic test in a new Phase 1 study. Additional companies are testing other drug candidates for treatment of high risk CVD patients by potentially lowering bad cholesterol such as LDL and Lp(a) or by blocking IL-1 production. Amgen, Sanofi, Novartis and the Medicines Company have active development programs in this area. 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. We are currently seeking strategic interest in this program.

Our ILUSTRA Program and Other Information

During the early part of the year ended December 31, 2016, our principal focus was on commercializing our ILUSTRA Program, with less emphasis on the sales of our Inherent Health brand of genetic tests and related programs. As part of our work force restructuring in March 2017, we are streamlining our commercial strategy for the ILUSTRA Program. We continue to support the ILUSTRA Program deployments with customers and will advance new customer relationships that expand the evidence base of this program's effectiveness. We will continue to refine our strategy for this program based on our financial resources and its commercial success.

The ILUSTRA Program 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 the ILUSTRA Program 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 the ILUSTRA Program 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 potential 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 ILUSTRA 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 the ILUSTRA Program 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 ILUSTRA Program.

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 2016 and 2015, revenues from this agreement accounted for approximately 24% and 45% of our revenues, respectively.

In 2012 and 2013, Access Business Group LLC (“ABG”), an affiliate of Alticor, placed purchase orders totaling approximately $3.3 million consisting of Weight Management kits. 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. Cash related to the 2013 promotional program, including the $519,000, will be treated as deferred revenue until 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 revenue until kits are redeemed for processing or on the final allowed redemption date of December 31, 2017. For the years ended December 31, 2016 and 2015, approximately 4% and 13%, 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. During the year ended December 31, 2016 $199,000 related to license fees was earned, compared to $191,000 for the same period in 2015.

Our research and development expenses are focused on our own development efforts related primarily to our ILUSTRA 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 year ended December 31, 2016 is $191,000 of breakage revenue related to unredeemed genetic test kits from the year ended December 31, 2013, compared to $218,000 of breakage revenue in the same period in 2015 related to unredeemed genetic test kits from the year ended December 31, 2012. 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.

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 2017 and beyond will be to develop the market for our personalized health products, in particular our ILUSTRA Program, and we will allocate considerable resources to commercialization of our ILUSTRA Program. 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.

Financing Transactions

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.

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, the Company entered into a Venture Loan and Security Agreement (the “Loan Agreement”) with Horizon Technology Finance Corporation (the “Lender”) under which the Company borrowed $5.0 million. The loan originally bore interest at a floating rate equal to the One Month LIBOR Rate (with a floor of 0.50%) plus 8.50%. The loan was 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 would have been due and payable. The Company’s obligations under the Loan Agreement were secured by a first priority security interest in substantially all of its assets other than its intellectual property. The Company had 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 2014 Lender Warrants. The 2014 Lender Warrants vested immediately, are all currently exercisable and have a term of ten (10) years. On August 25, 2016, the Company and the Lender entered into the First Amendment of Venture Loan and Security Agreement and an Amended and Restated Secured Promissory Note (collectively referred to herein as the “2016 Debt Restructuring”), which was effective as of August 1, 2016, pursuant to which the principal payments due from August 2016 through December 2016 will be reduced to 33% of the principal payments due for these periods under the Loan Agreement. In consideration of these changes, (i) the Company paid the Lender an amendment fee of $25,000 and reimbursed the Lender’s legal expenses in the amount of $5,000, (ii) the Company granted the Lender a first priority security interest in substantially all of its assets, including its intellectual property, (iii) the interest rate of the loan has been increased to 11.00% plus the amount by which the one month LIBOR Rate exceeds 0.50%, and (iv) the final payment was increased from 4.5% of the loan, or $225,000, to 6.5% of the loan, or $325,000. At December 31, 2016, the interest rate was 11.27% per annum. In connection with the 2016 Debt Restructuring, the Company also issued to the Lender an additional warrant to purchase up to 5,169,577 shares of the Company’s common stock at an exercise price of $0.0994 per share (the “2016 Lender Warrant”). The 2016 Lender Warrant vested immediately, is currently exercisable and has a term of ten (10) years.

On April 17, 2017, we entered into a series of agreements, including the Second Amendment of Venture Loan and Security Agreement and a warrant to purchase common stock, to restructure our existing debt under the Loan Agreement, which resulted in the deferral of the principal amount due to the Lender on April 1, May 1, and June 1, 2017, and the potential deferral of the principal amount due to the Lender on July 1, August 1 and September 1, 2017, such potential deferral of principal is dependent upon whether, as of June 15, 2017, we provide evidence reasonably satisfactory to the Lender that we are actively negotiating a clinical services or similar agreement, the terms of which are satisfactory to the Lender, which we believe, in good faith, we will enter into no later than September 1, 2017. In exchange for agreeing to defer principal payments, the Lender was granted a warrant to purchase our common stock. The number of shares of common stock issuable upon exercise of the warrant is determined by dividing the amount of principal payments deferred by the exercise price of the warrant, which could result in the warrant being exercisable for between approximately 5,519,604 and 11,039,209 shares. The warrant has an exercise price of $0.10438, is exercisable on a net issuance basis and has a 10-year term.

On July 29, 2016, the Company entered into a Securities Purchase Agreement (the “2016 Purchase Agreement”) with various accredited investors (the “2016 Investors”), pursuant to which the Company sold to the 2016 Investors in a private placement transaction (the “2016 Private Placement”) an aggregate of 56,262,571 shares of common stock at a price of $0.0994 per share for gross proceeds of approximately $5.6 million. The 2016 Investors also received warrants to purchase up to an aggregate of 56,262,571 shares of common stock at an exercise price of $0.0994 per share (the “2016 Warrants”). The 2016 Warrants vested immediately, are all currently exercisable and have a term of seven years.

On April 17, 2017, we sold $500,000 of Convertible Notes (the “2017 Notes”) to each of Bay City Capital and Horizon Technology Finance Corporation (the “Note Holders”), for a total of $1,000,000 in aggregate principal. The 2017 Notes will convert into common stock if certain conditions are met. In connection with the issuance of the 2017 Notes, we also issued warrants to purchase common stock to the Note Holders. See “Recent Developments” above and Item 9B “Other Information” for more details of this bridge financing.

Liquidity and Capital Resources

As of December 31, 2016, we had cash of $2.7 million.

Cash used in operations was $6.5 million for the year ended December 31, 2016 compared to $6.7 million for the year ended December 31, 2015. 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 $85,000 for the year ended December 31, 2016, compared to $82,000 for the year ended December 31, 2015. Capital additions were $85,000 for the year ended December 31, 2016 which was related to the costs of creating the new ILUSTRA product website. 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.

Cash provided by financing activities was $4.6 million for the year ended December 31, 2016, compared to cash provided by financing activities of $13,000 for the year ended December 31, 2015. In July 2016 the Company received approximately $5.5 million in net proceeds, after $63,000 in related expenses, from the 2016 Private Placement. This was partially offset by $967,000 in principal payments related to our venture loan and security agreement with the Lender entered into on December 23, 2014, as restructured in August 2016. The Company received $16,000 from stock purchases through the employee stock purchase plan during the year ended December 31, 2016 compared to $21,000 for the year ended December 31, 2015. The $21,000 received through the employee stock purchase plan for the year ended December 31, 2015 was offset by $8,000 in additional fees related to the December 2014 Private Placement.

