INTERLEUKIN GENETICS INC
Form 10-K/A
April 04, 2007

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

AMENDMENT NO. 1 TO 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, 2006

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 Exchange Act:

Common Stock, $0.001 par value per share	**American Stock Exchange and Boston Stock Exchange**

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

Common Stock, $0.001 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 o 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 o 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 o

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. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer o Accelerated filer x Non-accelerated filer o.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES o 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 fiscal quarter was $133,522,757.

As of March 31, 2007 there were 27,598,413 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 2007 Annual Meeting of Shareholders to be held on or about June 12, 2007, are incorporated by reference in Part III hereof.

Explanatory Note

We are filing this Amendment on Form 10-K/A to our Annual Report on Form 10-K to correct a typographical error as follows:

The income tax rate reconciliation disclosed in Note 15 of our Consolidated Financial Statements included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 2, 2007, inadvertently included an incomplete duplicate table and a three-year rate reconciliation that did not reflect the final version. This amended Form 10-K/A includes the final version of the rate reconciliation.

Forward-Looking Statements

This report on Form 10-K and the documents incorporated by reference within this document contain certain forward-looking statements within the meaning of Section 27A of the Securities Act 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, similar 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 Risk Factors 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 this Form 10-K. Unless required by law we accept no responsibility to update this information.

INTERLEUKIN GENETICS, INC.

FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2006

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PART I

Item 1. *Business*

Overview

Interleukin Genetics, Inc. is a Delaware corporation. We currently have two main segments to our business. The first is a personalized health segment primarily focused on the role that genetically determined variations in the inflammatory response have on health and disease. Our second segment, comprising the Alan James Group business, focuses on developing, selling and marketing both nutritional supplements and OTCeuticals® into retail consumer channels. These two segments contribute toward our overall mission of developing tests and products that can help individuals improve and maintain their health through preventive measures. We plan to pursue this by:

- developing genetic risk assessment tests for use in multiple countries and various demographics;
- processing genetic risk assessment tests in our Clinical Laboratory Improvement Act of 1988 (CLIA) certified lab;
- developing nutritional products and OTCeuticals to be distributed in multiple consumer channels globally; and may
- conduct research and development of personalized preventive and therapeutic botanicals based on individuals genetic information.

We believe that by identifying individuals whose risk for certain chronic diseases is potentially increased due to variants in one or more genes and combining this knowledge with personalized interventions, we can help individuals improve their health outcomes. We have patents covering the influence of certain gene variations on risk for a number of common chronic diseases and conditions.

We believe that one of the great challenges confronting medicine today is to understand why some people are more prone than others to developing serious chronic diseases and why some people respond to treatments for those diseases differently than others. Until doctors are able to understand the underlying causes of such variability, the practice of medicine will remain largely constrained to the current approach of prescribing therapies based on broad, sweeping recommendations in which very different individuals receive the same treatment.

Until recently, scientific study of chronic diseases has largely focused on identifying factors that cause a disease. Common examples of such factors include high levels of cholesterol in the case of heart disease, bacteria in the case of periodontal disease and reduced estrogen levels in the case of osteoporosis. However, the mere presence of these initiating factors does not necessarily mean a person will develop a disease. Common diseases arise in part as a result of how our bodies respond to various environmental factors.

In March 2003, we entered into a broad strategic alliance with Alticor. Alticor has a long history of manufacturing and distributing nutritional supplements and skin care products to a worldwide market. Although we are seeking to develop a pipeline of genetic tests and nutritional products for various market channels, we have devoted substantially all of our resources during the past three years in support of our collaboration with Alticor.

In August 2006, we acquired the assets and business of the Alan James Group, which develops, markets and sells nutritional supplements and OTCeuticals, which combine supplements with the United States Food and Drug Administration (FDA)-monographed ingredients, such as aspirin. This acquisition also brought us a team of experienced management, marketing and product development personnel, which is based in Boca Raton, Florida. We currently intend to commercialize our OTCeuticals through various marketing channels such as direct response, retail, and possibly other consumer channels. The nutritional

supplement market is characterized by rapid and frequent changes in demand for products and new product introductions. As a result, it is important for us to periodically evaluate our product mix and rapidly implement changes, including developing or acquiring rights to new products and programs and eliminating non-strategic products and programs.

