INTERLEUKIN GENETICS INC
Form S-1/A
June 07, 2016

As filed with the Securities and Exchange Commission on June 7, 2016

Registration Statement No. 333-211361

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

Amendment No 2

To

FORM S-1

REGISTRATION STATEMENT

under the

SECURITIES ACT OF 1933

INTERLEUKIN GENETICS, INC.

(*Exact Name of Registrant as Specified in Its Charter)*

Delaware	**2835**	**94-3123681**

(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(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	$ 9,000,000	
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	$ 9,000,000	
Common stock issuable upon conversion of the Series B Convertible Preferred Stock	$ 9,000,000	

Common stock issuable upon exercise of the warrants underlying the Class A Units and Class B Units			
Underwriters' warrants (4)			
Common stock issuable upon exercise of underwriters' warrants (4)	$ 1,600,000		
Total	$ 28,600,000	$ 2,880.02	(5)

(1) Pursuant to Rule 416 under the Securities Act of 1933, the securities registered also include such indeterminate 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. Includes the offering price of additional units that the underwriters have the option to purchase.

(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.

(4) 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 Convertible Preferred Stock sold in this offering but excluding any shares of common stock underlying the warrants issued in this offering).

(5) Previously paid.

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 June 7, 2016

PRELIMINARY PROSPECTUS

Up to $15,000,000 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 $15,000,000 of Class A Units (each consisting of one share of our common stock and a Series A warrant to purchase 0.5 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

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 $15,000,000 of Class A Units (and no Class B Units) being offered in this offering and a public offering price of $0.1442, the last reported price of our common stock on the OTCQB on June 6, 2016, we would issue in this offering an aggregate of 104,022,190 shares of our common stock and Series A warrants to purchase 52,011,095 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 June 6, 2016 was $0.1442 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 have applied for listing of our common stock and the Series A warrants on The NASDAQ Capital Market under the symbols “ILIU” and “ILIUW”, respectively, 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. In addition, we do not intend to apply for listing of 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 0.5 of a share of common stock)	Per Class B Unit (one share of Series B Preferred and a Series A warrant for shares of common stock)	Per Series A warrant	Total
Public offering price	$	$	$	$
Underwriting discounts and commissions(1)	$	$	$	$
Proceeds, before expenses, to Interleukin Genetics, Inc.	$	$	$	$

(1) We have agreed to reimburse the representative of the underwriters for certain of its expenses and to issue common stock purchase warrants to the representative of the underwriters (or its designees). See "Underwriting" on page 54 of this prospectus for a description of the compensation payable to the underwriters.

We have granted a -day option to the underwriters to purchase up to additional shares of common stock and/or Series A warrants to purchase up to an additional shares of common stock from us at the public offering price, less the underwriting discount, solely to cover over-allotments, if any. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable will be $, and the total proceeds to us, before expenses, will be $.

The underwriters expect to deliver the shares and the Series A warrants against payment in New York, New York on , 2016.

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 Inter 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.

- Relationship management tools. We utilize proprietary data base and contact management software to contact patients and care teams and to track responses to outreach and clinical interventions.

- Value-added commercial approach. We partner with health and wellness companies, employers and others to leverage the unique information provided by our tests, education and outreach initiatives 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.

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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

Class A Units offered by us:	We are offering up to $15,000,000 of Class A Units. Each Class A Unit will consist of one share of our common stock and a Series A warrant to purchase 0.5 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. 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 $15,000,000 of Class A Units (and no Class B Units) being offered in this offering and a public offering price of $0.1442, the last reported price of our common stock on the OTCQB on June 6, 2016, we would issue in this offering an aggregate of 104,022,190 shares of our common stock and Series A warrants to purchase 52,011,095 shares of our common stock.
Class B Units offered by us:	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.

Common stock to be outstanding after the offering:	277,052,030 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).
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 have applied for listing of our common stock and the Series A warrants on The NASDAQ Capital Market under the symbols "ILIU" and "ILIUW", respectively, 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 representative of the underwriters (the “Underwriter Warrants”) in connection with this offering (this prospectus also relates to the offering of shares of our common stock issuable upon exercise of the Underwriter 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 $1.4 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 gene or diagnostic patents generally or the ability of biotechnology and diagnostic companies to obtain or enforce their patents in the future. Such negative decisions by the Supreme Court could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

We also rely on trade secrets and proprietary know-how that we seek to protect, in part, with confidentiality agreements. The third parties we contract with may breach these agreements, and we may not have adequate remedies for any breach. If they do not protect our rights, third parties could use our technology, and our ability to compete in the market would be reduced. We also realize that our trade secrets may become known through other means not currently foreseen by us. Our competitors may discover or independently develop our trade secrets.

Third parties may own or control patents or patent applications and require us to seek licenses, which could increase our costs or prevent us from developing or marketing our products or services.

We may not have rights under patents or patent applications that are related to our current or proposed products. Third parties may own or control these patents and patent applications in the United States and abroad. Therefore, in some cases, to develop or sell any proposed products or services with patent rights controlled by third parties, our collaborators or ourselves may seek, or may be required to seek, licenses under third-party patents and patent applications. If this occurs, we may have to pay license fees, royalties or both, to the licensor. If licenses are not available to us on acceptable terms, our collaborators or we may be prohibited from developing or selling our products or services.

Risks Related to Development, Clinical Testing and Regulatory Approval of Our Tests

Any tests that may be developed by us may be subject to regulatory clearance or approval, which can be lengthy, costly and burdensome.

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

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

On February 3, 2016 we met with the director and staff members of Office of In Vitro Diagnostic Products, or OIR, to further discuss our letter response. The FDA issued minutes of the meeting on February 16, 2016, which confirmed that we do not offer an osteoarthritis test and that PerioPredict is currently offered only as an LDT and is therefore currently subject to FDA enforcement discretion. In addition, they confirmed their interest in obtaining further information on how we would come into compliance with respect to the Inherent Health tests, since those tests are offered DTC and therefore are not subject to FDA enforcement discretion. Subsequently, we clarified with the FDA that our Heart Health and Bone Health tests would only be available directly to consumers until May 22, 2016, at which time they will only be available if requested by an authorized healthcare provider. Any Heart Health and Bone Health tests purchased through retail channels prior to that date will be processed through September 19, 2016, after which the tests will only be processed for a licensed healthcare provider. We are continuing discussions with the FDA to determine appropriate next steps, if any, for our Weight Management test, which is marketed both through professional channels and DTC.

We are uncertain as to what, if any, regulatory requirements may apply to our tests in the future. We cannot provide any assurance that FDA regulation, including pre-market review or approval, will not be required in the future. If the FDA requires us to obtain clearance through its 510k premarket notification process or obtain approval through its premarket approval, or PMA process, either as a condition of continuing to market our tests or bringing future tests to market, our business could be negatively impacted. Requiring FDA clearance or approval could be lengthy, costly and burdensome. In addition, depending upon the FDA's response to a submission we may be required to stop selling our tests, revise our tests significantly, or delay introduction of new tests. Additionally, if our tests become subject to more active regulation as medical devices by the FDA, we would be required to comply with requirements including establishment registration, device listing, adverse event reporting, and good manufacturing practices. We would also be subject to penalties, including seizure and injunction, for noncompliance with FDA requirements. Complying with FDA requirements could add additional costs and burdens to our operations.

We are subject to government regulation which may significantly increase our costs and delay introduction of our products.

We are subject to a variety of federal and state legal requirements including CLIA, the FD&C Act, state clinical laboratory licensure laws and implementing regulations. The growth of our business may increase the potential of being found in violation of these laws. Our risk of being found in violation of these laws and regulations is further increased by the fact that the technologies at issue are new and the applicability of statutory and regulatory provisions to these technologies has not been fully developed, implemented, or subjected to judicial review, and the statutory and regulatory provisions themselves are open to a variety of interpretations. Any action brought against us, or any business partners, for violation of these laws or regulations, even if we or they successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If their or our operations are found to be in violation of any of these laws and regulations, they or we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, and they or we could be required to curtail or cease operations. Any of the foregoing consequences could seriously harm our business and our financial results.

