

INTERLEUKIN GENETICS INC
Form S-1
May 13, 2016

As filed with the Securities and Exchange Commission on May 13, 2016

Registration Statement No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM S-1

REGISTRATION STATEMENT

under the

SECURITIES ACT OF 1933

INTERLEUKIN GENETICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or other jurisdiction of incorporation
or organization)

2835

(Primary Standard Industrial
Classification Code Number)

94-3123681

(I.R.S. Employer
Identification Number)

135 Beaver Street

Waltham, Massachusetts 02452

(781) 398-0700

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Mark B. Carbeau

Chief Executive Officer

Interleukin Genetics, Inc.

135 Beaver Street

Waltham, Massachusetts 02452

(781) 398-0700

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: From time to time after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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.

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

CALCULATION OF REGISTRATION FEE

Title of securities to be registered (1)	Proposed maximum aggregate offering price (2)	Amount of Registration Fee (3)
Class A Units consisting of:		
(i) Common stock, par value \$0.001 per share, underlying the Class A Units		
(ii) Warrants to purchase common stock underlying the Class A Units		
Class B Units consisting of:		
(i) Series B Convertible Preferred Stock, par value \$0.001 per share, underlying the Class B Units		
(ii) Warrants to purchase common stock underlying the Class B Units		
Common stock issuable upon conversion of the Series B Convertible Preferred Stock		
Common stock issuable upon exercise of the warrants underlying the Class A Units and Class B Units		
Placement agent's warrants (4)		
Common stock issuable upon exercise of placement agent's warrants (4)		
Total	\$ 15,000,000	\$ 1,510.50

Pursuant to Rule 416 under the Securities Act of 1933, the securities registered also include such indeterminate (1) amounts and numbers of shares of common stock issuable to cover additional securities that may be offered or issued to prevent dilution resulting from stock splits, stock dividends or similar transactions.

(2)

Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

- (3) Calculated pursuant to Rule 457(o) based on an estimate of the total proposed maximum aggregate offering price. Represents warrants to purchase a number of shares of common stock equal to 7% of the common stock sold in this offering (including the number of shares of common stock issuable upon conversion of shares of Series B
- (4) Convertible Preferred Stock sold in this offering but excluding any shares of common stock underlying the warrants issued in this offering).

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. WE MAY NOT SELL THESE SECURITIES UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IS NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

SUBJECT TO COMPLETION, DATED May 13, 2016

PRELIMINARY PROSPECTUS

Up to of

Class A Units consisting of Common Stock and Warrants and

Class B Units consisting of Series B Convertible Preferred Stock and Warrants

(shares of Common Stock underlying the Series B Convertible Preferred Stock and Warrants)

We are offering up to of Class A Units (each consisting of one share of our common stock and a Series A warrant to purchase of a share of our common stock at an exercise price per share equal to % of the public offering price of the Class A Units (“Series A warrant”). The shares of common stock and Series A warrants underlying a Class A Unit are immediately separable and will be issued separately in this offering.

We are also offering to those purchasers, if any, whose purchase of Class A Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, the opportunity, in lieu of purchasing Class A Units, to purchase Class B Units. Each Class B Unit will consist of one share of our Series B Convertible Preferred Stock, or the Series B Preferred, with a stated value of \$1,000 per share and convertible into shares of our common stock at the public offering price of the Class A Units, together with the equivalent number of Series A warrants as would have been issued to such purchaser if they had purchased Class A Units based on the public offering price. The Series B Preferred does not generally have any voting rights but is convertible into shares of

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common stock. The shares of Series B Preferred and Series A warrants underlying a Class B Unit are immediately separable and will be issued separately in this offering.

We are also offering the shares of common stock that are issuable from time to time upon conversion of the Series B Preferred and upon exercise of the Series A warrants being offered by this prospectus.

Assuming we sell all _____ of Class A Units (and no Class B Units) being offered in this offering and a public offering price of \$ _____, the last reported price of our common stock on the OTCQB on _____, 2016, we would issue in this offering an aggregate of _____ shares of our common stock and Series A warrants to purchase _____ shares of our common stock.