Inflammation

One of the many benefits from the sequencing of the human genome is a new understanding of the role of genetic variations, such as single nucleotide polymorphisms (SNP) and haplotypes. Once used as a tool to help scientists decipher the human genome, SNP and haplotype analysis now is an important tool used to study the relevance of genetic variations to human health. A common SNP may cause a gene to make a different amount of a protein or to make a variant protein, both of which may lead to a discernible physiological impact. We have focused on the SNP variations associated with inflammation and have over the years conducted clinical studies involving over 20,000 individuals. During the last decade we have worked with the University of Sheffield in the United Kingdom, to identify several SNPs that influence the body s inflammatory response.

Inflammation is one of the body s most ancient protective mechanisms. Over the last dozen years, understanding of the role of inflammation in several diseases has increased. It is now accepted that many chronic diseases begin with a challenge to the tissues of the body and that the inflammatory response system of an individual mediates the clinical manifestation of the disease. The diagram below reflects some of the diseases that are thought to be significantly influenced by inflammation. It is 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.

Inflammation is the first organized response to any injurious challenge to the body, such as a bacterial infection. It is a well-defined process that involves the migration and activation of leukocytes from the blood to the site of challenge. The objective of inflammation is to localize and destroy the deleterious agent. If the deleterious agent cannot be cleared, the inflammation becomes chronic.

There are classic inflammatory diseases, such as rheumatoid arthritis, but in recent years inflammation has been found to affect several other major diseases. For example, it is now known that chronic inflammation can influence the process that leads to acute heart attacks. If an individual has a strong inflammatory response, he or she may be more successful in clearing a bacterial infection than an

individual with a less robust response. However, an individual with a strong response may actually be at increased risk for a more severe course in one or more of the chronic diseases of mid to later life, such as cardiovascular disease, osteoporosis, and Alzheimer s disease.

Historical Development

In the early 1990s, as we were beginning to focus on the importance of interleukin-1 (IL-1), Gordon Duff in the United Kingdom identified the first SNPs in the IL-1 and tumor necrosis factor alpha (TNFα) genes, and he and other investigators demonstrated that individuals with some of those variations produced higher levels of IL-1 and TNFα. In 1993, we initiated research collaborations with Dr. Duff, and in 1994, we initiated a joint venture agreement with the University of Sheffield to investigate and patent the clinical use of variations in the genes that control inflammation. The research collaboration relationship lasted for 10 years and helped us generate a number of patents. Dr. Duff continues to serve as a member of our scientific advisory board.

Studies by us and others have now shown that individuals who have certain IL-1 gene variations or patterns of variations tend to have increased levels of IL-1 and also tend to have increased levels of other inflammatory mediators that are produced downstream of IL-1.

Individuals with another specific genotype pattern tend to have lower levels of inflammatory mediators. It is also important to note that the IL-1 gene variations on which we are focused are highly prevalent in the population, with 8-10% of the Caucasian population being homozygous (having two copies) for the less frequent variant and an estimated 30% of the Caucasian population having one copy of the gene variant. Also, up to 59% of the Caucasian population will test positive for some of the IL-1 high risk patterns.

Interleukin s Current Approach to Test Development

Our intellectual property is focused on the discoveries that link genetic variations in key inflammation genes to risk for disease. We have concentrated our efforts on variations in the genes for IL-1, since the IL-1 gene appears to be one of the strongest control points for the development and severity of inflammation. We have patents issued on single SNPs and SNP patterns in the IL-1 gene cluster as they relate to use for identifying individuals on a rapid path to chronic disease complications and use for guiding selection of preventive and therapeutic agents. Groups of IL-1 SNPs are often inherited together as patterns called haplotypes. We have a U.S. patent issued on haplotypes in the IL-1 gene cluster and their biological and clinical significance.

We believe these patents are controlling relative to IL-1 SNP and haplotype patterns that would be used for genetic risk assessment tests. To date, this intellectual property has not led to significant revenues.

Multiple genes and complex gene interactions with environmental factors determine the risk for the common diseases for which we are developing tests. We will develop a test based on our proprietary genetic factors if: a) clinical studies show that their effect has a critical and unique influence on the clinical expression of disease, or b) our genetic factors guide the development or use of preventive or therapeutic agents that modulate the specific actions of those genetic factors. In the former application, the risk effects of our genetic factors must be sufficiently powerful such that these genetic factors cannot be excluded from a test panel without substantially reducing the practical clinical usefulness of the test. For example, in patients with a history of heart disease, higher levels of inflammation (as measured by C-reactive protein) are as predictive of future heart attacks as higher levels of LDL cholesterol. We believe that our proprietary genetic variations identify healthy individuals who have a lifelong tendency to experience elevated inflammation and therefore to have higher risk for heart disease.