If we do not comply with governmental regulations applicable to our CLIA-certified laboratory, we may not be able to continue our operations.

The establishment and operation of our laboratory is subject to regulation by numerous federal, state and local governmental authorities in the United States. The laboratory holds a CLIA certificate of compliance and is licensed by the Commonwealth of Massachusetts, and other states as required, which enables us to provide testing services to residents of all states. Failure to comply with state regulations or changes in state regulatory requirements, could result in a substantial curtailment or even prohibition of the operations of our laboratory and could have a material adverse effect on our business. CLIA is a federal law that regulates clinical laboratories that perform testing on human specimens for the purpose of providing information for the diagnosis, prevention or treatment of disease. To renew CLIA certification, laboratories are subject to survey and inspection every two years. Moreover, CLIA inspectors may make unannounced inspections of these laboratories. If we were to lose our CLIA certification or our state licenses, whether as a result of a revocation, suspension or limitation, we would no longer be able to continue our testing operations which would have a material adverse effect on our business.

Tests based on our technology may require clinical trial testing, which can be lengthy, costly and burdensome.

If the FDA decides to require pre-market clearance or approval of LDT's, we may be required to perform clinical trials prior to submitting a marketing application. If we are required to conduct clinical trials, whether using prospectively acquired tissue samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase development costs and delay commercialization. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population and the nature of the disease or condition being studied.

Future therapeutic collaborators, if any, may be unable to obtain regulatory approval of any therapeutic product that they may develop.

If, in the future, we enter into any collaborations relating to the use of our technology in the development of therapeutic products, any therapeutic products that our collaborators may develop will be subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization. Rigorous preclinical testing and clinical trials and an extensive regulatory review process are required to be successfully completed in the United States and in many foreign jurisdictions before a new therapeutic product can be sold. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. The time required to obtain FDA and other approvals for therapeutic products is unpredictable but typically exceeds several years. It is possible that none of the therapeutic products our collaborators may develop will obtain the appropriate regulatory approvals necessary for us or our collaborators to begin selling them. In addition, if the use of any test that we develop is necessary for the safe use of a collaborator's therapeutic product, we might be required to obtain clearance or approval of our test.

Furthermore, any regulatory approval to market a therapeutic product may be subject to limitations on the indicated uses. These limitations may limit the size of the market for the therapeutic product. Any therapeutic product that our collaborators may develop will also be subject to numerous foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Therefore, approval by the FDA of a therapeutic product does not assure approval by regulatory authorities outside the United States or vice versa.

If we fail to comply with regulatory requirements, we could be subject to enforcement actions, which could affect our ability to market and sell our tests and may harm our reputation.

If we in the future fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect the ability to successfully develop, market and sell our tests and could harm our reputation and lead to reduced acceptance of such tests or products by the market. These enforcement actions could include:

- warning letters;
- recalls, public notification or medical device safety alerts;
- restrictions on, or prohibitions against, marketing such tests or products;
- product seizures;
- injunctions;
- civil penalties, including monetary fines; and

. criminal penalties.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research and development activities involve the use of hazardous and chemicals materials, and we maintain quantities of various flammable and toxic chemicals in our facilities. We believe our procedures for storing, handling and disposing these materials in our facilities comply with the relevant local and Federal guidelines. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Changes in healthcare policy could impact commercialization of our tests.

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

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

Risks Related to Our Common Stock

Our common stock is traded on the OTCQB, which could result in a limited market for our common stock, and we may not be able to list on another exchange.

Our common stock was listed on the NYSE Amex until August 16, 2010, when it was suspended for failure to comply with the NYSE Amex continued listing standards. Our common stock then began trading on the OTCQB™ under the symbol ILIU. This delisting could hurt our investors by reducing the liquidity and market price of our common stock. Additionally, the delisting could negatively affect us by reducing the number of investors willing to hold or acquire our common stock, which could negatively affect our ability to raise capital. Prior to the effectiveness of the registration statement of which this prospectus is a part, we intend to effect the Listing Reverse Split in a range of not less than 1-for-5 and not more than 1-for-40, and we have applied to list our common stock and the Series A warrants on The NASDAQ Capital Market under the symbols “ILIU” and “ILIUW”, respectively, subject to and upon completion of this offering. Whether we meet the initial listing requirements for The NASDAQ Capital Market depends upon, among other things, (i) whether the closing bid price of our common stock following the Listing Reverse Split and upon completion of this offering meets the initial listing requirements of the NASDAQ Capital Market and (ii) our ability to raise at least $ from the sale of units in this offering to unaffiliated investors. We can give no assurance that we will meet the initial listing requirements for The NASDAQ Capital Market upon completion of this offering, or that our application will be approved even if we do meet such requirements. We can give no assurance that our common stock will ever trade on The NASDAQ Capital Market or any other securities exchange.

Our stock price has been and is likely to continue to be volatile and the market price of our common stock may drop.

In the three years ended December 31, 2015, our stock price has fluctuated from a low of $0.01 to a high of $0.55. Furthermore, the stock market has experienced significant volatility. The volatility of stocks for companies in our industry often does not relate to the operating performance of the companies represented by the stock. Some of the factors that may cause the market price of our common stock to fluctuate include:

· the commercial success of the PerioPredict test;

- demand for and acceptance of our products;
- our ability to develop new relationships and maintain and enhance existing relationships with strategic partners;
- regulatory developments or enforcement in the United States and foreign countries;
- developments or disputes concerning patents or other proprietary rights;
- introduction of technological innovations or new products or services by us or our competitors;
- failure to secure adequate capital to fund our operations, or the issuance of equity securities at prices below fair market price;
- changes in estimates or recommendations by securities analysts, if any cover our common stock;
- litigation;
- future sales of our common stock;
- general market conditions;
- economic and other external factors or other disasters or crises;
- period-to-period fluctuations in our financial results;
- the effect of the Listing Reverse Split;
- our ability to obtain and then maintain a listing on The NASDAQ Capital Market or maintain our current status on the OTCQB or obtain a listing on a national securities exchange; and
- overall fluctuations in U.S. equity markets.

These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may

otherwise negatively affect the liquidity of our common stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

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

As of April 30, 2016, our executive officers, directors and their respective affiliates, beneficially owned approximately 44.0% of our outstanding common stock. Accordingly, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. This concentration of ownership could have the effect of entrenching our management and/or the board of directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

We do not expect to pay dividends for the foreseeable future and you should not expect to receive any funds without selling your shares of common stock, which you may only be able to do at a loss.

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. In addition, our ability to pay cash dividends is currently prohibited by the terms of the Loan Agreement with Horizon Technology Finance Corporation, and any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Therefore, you should not expect to receive any funds without selling your shares, which you may only be able to do at a loss.

Risks Relating to this Offering

If you purchase Units in this offering, you will incur immediate and substantial dilution in the net tangible book value of your shares.

The public offering price is substantially higher than the net tangible book value per share of our common stock. Investors purchasing Units in this offering will pay a price per Unit that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing Units in this offering will incur immediate dilution of $0.1093 per share, based on an assumed public offering price of $0.1442 per Unit (the last reported price of our common stock on the OTCQB on June 6, 2016). As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of a liquidation of our company. See "Dilution."

Because our management will have broad discretion and flexibility in how the net proceeds from this offering are used, our management may use the net proceeds in ways with which you disagree or which may not prove effective.

We currently intend to use the net proceeds from this offering as discussed under "Use of Proceeds" in this prospectus. We have not allocated specific amounts of the net proceeds from this offering for any such purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

There is no established public market for the Units, the Series B Preferred or the Series A warrants being offered in this offering.