Our common stock is traded on the OTCQB under the symbol "ILIU." The last reported sale price of our common stock on the OTCQB on May 12, 2016 was \$0.20 per share. At our 2015 annual meeting of stockholders, we received stockholder approval to effect a reverse stock split in a range of not less than 1-for-5 and not more than 1-for-40. Prior to the effectiveness of the registration statement of which this prospectus is a part, we intend to effect a reverse stock split within this range (the "Listing Reverse Split"), and we intend to apply for listing of our common stock on The NASDAQ Capital Market under the symbol "_____" subject to and upon completion of this offering. No assurance can be given that our application will be approved. There is no established public trading market for the Series A warrants or Series B Preferred, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series A warrants or the Series B Preferred on any securities exchange or trading system.

AN INVESTMENT IN OUR SECURITIES INVOLVES RISKS. SEE THE SECTION ENTITLED “RISK FACTORS” BEGINNING ON PAGE 5.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Class A Unit (one share of common stock and a Series A warrant for of a share of common stock)	Per Class B Unit (one share of Series C Preferred and a Series A warrant for shares of common stock)	Total
Public offering price	\$	\$	\$
Placement agent’s fees(1)	\$	\$	\$
Proceeds, before expenses, to Interleukin Genetics, Inc.	\$	\$	\$

We have agreed to reimburse the placement agent for certain of its expenses and to issue common stock purchase (1) warrants to the placement agent. See “Plan of Distribution” on page 54 of this prospectus for a description of the compensation payable to the placement agent.

We have engaged H.C. Wainwright & Co., LLC (“Wainwright” or the “Placement Agent”) to act as our exclusive placement agent in connection with this offering. Wainwright is not purchasing or selling the securities offered by us, and is not required to sell any specific number or dollar amount of securities, but will use its reasonable best efforts to arrange for the sale of the securities offered. We estimate total expenses of this offering, excluding the placement agent fees, will be approximately \$. Because there is no minimum offering amount required as a condition to closing in this offering, the actual public offering amount, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. This offering will terminate on , 2016, unless the offering is fully subscribed before that date or we decide to terminate the offering prior to that date. In either event, the offering may be closed without further notice to you. We may utilize a non-interest bearing escrow account in connection with the closing of this offering.

Rodman & Renshaw

a unit of H.C. Wainwright & Co.

The date of this prospectus is , 2016.

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ABOUT THIS PROSPECTUS

You should rely only on the information contained in this Prospectus and any free writing prospectus authorized by us. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. The information in this Prospectus is accurate only as of the date it is presented. You should read this Prospectus and any free writing prospectus that we have authorized for use in connection with this offering, in their entirety before investing in our securities.

We are offering to sell, and seeking offers to buy, the securities offered by this Prospectus only in jurisdictions where offers and sales are permitted. The distribution of this Prospectus and the offering of the securities offered by this Prospectus in certain jurisdictions may be restricted by law. This Prospectus does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this Prospectus in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

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..

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our securities, you should carefully read this entire prospectus, including our financial statements and the related notes thereto and the information set forth under the sections “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” in each case included in this prospectus. Unless the context otherwise requires, we use the terms “Interleukin,” “Interleukin Genetics,” “Company,” “we,” “us” and “our” in this prospectus to refer to Interleukin Genetics, Inc.

Overview

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

Our Platform

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

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

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

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

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

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

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

Business Strategy

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

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

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

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

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

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

PerioPredict is solely available through Interleukin Genetics. The web site for the PerioPredict test is www.PerioPredict.com. The information contained on our websites are not incorporated by reference into this prospectus. We have included our website addresses only as an inactive textual reference and do not intend them to be active links to our websites.

In addition, we plan to continue to sell tests under the Inherent Health brand, primarily through our relationships with Alticor's Amway Global Company and Access Business Group LLC. Under these agreements, Amway's independent business owners, or IBOs, are able to purchase genetic tests. We believe our proprietary genetic test brands supports the efforts of Amway to develop personalized consumer products for their independent business owners (IBOs) customers. Sales with Amway through these business arrangements began in December 2009.

Corporate 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 our corporate 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 *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 is not incorporated by reference into this prospectus. We have included our website addresses only as an inactive textual reference and do not intend them to be active links to our websites.