There are gene families that influence other non-inflammatory biological mechanisms involved in cardiovascular disease such as the genetic factors involved in cholesterol metabolism. For each targeted clinical disease area that meets our criteria, we are developing proprietary risk assessment tests that are anchored by our intellectual property plus additional candidate genes that have been validated and shown to be of value in assessing risk. Other genes to be added to a test panel may be in-licensed or may be available from the public domain. Since knowledge about the genes involved in health risks 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. The heart health risk assessment panel introduced in the Alticor channel in 2006 involves three SNPs in two genes covered by our intellectual property. The osteoporosis risk assessment panel we are developing for the Alticor channel includes multiple SNPs covered by our intellectual property plus additional genes that have been validated as risk factors for osteoporosis.

In the past few years, genome-wide association (GWA) studies have become possible as one approach to identify the association of many genes with specific health risks. These studies are now practical due to the commercial availability of genome-wide array technologies. Most of the GWA studies are being conducted through government-funded consortia. We have access to GWA technologies and expertise through some of our collaborators. In diseases/conditions for which GWA technologies are being used in large government-funded studies, we may in-license or access publicly available SNPs for our panels. In diseases/conditions for which other GWA studies are not available, we may choose to employ GWA technologies either internally or through external collaborations to add value to our test panels. All of these technologies are dependent on high quality clinical databases, which we are collecting throughout the world for selected health risks. The use of GWA approaches to health risks is new, and data coming out of the first studies may take many years to validate.

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. As recently reported studies support, 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. We have recently reported that the same SNP may have very different effects on gene function in different individuals depending on the haplotype context.

We have recently in-licensed international rights to the use of gene variations, or genotypes, that regulate one important mechanism involved in fat metabolism. U.S. patents have been filed to cover the use of these genetic factors. When an individual consumes more calories than he or she burns, the excess energy is stored in fat cells as lipid droplets. One of the key chemicals that regulates the mobilization of fat from the lipid droplet to be burned as energy is called perilipin. Investigators at Tufts University Medical School and Tufts Human Nutrition and Research Center have identified variations in the perilipin gene that appear to regulate fat metabolism and body weight. Studies have been completed on several thousand individuals showing that women with one specific perilipin genotype weigh an average of 22 pounds more than women with another perilipin genotype. Six clinical studies were published from 2004 through 2006 on the influence of perilipin genotypes on weight and related biological parameters. This work is under the direction of Dr. Jose Ordovas, an international expert on the genetics of cardiovascular disease and on the interactions of genetics and nutrition. We have licensed rights to the use of this genetic test for weight management and for the use of this genetic information to develop nutritional products to facilitate weight management in individuals who have certain perilipin gene variations. We and our collaborators have completed a substantial amount of research on the use of a perilipin genetic test for guiding weight loss and weight maintenance. We must perform a significant amount of additional research before we will know whether this information can also be used as the basis for nutritional products of value to consumers.

In some cases, we have and may continue to develop genetic test panels that have limited-to-no exclusive intellectual property but meet specific needs of Alticor, our distribution partner. The general nutrition panel launched in the U.S. and under development internationally, as described below, is an example of such a test panel.

Business Strategy

Our strategy is to develop products and perform services and commercialize such products and services through strategic alliances. In March 2003, we entered into a broad strategic alliance with Alticor to develop and market novel genetic risk assessment tests and nutritional and skin care products. The alliance utilizes our intellectual property and expertise in genetics to develop risk assessment tests and to aid Alticor in its effort to develop personalized consumer products. The alliance has included equity investments, multi-year research and development agreements, the deferment of outstanding loan repayment and the refinancing of bridge financing obligations. A licensing agreement includes sales of selected genetic tests to Alticor for distribution within their channel. In addition, we receive minimal royalties on marketed Alticor nutritional products that are linked to the genetic tests.

We expect that this alliance will open our products and services to our partner s proven marketing and distribution channels (including in Asia). Alticor and we share a belief that the future of personalized nutritional supplements and skin care will be based on an individual s genetic makeup. This alliance is currently focused on developing genetic risk assessment tests to determine a genetic profile of an individual and developing nutritional supplements and skin care products that will benefit individuals of that genetic profile. Our activities in the skin care field are at an early stage.