There is no established public trading market for the Units, the Series B Preferred or the Series A warrants being offered in this offering. Although we have applied to have the Series A warrants listed on The NASDAQ Capital Market, an active trading market may never develop or may not be sustained if one develops. In addition, we do not intend to apply for listing of the Units or the Series B Preferred on any securities exchange or trading system, and we do not expect a market to develop. Without an active market, the liquidity of such securities will be limited.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the information incorporated by reference in this prospectus contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, or Exchange Act, regarding our strategy, future, operations, future financial position, future revenues, projected costs, and plans and objectives of management. You can identify these forward-looking statements by their use of words such as “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions. You also can identify the fact that they do not relate strictly to historical or current facts. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. For a description of these risks and uncertainties, please refer to the section entitled “Risk Factors,” any other risk factors set forth in any information incorporated by reference in this prospectus, as well as any other risk factors and cautionary statements we include or incorporate by reference into this prospectus in the future. While we may elect to update forward-looking statements wherever they appear in this prospectus or in the documents incorporated by reference in this prospectus, we do not assume, and specifically disclaim, any obligation to do so, whether as a result of new information, future events or otherwise.

USE OF PROCEEDS

We estimate that we will receive approximately $13.5 million in net proceeds from the sale of 104,022,190 Units in this offering, based on an assumed offering price of $0.1442 per Unit (the last reported price of our common stock on the OTCQB on June 6, 2016) and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

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. We cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of the offering. The amount and timing of our actual expenditures may vary significantly depending upon numerous factors, including those described under “Risk Factors.” We may find it necessary or advisable to use the net proceeds for other purposes, and our management will retain broad discretion in the allocation of the net proceeds from this offering.

Pending use of our net proceeds from this offering, we plan to invest the proceeds in a variety of capital preservation investments, including investment-grade, interest-bearing instruments. We cannot predict whether the net proceeds will yield a favorable return.

MARKET FOR OUR COMMON STOCK

Market Information

Our common stock currently trades under the symbol “ILIU” on the OTCQB. The following table sets forth, for the periods indicated, the high and low sales prices for our common stock, as reported by the OTCQB.

	High	Low
2016:		
First Quarter	$ 0.11	$ 0.04
Second Quarter (through June 6, 2016)	$ 0.41	$ 0.0773

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

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

Stockholders

As of April 30, 2016, there were approximately 122 stockholders of record and according to our estimate, approximately 2,421 beneficial owners of our common stock.

DIVIDEND POLICY

We have never paid dividends to our stockholders. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. In addition, our ability to pay cash dividends is currently prohibited by the terms of the Loan Agreement with Horizon Technology Finance Corporation, and any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of March 31, 2016:

- on an actual basis; and
- on an as adjusted to give effect to our receipt of estimated net proceeds of approximately $13.5 million from the sale of 104,022,190 Units in this offering at an assumed public offering price of $0.1442 per Unit (the last reported price of our common stock on the OTCQB on June 6, 2016).

You should read this table together with "Selected Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes appearing elsewhere in this prospectus

	As of March 31, 2016	
	Actual	As adjusted
Cash and cash equivalents	$ 2,892,182	$ 16,367,182
Common stock, $0.001 par value — 450,000,000 shares authorized; 172,953,440 and 276,975,630 shares issued and outstanding at March 31, 2016 actual and as adjusted, respectively	172,955	276,978
Additional paid-in capital	126,574,513	139,945,491
Accumulated deficit	(130,506,061)	(130,506,061)
Total stockholders' equity	(3,758,593)	9,716,408
Total capitalization	$ (866,411)	$ 26,083,590

In the discussion and table above, we assume no exercise of outstanding options or warrants. The discussion above is based on 172,953,440 shares of common stock outstanding as of March 31, 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 March 31, 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 March 31, 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 March 31, 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 Underwriter Warrants to be issued in connection with this offering.

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DILUTION

Our net tangible book value as of March 31, 2016, was approximately $(3,809,109), or approximately $(0.0220) per share. Net tangible book value per share is equal to the amount of our total tangible assets, less total liabilities, divided by the aggregate number of shares of our common stock outstanding as of March 31, 2016. Dilution in net tangible book value per share represents the difference between the amount per Unit paid by purchasers in this public offering and the net tangible book value per share of our common stock immediately after this offering. After giving effect to the sale of 104,022,190 Units in this public offering (assuming only Series A Units are sold) at an assumed offering price of $0.1442 per Unit (the last reported price of our common stock on the OTCQB on June 6, 2016), and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of March 31, 2016 would have been approximately $9.7 million, or approximately $0.0349 per share. This represents an immediate dilution of $0.1093 per share to new investors purchasing Units in this offering. The following table illustrates this dilution.

Assumed public offering price per Series A Unit		$ 0.1442
Net tangible book value per share as of March 31, 2016	$ (0.0220)	
Increase in net tangible book value per share attributable to new investors in this offering	$ 0.0569	
As adjusted net tangible book value per share after giving effect to this offering		$ 0.0349
Dilution per share to investors in this offering		$ 0.1093

This information is based on 172,953,440 shares of common stock outstanding as of March 31, 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 March 31, 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 March 31, 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 March 31, 2016;
- up to shares of common stock issuable upon the exercise of the warrants to be sold in this offering; and
- up to shares of common stock issuable upon the exercise of the Underwriter Warrants to be issued in connection with this offering.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with our audited Financial Statements and the notes thereto included elsewhere in this prospectus. As a smaller reporting company, we have elected scaled disclosure reporting obligations and therefore are required to provide the information required herein for only the last two most recent fiscal years.

General Overview and Trends

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

During the year ended December 31, 2015 and the first quarter of 2016, our principal focus has been on commercializing our PerioPredict test, and on the sales of our Inherent Health brand of genetic tests and related programs.

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

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

employees.

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

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

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

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

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

Our Inherent Health brand of genetic tests includes the first-of-its-kind test for weight management that identifies an individual's genetic tendencies for weight gain related to either fat or carbohydrates in the diet. The Inherent Health brand also offers customers a full suite of affordable, easy-to-use and meaningful genetic tests in heart health, bone health and nutritional needs. In addition, we launched additional products under the name Wellness Select that allows our e-commerce customers to purchase any combination of our Inherent Health genetic tests at a discounted price.

We market our Inherent Health brand of genetic assessment tests primarily through our commercial relationships with Alticor Inc. affiliated companies. Alticor is a related party. On October 26, 2009, we entered into a Merchant Network and Channel Partner Agreement with Amway Corp., d/b/a/ Amway Global (Amway Global), a subsidiary of Alticor. Pursuant to this agreement, Amway Global sells our Inherent Health brand of genetic tests through its e-commerce website via a hyperlink to our e-commerce site. In 2015 and 2014, revenues from this agreement accounted for approximately 45% and 44% of our revenues, respectively. In the three months ended March 31, 2016 and 2015, revenues from this agreement accounted for 14% and 56% of our revenues, respectively.

Beginning in September 2012 and again in 2013, Access Business Group LLC (ABG), an affiliate of Alticor, placed purchase orders totaling approximately $3.3 million consisting of weight management kits. The kits are included as part of a promotional bundle of products that Amway is now selling to their Individual Business Owners (IBOs). Of the $3.3 million in orders received in 2013, $1.8 million was related to the 2014 program and $1.5 million was related to the 2013 program. Cash for the kits purchased for the 2013 program was received in the first quarter of 2013 and cash for the kits purchased for the 2014 program was received by December 31, 2013. As a component of the 2013 promotional program, and not reflective of actual product expiry, the kits were required to be redeemed before December 31, 2013. In February 2014, we removed the redemption date requirement for the 2013 promotional program, for which ABG paid us $519,000 as a retrospective increase in the product purchase price. All revenues related to the 2013 promotional program, including the $519,000, will remain deferred until the kits are redeemed or the breakage analysis determines the probability of eventual redemption is remote. In October 2014, we received $250,000 as a retrospective increase in the product purchase price for unsold kits as consideration for extending the required redemption date of the 2014 promotional program to December 31, 2017. Cash received for these kits will be treated as deferred revenues until specific kits are returned for processing or on the final allowed redemption date of December 31, 2017. For the years ended December 31, 2015 and 2014, approximately 13% and 32%, respectively, of our revenue came from sales through ABG's promotional product bundle program. In the three months ended March 31, 2016 and 2015, revenues from this arrangement accounted for 3% and 14% of our revenues, respectively.