The Offering

We are offering up to _____ of Class A Units. Each Class A Unit will consist of one share of our common stock and a Series A warrant to purchase _____ of a share of our common stock at an exercise price per share equal to _____ % of the public offering price of the Class A Units, (“Series A warrant”). The Class A Units will not be certificated and the share of common stock and warrants part of such unit are immediately separable and will be issued separately in this offering.

Class A Units
offered by us: This prospectus also relates to the offering of shares of our common stock issuable upon the exercise of the Series A warrants part of the Class A Units.

Assuming we sell all _____ of Class A Units (and no Class B Units) being offered in this offering and a public offering price of \$ _____, the last reported price of our common stock on the OTCQB on _____, 2016, we would issue in this offering an aggregate of _____ shares of our common stock and Series A warrants to purchase _____ shares of our common stock.

We are also offering to those purchasers, if any, whose purchase of Class A Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, the opportunity, in lieu of purchasing Class A Units, to purchase Class B Units. Each Class B Unit will consist of one share of our Series B Convertible Preferred Stock (the “Series B Preferred”), with a stated value of \$1,000 and convertible into shares of our common stock at the public offering price of the Class A Units, together with the equivalent number of Series A warrants as would have been issued to such purchaser if they had purchased Class A Units based on the public offering price. The Series B Preferred does not generally have any voting rights but is convertible into shares of common stock. The Class B Units will not be certificated and the share of Series B Preferred and warrants part of such unit are immediately separable and will be issued separately in this offering.

This prospectus also relates to the offering of shares of our common stock issuable upon conversion of the Series B Preferred Stock and upon exercise of the Series A warrants part of the Class B Units.

Series A
warrants: Each Series A warrant included in the Units will have an exercise price per share equal to _____ % of the public offering price of the Class A Units, will be exercisable upon issuance, and will expire five years from the date of issuance.

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Common stock to be outstanding after the offering: shares (assumes (i) the sale of all Units covered hereby, (ii) that only Class A Units are sold and (iii) no exercise of the Series A warrants. To the extent we sell any Class B Units, the same aggregate number of common stock equivalents resulting from this offering would be convertible under the Series B Preferred issued as part of the Class B Units).

after the offering:

Use of proceeds: We intend to use the net proceeds from this offering to primarily support commercialization of our PerioPredict genetic test and for working capital and other general corporate purposes. See “Use of Proceeds” beginning on page 15.

Risk factors: See “Risk Factors” beginning on page 5 and other information included in this prospectus for a discussion of factors that you should consider carefully before deciding to invest in our securities.

OTCQB trading symbol: ILIU. At our 2015 annual meeting of stockholders, we received stockholder approval to effect a reverse stock split in a range of not less than 1-for-5 and not more than 1-for-40. Prior to the effectiveness of the registration statement of which this prospectus is a part, we intend to effect the Listing Reverse Split within this range, and we intend to apply for listing of our common stock on The NASDAQ Capital Market under the symbol “ ” subject to and upon completion of this offering. No assurance can be given that our application will be approved.

The number of shares of our common stock to be outstanding after this offering is based on 173,029,840 shares of common stock outstanding as of April 30, 2016, and excludes the following:

- 22,089,527 shares of common stock issuable upon the exercise of outstanding options to purchase common stock as of April 30, 2016, at a weighted-average exercise price of \$0.20 per share;
- 88,301,079 shares of common stock issuable upon the exercise of warrants for shares of our common stock outstanding as of April 30, 2016, at a weighted-average exercise price of \$0.17 per share;
- 30,017,752 additional shares of common stock reserved for issuance under our stock plans as of April 30, 2016;
- up to _____ shares of common stock issuable upon the exercise of the Series A warrants to be sold in this offering; and
- up to _____ shares of common stock issuable upon the exercise of the warrants to be issued to the placement agent (the “Placement Agent Warrants”) in connection with this offering (this prospectus also relates to the offering of shares of our common stock issuable upon exercise of the Placement Agent Warrants).

RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully read and consider the risks described below, as well as the other information in this prospectus and other information incorporated by reference herein, before deciding to invest in our securities. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations or cash flows. In that case, the trading price of our common stock could decline, and you could lose all or part of your investment.