We develop tests and plan to develop products and services that can help individuals improve and maintain their health through preventive measures. We plan to:

- develop genetic risk assessment tests for use in multiple countries and various demographics;
- process genetic risk assessment tests in our CLIA certified lab;
- develop nutritional products and OTCeuticals to be distributed in multiple consumer channels globally; and may
- conduct research and development of personalized preventive and therapeutic botanicals based on individuals genetic information.

Product Development Focus

We expect our revenue model to consist of: 1) charging fees for processing genetic risk assessment tests; 2) receiving royalties from sales of products developed with and marketed by a partner, or profit sharing from product sales; 3) receiving fees for contract research; and 4) sales of consumer products, including those acquired in our August 2006 acquisition of the business and assets of the Alan James Group.

Products Available for Sale

Gensona Genetic Tests

We have research agreements with Alticor to develop certain genetic tests, which Alticor will market to consumers through its channels under Alticor s Gensona brand. In 2006, we provided two genetic risk assessment tests through Alticor. The Gensona Heart Health Genetic Test uses SNP testing of two genes to identify persons who may have an over-expression of inflammation and therefore may be at increased risk for cardiovascular disease. The Gensona General Nutrition Genetic Test identifies SNPs of potential importance in two genes that affect vitamin B metabolism and four genes involved in responding to oxidative stress. The Gensona tests are marketed solely through the Alticor business channel.

Nutritional Supplements and OTCeuticals

We currently market and sell a line of nutritional supplements to major retailers in the United States. We also have a distribution agreement for Kyolic® brand products. We currently intend to commercialize our OTCeuticals, which combine nutritional supplements with FDA-monographed ingredients, such as aspirin. We expect to commercialize these products through multiple channels such as direct response, retail and possibly other consumer channels. We intend to periodically evaluate our product mix and implement changes (including, where appropriate, the addition of new products and the elimination of existing products) to address trends in these markets in order to increase or even maintain market share.

Product Development

Our current plan is to develop products in three categories:

1. Genetic risk assessment tests these genetic tests identify healthy individuals who are at increased risk for early or more severe health risks. These tests may be combined with a complementary product or service.

2. OTCeuticals and other consumer nutritional products these include vitamins, minerals, herbs and other supplements which may be combined with FDA-monographed, U.S. Pharmacopeia (USP) grade ingredients in rational, safe, effective and convenient combinations.

3. Preventive and therapeutic botanicals We are considering conducting development and would expect these compounds to be either in-licensed from our strategic partner, Alticor, or developed all or in part by us to prevent or reduce signs and symptoms of common health risks. We may market these products through professional channels, requiring regulatory status consistent with the claims being made. This effort will require significant financial resources over many years before any material revenues are likely to be realized.

As of December 31, 2006, the following products were in our development pipeline:

- IL-1 Cardiovascular Genetic Test International
- General Nutrition Genetic Test International
- Osteoporosis Genetic Test North America and International
- Weight Management Genetic Test North America and International

- OTCeuticals United States

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IL-1 Cardiovascular Genetic Test International

In the last decade, studies in men and women have shown that inflammation is an important risk factor for cardiovascular disease. Recent scientific discoveries indicate that some of the risk for cardiovascular disease, including heart attacks, is due to variations in the genes that we inherit. Just as with conventional cardiovascular risk factors such as high cholesterol, smoking and diabetes, the presence of one or more of these DNA variations does not mean that an individual will develop cardiovascular disease. However, using knowledge about genetic risk factors to make informed choices about diet and lifestyle may reduce the risk of developing cardiovascular disease in the future.

Our heart health genetic test analyzes two IL-1 genes for variations that identify an individual s predisposition for over-expression of inflammation and which may cause an increased risk for cardiovascular disease. This test is not intended to and does not diagnose an existing disease but rather is intended for healthy individuals to help assess their risk for future disease. The IL-1 cardiovascular genetic test is based on data from genetic association studies obtained through collaborations with experts in cardiovascular disease at leading academic institutions. This genetic test provides risk information independent of traditional risk factors (such as family history, hypertension and smoking) in assessing risk for heart disease. This test panel was introduced in the Alticor North American channel in the first quarter of 2006. To date, we have determined that the high risk patterns are commonly found in all major ethnic populations. We have genetic association studies on cardiovascular disease in progress in Korea and China to determine how the risk assessment test will translate into other ethnic groups in specific environments.