The amount of cash we generate from operations is currently not sufficient to continue to fund operations and grow our business. We expect that, taking into account the transactions described in Recent Developments above, our current financial resources will be adequate to maintain our current and planned operations through the second quarter of 2017. We believe our success depends on our ability to consummate a material collaboration related to our CVD test and to generate significant revenues for the ILUSTRA Program through potential partners. The timing of any revenues that we may receive from either the CVD asset or the ILUSTRA Program is uncertain at this time, and is contingent upon a number of factors, including our ability to consummate arrangements with other partners for the CVD asset or to promote the ILUSTRA Program, our partners' ability to develop reimbursed insurance plans and to develop a viable market for such plans, and the timing of utilization of the ILUSTRA Program pursuant to insured plans, or other possible arrangements. We do not expect to receive any material revenues from either the CVD asset or the ILUSTRA Program until mid to late 2017, at the earliest, and the timing of any such revenues may be substantially later. We may never receive significant revenues.

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, 2016 and 2015

Total revenue was $2.51 million for the year ended December 31, 2016 compared to $1.44 million for the year ended December 31, 2015. The change in total revenue is largely attributable to contracted research projects, partially offset by a decrease in kits returned for processing related to ABG's promotional product bundle.

During the year ended December 31, 2016, 24% of our sales revenue came through our Merchant Network and Channel Partner Agreement with Amway Global compared to 45% during the year ended December 31, 2015. During the same periods, 4% and 13%, respectively, of our revenue came from sales through ABG's promotional product bundle program.

Cost of revenue for the year ended December 31, 2016 was $1.60 million, or 63.7% of revenue, compared to $1.41 million, or 98.1% of revenue, for the year ended December 31, 2015. The decrease in the cost of revenue as a percentage of revenue in the year ended December 31, 2016 is primarily attributable to the fixed laboratory costs being applied to higher revenue in the period, which was due to contracted research projects. Deferred cost of revenue related to breakage revenue was $10,000 for the year ended December 31, 2016 compared to $10,000 for the year ended December 31, 2015. Also included in cost of revenue for the year ended December 31, 2016 is a charge of $17,000 from the write off of obsolete raw materials and kits related to the PerioPredict test.

Research and development expenses were $1.5 million for the year ended December 31, 2016, compared to $1.3 million for the year ended December 31, 2015. The 14% increase of $181,000 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 and our patient engagement study.

Selling, general and administrative expenses were $6.1 million for the year ended December 31, 2016, compared to $5.9 million for the year ended December 31, 2015. The 3.3% increase is primarily attributable to higher legal fees and expenses related to the rebranding of the ILUSTRA Program partially offset by lower recruiting and patent fees as well as lower commissions related to our Merchant Network and Channel Partner Agreement with Amway Global.

Interest expense was $741,000 for the year ended December 31, 2016, compared to $609,000 for the year ended December 31, 2015. The interest expense is entirely related to our venture loan and security agreement with the Lender entered into on December 23, 2014, as restructured in August 2016.

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.

INDEX TO FINANCIAL STATEMENTS

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, 2016 and 2015, 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, 2016 and 2015, 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 and negative cash flows from operations and as of December 31, 2016 the Company's current liabilities exceeded its current assets. These conditions, along with other matters as set forth in Note 2, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Grant Thornton LLP

Boston, Massachusetts
April 17, 2017

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INTERLEUKIN GENETICS, INC.

BALANCE SHEETS

	December 31, 2016	2015
ASSETS		
Current assets:		
Cash	$2,657,214	$4,706,018
Accounts receivable from related party	74,535	39,989
Trade accounts receivable	31,354	45,973
Inventory	73,064	124,583
Prepaid expenses	434,983	778,970
Total prepaid expenses and other current assets	3,271,150	5,695,533
Fixed assets, net	511,192	643,900
Intangible assets, net	25,429	58,879
Other assets	28,001	93,208
Total assets	$3,835,772	$6,491,520
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$505,630	$408,374
Accrued expenses	238,087	497,688
Deferred revenue	2,502,966	3,238,541
Short term debt	2,304,545	1,333,333
Total current liabilities	5,551,228	5,477,936
Long term debt	1,130,094	3,474,984
Total liabilities	6,681,322	8,952,920
Stockholders' deficit:		
Convertible preferred stock, $0.001 par value — 6,000,000 shares authorized; 0 shares issued and outstanding at December 31, 2016 and 2015, respectively	—	—
Common stock, $0.001 par value — 450,000,000 and 300,000,000 shares authorized; 229,381,059 and 172,887,221 shares issued and outstanding at December 31, 2016 and 2015, respectively	229,383	172,889
Additional paid-in capital	133,327,491	126,354,036
Accumulated deficit	(136,402,424)	(128,988,325)
Total stockholders' deficit	(2,845,550)	(2,461,400)
Total liabilities and stockholders' deficit	$3,835,772	$6,491,520

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,	
	2016	2015
Genetic testing	$ 1,032,317	$ 1,155,980
Other	1,481,139	284,930
Total revenue	2,513,456	1,440,910
Cost of revenue	1,601,958	1,414,113
Gross profit	911,498	26,797
Operating expenses:		
Research and development	1,480,882	1,299,542
Selling, general and administrative	6,070,746	5,878,940
Amortization of intangibles	33,450	136,886
Total operating expenses	7,585,078	7,315,368
Loss from operations	(6,673,580)	(7,288,571)
Other income (expense):		
Interest income	—	222
Interest expense	(740,519)	(609,664)
Total other expense	(740,519)	(609,442)
Loss before income taxes	(7,414,099)	(7,898,013)
Net loss	$ (7,414,099)	$ (7,898,013)
Basic and diluted net loss per common share	$ (0.04)	$ (0.05)
Weighted average common shares outstanding, basic and diluted	197,089,020	172,813,224

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

INTERLEUKIN GENETICS, INC.

STATEMENTS OF STOCKHOLDERS' DEFICIT

For the Years Ended December 31, 2016 and 2015

	Convertible Preferred Stock		**Common Stock**		**Additional Paid-in**	**Accumulated**	
	Shares	Par Value	Shares	Par Value	Capital	Deficit	**Total**
Balance as of December 31, 2015	—	—	172,887,221	$172,889	$126,354,036	$(128,988,325)	$(2,461,400)
Net loss	—	—	—	—	—	(7,414,099)	(7,414,099)
Common stock issued:							
Private placement of common stock, net of offering costs of $62,849	—	—	56,262,571	56,263	5,473,388	—	5,529,651
Horizon warrant	—	—	—	—	503,667	—	503,667
Danforth warrant	—	—	—	—	8,885	—	8,885
Exercise of employee stock options	1,316	1	66	—	67		
Employee stock purchase plan	—	—	229,951	230	15,761	—	15,991
Stock-based compensation expense	—	—	—	—	971,688	—	971,688
Balance as of December 31, 2016	—	—	229,381,059	$229,383	$133,327,491	$(136,402,424)	$(2,845,550)

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

INTERLEUKIN GENETICS, INC.