On September 21, 2012, we entered into a License Agreement (the License Agreement) with Access Business Group International LLC (ABGI), an affiliate of Alticor. Pursuant to this License Agreement, we granted ABGI and its affiliates (the Licensees) a non-exclusive license to use the technology related to our Weight Management genetic test and to sell the Weight Management test in Europe, Russia and South Africa. ABGI, or a laboratory designated by ABGI, is responsible for processing the tests, and we receive a royalty for each test sold. The License Agreement has an initial term of five years from the date of first commercial sale of the Weight Management test under the agreement. For the years ended December 31, 2015 and 2014, $191,000 and $150,000, respectively, in license fees have been received pursuant to the License Agreement. For the three months ended March 31, 2016 and 2015, $59,000 and $54,000, respectively, in license fees have been earned pursuant to the License Agreement. The increase in license fees is due primarily to higher per-unit royalties resulting from the issuance of patents in the European Union and Russia, and additional unit volume from new Eastern European markets.

Our research and development expenses are focused on our own development efforts related primarily to our PerioPredict and cardiovascular disease genetic tests. We are also focusing on seeking potential commercial partners to validate our technology within their specific business model as a collaboration with little or no cost to us. This is different than in prior years when our development focus was concentrated in research and development to bring new test configurations to market.

We recognize revenue from genetic testing services when there is persuasive evidence of an arrangement, service has been rendered, the sales price is determinable and collectability is reasonably assured. Service is deemed to be rendered when the results have been reported to the individual who ordered the test. To the extent that tests have been prepaid but results have not yet been reported, recognition of all related revenue is deferred. During the fourth quarter of 2013, we concluded that sufficient historical customer genetic test redemption patterns existed to determine the period of time after which the likelihood of test redemption was remote for Inherent Health tests purchased. Based on our analysis of the redemption data, we estimate that period of time to be three years after the sale of a genetic test kit. Prior to making this determination, revenue was recognized only on test kits returned and processed. Beginning in the fourth quarter of 2013, we began to recognize breakage revenue based on the likelihood of test redemption becoming remote. The term remote requires statistical analysis of customer redemption patterns for all tests sold and returned. We analyzed redemption patterns from 2009 through 2015. Included in genetic test revenue in the years ended December 31, 2015 and December 31, 2014 is $218,000 and $309,000, respectively, of breakage revenue related to unredeemed genetic test kits from 2012 and 2011. We expect to continue to recognize breakage revenue and the corresponding deferred cost of goods as well as analyze the data on a quarterly basis based on the historical analysis.

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

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

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

On December 23, 2014, we also entered into a venture loan and security agreement (the Loan Agreement) with Horizon Technology Finance Corporation (the Lender) under which we have borrowed $5.0 million (the December 2014 Debt Transaction). The loan bears interest at a floating rate equal to the One Month LIBOR Rate (with a floor of 0.50%) plus 8.50%. In the event that the One Month LIBOR Rate, as reported in the Wall Street Journal, exceeds 0.50%, the interest rate will be adjusted by an amount equal to the difference between such rates at the end of that particular month. At December 31, 2015 and March 31, 2016, the rate was 9.0% per annum. The loan is to be repaid in forty-five (45) monthly payments consisting of fifteen (15) monthly payments of only interest followed by thirty (30) equal monthly payments of principal and interest. In addition, at the end of the repayment term (or at early termination of the loan) a final payment equal to 4.5% of the loan will be due and payable. Our obligations under the Loan Agreement are secured by a first priority security interest in substantially all of our assets other than our intellectual property. We have also agreed not to pledge or otherwise encumber our intellectual property assets, subject to certain exceptions. In connection with the Loan Agreement, we issued to the Lender and its affiliates warrants to purchase a total of 2,492,523 shares of common stock at an exercise price of $0.1003 per share, which we refer to herein as the Lender Warrants. The Lender Warrants have a term of ten (10) years.

In the genetic test business, competition is in flux and the markets and customer base are not well established. Adoption of new technologies by customers requires substantial market development and customer education.

Historically, we have focused on our relationship with our primary customer, Alticor, a significant direct marketing company, in order to assist us in developing the market for our products and educating our potential customers. Our challenge in 2016 and beyond will be to develop the market for our personalized health products, in particular our PerioPredict test, and we will allocate considerable resources to commercialization of our PerioPredict genetic test. Due to the early stage of this initiative, we cannot predict with certainty fluctuations we may experience in our genetic test revenues or whether such revenues will ever be material, or if material, will be sustained in future periods.

Liquidity and Capital Resources

As of March 31, 2016 and December 31, 2015, we had cash and cash equivalents of $2.9 million and $4.7 million, respectively.

Cash used in operations was $1.8 million for the three months ended March 31, 2016 and $1.8 million for the three months ended March 31, 2015. There was an increase in prepaid expenses in the three months ended March 31, 2016, offset by cash received related to contracted research revenue.

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

Cash used in investing activities was $9,000 for the three months ended March 31, 2016, compared to $17,000 for the three months ended March 31, 2015. The $9,000 in 2016 relates to the purchase of new lab equipment. The majority of the $17,000 in 2015 relates to the purchase of new computer equipment that was part of Projects in Progress as of March 31, 2015.

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

Cash provided by financing activities was $3,300 for the three months ended March 31, 2016, compared to $1,400 for the three months ended March 31, 2015. The Company received $3,300 from stock purchases through the employee stock purchase plan during the three months ended March 31, 2016 compared to $5,500 for the three months ended March 31, 2015. The $5,500 received through the employee stock purchase plan for the three months ended March 31, 2015 was offset by $4,100 in additional fees related to the December 2014 Private Placement.

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

The amount of cash we generate from operations is currently not sufficient to continue to fund operations and grow our business. We expect that our current financial resources will be adequate to maintain our current and planned operations into the second half of 2016. We believe our success depends on our ability to generate significant revenues for the PerioPredict test. The timing of any revenues that we may receive for the PerioPredict test is uncertain at this time, and is contingent upon a number of factors, including our ability to attract employer and insurance carriers as customers directly, to consummate arrangements with additional partners to promote the PerioPredict test, our partners' ability to attract customers for PerioPredict, and the timing of utilization of the PerioPredict test by customers, among other possible variables. We do not expect to receive any material revenues from the PerioPredict test until mid to late 2016, at the earliest, and the timing of any such revenues may be substantially later. We may never receive significant revenues from the PerioPredict test.

Until such time, if ever, that we generate revenues sufficient to fund operations, we may fund our operations by issuing common stock, debt or other securities in one or more public or private offerings, as market conditions permit, or through the incurrence of debt from commercial lenders. However, no assurance can be given at this time as to whether we will be able to achieve these objectives. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends. There can be no assurance that additional funds will be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or cease activities or operations or enter into licenses or other arrangements with third parties on terms that may be unfavorable to us or sell, license or relinquish rights to develop or commercialize our products, technologies or intellectual property, or seek protection under U.S. bankruptcy laws. The financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Results of Operations

Three Months Ended March 31, 2016 and 2015

Total revenue was $961,000 for the three months ended March 31, 2016 compared to $403,000 for the three months ended March 31, 2015. The change in total revenue is largely attributable to a contracted research project, partially offset by a decrease in kits returned for processing related to ABG’s promotional product bundle.

During the three months ended March 31, 2016, 14% of our sales revenue came through our Merchant Network and Channel Partner Agreement with Amway Global, compared to 56% during the three months ended March 31, 2015. During the same periods, 3% and 14%, respectively, of our revenue came from sales through ABG's promotional product bundle program.

Cost of revenue for the three months ended March 31, 2016, was $527,000, or 55% of total revenue, compared to $331,000, or 82% of total revenue, for the three months ended March 31, 2015. The decrease in the cost of revenue as a percentage of revenue in the three months ended March 31, 2016 is primarily attributable to the fixed laboratory costs being applied to higher revenue in the period, which was largely due to a contracted research project.

Research and development expenses were $480,000 for the three months ended March 31, 2016, compared to $183,000 for the three months ended March 31, 2015. The 163% increase of $298,000 is primarily attributable to expenses related to Dr. Kornman moving back to the R&D department in April 2015 as President and Chief Scientific Officer from his previous position as CEO. While he served as CEO, expenses generated by Dr. Kornman were recorded as selling, general and administrative expenses. The increase in research and development expenses was also partially due to increased compensation expense related to annual salary increases for existing staff.