General Nutrition Genetic Test International

To function properly, cells depend on the action of a vast number of genes. Our general nutrition genetic test analyzes variations in several genes that influence how the body uses certain vitamins and micronutrients. The test identifies individuals who may have altered B vitamin dependent metabolism or reduced response to oxidative stress. It analyzes two genes important to B vitamin utilization and four genes that are important in managing oxidative stress. This test, which is not proprietary, may be able to identify individuals who may benefit from particular nutritional supplements, and who may be at increased likelihood for health complications. This test is not intended to and does not diagnose a specific disease or assess a specific health condition. It is intended to provide information to individuals who are interested in knowledge that may help them make choices about the consumption of certain vitamins and anti-oxidants.

- **B Vitamin Genes:** The genes analyzed related to B vitamin metabolism are 5-10-methylenetetrahydrofolate reductase gene (MTHFR) and the transcobalamin 2 gene (TCN2). The variant of the MTHFR gene that was tested has been associated with less efficient activity of certain enzymes that depend on B vitamins for optimal function. The variant of the TCN2 gene that was tested has been associated with affecting the body s need for vitamin B-12 and how effectively it reaches cells.

- **Oxidative Stress Genes:** The genes analyzed related to oxidative stress are manganese superoxide dismutase 2 (SOD2), glutathione s-transferase M1 (GSTM1), paroxanase 1 (PON1), and x-ray repair cross complementing gene (XRCC1). In some studies, individuals with these genetic variations have a different response to oxidative stress. Knowing genetic variations associated with nutrient and vitamin metabolism may help guide decisions about use of vitamins and anti-oxidants.

Osteoporosis Genetic Test North America and International

Osteoporosis, the most common age-related bone disease, results in a decrease in the strength of the bone that leaves the affected individual more susceptible to fractures. According to the National Institute of Health, 10 million Americans suffer from the disease and another 34 million have low bone mass, placing them at increased risk for the disease. Although osteoporosis occurs in both men and women, it begins earlier and progresses more rapidly in women after menopause. The consequences of osteoporosis

can be both physical and financial. Hip and vertebral fractures, which are commonly associated with osteoporosis, have a profound impact on quality of life. We have conducted research projects with major osteoporosis centers. Results of these studies have indicated that a number of small variations in the IL-1 gene cluster, referred to as polymorphisms, are associated with a more rapid rate of bone loss and an increased risk of vertebral fracture in post-menopausal Caucasian women. A genetic risk assessment test could identify women at elevated risk for developing osteoporosis-related vertebral fracture comparatively early in the course of the disease and allow these women and their physicians to pursue risk reduction practices. This would enable nutritional or therapeutic intervention or recommendations for changes in lifestyle or diet at an early stage, so that bone loss and fractures are minimized or prevented.

Interleukin is developing an osteoporosis risk assessment test that combines the IL-1 SNPs with SNPs in other genes known to be associated with bone loss to form a test panel. This test panel has been evaluated in one of the largest clinical databases of fractures caused by osteoporosis, the Study of Osteoporotic Fractures (SOF), directed out of the University of California at San Francisco. The IL-1 SNPs are proprietary to Interleukin, and other genes in the panel are either public domain or will be in-licensed as needed. Efforts to develop the osteoporosis risk assessment test and the marketing have been driven in part by our research agreement with Alticor. We have genetic association studies on osteoporosis disease in progress in Korea to determine how the risk assessment test will translate into other ethnic groups in specific environments.

Weight Management Genetic Test North America and International

According to the 1999-2003 National Health and Nutrition Examination Survey, an estimated 65% of adults in the U.S. are overweight (Body Mass Index > 25). Overweight and obese individuals are at increased risk for many diseases including heart disease, type II diabetes, and some types of cancer. Our objective is to develop a test that offers information about how specific individuals gain and maintain weight. Interleukin has developed the basic elements of a genetic test panel that identifies genetically-determined metabolic differences that may contribute to weight management. This test panel will guide nutritional and exercise choices to enhance an individual s efforts to maintain a desirable weight. The genes and SNPs in the weight management test panel are either public domain or will be in-licensed as needed.

OTCeuticals

OTCeuticals are vitamins, minerals, herbs and supplements, which are combined with FDA-monographed, USP grade ingredients in rational, safe, effective and convenient combinations. The products currently under development include products for gastrointestinal and bone and joint support. We currently intend to market these products through direct response, retail, and possibly other consumer channels.