STATEMENTS OF CASH FLOWS

	For the Year Ended December 31,	
	2016	2015
CASH FLOW FROM OPERATING ACTIVITIES:		
Net loss	$ (7,414,099)	$ (7,898,013)
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	251,021	349,254
Amortization of loan issuance costs and FV of warrants	171,127	108,224
Stock-based compensation expense	971,688	892,087
Changes in operating assets and liabilities:		
Receivable from related party	(34,546)	(16,445)
Trade accounts receivable	14,619	(31,960)
Inventory	51,519	46,992
Prepaid expenses and other assets	343,987	(274,251)
Accounts payable	97,256	(105,553)
Accrued expenses	(259,601)	154,463
Deferred revenue	(735,575)	84,043
Net cash used in operating activities	(6,542,604)	(6,691,159)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Capital additions	(84,863)	(82,489)
Net cash used in investing activities	(84,863)	(82,489)
CASH FLOW FROM FINANCING ACTIVITIES:		
Proceeds from private placement of common stock and warrants	5,592,500	—
Private placement offering costs	(62,849)	(8,095)
Payment of notes payable	(967,045)	—
Proceeds from employee stock purchase plan and employee option exercises	16,057	20,954
Net cash provided by financing activities	4,578,663	12,859
Net decrease in cash and equivalents	(2,048,804)	(6,760,789)
Cash, beginning of period	4,706,018	11,466,807
Cash, end of period	$ 2,657,214	$ 4,706,018
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 429,267	$ 467,500
Supplemental disclosures of non-cash investing and financing activities:		
Warrants issued in connection with long term debt amendment	$ 5,169,577	$ —

The accompanying notes are an integral part of these financial statements

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INTERLEUKIN GENETICS, INC.

NOTES TO FINANCIAL STATEMENTS

December 31, 2016

Note 1—Company Overview

Interleukin Genetics, Inc. ("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 or therapeutic measures. The Company's principal operations and markets are located in the United States.

Through 2016, the Company's focus was on commercializing its ILUSTRA™ Inflammation Management Program (the "ILUSTRA Program") and its Inherent Health® brand of genetic tests. The Company is continuing to support the ILUSTRA Program deployments with customers and will advance new customer relationships that expand the evidence base of this program's effectiveness. The Company will continue to refine its strategy for the ILUSTRA Program based on the Company's financial resources and its commercial success. During late 2016 and early 2017, the Company redefined its strategy to add emphasis on a cardiovascular disease (CVD) program.

Note 2—Operating Matters and Liquidity

The Company has experienced net operating losses since its inception through December 31, 2016. The Company had net losses of $7.4 million and $7.9 million for the years ended December 31, 2016 and 2015, respectively, contributing to an accumulated deficit of $136.4 million as of December 31, 2016. In addition, the Company's current liabilities exceed its current assets as of December 31, 2016 and the Company has primarily relied on external financing to fund its operations.

As of March 31, 2017, the Company has cash of approximately $791,000, and has no access to credit. The Company has accounts payable and accrued expenses of $1.1 million, and owes $3.6 million in principal payments to Horizon. The Company estimates that $5.5 million in additional capital would be required to maintain the Company's operations for one year from March 31, 2017.

As further discussed in Note 15 “Subsequent Events”, the Company issued and sold $1,000,000 in aggregate principal Subordinated Convertible Promissory Notes, amended the Venture Loan and Security Agreement to defer principal amounts due in 2017, and implemented a work force reduction. The Company expects that, taking into account these transactions, current financial resources will be adequate to maintain the current and planned operations through the second quarter of 2017. The Company believes its success depends on its ability to consummate a material collaboration related to its CVD test and to generate significant revenues for the ILUSTRA Program through potential partners. The timing of any revenues that the Company may receive from either the CVD asset or the ILUSTRA Program is uncertain at this time, and is contingent upon a number of factors, including the Company’s ability to consummate arrangements with other partners for the CVD asset or to promote the ILUSTRA Program, the Company’s partners’ ability to develop reimbursed insurance plans and to develop a viable market for such plans, and the timing of utilization of the ILUSTRA Program pursuant to insured plans, or other possible arrangements. The Company does not expect to receive any material revenues from either the CVD asset or the ILUSTRA Program until mid to late 2017, at the earliest, and the timing of any such revenues may be substantially later. The Company may never receive significant revenues.

These conditions, among others, considered in the aggregate raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the financial statements are issued.

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 amount of cash the Company generates from operations is currently not sufficient to continue to fund operations and grow the business.

Until such time, if ever, that the Company generates revenues sufficient to fund operations, the Company may fund its 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. Debt financing, if available, may involve agreements that include covenants limiting or restricting the Company’s 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 the Company needs them on terms that are acceptable to the Company, or at all. If adequate funds are not available to the Company on a timely basis, the Company 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 the Company or sell, license or relinquish rights to develop or commercialize its products, technologies or intellectual property. However, no assurance can be given at this time as to whether the Company will be able to achieve these objectives.

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.

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 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 at an exercise price of $0.1003 per share. The 2014 Warrants vested immediately, are all currently exercisable and have a term of seven years.

On December 23, 2014, the Company entered into a Venture Loan and Security Agreement (the "Loan Agreement") with Horizon Technology Finance Corporation (the "Lender") under which the Company borrowed $5.0 million. The loan originally bore interest at a floating rate equal to the One Month LIBOR Rate (with a floor of 0.50%) plus 8.50%. The loan was 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 would have been due and payable. The Company's obligations under the Loan Agreement were secured by a first priority security interest in substantially all of its assets other than its intellectual property. The Company had 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 2014 Lender Warrants. The 2014 Lender Warrants vested immediately, are all currently exercisable and have a term of ten (10) years.

On August 25, 2016, the Company and the Lender entered into the First Amendment of Venture Loan and Security Agreement and an Amended and Restated Secured Promissory Note (collectively referred to herein as the "2016 Debt Restructuring"), which was effective as of August 1, 2016, pursuant to which the principal payments due from August 2016 through December 2016 were reduced to 33% of the principal payments due for these periods under the Loan Agreement. Principal payments were also subject to reduction in future periods upon the achievement of certain milestones by the Company. These milestones were not achieved. In consideration of these changes, (i) the Company

paid the Lender an amendment fee of $25,000 and reimbursed the Lender's legal expenses in the amount of $5,000, (ii) the Company granted the Lender a first priority security interest in substantially all of its assets, including its intellectual property, (iii) the interest rate of the loan was increased to 11.00% plus the amount by which the one month LIBOR Rate exceeds 0.50%, and (iv) the final payment was increased from 4.5% of the loan, or $225,000, to 6.5% of the loan, or $325,000. At December 31, 2016, the interest rate was 11.27% per annum. In connection with the 2016 Debt Restructuring, the Company also issued to the Lender an additional warrant to purchase up to 5,169,577 shares of the Company's common stock at an exercise price of $0.0994 per share (the "2016 Lender Warrant"). The 2016 Lender Warrant vested immediately, is currently exercisable and has a term of ten (10) years. See Note 15 "Subsequent Events" for additional information with respect to an amendment to the Venture Loan and Security Agreement entered into in April 2017.