Selling, general and administrative expenses were $1.3 million for the three months ended March 31, 2016, compared to $1.6 million for the three months ended March 31, 2015. The 16% decrease is primarily attributable to lower compensation costs related to terminated employees, CEO recruiting expenses in 2015 that did not recur in 2016 and Dr. Kornman's expenses being recorded in research and development, partially offset by increased expenses related to the new CEO in 2016.

Interest expense was $152,000 for the three months ended March 31, 2016, compared to $151,000 for the three months ended March 31, 2015. The interest expense is entirely related to our venture loan and security agreement with Horizon entered into on December 23, 2014.

Years Ended December 31, 2015 and 2014

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

ended December 31, 2014, partially offsetting the decrease in total revenue.

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

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

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

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

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

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements. The preparation of these financial statements and related disclosures in conformity with accounting principles generally accepted in the United States of America requires us to (i) make judgments, assumptions and estimates that affect the reported amounts of assets, liabilities, revenue and expenses; and (ii) disclose contingent assets and liabilities. A critical accounting estimate is an assumption that could have a material effect on our consolidated financial statements if another, also reasonable, amount were used or a change in the estimates is reasonably likely from period to period. We base our accounting estimates on historical experience and other factors that we consider reasonable under the circumstances. However, actual results may differ from these estimates. To the extent there are material differences between our estimates and the actual results, our future financial condition and results of operations will be affected. Our most critical accounting policies and estimates upon which our financial condition depends, and which involve the most complex or subjective decisions or assessments are set forth in Note 3 to our financial statements included elsewhere herein.

BUSINESS

Overview

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

Our Platform

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

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

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

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

- Ability to support drug development. Our development platform may also be 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.

- Relationship management tools. We utilize proprietary data base and contact management software to contact patients and care teams and to track responses to outreach and clinical interventions.

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

Market Conditions and Trends

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

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

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

We have focused our research, development and commercialization efforts on identifying combinations of SNP variations that alter biology involved in inflammation or metabolic disease. We have worked with leading universities throughout the world to identify genetic variations that influence the body's inflammatory response. Our scientific advisory board includes Sir Gordon Duff, a pioneer in understanding the role that genetics plays in inflammatory disease pathways. In addition, we have conducted clinical studies for various indications throughout the world involving tens of thousands of individuals to demonstrate clinical value of our tests. To date, some of our clinical research collaborations include studies at: Stanford University; the University of North Carolina at Chapel Hill; the Mayo Clinic; Brigham & Women's Hospital (Harvard Medical School); University of California at San Francisco; University of California at San Diego; New York University Medical Center; University of Sheffield, (UK); Yonsei University Medical Center, (Korea); Tongji Medical College, (China); and Tuft's University Medical Center.

Inflammation is one of the body's most basic protective mechanisms, and the understanding of the role of inflammation in disease has increased over the past few years. It is generally accepted that many chronic conditions begin with a challenge to the tissues of the body and that the inflammatory response system of an individual mediates the clinical manifestation. It is also now thought that SNP variations in the genes that influence the inflammatory process can have an important impact on the variation of disease progression among individuals who experience the same initiating events or conditions.

Chronic conditions that have traditionally been considered to be primarily inflammatory diseases include periodontitis and rheumatoid arthritis. In recent years, inflammation has been found to affect several other major diseases of aging that were not previously thought of as inflammatory diseases, including heart disease, diabetes and osteoarthritis. For example, an individual who has a strong inflammatory response may be more successful in clearing a bacterial infection than an individual with a less robust inflammatory response. However, that strong inflammatory response may actually cause that individual to be at increased risk for a more severe course in one or more of the chronic diseases that generally affect people in mid to later life, such as cardiovascular disease, osteoarthritis, and periodontal disease. There is growing evidence that genetic variants in IL-1 influence individual risk of developing these diseases and their severity and complications.

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

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

Our Product Focus

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

Product Definition and Positioning

PerioPredict is a genetic risk test that analyzes genetic variations associated with inflammation and identifies individuals with a life-long predisposition to over-produce inflammation. PerioPredict identifies specific polymorphisms (genetic variations) in genes that regulate the production of interleukin-1 cytokines. Higher gingival levels of these proteins are associated with destruction of soft tissue attachment and bone, and increased severity of periodontitis in certain patient populations. Results from several clinical studies indicate that certain inflammatory cytokine levels in the gingival crevicular fluid were significantly higher in PerioPredict positive patients than in patients who were PerioPredict negative. PerioPredict testing need only be done once in a lifetime and identifies “at risk” patients early on, often before the onset of clinical symptoms, to enable targeted treatment. This objective information allows the dentist and hygienist to better guide treatment to reduce complications and costs associated with chronic inflammatory disease, such as severe periodontitis. The test may also help to establish long-term patient relationships based on the patient’s prevention and care plan guided by the individual’s genetic predisposition. Sample collection requires only a simple, easy-to-use cheek swab, and PerioPredict has been validated for use in all major ethnic groups. PerioPredict identifies adults at increased risk for severe periodontal disease who would not have otherwise been identified by a history of smoking or diabetes.

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

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

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

Clinical Utility and Health Economics

The clinical utility of the PerioPredict test is supported by the large validation study conducted by the University of Michigan and referred to as the Michigan Personalized Prevention Study, or MPPS. The objective of the MPPS was to improve dental care by identifying and using certain risk factors to set preventative treatment regimens. On August 6, 2012, we announced that we had received top line results from the MPPS, and on June 10, 2013, we announced the publication of the MPPS results in the *Journal of Dental Research.* The study examined data from 5,117 patients monitored for 16 consecutive years. These results indicated that in low risk patients (those with none of three risk factors: smoking, diabetes, and a PerioPredict result indicating the individual was at high risk of contracting periodontitis) there was no significant difference between two dental preventive visits per year and one preventive visit per year in the percentage of patients who had tooth extractions over the 16 year monitoring period; 13.8% versus 16.4%, respectively. In addition, these results indicate that in high risk patients (those with any one of the three risk factors, with PerioPredict being the most common of the three), two preventive visits per year significantly reduced the percentage of patients who had extractions over a 16 year monitoring period compared to one preventive visit per year; 16.9% vs. 22.1%. There was also a positive relationship between the number of risk factors and the percentage of patients with extractions. For patients with two or three risk factors, and smoking plus PerioPredict positive represented approximately 67% of those patients, two cleanings annually did not appear to be sufficient to control risk for tooth loss.

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

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

Business Strategy

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

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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, which represents approximately 45 million people in the U.S., 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 relationship 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 anticipate establishing demonstration projects aimed at providing evidence of the efficacy of our program in driving patient engagement, compliance and ultimately reducing 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 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.

Additional Products Marketed

We market additional genetic tests through our Inherent Heath brand:

- *Weight Management Genetic Test*: This test determines whether individuals will lose weight more predictably on a low fat, low carbohydrate or balanced diet and whether normal or vigorous exercise is needed to most efficiently lose existing body fat. The test results guide more effective long-term weight loss.
- *Bone Health Genetic Test*: This test is designed to identify whether an individual is more likely to be susceptible to spine fractures and low bone mineral density associated with osteoporosis.
- *Heart Health Genetic Test*: This test is designed to identify genetic predisposition to excess inflammation, which is a risk factor for heart attack.
- *Nutritional Needs Genetic Test*: This test is designed to identify DNA variations in genes crucial to B-vitamin metabolism and the ability to manage oxidative stress.
- *Wellness Select Genetic Test:* This allows buyers to purchase any combination of Inherent Health genetic tests at a discounted price.

Weight Management Genetic Test

Our Weight Management Genetic Test helps take the guesswork out of finding an effective diet and exercise solution by revealing actionable steps to achieve weight goals based on genetics. The test determines whether a low fat, low carbohydrate or balanced diet may be best, as well as whether normal or vigorous exercise is needed to most efficiently lose existing body fat. The test provides new information beyond traditional assessments, so that nutritional intake and fitness routines can be tailored for improved, sustainable results. This test identifies five SNPs in four human genes that are involved in certain physiological pathways relating to body weight. Certain patterns of markers are associated with differential response to certain diet and exercise regimens.