Laboratory Testing Procedure

To conduct a genetic risk assessment test, the consumer collects cells from inside the cheek on a brush and submits it by mail to our laboratory. Samples from some states can not be processed unless we first obtain a requisition signed from a physician. Our clinical laboratory then performs the test following our specific protocol and informs the consumer and, depending on the regulations in the particular state or (in Canada) province, his designated health care provider, of the results.

During 2004, we completed the construction of our genetic testing laboratory (for which we obtained registration under CLIA in 2005) to process the test samples. The regulatory requirements associated with a clinical laboratory are addressed under the section titled Government Regulation. Our lab is CLIA certified and in early 2007 we obtained a clinical laboratory permit from the State of New York for our IL-1 Cardiovascular Genetic Test.

Marketing and Distribution Strategy

We market and distribute our genetic tests through our strategic partnership with Alticor. We market and distribute our nutritional products through major retailers. We currently intend to commercialize our OTCeuticals through multiple marketing channels, including direct response, retail and possibly other consumer channels.

Reimbursement

Under our distribution agreement with Alticor, Alticor pays us directly for the processed tests. If in the future we develop products that are sold through the medical channel, our ability to successfully commercialize these products may depend on obtaining adequate reimbursement from third-party payers.

Partnerships with Academic Researchers

We have (or have had) research collaborations at the University of Sheffield (UK), Tufts University, Harvard University, the Mayo Clinic, California Pacific Medical Center, Boston University, the University of Arkansas, Tongji Medical College (China) and Yonsei University (Korea). Through these research collaborations, we have been able to take advantage of research done by these third parties in connection with the development of our genetic risk assessment tests and other possible products.

Intellectual Property

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 drug discovery and diagnostic products and methods. We currently own rights in twenty issued U.S. patents, which have expiration dates between 2015 and 2020, and have twenty-one additional U.S. patent applications pending, which are based on novel genes or novel associations between particular gene sequences and certain inflammatory diseases, and disorders. Of the twenty issued U.S. patents, sixteen relate to genetic tests for periodontal disease, osteoporosis, asthma, coronary artery disease, sepsis and other diseases associated with IL-1 inflammatory haplotypes.

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.

In addition, through our Alan James Group subsidiary which we acquired in August 2006, we own a portfolio of nutritional products brands, including Ginkoba®, Ginsana®, and Venastat®. We have received trademark protection for PST®, our periodontal genetic risk assessment test.

Competition

The competition in the field of personalized health is defined, but 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. The companies in the industry break down into four sectors, including, 1) predictive medicine companies, 2) SNP discovery companies, 3) personalized health companies, and 4) technology platform companies.

Our potential competitors in the United States and abroad are numerous and include, among others, major pharmaceutical and diagnostic companies, specialized biotechnology firms, universities and other research institutions. Many of our potential competitors have considerably greater financial, technical, marketing and other resources than we have, which may allow these competitors to discover important genes or successfully commercialize these discoveries before us. If we do not discover genes that are linked to a health risk, characterize their functions, develop genetic tests and related information services based on such discoveries, obtain regulatory and other approvals, and launch these services or products before competitors, we could be adversely affected. Additionally, some of our competitors receive data and

funding from government agencies. To the extent our competitors receive data and funding from those agencies at no cost to them, they may have a competitive advantage over us.

In the case of newly introduced products requiring change of behavior (such as genetic risk assessment tests), 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.

The business of manufacturing, distributing and marketing nutritional supplements and OTCeuticals is highly competitive. Many of our competitors are substantially larger and have greater financial resources with which to manufacture and market their products. The barriers to competition are low in the nutritional products and OTCeutical markets because the products are generally not protected by patents. In particular, the retail segment is highly competitive. In many cases, competitors are able to offer price incentives for retail purchasers and establish frequent buyer programs for consumers. Some retail competitors also manufacture their own products and therefore they have the ability and financial incentive to promote sales of their own products. Our ability to remain competitive depends on the successful introduction and addition of new offerings to our product line. We will also continue to focus on increased sales and marketing of our current products.

Government Regulation

The genetic risk assessment tests that we are developing and our current and future nutritional supplements will be subject to regulation by governmental entities.

