INTERLEUKIN GENETICS INC
Form 10-K
March 29, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES AND EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2011
.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number: 001-32715

INTERLEUKIN GENETICS, INC.

(Name of Registrant in its Charter)

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

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

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

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

Common Stock, $.001 par value per share

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES xNO ¨

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

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

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

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

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

As of March 9, 2012 there were 36,756,236 shares of the registrant's Common Stock and 5,000,000 shares of the registrant's Series A Preferred Stock, issued and outstanding.

Documents Incorporated By Reference

Portions of the registrant's Definitive Proxy Statement for the 2012 Annual Meeting of Shareholders are incorporated by reference in Part III hereof.

INTERLEUKIN GENETICS, INC.

FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2011

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PART I

Special Note Regarding Forward-Looking Statements

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

Smaller Reporting Company – Scaled Disclosure

Pursuant to Item 10(f) of Regulation S-K promulgated under the Securities Act of 1933, as indicated herein, we have elected to comply with the scaled disclosure requirements applicable to "smaller reporting companies," including providing two years of audited financial statements.

Item 1. ***Business***

Overview

Interleukin Genetics, Inc. is a personalized health company that develops unique genetic tests to provide information to better manage health and specific health risks. Our overall mission is to provide genetic testing services to empower

individuals, physicians and dentists to better guide lifestyle and treatment options that can help individuals maintain or improve their health. We believe that our proprietary genetic tests can help our commercial distribution partners provide improved services to their customers, empower individuals to personalize their health, and assist pharmaceutical companies to improve drug development and use by identifying subpopulations that are more responsive to a therapy. Our business focuses on personalized health, by providing genetic tests with strong clinical value. Our tests are made available via marketing partners or directly to end users. The business focus contributes toward our overall mission of providing services that can help individuals maintain or improve their health through preventive or treatment measures.

We believe that by providing important genetic information combined with a set of actions and recommendations about possible interventions and therapies, we can help individuals improve their health outcomes. We have patents covering the use of certain gene variations and specific combinations of gene variations for a number of common chronic diseases and conditions.

We believe that one of the great challenges confronting healthcare today is to better understand why some people are more prone than others to develop various medical conditions and why some people respond to treatments for those conditions differently than do others. Until individuals or their providers are able to understand the underlying causes of such variability, healthcare will remain largely constrained by the current approach of broad treatment rather than customized prevention and therapy. Most recommendations for a given condition do not consider genetic differences among individuals and, as a result, individuals whose conditions may be different because of genetic variation all receive the same treatment.

Until recently, scientific study of chronic health conditions has largely focused on identifying initiating factors that are causative and ways to alter or reverse the cause or condition. Common examples of altering or reversing initiating factors include calorie reduction in the case of being overweight, reducing levels of cholesterol in the case of heart disease, elimination of bacteria in the case of periodontal disease and increasing estrogen levels in the case of osteoporosis. However, it is now well established that while intiating factors are essential for disease, the mere presence of such factors does not necessarily determine whether a single individual will develop an illness, have mild or severe disease, or respond the same way as everyone else. Many common conditions arise in part as a result of how our bodies respond and interact with various environmental factors.

Genetic Tests

Many people have the mistaken impression that genetics dictate how an individual will look or feel and that there is nothing one can do to change the destiny set by one's genes. While it is true that some genetics have a permanent effect on a person's appearance or condition (referred to as a phenotype), the vast majority of genetic influences of one's phenotype can be modified. An active field of research in healthcare today is better to understand the interaction between our environment and our genes. The scientific community is learning more each day about the role and significance of genetic variations, such as single nucleotide polymorphisms, or SNPs, and haplotypes, on an individual's health. SNP and haplotype analysis coupled with detailed knowledge of environmental factors now is an important area of study in order to improve human health. A SNP may cause a gene to make a different amount of a protein for a given condition, change the timing of protein synthesis or make a variant form of the protein; each of these changes may lead to a discernible physiological impact. However, certain lifestyle changes can influence significantly whether a set of genes are activated or inactivated despite the variation in the gene. Thus while the propensity for physiological impact is always present for a given set of genes and their variants, whether or not the condition manifests itself is often controlled by our environment and the lifestyle choices we make.

We have focused our research, development and commercialization efforts on identifying combinations of SNP variations for which there is biological understanding for certain uses associated with inflammation or metabolic disease. We have worked with several universities including the University of Sheffield in the United Kingdom to identify several SNPs and other factors that influence the body's inflammatory response. Our scientific advisory board includes Sir Gordon Duff, one of the pioneers in the understanding of the role that genetics plays in inflammatory disease pathways. In addition, we have conducted clinical studies for various indications throughout the world involving over 22,000 individuals to demonstrate clinical utility. To date, some of our clinical research collaborations include, or have included, studies at Stanford University, the University of North Carolina at Chapel Hill, the Mayo Clinic; Brigham & Women's Hospital (Harvard Medical School); University of California at San Francisco; University of California at San Diego; New York University Medical Center; University of Sheffield, (UK); Yonsei University Medical Center, (Korea); Tongji Medical College, (China); and Tuft's University Medical Center. We have also conducted research with the Geisinger Clinic.