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

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

We expect that our current and anticipated financial resources will be adequate to maintain our current and planned operations only into the second half of 2016. We need significant additional capital to fund our continued operations, including for the commercialization efforts for our PerioPredict genetic test, continued research and development efforts, obtaining and protecting patents and administrative expenses. We have retained a financial advisor and are actively seeking additional funding, however, based on current economic conditions, additional financing may not be available, or, if available, it may not be available on favorable terms. In addition, the terms of any financing may adversely affect the holdings or the rights of our existing shareholders. For example, if we raise additional funds by issuing equity securities, further dilution to our then-existing shareholders will result. Debt financing, if available, may involve restrictive covenants that could limit our flexibility in conducting future business activities. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, tests or products in development. If we cannot obtain additional funding on acceptable terms, we may have to discontinue operations and seek protection under U.S. bankruptcy laws.

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

Our financial statements have been prepared assuming that we will continue as a going concern which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We expect to incur further losses in the development of our business and have been dependent on funding operations through the issuance of convertible debt and the sale of equity securities. These conditions raise substantial doubt about our ability to continue as a going concern. Management's plans include increasing revenue through new arrangements with commercial distribution partners and continuing to finance operations through the private or public placement of debt and/or equity securities. However, no assurance can be given at this time as to whether we will be able to achieve these objectives. The financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to

continue as a going concern. We can provide no assurance that we will be successful in increasing revenues, or that we will receive additional funding on reasonable terms, or at all.

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

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

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

We have experienced significant operating losses since our inception and expect these losses to continue for some time. We incurred losses from operations of \$6.3 million in 2014, \$7.3 million in 2015 and \$1.5 million in the three months ended March 31, 2016. As of March 31, 2016, our accumulated deficit was \$130.5 million. Our losses result primarily from research and development, selling, general and administrative expenses and amortization of intangible assets. Although we generate revenues from sales of our genetic risk assessment tests, this may not be sufficient to result in net income in the foreseeable future. We will need to generate significant revenue to continue our research and development programs and achieve profitability. We cannot predict when, if ever, we will achieve profitability.

The market for personalized health generally and genetic risk assessment tests in particular is unproven.

The markets and customer base in the field of personalized health are not well established. Adoption of technologies in this emerging field requires substantial market development and there can be no assurance that channels for marketing our products can or will be successfully developed by us or others. As a result, there can be no assurance that our products will be successfully commercialized or that they can be sold at sufficient volumes to make them profitable. If our potential customers do not accept our products, or take a longer time to accept them than we anticipate, it will reduce our anticipated sales and materially harm our business.

The market for genetic risk assessment tests, as part of the field of personalized health, is at an early stage of development and may not continue to grow. The scientific community, including us, has only a limited understanding of the role of genes in predicting disease. The success of our genetic risk assessment tests will depend upon their acceptance as being useful and cost-effective to the customers who purchase these products, the physicians and other members of the medical community who recommend or prescribe them, as well as third-party payers, such as insurance companies and the government. We can only achieve broad market acceptance with substantial education about the benefits and limitations of genetic risk assessment tests while providing the tests at a fair cost. We expect to expend significant funds and resources to educate patients, dentists and other providers, and payers on the benefits of our PerioPredict test. There is no assurance that we will be able to successfully do so. Furthermore, while positive media attention resulting from new scientific studies or announcements can spur rapid growth in individual segments of the market, and also impact individual brands, news that challenges individual segments or products can have a negative impact on the industry overall as well as on sales of the challenged segments or products. The marketplace may never accept our products, and we may never be able to successfully commercialize our products, including the PerioPredict test.

We could become subject to intense competition from other companies, which may damage our business.

The field of personalized health is highly competitive. Our potential competitors in the United States and abroad are numerous and include, among others, major pharmaceutical and diagnostic companies, consumer products companies, specialized biotechnology firms, universities and other research institutions. Many of our competitors have considerably greater financial, technical, marketing and other resources. Furthermore, many of these competitors are more experienced than we are in discovering, commercializing and marketing products. These greater resources may allow our competitors to discover important genes or genetic markers and more quickly and effectively develop and commercialize genetic tests than we or our partners are able to do. If we are not able to successfully market genetic tests, either alone or through collaborations, our business will be materially harmed. We expect competition to intensify in our industry as technical advances are made and become more widely known.

Ethical, legal and social issues related to genetic testing may reduce demand for our products.