Genetic Tests

CLIA

CLIA provides for the regulation of clinical laboratories by the United States Department of Health and Human Services. CLIA requires the certification of clinical laboratories that perform tests on human specimens and imposes specific conditions for certification. CLIA is intended to ensure the accuracy, reliability and timeliness of patient test results performed in clinical laboratories in the United States by mandating specific standards in the areas of personnel qualification, administration participation in proficiency testing, patient test management, quality control, quality assurance and inspections. CLIA contains guidelines for the qualification, responsibilities, training, working conditions and oversight of clinical laboratory employees. In addition, specific standards are imposed for each type of test that is performed in a laboratory. The categorization of commercially marketed in vitro diagnostic tests marketed under CLIA is the responsibility of the FDA. The FDA will assign commercially marketed test systems into one of three CLIA regulatory categories based on their potential risk to human health. Tests will be designated as waived, of moderate complexity or of high complexity. CLIA and the regulations promulgated thereunder are enforced through quality inspections of test methods, equipment, instrumentation, materials and supplies on a periodic basis.

Other Laboratory Regulations

CLIA does not preempt state laws that are more stringent than federal law. Some states independently regulate clinical laboratories and impose standards and requirements in addition to or more stringent than the CLIA regulations. Moreover, some states impose regulations on out-of-state laboratories that conduct tests on their residents. Finally, some foreign jurisdictions may also impose

regulations on our process of tests for their residents. We will be required to comply with all applicable laboratory regulations.

Food and Drug Administration

The FDA regulates the sale and distribution, in interstate commerce, of medical devices, including in vitro diagnostic test kits. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls, including labeling, pre-market notification and adherence to FDA s quality system regulations, which are device-specific good manufacturing practices. Class II devise are subject to general controls and special controls, including performance standards and post-market surveillance. Class III devices are subject to most of the previously identified requirements as well as to pre-market approval. Most in vitro diagnostic kits are regulated as Class I or II devices. Entities that fail to comply with FDA requirements can be liable for criminal or civil penalties, such as recalls, detentions, orders to cease manufacturing and restrictions on labeling and promotion.

The FDA presently requires clearance or approval of diagnostic test kits that are sold widely to labs, hospitals and doctors, considering them to be medical devices. However, diagnostic tests that are developed and performed by a CLIA-certified reference laboratory, also known as home-brew, in-house or laboratory-developed tests, have been generally considered clinical laboratory services. The FDA has stated that it has the power to regulate laboratory-developed tests such as the ones that we hope to develop. Nevertheless, it has exercised enforcement discretion in not regulating most laboratory-developed tests performed by high complexity CLIA certified laboratories.

On September 7, 2006, the FDA published a Draft Guidance describing the Agency s current thinking about potential regulation of In Vitro Diagnostic Multivariate Index Assays (IVDMIA). An IVDMIA is generally a test system that employs data derived in part from one or more in vitro assays and an algorithm that usually, but not necessarily, runs on software, to generate a result that diagnoses a disease of condition or is used in the cure, mitigation, treatment, or prevention of disease. IVDMIA tests may include prognostic tests using multiple genes to determine whether a patient has a high or low risk of recurrence or response to a particular chemotherapy. The comment period for the Draft Guidance ended on March 7, 2007, but the FDA has not yet issued a final guidance.

Although we are not currently offering or developing IVDMIAs, the FDA s interest in or actual regulation of laboratory-developed tests or increased regulation of the medical devices used in laboratory-developed testing could lead to periodic inquiry letters from the FDA and increased costs and delays in introducing new tests, including genetic tests. At the request of the FDA, we have met with it to discuss our tests and have submitted material for its review. It is possible that a changing regulatory climate could someday require advance regulatory approval of the launch of genetic risk assessment tests, which could have a material adverse effect on our business.

The degree to which laboratory-developed tests are regulated by FDA has also been the focus of recent Congressional attention, and Congress is considering the introduction of legislation that would subject all such tests (not only IVDMIAs) to premarket review or approval by the FDA.

HIPAA Compliance and Privacy Protection.

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 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. Covered Entities must have in place administrative, physical and technical standards to guard against the misuse of

individually identifiable health information. Additionally, some state laws impose privacy protections more stringent than those of HIPAA. There are also international privacy laws, such as the European Data Directive, that impose restrictions on the access, use, and disclosure of health information. Any of these laws may impact our business. 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.

Dietary Supplements

The manufacturing, processing, formulation, packaging, labeling and advertising of our nutritional products and OTCeuticals are subject to regulation by a number of federal agencies, including the FDA and the Federal Trade Commission (FTC). Our activities are also regulated by various state and local agencies where our products are sold.