On July 29, 2016, the Company entered into a Securities Purchase Agreement (the "2016 Purchase Agreement") with various accredited investors (the "2016 Investors"), pursuant to which the Company sold to the 2016 Investors in a private placement transaction (the "2016 Private Placement") an aggregate of 56,262,571 shares of common stock at a price of $0.0994 per share for gross proceeds of approximately $5.6 million. The 2016 Investors also received warrants to purchase up to an aggregate of 56,262,571 shares of common stock at an exercise price of $0.0994 per share (the "2016 Warrants"). The 2016 Warrants vested immediately, are all currently exercisable and have a term of seven years.

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, 2016 and December 31, 2015, the Company had deferred genetic test revenue of $2.5 million and $3.2 million, respectively. Included in deferred revenue at December 31, 2016 is $2.4 million for kits that are still outstanding one year or longer after initial kit sale, of which $0.15 million was sold directly to consumers (credit card payments) and $2.3 million was sold to distributors as a promotional bundle. In 2012 and 2013, Access Business Group LLC ("ABG"), an affiliate of Alticor Inc., a related party ("Alticor"), placed purchase orders totaling approximately $3.3 million consisting of Weight Management test kits. The kits were included as part of a promotional bundle of products that ABG 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, 2016 and 2015 is $191,000 and $218,000, respectively, of breakage revenue related to unredeemed genetic test kits sold in 2013 and 2012, 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 $225,000 and $302,000 for the years ended December 31, 2016 and 2015, 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, 2016 as all accounts receivable are expected to be collected.

Inventory

Kit inventory is carried at lower of cost (first-in, first-out method) or market and no inventory reserve was deemed necessary for the years ended December 31, 2016 and 2015. As the Company does not manufacture any products, no overhead costs are included in inventory. Inventory is stored at a fulfillment provider. Inventory consisted of the following at December 31, 2016 and 2015:

	December 31, 2016	December 31, 2015
Raw materials	$ 68,447	$ 112,372
Finished goods	4,617	12,211
Total inventory, net	$ 73,064	$ 124,583

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 $36.4 million as of December 31, 2016, 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, December 31, 2014 and September 30, 2016 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. The Company has not performed an analysis to determine the extent of such limitations, if any.

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, 2016.

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,	
	2016	2015
Options outstanding	31,363,319	21,657,776
Warrants outstanding	149,733,227	88,301,079
Total	181,096,546	109,958,855

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, 2016 and 2015, 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, 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

The Company maintains its cash with a domestic financial institution that the Company believes to be of high credit standing. The Company believes that, as of December 31, 2016, its concentration of credit risk related to cash was not significant. Cash is available on demand and is 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.

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, 2016.

Segment Reporting

As of December 31, 2016 and 2015, 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 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.

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. Revenue from the Company’s 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 or the requesting physician. To the extent that tests have been prepaid but results have not yet been reported, recognition of all related revenue is deferred. The Company is not electing to adopt early and is evaluating the impact of ASU 2014-09 on the Company’s financial disclosures.

FASB ASU 2016-02 - Leases (Topic 842).

In February 2016, the FASB issued ASU No. 2016-02, “Leases” (Topic 842). The updated standard aims to increase transparency and comparability among organizations by requiring lessees to recognize lease assets and lease liabilities

on the balance sheet and requiring disclosure of key information about leasing arrangements. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating the impact of ASU 2016-02 on its consolidated financial statements.

FASB ASU No. 2016-09, - Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting.

In March 2016, the FASB issued ASU No. 2016-09. The standard is intended to simplify several areas of accounting for share-based compensation arrangements, including the income tax impact, classification on the statement of cash flows and forfeitures. ASU 2016-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016, and early adoption is permitted. The Company is currently evaluating the impact of ASU 2016-09 on its consolidated financial statements.

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. 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. The Company paid Amway Global $225,000 and $302,000 in commissions for the years ended December 31, 2016 and 2015, 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.

In 2012 and 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 (the “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, 2016 and 2015, $199,000 and $191,000, 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, 2016 and 2015 under the PSA.

For years ended December 31, 2016 and 2015, approximately 24% and 45%, respectively, of our revenue came from sales through our Merchant Network and Channel Partner Agreement with Amway Global, a subsidiary of Alticor, and 4% and 13%, 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 ILUSTRA Test that the Company processed. This amended

agreement had a term of three years beginning February 25, 2013 and terminated on February 25, 2016. A revised agreement with substantially similar terms was executed in April 2016.

Note 5—Debt Instruments

Venture Loan and Security Agreement

On December 23, 2014, the Company entered into a Venture Loan and Security Agreement (the "Loan Agreement") with Horizon Technology Finance Corporation (the "Lender") under which the Company borrowed $5.0 million. The loan bore 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, exceeded 0.50%, the interest rate would have been adjusted by an amount equal to the difference between such rates at the end of that particular month. The loan was 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 (the "Payment Terms"). 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 would have been due and payable. The Company's obligations under the Loan Agreement were secured by a first priority security interest in substantially all of its assets other than its intellectual property. The Company had 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 2014 Lender Warrants. The 2014 Lender Warrants vested immediately, are all currently exercisable and have a term of ten (10) years.

On August 25, 2016, the Company and the Lender entered into the First Amendment of Venture Loan and Security Agreement and an Amended and Restated Secured Promissory Note (collectively referred to herein as the "2016 Debt Restructuring"), which was effective as of August 1, 2016, pursuant to which the principal payments due from August 2016 through December 2016 was reduced to 33% of the principal payments due for these periods under the Loan Agreement. In consideration of these changes, (i) the Company paid the Lender an amendment fee of $25,000 and reimbursed the Lender's legal expenses in the amount of $5,000, (ii) the Company granted the Lender a first priority security interest in substantially all of its assets, including its intellectual property, (iii) the interest rate of the loan was increased to 11.00% plus the amount by which the one month LIBOR Rate exceeds 0.50%, and (iv) the final payment was increased from 4.5% of the loan, or $225,000, to 6.5% of the loan, or $325,000. At December 31, 2016, the interest rate was 11.27% per annum. In connection with the 2016 Debt Restructuring, the Company also issued to the Lender a warrant to purchase up to 5,169,577 shares of the Company's common stock at an exercise price of $0.0994 per share (the "2016 Lender Warrant"). The 2016 Lender Warrant vested immediately, is currently exercisable and has a term of ten (10) years. See Note 15 "Subsequent Events" for additional information with respect to an amendment to the Venture Loan and Security Agreement entered into in April 2017.