Bone Health Genetic Test

Our Bone Health Genetic Test is designed to identify whether an individual is more likely to develop spine fractures and low bone mineral density associated with osteoporosis. Although it typically starts later in life, early intervention can help prevent osteoporosis. Preventive measures can reduce the risk for bone loss and fractures, which in the case of vertebral fractures leads to a hunched over appearance. The test identifies a SNP in each of three genes involved in processes that affect bone; estrogen receptor alpha (ER1 Xba1), vitamin D receptor (VDR), and interleukin-1 (IL-1). Certain patterns of variations are associated with increased risk of spine fracture and/or low bone mineral density. The test can be used as an aid to making diet, exercise, and other lifestyle choices to maintain and improve bone health.

Heart Health Genetic Test

Our Heart Health Genetic Test is designed to identify genetic predisposition to excess inflammation, which is a risk factor for heart attack. The genetic analysis identifies individuals that have a lifelong tendency to overproduce certain chemicals in the body that lead to inflammation. Overproduction of these chemicals may start a chain reaction that ultimately may lead to a heart attack. Knowing genetic risk will enable individuals to take specific actions to decrease overall risk. The test identifies three SNPs in two genes involved in inflammation, IL-1 alpha and IL-1 beta. Certain IL-1 variations are associated with increased inflammation, which is a risk factor for early heart attack. The test may be used as an aid to making diet, exercise, and other lifestyle choices to reduce inflammation-based risk.

Nutritional Needs Genetic Test

Our Nutritional Needs Genetics Test is designed to identify DNA variations in genes crucial to B-vitamin metabolism and the ability to manage oxidative stress. Individuals with certain variations in these genes may be at increased risk for ineffective utilization of B-vitamins and potential for cell damage caused by oxidative stress, both of which can in some cases lead to increased risk for certain diseases. The test identifies the presence or absence of human genotypic markers involved in vitamin B metabolism and markers in response to oxidative stress. Certain variations are associated with less efficient B-vitamin metabolism or reduced activity of endogenous anti-oxidant systems. The test may be used to aid individuals in deciding whether to supplement their diet with B vitamins and/or antioxidants.

Wellness Select Genetic Test

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

Marketing and Distribution of Inherent Health Tests

We market our Inherent Health brand of genetic tests using our e-commerce website and under contract with Amway-affiliated companies, which are affiliates of Alticor, Inc., the parent of Pyxis Innovations Inc., a significant stockholder ("Pyxis"), and several regional weight management focused organizations. Amway sells the Inherent Health Weight Management test in the U.S. and fifteen countries in Europe. The European tests are processed through two European laboratories that have been validated for quality assurance purposes by Interleukin Genetics. We receive a royalty payment from each test processed in Europe but do not receive a test processing fee. We have developed a complete e-commerce solution for our Inherent Health brand of genetic tests. We have subcontracted with a fulfillment center to distribute tests to customers ordering via our online store. The e-commerce solution has provided a friendly and easy to use method for the purchase of our genetic tests. We are partnered with a number of websites that have established a link to our site in order to distribute tests. We pay these sites commissions for all orders made via a click through from their site to ours. See also "Government Regulations – Food and Drug Administration."

Laboratory Testing Procedure

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

We process test samples in our CLIA-certified genetic testing laboratory. The regulatory requirements associated with a CLIA-certified clinical laboratory are addressed under the section titled "Government Regulation." We have upgraded the systems and processes for the laboratory with the addition of high volume analytical equipment as well as updated protocols for all of the laboratory processes. We currently hold laboratory permits or licenses for all US states that require a genetic test processing license and meet the regulatory requirements as needed for other countries.

Platform Extensions and Genetic Test Pipeline

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

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

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

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

Osteoarthritis

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

We have published findings on the genetics of OA in the *Annals of Rheumatic Diseases*, where we reported that a novel, patent-pending panel of genetic markers was highly predictive of which patients with knee OA were likely to develop severe disease as they age. The studies were done as a collaboration between Interleukin and New York University (NYU) Hospital for Joint Diseases, and this information may allow pharmaceutical companies that are developing the first disease-modifying OA drugs (DMOADs) to screen patients and include in their clinical trials only those patients who have progressive disease. In 2015, we signed a license agreement with NYU School of Medicine related to the development and commercialization of the first genetic test of its kind to identify individuals at increased risk for progression of OA and related complications.

In addition to development efforts outlined above, we anticipate that further extensions of our commercial platform will have value to potential partners in diabetes disease management. Given the substantial role of IL-1 in the onset and management of Type 2 diabetes, we believe our genetic tests have the potential to offer insights to caregivers to enhance medical management of each case and to direct patient outreach efforts. For example, genetic test results may inform a risk-stratification framework that can individualize care plans and prioritize case management. Further, our relationship management system will potentially capture valuable patient behavioral insights that other care delivery systems will not provide. We also note growing interest in managing high-risk patients more holistically—integrating oral and medical health management. We believe that our growing relationships with the dental care team may play an important role to facilitate this trend toward integrated care management. We believe that these elements of our commercial platform may have potential value to diabetes disease management enterprises and may form the bases of one or more collaborations.

Intellectual Property

Our intellectual property is focused on the discoveries that link variations in key inflammation and metabolic genes to various conditions or illnesses. We initially concentrated our efforts on variations in the genes for the interleukin family of cytokines, because these compounds appear to be one of the strongest control points for the development and severity of inflammation. Some of our tests may include our proprietary genetic variations plus other gene variations that may be publicly available or in-licensed by Interleukin Genetics.

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

Our patents are “use” patents that claim that a SNP, or set of SNPs in unique patterns can be used in a novel way to predict disease development or progression, predict responses to preventive or therapeutic interventions and identify specific actions that improve health outcomes. We currently own rights in nine issued U.S. patents that have expiration dates between 2016 and 2029, six U.S. patent applications and one U.S. Provisional patent application pending, that are based on novel associations between particular gene sequences and certain metabolic and inflammatory conditions and disorders. The nine issued U.S. patents relate to genetic tests for, periodontal disease, osteoporosis, coronary artery disease, and other diseases associated with interleukin inflammatory haplotypes. Our newest patent applications relate to the commercial use of SNP panels in the fields of weight management, periodontal disease, osteoarthritis and IL-1 blocking drug indications. If granted, we expect many of these patents are not likely to expire until between 2028 and 2037.

Our intellectual property and proprietary technology are subject to numerous risks, which we discuss in “Risk Factors” above. Our commercial success will depend at least in part on our ability to obtain appropriate patent protection on our therapeutic and diagnostic products and methods and our ability to avoid infringing on the intellectual property of others.

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

Competition

The competition in the field of personalized health is changing. The markets and customer base are not well established. There are a number of companies involved in identifying and commercializing genetic markers. The companies differ in product end points and target customers. There are companies that market individual condition genetic tests for complex diseases to consumers and those that sell only to physicians. There are companies that market testing services for rare monogenic diseases mainly to physicians. There are companies that sell genome-scanning services to provide customers (usually the consumer directly) reports on large numbers of SNPs or the person’s entire genome. There are also technology platform companies that sell SNP testing equipment.

The key competitive factors affecting the success of any genetic test is its perceived benefit by the user, price (potentially including availability of reimbursement) and the level of market acceptance. In the case of newly introduced products requiring “change of behavior” (such as genetic risk assessment tests), we believe the presence of multiple competitors may accelerate market acceptance and penetration through increasing awareness. Moreover, two different genetic risk assessment tests for the same disease may in fact test or measure different components, and thus, actually be complementary when given in parallel as an overall assessment of risk, rather than being competitive with each other. Furthermore, the primary focus of most companies in the field is performing gene-identification research for pharmaceutical companies for therapeutic purposes, with genetic risk assessment testing being a secondary goal. In

contrast, our primary business focus is developing and commercializing genetic risk assessment tests for health risks and forward-integrating these tests with additional products and services.