Genetic testing has raised concerns regarding the appropriate utilization and the confidentiality of information provided by genetic testing. Genetic tests for assessing a person's likelihood of developing a chronic disease have focused public attention on the need to protect the privacy of genetic information. For example, concerns have been expressed that insurance carriers and employers may use these tests to discriminate on the basis of genetic information, resulting in barriers to the acceptance of genetic tests by consumers. This could lead to governmental authorities prohibiting genetic testing or calling for limits on or regulating the use of genetic testing, particularly for diseases for which there is no known cure. Any of these scenarios could decrease demand for our products.

Technological changes may cause our tests to become obsolete.

We have to date focused our efforts on genetic tests based on a small number of candidate genes and genetic variants. It is now possible to use array technology to conduct whole genome association studies for risk assessment, which may make our technologies obsolete. In order to develop customers and markets for our genetic risk assessment tests, we may be required to invest substantial additional capital and other resources.

We have limited experience and capabilities with respect to distributing, marketing and selling genetic tests on our own and will continue to depend substantially on third parties to commercialize our tests.

We have limited experience and capabilities with respect to distributing, marketing and selling genetic risk assessment tests on our own. In June 2009, we announced the launch of our new Inherent Health brand of genetic tests. On October 26, 2009, we entered into an agreement with Amway Global, an affiliate of Alticor, pursuant to which it sells our Inherent Health brand of genetics tests through its e-commerce Web site via a hyperlink to our e-commerce site. In 2015 and 2014, revenues from this agreement accounted for 45% and 44% of our revenues, respectively. In the three months ended March 31, 2016 and 2015, revenues from this agreement accounted for 14% and 56% of our revenues, respectively. In addition, beginning in September 2012 and again in 2013, Access Business Group LLC, an affiliate of Alticor, placed purchase orders totaling approximately \$3.3 million consisting of weight management kits. The kits are included as part of a promotional bundle of products that Amway is now selling to their Individual Business Owners. In 2015 and 2014, revenues from this arrangement accounted for 13% and 32% of our revenues, respectively. In the three months ended March 31, 2016 and 2015, revenues from this arrangement accounted for 3% and 14% of our revenues, respectively. We continue to engage in discussions for the use of our PerioPredict test with insurance companies and large employers who might ultimately adopt enhanced benefits designs or employer-sponsored wellness initiatives that incorporate PerioPredict, or utilize PerioPredict through other arrangements, through the use of consultants, channel partners and our internal management team. We have, to date, had very limited success in marketing and selling our genetic tests, including PerioPredict, and we can provide no assurance that our current or planned commercialization efforts will be successful.

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

Entering into additional strategic alliances for the development and commercialization of products and services based on our discoveries is an important element of our business strategy. We face significant competition in seeking appropriate collaborators. If we fail to maintain our existing alliances or to establish additional strategic alliances or other alternative arrangements, then our ability to develop and market products and services will be damaged. In addition, the terms of any future strategic alliances may be unfavorable to us or these strategic alliances may be unsuccessful.

Because our products are based on emerging science, if we make changes to our tests based on new scientific findings, market acceptance of our products may decrease and we may be exposed to liability in excess of our product liability insurance coverage.

Our genetic test products are based on emerging science, and we continue to conduct studies to further enhance the usefulness and scientific credibility of our products. If we make changes to our tests based on new data, it could harm our credibility, decrease market acceptance of our products or expose us to liability claims. We currently maintain product liability insurance, but it is often difficult to obtain, is expensive and may not be available in the future on

economically acceptable terms. In addition, potential product liability claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of our policy. We may become subject to product liability claims that, even if they are without merit, could result in significant legal defense costs to us. If we are held liable for claims for which we are not indemnified or for damages exceeding the limits of our insurance coverage, those claims could materially damage our business and our financial condition. Any product liability claim against us or resulting recall of our products could create significant negative publicity.

Current economic conditions could adversely affect our business and results of operations.

Economic conditions and financial markets have been experiencing extreme disruption including, among other things, extreme volatility in prices of publicly traded securities, rating downgrades of certain investments and declining valuations of others. We believe current economic conditions and financial market turmoil could adversely affect our operations. Uncertainty about current and future economic conditions may cause consumers to reign in their spending generally, the impact of which may be that they stop or delay their purchases of our genetic tests and consumer products. If these circumstances persist or continue to worsen, our future operating results could be adversely affected, particularly relative to our current expectations.