The Company recorded a discount on the loan comprised of (i) $89,000 in cash fees paid to the Lender related to the Loan Agreement, (ii) $261,000 as the intrinsic value of the 2014 Lender Warrants, (iii) $30,000 in cash fees paid to the Lender related to the 2016 Debt Restructuring and (iv) $504,000 as the intrinsic value of the 2016 Lender Warrants. The discount on the loan is amortized over the term of the loan in the Company's Statements of Operations. As of December 31, 2016, the unamortized discount associated with the loan was $579,000. The amended final non-principal payment of $325,000 will be accrued as additional interest expense, using the effective interest method, over the term of the loan. Cash interest expense for the years ended December 31, 2016 and 2015 was $429,000 and $456,000, respectively. Non-cash interest expense was $294,000 for the year ended December 31, 2016 compared to $153,000 for the year ended December 31, 2015.

Note 6—Fixed Assets

The useful lives and balances of fixed assets at December 31, 2016 and 2015 consisted of the following:

	Useful Life	2016	2015
Computer software, computer equipment and office equipment	3 years	$516,511	$516,511
Laboratory equipment	5 years	1,896,417	1,887,454
Furniture and fixtures	5 years	40,349	40,349
Leasehold improvements	5 years	309,618	309,618
Website development	3 years	374,453	298,553
		3,137,348	3,052,485
Less — Accumulated depreciation and amortization		(2,626,156)	(2,408,585)
Total		$511,192	$643,900

Depreciation and amortization expense was $218,000 and $212,000, for the years ended December 31, 2016 and 2015, respectively.

Note 7—Intangible Assets

Intangible assets at December 31, 2016 and 2015 consisted of the following:

	2016	2015
Patent costs	$1,154,523	$1,154,523
Less — Accumulated amortization	(1,129,094)	(1,029,497)
Less — Write off related to patents no longer in use	—	(66,147)
Total	$25,429	$58,879

Patent amortization expense was $33,000 and $137,000 for the years ended December 31, 2016 and 2015, 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,	
2017	19,117
2018	6,312
	$25,429

Note 8—Accrued Expenses

Accrued expenses at December 31, 2016 and 2015 consisted of the following:

	2016	2015
Payroll and vacation	$81,928	$412,674
Other	156,159	85,014
Total accrued expenses	$238,087	$497,688

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

On May 19, 2016, the Company entered into an employment agreement with Stephan Toutain for the position of Chief Commercial Officer beginning on August 15, 2016 (the “Start Date”). The agreement provides for a minimum annual base salary of $315,000 and he is eligible for a bonus of 30% of his base salary pursuant to the Company’s bonus plan. Pursuant to the agreement, Mr. Toutain was granted options to purchase 3,738,933 shares of the Company’s common stock, which was equal to 1% of the Company’s fully diluted shares of the Company as of his

Start Date, at an exercise price equal to fair market value of the Company's common stock on the grant date of the option. The option will vest as to 25% of the shares on the first anniversary of the Start Date, and as to an additional 2.083% of the shares monthly thereafter. Mr. Toutain's agreement is terminable at will by the Company or Mr. Toutain. If the Company terminates Mr. Toutain without cause, the Company will pay Mr. Toutain, in addition to any accrued, but unpaid compensation prior to termination, an amount equal to six months of his base salary in effect at the time of the termination.

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. For the year ended December 31, 2016 there was no bonus accrual and will be no bonus payout in the first quarter of 2017.

Operating Leases

The Company leases its office and laboratory space under a non-cancelable operating lease which is scheduled to expire on March 31, 2017. The lease agreement includes an initial base rent beginning in March 2014 with an escalation of 2.06% of the base rent in year two and another 2.06% increase in year three. In September 2016, the Company entered into the third amendment to the commercial lease ("Third Amendment") to extend the lease from April 1, 2017 through March 31, 2019. The Third Amendment includes an initial base rent beginning in April 2017 with an escalation of 2.88% of the base rent in year two.

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
2017	335,279	6,624	341,903	2,226	344,129
2018	345,020	1,104	346,124	1,484	347,608
2019	86,864	—	86,864	—	86,864
	$ 767,163	7,728	$ 774,891	$ 3,710	$ 778,601

Rent expense was $347,000 and $352,000 for the years ended December 31, 2016 and 2015, respectively

Note 10—Capital Stock

Authorized Preferred and Common Stock

As of December 31, 2016, 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, 2016 the Company has 229,381,059 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	52,092,463		
Rights associated with Employee Stock Purchase Plan	70,122		
Warrants to purchase common stock associated with the 2016 Debt Restructuring	5,169,577	$0.0994	Aug 1, 2026
Warrants to purchase common stock associated with July 2016 private placement	56,262,571	$0.0994	Jul 29, 2023
Warrants to purchase common stock associated with December 2014 private placement	50,189,431	$0.1003	Dec 23, 2021

Warrants to purchase common stock associated with December 2014 venture loan and security agreement	2,492,523	$0.1003	Dec 23, 2024
Warrants to purchase common stock associated with September 2014 consulting agreement with Danforth Advisors	100,000	$0.2500	Sep 8, 2024
Outstanding warrants issued in May 2013, vesting August 2013	14,426,230	$0.2745	Aug 9, 2020
Outstanding warrants issued in May 2013, vesting May 2013	20,655,737	$0.2745	May 17, 2020
Outstanding warrants issued in June 2012	437,158	$0.2745	Jun 29, 2017
Total common shares reserved for issuance at December 31, 2016	201,895,812		
Total common shares issued and outstanding at December 31, 2016	229,381,059		
Total common shares outstanding and reserved for issuance at December 31, 2016	431,276,871		

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 its 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 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 the May 2013 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 (the "2013 Preferred Conversion") and $14,316,255 in principal amount of outstanding convertible debt held by a related party was converted into 2,521,222 shares of common stock (the "2013 Debt Conversion").

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 (10) year term and vested on a monthly basis over two years. These warrants have fully vested as of December 31, 2016. The fair value of the warrants at issuance was recorded as equity totaling $24,000 and was fully amortized as of December 31, 2016. The non-cash compensation expense for the years ended December 31, 2016 and 2015 was $9,000 and $12,000 respectively.

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, its legal counsel and the Company's 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 and the 2014 Placement Agent Warrants were recorded as equity at fair value on the date of issuance. 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.

On July 29, 2016, the Company entered into the 2016 Purchase Agreement with the 2016 Investors, pursuant to which the Company sold to the 2016 Investors in the 2016 Private Placement an aggregate of 56,262,571 shares of common stock at a price of $0.0994 per share for gross proceeds of approximately $5.6 million. The 2016 Investors also received the 2016 Warrants to purchase up to an aggregate of 56,262,571 shares of common stock at an exercise price of $0.0994 per share. The 2016 Warrants vested immediately, are all currently exercisable and have a term of seven years.

For services related to this transaction, the Company’s legal counsel received $63,000 in cash fees.

The fair value of the 2016 Warrants at issuance was $6.5 million. Fair value of the 2016 Warrants was calculated using the following inputs in a Black-Scholes model:

	July 29, 2016	
Risk-free interest rate	1.52	%
Expected life	7 years	
Expected volatility	147.03	%
Dividend yield	0	%

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.