For a discussion of the risks associated with competition, see “Risks Related to Our Business, Our Financial Results and Need for Financing - We could become subject to intense competition from other companies, which may damage our business.” under "Risk Factors" above.

Government Regulation

Federal and state governmental authorities regulate the testing services that we provide. Failure to comply with the applicable laws and regulations can subject us to civil and criminal penalties, loss of licensure, certification, or accreditation. We intend to comply with all applicable government regulations and believe that we are currently in compliance. We cannot predict what new legislation or regulations governing our operations will be enacted by legislative bodies or promulgated by agencies that regulate its activities, or what changes in interpretations of existing regulations may be adopted. In particular, the FDA’s approach to regulating laboratory developed tests is evolving, including such tests that are made available directly to the consumer, and we are in discussions with the FDA about how our tests, primarily certain of our Inherent Health tests, may be impacted, as discussed further in the “Government Regulation - Food and Drug Administration” section below.

CLIA and Other Laboratory Licensure

Our clinical laboratory must hold certain licenses, certifications, and permits to conduct our business. Laboratories that perform testing on human specimens for the purpose of providing information for the diagnosis, prevention or treatment of disease or assessment of health are subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). CLIA requires such a laboratory to be certified by the federal government and mandates compliance with various operational, personnel, facilities, administration, quality and proficiency testing requirements intended to insure that testing services are accurate, reliable and timely. Requirements for testing under CLIA vary based on the level of complexity of the testing performed. Laboratories performing high complexity tests, such as genetic tests, must comply with more stringent requirements than laboratories performing moderate or waived testing.

As a condition of CLIA certification, our laboratory is subject to survey and inspection every other year, in addition to being subject to additional random inspections. The biennial survey is conducted by the Centers for Medicare & Medicaid Services, or CMS, a CMS agent (typically a state agency), or, if the laboratory is accredited, a CMS-approved accreditation organization.

CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law. In some cases, state licensure programs actually substitute for the federal CLIA program. In other instances, the state's regulations may be in addition to the CLIA requirements. In addition, our laboratory holds multiple state licenses to the extent that we accept specimens from one or more of these states, each of which require out-of-state laboratories to obtain licensure. If a laboratory is out of compliance with state laws or regulations governing licensed laboratories, penalties for violation vary from state to state but may include suspension, limitation, revocation or annulment of the license, assessment of financial penalties or fines, or imprisonment. We believe that we are in material compliance with all applicable licensing laws and regulations.

We may become aware from time to time of other states that require out-of-state laboratories to obtain licensure to accept specimens from the state, and other states may impose such requirements in the future. If we identify any other state with such requirements, or if we are contacted by any other state advising us of such requirements, we intend to follow all instructions from the state regulators regarding compliance with such requirements.

Laboratories must renew certification every two years, which typically includes an inspection of the laboratory. Our laboratory was most recently inspected in September 2015 and no deficiencies or other issues were noted and our CLIA license was renewed.

Food and Drug Administration

Although the Food and Drug Administration (FDA) has consistently claimed that it has the authority to regulate laboratory-developed tests, or LDTs, that are validated by the developing laboratory and performed only by that laboratory, it has generally exercised enforcement discretion in not otherwise regulating most tests developed and performed by high complexity CLIA-certified laboratories.

In July 2010, FDA held a public meeting in which FDA officials including those from the Office of In Vitro Diagnostic Products (OIR), within the Center for Devices and Radiological Health (CDRH) announced their intention to develop a regulatory framework for LDTs that would be based on the risks posed by such tests. In particular, FDA officials stated that laboratory developed tests offered directly to consumers would no longer be subject to enforcement discretion. Concomitant with that meeting, FDA sent letters to more than a dozen companies offering direct-to-consumer, or DTC, genetic tests, including us, stating that their tests appeared to be subject to regulation as medical devices and requesting information on how the companies planned to come into compliance with FDA requirements. The FDA letter inquired about our Inherent Health brand of DTC genetic tests and stated that these tests appeared to meet the definition of a "device" under the Federal Food, Drug, and Cosmetic (FD&C) Act. The letter requested that Interleukin provide FDA with the clearance or approval number for the tests or with the basis for determination that the tests do not require FDA clearance or approval. In the letter, FDA offered to meet with us, "to discuss whether there are tests you are promoting that do not require review by FDA and what information you would

need to submit in order for your products to be legally marketed."

In March 2011, FDA convened an expert advisory panel to discuss and make recommendations on scientific issues concerning DTC genetic tests that make medical claims. The panel expressed a variety of concerns regarding DTC genetic testing and recommended that certain tests not be permitted to be sold DTC. We submitted a position paper to the FDA in advance of the meeting and presented testimony to the panel at a public meeting on March 8, 2011. After that meeting, the OIR director publically stated that FDA would likely take a case-by-case approach with respect to which types of genetic tests may be offered DTC. He also stated that OIR planned to issue three guidance documents addressing oversight of laboratory-developed tests. However, he did not provide a timeframe for OIR's release of these documents. In March 2012, an FDA spokesperson stated that FDA's plan to adjust its enforcement discretion policy for LDT's is currently under "administrative review."

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

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

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

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

On February 3, 2016 we met with the director and staff members of OIR to further discuss our letter response. The FDA issued minutes of the meeting on February 16, 2016, which confirmed that we do not offer an Osteoarthritis test and that PerioPredict is currently offered only as an LDT and is therefore currently subject to FDA enforcement discretion. In addition, they confirmed their interest in obtaining further information on how we would come into compliance with respect to the Inherent Health tests, since those tests are offered DTC and therefore are not subject to FDA enforcement discretion. Subsequently, we clarified with the FDA that our Heart Health and Bone Health tests would only be available directly to consumers until May 22, 2016, at which time they will only be available if requested by an authorized healthcare provider. Any Heart Health and Bone Health tests purchased through retail channels prior to that date will be processed through September 19, 2016, after which the tests will only be processed for a licensed healthcare provider. We continue discussions with the FDA to determine appropriate next steps, if any, for our Weight Management test, which is marketed both through professional channels and DTC.

HIPAA and Other Privacy Laws

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) established for the first time comprehensive federal protection for the privacy and security of health information. The Health Information Technology for Economic and Clinical Health Act (HITECH), part of the American Recovery and Reinvestment Act of 2009, significantly expanded the scope of HIPAA and increased penalties for violating HIPAA. The HIPAA standards apply to three types of organizations ("Covered Entities"): health plans, health care clearing houses, and health care providers who conduct certain health care transactions electronically. They also apply to vendors of Covered Entities called "Business Associates" that access protected health information to provide services to or perform functions on behalf of Covered Entities. Covered Entities and Business Associates must have in place administrative, physical and technical standards to guard against the misuse of individually identifiable health information. We are not currently a Covered Entity subject to the HIPAA privacy and security standard. It is possible that in the future we will become a Covered Entity (for example if any of the tests that we perform become reimbursable by insurers). Regardless of our own Covered Entity status, HIPAA may apply to our customers, such as health care providers and health plans. Even though we are not directly subject to HIPAA, we could be subject to penalties, lawsuits and experience other adverse consequences if we wrongfully acquire protected health information, aid and abet a HIPAA violation by a customer or if we obtain or disclose protected health information maintained by a Covered Entity without authorization in violation of HIPAA. In addition, some lawsuits, including class action lawsuits, have been pursued at the state level against both covered entities and entities that are not directly subject to HIPAA for breach of confidentiality and security violations.

Our activities must also comply with other applicable privacy laws, including state data security laws that apply to personal data of our employees as well as our customers. "Personal data" includes information such as name coupled with social security number, state issued identification number, or financial account number. State data security laws impose specific security measures for the protection of personal data and require notification to affected individuals and government authorities in the event of breach. Non-compliance may result in government investigations, fines and significant negative publicity for our company.

Many states protect health information with confidentiality laws that are more stringent than HIPAA and that are not preempted by HIPAA. Most states protect certain categories of sensitive health information, such as infectious disease status or behavioral health history. Genetic information, including genetic test results, is often a protected category of health information. We must comply with all of these state-imposed laws. There are also international privacy laws, such as the European Data Directive, that impose restrictions on the access, use, and disclosure of health information and personal data across national lines.