Our dependence on key executives and scientists could adversely impact the development and management of our business.

Our success depends on the ability, experience and performance of our senior management and other key personnel. If we lose one or more of the members of our senior management or other key employees, it could damage our business. In addition, our success depends on our ability to continue to hire, train, retain and motivate skilled managerial and scientific personnel. The pool of personnel with the skill that we require is limited. Competition to hire from this limited pool is intense. We compete with numerous pharmaceutical and healthcare companies, as well as universities and non-profit research organizations in the highly competitive Boston, Massachusetts business area. Our current senior management team is employed by us under agreements that may be terminated by them for any reason upon adequate notice. There can be no assurances, therefore, that we will be able to retain our senior executives or replace them, if necessary. We do not maintain key man life insurance on any of our personnel.

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

We have entered into an agreement with our stockholder, Pyxis (collectively, with its affiliates, the “Interested Parties”), allocating corporate opportunities as permitted under Section 122(17) of the Delaware General Corporation Law. This agreement regulates and defines the conduct of certain of our affairs as they may involve the Interested Parties, and our powers, rights, duties and liabilities and those of our officers and directors in connection with corporate opportunities. Except under certain circumstances, the Interested Parties have the right to engage in the same or similar activities or lines of business or have an interest in the same classes or categories of corporate opportunities as we do. If any Interested Parties or one of our directors appointed by an Interested Party acquire knowledge of a potential transaction or matter that may be a corporate opportunity for both the Interested Party and us, to the fullest extent permitted by law, the Interested Party will not have a duty to inform us about the corporate opportunity. In addition, the Interested Party will not be liable to us or to other stockholders for breach of any fiduciary duty as a stockholder of ours for not informing us of the corporate opportunity, keeping it for its own account, or referring it to another person. Additionally, except under limited circumstances, if an officer or employee of an Interested Party who is also one of our directors is offered a corporate opportunity, such opportunity shall not belong to us. In addition, we agreed that such director will have satisfied his duties to us and not be liable to us or to you in connection with such opportunity.

We may be prohibited from fully using our net operating loss carryforwards, which could affect our financial performance.

As a result of the losses incurred since inception, we have not recorded a federal income tax provision and have recorded a valuation allowance against all future tax benefits of our net operating loss carryforwards. As of December 31, 2015, we had gross net operating loss (NOL) and research tax credit carryforwards of approximately \$88.2 million and \$1.6 million, respectively for federal income tax purposes, and of approximately \$11.0 million and \$1.0 million for state income tax purposes, expiring in varying amounts through the year 2035. Our ability to use these NOLs and credit carryforwards is subject to restrictions contained in the Internal Revenue Code which provide for limitations on our utilization of our net operating loss and credit carryforwards following a greater than 50% ownership change during the prescribed testing period. On March 5, 2003, we had such a change. As a result, all of our NOL carryforwards as of that date are limited as to utilization. The annual limitation may result in the expiration of certain of the carryforwards prior to utilization. In addition, our equity offerings, including those in 2013 and 2014, may have resulted in qualifying changes in ownership. A formal study, which we have not undertaken, is required to determine applicability of restrictions and might indicate that our NOL carryforwards are subject to additional limitations on utilization. In addition, in order to realize the future tax benefits of our net operating loss and tax credit carryforwards, we must generate taxable income, of which there is no assurance.

Risks Related to Our Intellectual Property

If we fail to obtain patent protection for our products and preserve our trade secrets, then competitors may develop competing products and services, which will likely decrease our sales and market share.

Our success will depend on our ability to obtain patent protection in the United States and in other countries for our products and services. In addition, our success will also depend upon our ability to preserve our trade secrets and to operate without infringing upon the proprietary rights of third parties. We own rights to nine issued U.S. patents and have a number of additional U.S. patent applications pending. We have also been granted a number of corresponding foreign patents and have a number of foreign counterparts of our U.S. patents and patent applications pending. Our patent positions, and those of other pharmaceutical and biotechnology companies, are generally uncertain and involve complex legal, scientific and factual questions. Our ability to develop and commercialize products and services depends on our ability to:

obtain patents;

obtain licenses to the proprietary rights of others;

prevent others from infringing on our proprietary rights; and

protect trade secrets.