In connection with the July 2016 Private Placement, on July 29, 2106, the Company also entered into a Registration Rights Agreement with the 2016 Investors, pursuant to which the Company was required to file a registration statement on Form S-1 within 45 days of July 29, 2016 to cover the resale of the shares of common stock sold to the 2016 Investors and the shares of common stock underlying the 2016 Warrants. The Company filed the registration statement on September 12, 2016, and it was declared effective on September 27, 2016.

Venture Loan and Security Agreement

On December 23, 2014, the Company entered into the Loan Agreement with 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 2014 Lender Warrants to purchase a total of 2,492,523 shares of common stock at an exercise price of $0.1003 per share. The 2014 Lender Warrants vested immediately, are all currently exercisable and have a term of ten (10) years. The fair value of the 2014 Lender Warrants at issuance was $261,000

On August 25, 2016, the Company and The Lender agreed to the 2016 Debt Restructuring, which was effective as of August 1, 2016, pursuant to which the principal payments due from August 2016 through December 2016 were reduced to 33% of the principal payments due for these periods under the Loan Agreement. In connection with the 2016 Debt Restructuring, the Company issued to the Lender the 2016 Lender Warrant to purchase up to 5,169,577 shares of the Company's common stock at an exercise price of $0.0994 per share. The 2016 Lender Warrant vested immediately, is currently exercisable and has a term of ten (10) years.

The 2014 Lender Warrants and 2016 Lender Warrants were recorded as equity at fair value on the date of issuance. Fair value of the 2014 Lender Warrants and 2016 Lender Warrants was calculated using the Black-Scholes model. Fair value of the 2016 Lender Warrants was calculated using the following inputs in a Black-Scholes model:

	August 1, 2016	
Risk-free interest rate	1.78	%
Expected life	10 years	
Expected volatility	138.81	%
Dividend yield	0	%

The fair value of the 2016 Lender Warrants at issuance was $504,000. Cash interest paid during the years ended December 31, 2016 and 2015 totaled $429,000 and $456,000, respectively. Non-cash interest related to debt discounts was $294,000 for the year ended December 31, 2016, compared to $153,000 for the year ended December 31, 2015. The debt discount balance was $579,000 as of December 31, 2016.

Principal payments due under the terms of the Loan Agreement and the 2016 Debt Restructuring are as follows:

2017	2,304,545
2018	1,920,455
	$4,225,000

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. 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. During the year ended December 31, 2016, the Company granted 10,622,392 stock options under the 2013 Plan. At December 31, 2016, the Company had an aggregate of 20,729,144 shares of common stock available for grant under the 2013 Plan.

Stock Option Grants

Per his employment agreement, Mark Carbeau was entitled to receive a grant of options to purchase shares of the Company's common stock equal to 5% of the number of shares of the Company's stock issued in the 2016 Private Placement, assuming the conversion of all convertible securities issued in the 2016 Private Placement, which equals 5,626,257 shares, at a per share exercise price equal to the fair market value of the Company's common stock on the date of the grant. Pursuant to the terms of the 2013 Plan, the Company cannot issue options or other grants for more than 5,000,000 shares to any one person in a calendar year. Consequently, on October 20, 2016, the Company granted Mr. Carbeau options to purchase 5,000,000 shares of the Company's common stock at an exercise price of $0.17544 per share and expects to grant the remaining options to which Mr. Carbeau is entitled in 2017. These options will vest as to 25% of the shares on July 29, 2017 and as to an additional 2.083% of the shares on the last day of each successive month thereafter, provided that Mr. Carbeau remains employed by the Company on the vesting date.

Per his employment agreement, Stephan Toutain was entitled to receive a grant of options to purchase shares of the Company's common stock equal to 1% of the Company's fully diluted shares as of his start date at an exercise price equal to fair market value of the Company's common stock on the grant date of the option. Consequently, on October 20, 2016, the Company granted Mr. Toutain options to purchase 3,738,933 shares of the Company's common stock at an exercise price of $0.17544 per share. These options will vest as to 25% of the shares on August 15, 2017, and as to

an additional 2.083% of the shares monthly thereafter.

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, and stock options to employees generally vest over four years based upon continuous service. 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.

For purposes of determining the stock-based compensation expense for stock option awards in 2016 and 2015, the Black-Scholes option-pricing model was used with the following weighted-average assumptions:

	2016		2015	
Risk-free interest rate	1.24	%	1.54	%
Expected life	5.73 years		5.73 years	
Expected volatility	146.3	%	138.8	%
Dividend yield	0	%	0	%

Using these assumptions, the weighted average grant date fair value of options granted in 2016 and 2015 was $0.15 and $0.16, 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, 2016 and 2015, 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, 2016 and 2015, employees purchased 229,951 and 203,879 shares, respectively, of common stock at a weighted-average purchase price of $0.08 and $0.10, respectively, while the weighted-average market value was $0.09 and $0.12 per share, respectively, resulting in compensation expense of $2,921 and $4,053, respectively.

The following table details stock option and restricted stock activity for the years ended December 31, 2016 and 2015.

	2016		2015	
	Shares	Weighted Avg. Exercise Price	Shares	Weighted Avg. Exercise Price
Outstanding, beginning of period	21,657,776	$ 0.21	4,523,900	$ 0.39
Granted	10,622,392	0.16	18,193,027	0.17
Stock options exercised	(1,316)	.05	—	0.00
Restricted stock exercised	—	0.00	—	0.00
Forfeited/Expired	(915,533)	0.33	(1,059,151)	0.17
Outstanding, end of period	31,363,319	$ 0.19	21,657,776	$ 0.21
Exercisable, end of period	10,860,050	$ 0.23	3,665,124	$ 0.32

The following table details further information regarding stock options and restricted stock outstanding and exercisable at December 31, 2016:

	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	31,318,319	8.55	$ 0.19	10,815,050	$ 0.23
$1.01–$2.00	45,000	1.25	1.40	45,000	1.40
$2.01–$3.00	—	—	—	—	—
$3.01–$4.00	—	—	—	—	—
$4.01–$5.00	—	—	—	—	—
	31,363,319	8.54	$ 0.19	10,860,050	$ 0.23
Aggregate intrinsic value	$ 69,547			$ 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, 2016, of $0.11.

The following table summarizes the status of the Company's non-vested options for the years ended December 31, 2016 and 2015:

	2016		2015	
	Shares	Weighted Avg. Exercise Price	Shares	Weighted Avg. Exercise Price
Non-vested options, beginning of year	17,992,652	$ 0.18	2,878,739	$ 0.37
Granted	10,622,392	0.16	18,193,027	0.17
Vested	(8,035,609)	0.15	(2,038,435)	0.33
Forfeited	(76,166)	0.25	(1,040,679)	0.17
Non-vested options, end of year	20,503,269	$ 0.17	17,992,652	$ 0.18

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

	Year Ended December 31,	
	2016	2015
Stock option grants beginning of period	$ 846,347	$ 730,102
Stock-based arrangements during the period:		
Stock option grants	122,420	157,932
Restricted stock issued:		
Employee stock purchase plan	2,921	4,053
Director agreements	—	—
	$ 971,688	$ 892,087

As of December 31, 2016 and 2015, there was approximately $2,705,027 and $2,248,591 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 2.8 and 3.11 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, 2016 and 2015, $13,520 and $2,239, respectively, was contributed by the Company to the plan.