Metabolism and Inflammation

Metabolism is the physical and chemical processes in an organism by which the organism's material substances are produced, maintained or destroyed and by which energy is made available. These processes maintain life and permit organisms to grow and reproduce as well as respond to their environments. Metabolism consists of two different categories; catabolism which breaks down organic matter to release energy and anabolism which uses energy to construct components of cells such as proteins, nucleic acids, or other components. The speed of metabolic processes can influence how much food an organism will require to live. Recent scientific results have shown that there are significant SNP variations in the genes that control various metabolic pathways and processes.

A person's weight or nutritional needs can be governed by the genetics involved in various metabolic pathways. The onset of a metabolic condition such as diabetes or obesity has been shown to be linked to lifestyle as well as genetic factors. Thus one's diet, exercise and nutrition choices have a strong effect on how the genetics that influence metabolism behave and thereby influence one’s overall health and well-being.

Inflammation is one of the body’s most basic protective mechanisms, and the understanding of the role of inflammation in disease and various other conditions has increased over the past few years. It is generally accepted that many chronic conditions begin with a challenge to the tissues of the body and that the inflammatory response system of an individual mediates the clinical manifestation. It is also now thought that SNP variations in the genes that influence the inflammatory process can have an important impact on a person’s risk/trajectory of a disease for the same set of initiating events or conditions.

Typical inflammatory diseases include rheumatoid arthritis and periodontitis. In recent years, inflammation has been found to affect several other major diseases of aging that were not previously considered inflammatory diseases, including heart disease and osteoarthritis. Chronic inflammation can influence the process that leads to acute heart attacks. For example, an individual who has a strong inflammatory response may be more successful in clearing a bacterial infection than an individual with a less robust inflammatory response. However, that strong inflammatory response may actually cause that individual to be at increased risk for a more severe course in one or more of the chronic diseases that generally affect people in mid to later life, such as cardiovascular disease, osteoporosis, osteoarthritis, asthma, periodontal disease and Alzheimer's disease. Individuals' gene variations influence the severity of the risks and predispositions to these diseases.

Intellectual Property

Our intellectual property is focused on the discoveries that link variations in key inflammation and metabolic genes to various conditions or illnesses. We initially had concentrated our efforts on variations in the genes for the interleukin family of cytokines, because these compounds appear to be one of the strongest control points for the development and severity of inflammation. Our patents also cover genetic variations in the Perilipin family of proteins and others that are involved in fat storage and metabolism.

We have patents issued on single SNPs and SNP patterns in gene clusters as they relate to use for identifying individuals on a rapid path to several medical conditions or for use in guiding the selection of diets, exercise, vitamin needs, preventive care and also therapeutic agents. Groups of SNPs are often inherited together as patterns called haplotypes. We have a U.S. patent issued on haplotypes in an interleukin gene cluster and their biological and clinical significance. We believe these patents are controlling relative to interleukin SNPs and haplotype patterns that would be used for genetic risk assessment tests.

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

Our intellectual property and proprietary technology are subject to numerous risks, which we discuss in the section entitled "Risk Factors" of this report. Our commercial success may depend at least in part on our ability to obtain appropriate patent protection on our therapeutic and diagnostic products and methods and our ability to avoid

infringing on the intellectual property of others.

We have been granted a number of corresponding foreign patents and have a number of foreign counterparts of our U.S. patents and patent applications pending.

Our Approach to Test Development

We seek to develop tests that will benefit individuals wishing to understand ways to reduce risk of certain chronic conditions and illnesses or treatment guidance for their particular conditions. In order to do so, we believe a genetic test should be useful, understandable, credible and provide actionable guidance. The action resulting from the information we seek to provide through our genetic tests could be some form of medical treatment, dietary alteration, lifestyle change, or more careful monitoring of the person's condition. Before developing a genetic test, we make it a priority to understand both its market potential and our ability to launch and sell effectively.

Multiple genes and complex gene interactions along with environmental factors determine the probability for an individual contracting many common diseases. We may develop a test based on our proprietary genetic markers or public markers including important SNPs we have identified if: a) clinical studies show that their effect has a critical and unique influence on the clinical expression of disease, or b) the genetic markers guide the development or use of lifestyle, preventive measures or therapeutic agents that modulate the specific actions of those genetic factors. The effects of our genetic factors must be sufficiently powerful so that these genetic markers cannot be excluded from a test panel without substantially reducing the practical clinical usefulness of the test. For example, clinical studies have shown that in patients with a history of heart disease, higher levels of inflammation (as measured by certain markers such as C-reactive protein, a transient marker for inflammation) are one predictor of many for future heart attacks. Indeed, published studies indicate that chronic underlying inflammation is a critical factor for increased heart attack risk. We believe that our proprietary genetic variations reliably identify those individuals who have a lifelong tendency to experience elevated inflammation and therefore to have higher inflammation-based risk for heart disease. Development efforts will continue to use our proprietary genetic technology as part of a broader genetic panel that predicts an individual’s risk for disease as he or she ages or predicts a patient’s likelihood of severe complications from disease or response to specific treatment if the individual has already been diagnosed with disease.