FDA

The FDA is primarily responsible for the regulation of the manufacturing, labeling and sale of our nutritional products and OTCeuticals as dietary supplements. The Dietary Supplement Health and Education Act of 1994 (DSHEA) amended the Federal Food, Drug and Cosmetic Act by defining dietary supplements, which include vitamins, minerals, nutritional supplements and herbs, and by providing a regulatory framework to ensure safe, quality dietary supplements and the dissemination of accurate information about such products. Dietary supplements are regulated as foods under DSHEA and the FDA is generally prohibited from regulating the active ingredients in dietary supplements as food additives, or as drugs unless product claims trigger drug status. Generally, dietary ingredients not used in dietary supplements marketed before October 15, 1994, the date of DSHEA s enactment, require pre-market submission to the FDA of evidence of a history of their safe use, or other evidence establishing that they are reasonably expected to be safe. To date, our nutritional supplements and OTCeuticals have used ingredients that have been previously submitted to and approved by the FDA. There can be no assurance that the FDA will accept the evidence of safety for any new dietary ingredient that we may decide to use. FDA's refusal to accept such evidence could result in regulation of such dietary ingredients as food additives, requiring FDA approval based on newly conducted, costly safety testing.

DSHEA provides for specific nutritional labeling requirements for dietary supplements and permits substantiated, truthful and non-misleading statements of nutritional support to be made in labeling, such as statements describing general well being from consumption of a dietary ingredient or the role of a nutrient or dietary ingredient in affecting or maintaining structure or function of the body. There can be no assurance that the FDA will not consider particular labeling statements used by us to be drug claims rather than acceptable statements of nutritional support, necessitating approval of a costly new drug application. It is also possible that the FDA could allege false statements were submitted to it if structure/function claim notifications were either non-existent or so lacking in scientific support as to be plainly false.

In addition, the DSHEA authorizes the FDA to promulgate current good manufacturing practices (cGMPs) specific to the manufacture of dietary supplements, to be modeled after food cGMPs. We currently use a third-party manufacturer for our dietary supplement products, which manufacturer must comply with food cGMPs.

Dietary supplements are also subject to the Nutrition, Labeling and Education Act (NLEA), which regulates health claims, ingredient labeling and nutrient content claims characterizing the level of a nutrient in a product. NLEA prohibits the use of any health claim for dietary supplements unless the health claim is supported by significant scientific agreement and is pre-approved by the FDA.

In certain markets, including the United States, claims made with respect to dietary supplements may change the regulatory status of our products. For example, in the United States, the FDA could possibly take the position that claims made for some of our products make those products new drugs requiring approval or compliance with a published FDA over the counter (OTC) monograph. If the FDA were to assert that our product claims cause them to be considered new drugs or fall within the scope of OTC regulations, we would be required to either, file a new drug application, comply with the applicable monographs, or change the claims made in connection with those products.

The FTC regulates the marketing practices and advertising of all our products. In recent years, the FTC instituted enforcement actions against several dietary supplement companies for false and misleading marketing practices and advertising of certain products. 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.

We believe that we are currently in compliance with all applicable government regulations. We cannot predict what new legislation or regulations governing our operations will be enacted by legislative bodies or promulgated by agencies that regulate its activities.

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 a website at www.ilgenetics.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 our website 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 website is not incorporated by reference into this Form 10-K. We have included our website address only as an inactive textual reference and do not intend it to be an active link to our website.

Employees

As of March 31, 2007, we had 27 full-time and part-time employees. Of our employees, eight were engaged primarily in the research development, five were engaged in laboratory testing, six were engaged primarily in administrative or managerial activities and eight were engaged in running our products business.

Item 1A. *Risk Factors*

The market for genetic risk assessment tests is unproven.

The market for genetic risk assessment tests is at an early stage of development and may not continue to grow. The general scientific community, including us, has only a limited understanding of the role of genes in predicting disease. When we identify a gene or genetic marker that may influence risk for disease, we conduct clinical trials to confirm the initial scientific discovery and to establish the scientific discovery s clinical utility in the marketplace. The results of these clinical trials could limit or delay our ability to bring the test to market, reduce the test s acceptance by our customers or cause us to cancel the program, any of which would limit or delay sales and cause additional losses. The marketplace may never accept our products, and we may never be able to sell our products at a profit. We may not complete development of or commercialize our other genetic risk assessment tests.

The success of our genetic risk assessment tests will depend upon their acceptance as medically useful and cost-effective by patients, physicians, other members of the medical community and by third-party payers, such as insurance companies and the government. Our efforts to commercialize our intellectual