Note 13—Income Taxes

For the years ended December 31, 2016 and 2015, 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 2016 or 2015 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, 2016 and 2015, the expected income tax effect of the Company's deferred tax assets (liabilities) consisted of the following:

	2016	2015
Deferred tax asset:		
Tax effect of:		
Net operating loss carryforwards	$31,398,000	$29,122,000
Accrued expenses	19,000	87,000
Amortization of definite lived intangible assets	—	10,000
Non-qualified stock option compensation	598,000	315,000
Depreciation	68,000	72,000
Deferred revenue	943,000	880,000
Other	1,000	139,000
Patents	—	(23,000)
Deferred gain on installment sale	(1,000)	—
State net operating loss carryforwards, net of federal tax benefit	929,000	579,000
Research tax credit carryforwards	2,433,000	2,274,000
Total deferred tax assets	36,388,000	33,455,000
Valuation allowance	(36,388,000)	(33,455,000)
Net deferred tax assets	$-	$-

As of December 31, 2016, the Company had gross net operating loss (NOL) and research tax credit carryforwards of approximately $94.9 million and $1.7 million, respectively, for federal income tax purposes, expiring in varying amounts through the year 2036. Of the $94.9 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, 2016, the Company had gross NOL and research tax credit carryforwards of approximately $17.6 million and $1.1 million for state income tax purposes, expiring in varying amounts through the year 2036.

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 May 2013, December 2014 and July 2016, 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, 2016, tax years for 2013, 2014 and 2015 are subject to examination by the tax authorities. Since the Company is in a loss carry-forward position, the Company is generally subject to U.S. federal and state income tax examinations by tax authorities for all years for which a loss carry-forward is utilized. However, carryforward attributes from prior years may still be adjusted upon examination by tax authorities if they are used in an open period.

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

	2016	2015
Tax at statutory rate	(34.0)%	(34.0)%
State taxes, net of federal benefit	0.0	0.0
Research and development credit	(0.69)	(1.3)
Share based payment expense	0.0	1.6
Other	0.42	0.7
Removal of deferred tax asset on federal net operating losses	0.00	0.0
Establishment of deferred tax asset on state net operating losses and state deferred taxes, net of federal income tax benefits	(5.3)	(4.9)
Change in valuation allowance	39.6	37.9
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, 2016, the Company has introduced five 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, 2016 and 2015, approximately 24% and 45%, 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 4% and 13%, respectively, of our revenue came from sales through ABG's promotional product bundle program.

Note 15—Subsequent Events

In January 2017, Mark Carbeau was granted an option to purchase 1,278,653 shares of the Company's common stock related to the 2016 performance review process. This option has an exercise price of $0.1237 per share. The option vests as to ¼ of the shares on January 25, 2018, and as to 1/36 of the remaining unvested shares at the beginning of each calendar month thereafter beginning on February 1, 2018

In January 2017, Kenneth Kornman was granted an option to purchase 3,625,746 shares of the Company's common stock related to the 2016 performance review process. This option has an exercise price of $0.1237 per share. The option vests as to ¼ of the shares on January 25, 2018, and as to 1/36 of the remaining unvested shares at the beginning of each calendar month thereafter beginning on February 1, 2018

In January 2017, Stephan Toutain was granted an option to purchase 365,093 shares of the Company's common stock related to the 2016 performance review process. This option has an exercise price of $0.1237 per share. The option vests as to ¼ of the shares on January 25, 2018, and as to 1/36 of the remaining unvested shares at the beginning of each calendar month thereafter beginning on February 1, 2018.

On April 17, 2017, the Company sold $500,000 of Convertible Notes (the "2017 Notes") to each of Bay City Capital and Horizon Technology Finance Corporation (the "Note Holders"), for a total of $1,000,000 in aggregate principal. The 2017 Notes will convert into common stock if certain conditions are met. In connection with the issuance of the 2017 Notes, the Company also issued warrants to purchase common stock to the Note Holders. See Item 9B "Other Information" for more details.

Also on April 17, 2017, the Company entered into a series of agreements, including the Second Amendment of Venture Loan and Security Agreement and a warrant to purchase common stock, to restructure its existing debt under the Loan Agreement with the Lender, which resulted in the deferral of the principal amount due to the Lender on April 1, May 1, and June 1, 2017, and the potential deferral of the principal amount due to the Lender on July 1, August 1 and September 1, 2017, such potential deferral of principal is dependent upon whether, as of June 15, 2017, the Company provides evidence reasonably satisfactory to the Lender that the Company is actively negotiating a clinical services or similar agreement, the terms of which are satisfactory to the Lender, which the Company believes, in good faith, it will enter into no later than September 1, 2017. In exchange for agreeing to defer principal payments, the Lender was granted a warrant to purchase common stock. The number of shares of common stock issuable upon exercise of the warrant is determined by dividing the amount of principal payments deferred by the exercise price of the warrant, which could result in the warrant being exercisable for between approximately 5,519,604 and 11,039,209 shares. The warrant has an exercise price of $0.10438 per share, is exercisable on a net issuance basis and has a 10-year term. See Item 9B “Other Information” for more details.

On March 31, 2017, the Company announced that the Board of Directors had approved a work force restructuring, which became effective and was completed on March 30, 2017, to better utilize the Company’s resources, to align the Company’s organization to support its emerging cardiovascular testing program, for which it is seeking strategic interest, and to streamline its commercial strategy for its ILUSTRA Inflammation Management Program. As a consequence of the restructuring, the Company reduced its workforce in its commercial organization and administrative functions by eight persons. We continue to support the ILUSTRA Program deployments with customers and will advance new customer relationships that expand the evidence base of this program’s effectiveness.

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, 2016. 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, 2016, 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***

Bridge Financing

On April 17, 2017, we entered into a Subscription Agreement (the "Subscription Agreement"), with funds affiliated with Bay City Capital ("Bay City Capital") and Horizon Technology Finance Corporation ("Horizon") under which we issued and sold $500,000 of Subordinated Convertible Promissory Notes (the "2017 Notes") to each of Bay City Capital and Horizon (the "Note Holders"), for a total of $1,000,000 in aggregate principal amount. The 2017 Notes will convert in common shares:

(a) Upon the closing of a Qualified Financing (defined as our next common stock financing, whether in a single transaction or series of related transactions, whether a public or private financing, yielding aggregate cash proceeds to us (inclusive of amounts converted under the 2017 Notes or other outstanding indebtedness) of at least $5.0 million on or before January 1, 2022. The unpaid principal amount and accrued interest outstanding under the 2017 Notes shall automatically convert in whole into fully paid and nonassessable shares of our common stock. The total number of shares of common stock issuable upon conversion of the 2017 Notes in this circumstance shall be determined by dividing (i) the then outstanding principal amount and accrued interest under the 2017 Notes by (ii) a conversion price equal to (A) eighty percent (80%) multiplied by (B) the lowest price per share of the common stock paid by investors in such Qualified Financing;