For each targeted clinical area that meets our criteria, we may develop one or more proprietary tests that are anchored by our intellectual property, plus additional candidate genes that have been validated and shown to be of value. Other genes that are added to a test panel may be in-licensed or may be available from the public domain. For example, the osteoporosis risk assessment panel we launched in December 2009 includes multiple SNPs covered by our intellectual property, plus additional genes that have been validated as risk factors for osteoporosis. Since knowledge about the genes involved in human health will continue to evolve over many years, we may introduce test panels that initially have our proprietary genetic factors with successive versions of additional genes.

We also believe that combining, in non-obvious ways, single gene variations to create a unique or novel tool may result in new, proprietary intellectual property for us. For example, the weight management genetic test panel we introduced in June 2009 involves five SNPs in four genes that we combined into novel patterns. We have filed patent applications covering this product.

In the past few years, the use of haplotypes has become a standard approach to genetic risk assessment for complex diseases. Haplotypes are blocks of SNPs that are inherited together from one parent and in some cases the specific block of SNPs has functional significance beyond the biological functions attributable to the individual SNPs. The same SNP may have very different effects on gene function in different individuals depending on the haplotype context. We believe that we have expertise, experience and intellectual property related to the use of haplotypes in assessing genetic risk for complex diseases and we have filed patent applications in this area as well.

Business Strategy

Our revenue model consists of:

- sales from our Inherent Health® brand of genetic tests either directly to end users or through partnerships such as the Amway Global channel;
- sales of our genetic tests to commercial distribution partners such as regional weight loss centers and insurance providers;
- royalties or profit sharing from sales of genetic test products developed by us and marketed by a partner such as LABEC Pharma and Quest Diagnostics' OralDNA Labs division;
- fees for contract research with third parties; and

- license fees for our intellectual property to our tests.

In August 2008, we entered into a nonexclusive license agreement with OralDNA Labs, Inc., a division of Quest Diagnostics to market our PST genetic risk assessment test for the prediction of periodontal disease. Quest Diagnostics, partnered with Henry Schein, sells the PST test directly to dentists throughout the United States. We earn a royalty from each sale of the PST test and can earn processing fees when samples are sent to our laboratory.

In April 2009, we entered into an exclusive license agreement with LABEC Pharma to market in Spain and Portugal our heart health genetic risk assessment test for the prediction of early heart attack. The test is marketed under the brand name Cardiohealth™. In January 2010, European regulatory authorities authorized LABEC Pharma to begin selling the CardioHealth product. Labec has begun delivering samples to us for processing.

In June 2009, we launched our own brand of consumer genetic tests under the name Inherent Health®. Our business strategy is to develop tests for our own business needs under the Inherent Health® brand and perform R&D services for partners interested in developing genetic tests to support their products. In addition, we plan to commercialize R&D tests through strategic alliances. We plan to continue to grow the Inherent Health® business and to continue to launch tests in new channels, including through distribution partners. In 2010 we added a number of commercial partners to distribute our weight management test.

In October 2009, we entered into a Merchant Network and Channel Partner Agreement with Alticor's Amway Global Company to market our Inherent Health® genetic assessment tests. Under this agreement, Amway Global's independent business owners, or IBOs, are able to purchase the Inherent Health® brand of genetic tests via a hyperlink from the Amway Global website to the Inherent Health® website. We believe our proprietary genetic test brands supports the efforts of Amway Global to develop personalized consumer products for their IBO's customers. Sales with Amway Global through this business arrangement began in December 2009.

Our Products and Product Development Pipeline

Our current business plan includes focusing our efforts on commercializing our existing genetic tests and developing additional genetic tests. Our plan is to develop and commercialize tests that (1) identify healthy individuals who have a higher probability of increased risk for early or more severe health risks, (2) allow for an individual to understand which lifestyles will be best suited for his or her needs and (3) may be used in patients who have already been diagnosed with a specific disease to identify those patients who are more likely to develop severe disease complications and to guide better treatment.

Inherent Health® Brand of Genetic Tests

Weight Management Genetic Test

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

Our *Weight Management Genetic Test* helps take the guesswork out of finding an effective diet and exercise solution by revealing actionable steps to achieve weight goals based on genetics. The test determines whether a low fat, low carbohydrate or balanced diet may be best and whether normal or vigorous exercise is needed to most efficiently lose existing body fat. The test provides new information beyond traditional assessments, so that nutritional intake and fitness routines can be tailored for improved, sustainable results. This test identifies five SNPs in four human genes; fatty acid binding protein 2 (FABP2), adrenergic receptor beta 2 (ADRB2 –two variations), adrenergic receptor beta 3

(ADRB3), peroxisome proliferator-activated receptor gamma (PPAR-). These markers are involved in certain physiological pathways relating to body weight. Certain patterns of markers are associated with differential response to certain diet and exercise regimens.

We have conducted a number of studies that demonstrate a gene-diet interaction based on the multi-locus patterns noted above. The first study, completed in 2010, involved subjects who originally participated in Stanford Univ