Our pending patent applications may not result in issued patents and any issued patents may never afford meaningful protection for our technology or products or provide us with a competitive advantage. Further, others may develop competing products, which avoid legally infringing upon, or conflicting with, our patents. There is no assurance that another company will not replicate one or more of our products, and this may harm our ability to do business. In addition, competitors may challenge any patents issued to us, and these patents may subsequently be narrowed, invalidated or circumvented.

From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability and any such changes could have a negative impact on our business. There have been several cases involving “gene patents” and diagnostic claims that have been considered by the U.S. Supreme Court. A suit brought by multiple plaintiffs, including the American Civil Liberties Union, or ACLU, against Myriad Genetics, or Myriad, and the USPTO, could impact biotechnology and diagnostic patents. That case involves certain of Myriad’s U.S. patents related to the breast cancer susceptibility genes BRCA1 and BRCA2. The Federal Circuit issued a written decision on July 29, 2011 that reversed the decision of the U.S. District Court for the Southern District of New York that Myriad’s composition claims to “isolated” DNA molecules cover unpatentable subject matter. The Federal Circuit court instead held that the breast cancer genes are patentable subject matter. Subsequently, on March 20, 2012, the Supreme Court issued a decision in *Mayo Collaborative v. Prometheus Laboratories*, or Prometheus, a case involving patent claims directed to optimizing the amount of drug administered to a specific patient. According to that decision, Prometheus’ claims failed to add enough inventive content to the underlying correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws. The Supreme Court subsequently granted *certiorari* in the Myriad case, vacated the judgment, and remanded the case back to the Federal Circuit for further consideration in light of their decision in the Prometheus case. The Federal Circuit heard oral arguments on July 20, 2012, and issued a decision on August 16, 2012. The Federal Circuit reaffirmed its earlier decision and held that composition of matter claims directed to isolated nucleic acids are patent-eligible subject matter, but that method claims consisting of only abstract mental processes are not patent-eligible. On September 25, 2012, the ACLU filed a petition for a *writ of certiorari* asking the Supreme Court to review the Federal Circuit’s decision with respect to the composition of matter claims. On November 30, 2012, the Supreme Court granted the petition and agreed to review the case. On June 13, 2013, the Supreme Court issued a decision in the Myriad case. According to the decision, claims directed to genomic DNA cover unpatentable subject matter. However, claims directed to cDNA are patent eligible subject matter.

On March 4, 2014, the USPTO issued a memorandum to patent examiners providing guidelines for examining process claims for patent eligibility in view of the Supreme Court decision in Prometheus. On December 16, 2014 an interim guidance was issued that supersedes the March 4, 2014 memorandum but essentially followed the same direction for patent eligibility. The guidance indicates that claims directed to a law of nature, a natural phenomenon, or an abstract idea that do not meet the eligibility requirements should be rejected as non-statutory subject matter. We cannot assure you that our patent portfolio will not be negatively impacted by the decision described above, rulings in other cases or changes in guidance or procedures issued by the USPTO.

Congress directed the USPTO to study effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist. This study will examine the impact that independent second opinion testing has on providing medical care to patients; the effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test; the impact of current practices on testing results and performance; and the role of insurance coverage on the provision of genetic diagnostic tests. The USPTO was directed to report the findings of the study to Congress and provide recommendations for establishing the availability of independent confirming genetic diagnostic test activity by June 16, 2012. On August 28, 2012, the Department of Commerce sent a letter to the House and Senate Judiciary Committee leadership updating them on the status of the genetic testing report. The letter stated in part: “Given the complexity and diversity of the opinions, comments, and suggestions provided by interested parties, and the important policy considerations involved, we believe that further review, discussion, and analysis are required before a final report can be submitted to Congress.” The USPTO issued a Request for Comments and Notice of Public Hearing on Genetic Diagnostic Testing on January 25, 2012, and held additional public hearings in February and

March 2013. It is unclear whether the results of this study will be acted upon by the USPTO or result in Congressional efforts to change the law or process in a manner that could negatively impact our present or future patent portfolio.

There can be no assurance that the Supreme Court's decision in either the Myriad or Prometheus case will not have a negative impact on 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.

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