(b) In the event that a change of control occurs before the closing of a Qualified Financing and on or before January 1, 2022, then upon the written election of the holders of 2017 Notes representing at least fifty percent (50%) of the aggregate principal amount of all 2017 Notes, the unpaid principal amount and accrued interest outstanding under the 2017 Notes shall convert in whole into fully paid and nonassessable shares of common stock immediately before the closing of the change of control. The total number of shares of common stock issuable upon conversion of the 2017 Notes in this circumstance shall be determined by dividing (i) the then outstanding principal amount and accrued interest under the 2017 Notes by (ii) a conversion price equal to (A) eighty percent (80%) multiplied by (B) the price per share of our common stock in such change of control; or

(c)

At the option of the individual Note Holder at any time before the Maturity Date, the unpaid principal amount and accrued interest outstanding under the 2017 Note may be converted in whole or in part into fully paid and nonassessable shares of common stock. The total number of shares of common stock issuable upon conversion of the particular 2017 Note in this circumstance shall be determined by dividing (i) the then outstanding principal amount and accrued interest under the 2017 Note by (ii) a conversion price equal to $0.125256.

The 2017 Notes are secured by a security interest in all of our assets and are subordinated to our existing venture loan with Horizon.

In addition, under the Subscription Agreement, each Note Holder received a Warrant to purchase our common stock (the “2017 Note Warrants”). The 2017 Note Warrants have an exercise price per share of $0.10438 and are exercisable for that number of shares of our common stock equal to the original principal amount of the corresponding 2017 Note divided by such exercise price, or an aggregate of approximately 9,580,379 shares. The 2017 Note Warrants are exercisable on a net issuance basis and have a 5-year term.

The 2017 Notes and 2017 Note Warrants were issued in a private placement pursuant to the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

Copies of the Subscription Agreement, the form of 2017 Notes and the form of the 2017 Note Warrants are filed as Exhibits 10.21, 4.12 and 4.11, respectively, to this Annual Report on Form 10-K and are incorporated herein by reference. The foregoing description does not purport to be complete and is qualified in its entirety by reference to such Exhibits.

Amendment to Venture Loan and Security Agreement

Also on April 17, 2017, we entered into a series of agreements, including the Second Amendment of Venture Loan and Security Agreement and a warrant to purchase common stock, to restructure our existing debt with Horizon, which resulted in the deferral of the principal amount due to Horizon on April 1, May 1, and June 1, 2017, and the potential deferral of the principal amount due to Horizon on July 1, August 1 and September 1, 2017, such potential deferral of principal is dependent upon whether, as of June 15, 2017, we provide evidence reasonably satisfactory to Horizon that we are actively negotiating a clinical services or similar agreement, the terms of which are satisfactory to Horizon, which we believe, in good faith, we will enter into no later than September 1, 2017. In exchange for agreeing to defer principal payments, Horizon was granted a warrant to purchase our common stock. The number of shares of common stock issuable upon exercise of the warrant is determined by dividing the amount of principal payments deferred by the exercise price of the warrant, which could result in the warrant being exercisable for between approximately 5,519,604 and 11,039,209 shares. The warrant has an exercise price of $0.10438 per share, is exercisable on a net issuance basis and has a 10-year term.

The warrant issued to Horizon in connection with the debt restructuring was issued as a private placement pursuant to the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

Copies of the Second Amendment of Venture Loan and Security Agreement and the form of warrant issued to Horizon in connection with the Second Amendment are filed as Exhibits 10.18.3 and 4.10, respectively, to this Annual Report on Form 10-K and are incorporated herein by reference. The foregoing description does not purport to be complete and is qualified in its entirety by reference to such Exhibits.

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 2017 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 2017 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 2017 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 2017 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 2017 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)
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))
4.8	Form of Warrant issued to Investors in the 2016 Private Placement (incorporated herein by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on August 1, 2016)
4.9	Form of Warrant issued to Horizon Technology Finance Corporation and its affiliates in the 2016 Debt Restructuring (incorporated herein by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on August 26, 2016)
4.10*	Form of Warrant issued to Horizon Technology Finance Corporation and its affiliates in the April 2017 Debt Restructuring
4.11*	Form of Warrant issued to Investors in the April 2017 Bridge Financing
4.12*	Form of Subordinated Convertible Promissory Note issued to Investors in April 2017 Bridge Financing
	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)

Exhibit No.	Identification of Exhibit
10.1.3	Third Amendment to Commercial Lease, dated as of September 27, 2016, 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 September 30, 2016)
	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)
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 May 19, 2016 and effective as of August 15, 2016, by and between Interleukin and Stephan Toutain (incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q filed on November 14, 2016)
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)
	Financing Agreements
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)

Exhibit No.	Identification of Exhibit
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)
10.18.1	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)
10.18.2	First Amendment of Venture Loan and Security Agreement, dated August 25, 2016, by and among Interleukin Genetics, Inc. and Horizon Credit II LLC, as assignee of Horizon Technology Finance Corporation (incorporated herein by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on August 26, 2016)
10.18.3*	

	Second Amendment of Venture Loan and Security Agreement, dated April 17, 2017, by and among Interleukin Genetics, Inc. and Horizon Credit II LLC, as assignee of Horizon Technology Finance Corporation
10.19	Securities Purchase Agreement, dated July 29, 2016, by and among Interleukin and the Investors in the 2016 Private Placement (incorporated herein by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on August 1, 2016)
10.20	Registration Rights Agreement, dated July 29, 2016, by and among Interleukin and the Investors in the 2016 Private Placement (incorporated herein by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed on August 1, 2017)
10.21*	Subscription Agreement, dated April 17, 2017 by and among Interleukin and the Investors in the April 2017 Bridge Financing
	Agreements with respect to Collaborations, Licenses and Research and Development
10.22.1	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)

Exhibit No.	Identification of Exhibit
10.22.2	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)
10.23	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)
10.24+	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)
10.25	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)
10.26+	Services Agreement, effective as of February 1, 2016, by and between Interleukin Genetics, Inc. and Metagenics, Inc. (incorporated by reference to Exhibit 10.23 of the Company's Annual Report on Form 10-K filed on March 16, 2016)
10.27+	Services Agreement, dated July 1, 2016, by and between Interleukin Genetics, Inc. and Alticor Inc. (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on November 14, 2016)
	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, 2016, 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.

** To be filed by amendment.

+ 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: April 17, 2017

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)	April 17, 2017
/s/ Stephen J. DiPalma Stephen J. DiPalma	Interim Chief Financial Officer (Principal Financial and Accounting Officer)	April 17, 2017
/s/ JAMES M. WEAVER James M. Weaver	Chairman of the Board	April 17, 2017
/s/ Lionel Carnot Lionel Carnot	Director	April 17, 2017
/s/ Joseph M. Landstra Joseph M. Landstra	Director	April 17, 2017

/s/ Kenneth S. Kornman Kenneth S. Kornman	Director	April 17, 2017
/s/ William C. Mills III William C. Mills III	Director	April 17, 2017
/s/ Dayton Misfeldt Dayton Misfeldt	Director	April 17, 2017