In addition to health care privacy and data security laws, many states have adopted laws governing genetic testing and the use and disclosure of genetic test results. These laws typically require a specific form of written consent in advance of genetic testing and require special protections for test results. Given the complexity of genetic testing and the variety of techniques available for evaluating similar clinical conditions, these laws can be difficult to apply, making compliance more complex and potentially delaying implementation of a testing program when parties disagree on interpretation. Our failure to comply with these laws may result in fines, government enforcement, privacy litigation and adverse publicity for our company.

If we become subject to HIPAA or other state or federal privacy and security laws, we will have to establish and maintain an active compliance program. We will be subject to audit and investigation and may also be audited in connection with a complaint. We would also be subject to prosecution and/or administrative enforcement and increased civil and criminal penalties for non-compliance, including a new, four-tiered system of monetary penalties adopted under HITECH. We would also subject to enforcement by state attorneys general who were given authority to enforce HIPAA under HITECH.

We are subject to laws and regulations related to the protection of the environment, the health and safety of employees and the handling, transportation and disposal of medical specimens, infectious and hazardous waste and radioactive materials. For example, the U.S. Occupational Safety and Health Administration, or OSHA, has established extensive requirements relating specifically to workplace safety for healthcare employers in the U.S. This includes requirements to develop and implement multi-faceted programs to protect workers from exposure to blood-borne pathogens, such as HIV and hepatitis B and C, including preventing or minimizing any exposure through needle stick injuries. For purposes of transportation, some biological materials and laboratory supplies are classified as hazardous materials and are subject to regulation by one or more of the following agencies: the U.S. Department of Transportation, the U.S. Public Health Service, the United States Postal Service and the International Air Transport Association. We generally use third-party vendors to dispose of regulated medical waste, hazardous waste and radioactive materials and contractually require them to comply with applicable laws and regulations.

GINA Legislation

In 2008, the Congress passed and the President signed into law, the Genetic Information Non-discrimination Act or GINA. GINA prohibits certain entities from discriminating using genetic information, which includes information from genetic tests, genetic tests of family members and family medical history. It also includes information about an individual’s or family member’s request for or receipt of genetic services. This law generally prohibits health insurers or health benefit plans from:

- increasing the group premium or contribution amounts (such as co-payments) based on genetic information;
- requesting or requiring an individual or family member to undergo a genetic test; or

- requesting, requiring or purchasing genetic information prior to or in connection with enrollment, or at any time for underwriting purposes.

The law also prohibits employers and certain other entities, including employment agencies, from using genetic information in employment decision-making and from requesting, requiring, or purchasing genetic information. It also strictly limits such entities from disclosing genetic information.

In October 2009, the Department of Health and Human Services issued a proposed rule to modify the HIPAA Privacy Rule to implement Title I of GINA. Final regulations were adopted in January, 2013. Among other things, this rule revises the definition of health information under HIPAA to include genetic information.

GINA applies to some of our customers and to us as an employer. We could be subject to penalties, lawsuits or experience other adverse consequences if our operations violate GINA or cause another entity to violate GINA.

Federal Trade Commission

The Federal Trade Commission (FTC) has jurisdiction over the advertisements of many types of products, including most medical devices, and prohibits unfair or deceptive trade practices. Advertising for our tests, including statements made on our website, is subject to FTC requirements. In recent years, the FTC instituted enforcement actions against several dietary supplement companies for false and misleading marketing practices and advertising of certain products, including those intended for weight loss. These enforcement actions have resulted in consent decrees and monetary payments by the companies involved. Although the FTC has never threatened an enforcement action against us for the advertising of our products, there can be no assurance that the FTC will not question the advertising for our products in the future.

Employees

As of April 30, 2016, we had 14 full time employees. Our employees are not represented by any collective bargaining unit, and we believe our relations with our employees are good.

Properties

We lease approximately 13,000 square feet of office and laboratory space at 135 Beaver Street, Waltham, Massachusetts 02452, pursuant to a lease that expires in March 2017.

Legal Proceedings

We are currently not a party to any material legal proceedings.

MANAGEMENT

The Board of Directors and Management

We are managed under the direction of our Board of Directors. On December 23, 2014, we entered into a Securities Purchase Agreement (the "2014 Purchase Agreement") with various accredited investors, pursuant to which we sold securities in a private placement transaction, which we refer to herein as the 2014 Private Placement. Pursuant to the terms of the 2014 Purchase Agreement, as amended on April 6, 2015, the number of persons which constitutes the entire Board is set at eight (8), and is composed of the following:

(i) two (2) Class I directors with terms ending at the 2016 annual meeting of stockholders, consisting of one independent director (currently William C. Mills III) and one director designated by Pyxis Innovations Inc. ("Pyxis") (currently Joseph M. Landstra);

(ii) three (3) Class II directors with terms ending at the 2017 annual meeting of stockholders, consisting of our Chief Executive Officer (currently Mark B. Carbeau), Kenneth S. Kornman, Ph.D., Interleukin's founder and Chief Scientific Officer (for so long as Dr. Kornman remains employed by Interleukin), and one director designated by Bay City Capital Fund V, L.P. ("Bay City") (currently Dayton Misfeldt); and

(iii) three (3) Class III directors with terms ending at the 2018 annual meeting of stockholders, consisting of one director designated by Pyxis (currently Roger C. Colman), one independent director (currently James Weaver), and one director designated by Bay City (currently Lionel Carnot).

The 2014 Purchase Agreement also provides that a board member designated by Pyxis shall serve on the Audit Committee and a board member designated by Bay City shall serve on each of the Audit Committee, the Compensation Committee and the Nominating Committee. Currently, Joseph Landstra serves as the Pyxis designee on the Audit Committee, Lionel Carnot serves as the Bay City designee on the Audit and Nominating Committees and Dayton Misfeldt serves as the Bay City designee on the Compensation Committee. Upon the listing of our common stock on The NASDAQ Capital Market, James Weaver will replace Lionel Carnot on the Audit Committee.

Set forth below are the names of our directors and our executive officers, their ages, their position in the company, their principal occupations or employment for at least the past five years, the length of their tenure as directors and, for our directors, the names of other public companies in which they hold or have held directorships during the past five years.

Name	Age	Position with the Company
Mark B. Carbeau	55	Chief Executive Officer and Director
Kenneth S. Kornman, DDS, Ph.D.	69	President and Chief Scientific Officer and Director
Stephen DiPalma	57	Interim Chief Financial Officer
James M. Weaver (4)	52	Director and Chairman of the Board
Lionel Carnot (1)(2)	48	Director
Roger C. Colman (2)(3)	62	Director
Joseph M. Landstra (1)	38	Director
William C Mills III (1)(3)	60	Director
Dayton Misfeldt (3)	42	Director

(1) Member of our Audit Committee
(2) Member of our Nominating Committee
(3) Member of our Compensation Committee
(4) Upon the listing of our common stock on The NASDAQ Capital Market, Mr. Weaver will replace Mr. Carnot on the Audit Committee.

MARK B. CARBEAU has been our Chief Executive Officer and has served as a member of our Board of Directors since April 6, 2015. Prior to joining Interleukin, from December 2013 to March 2015, Mr. Carbeau was CEO of Diagnostyx, a technology-based healthcare company focused on intelligent drug infusion systems that he co-founded. Prior to Diagnostyx, from January 2010 to June 2013, Mr. Carbeau served as CEO of PolyRemedy®, a technology enabled services business that combines health information technology with personalized therapeutics to improve wound healing outcomes. From January 2008 to October 2009, Mr. Carbeau was the President and CEO of HyperMed, Inc., a commercial stage medical device and diagnostics company using novel hyperspectral imaging technology. Prior to HyperMed, Mr. Carbeau served as President USA of Kinetic Concepts, Inc. Prior to that, Mr. Carbeau served as Vice President, Corporate Development at OraPharma, Inc., during its commercial launch of a periodontal therapeutic, a successful IPO, and the eventual sale of the company to Johnson & Johnson. Mr. Carbeau also founded CM Partners, a strategic life science consulting firm, and was a member of The Boston Consulting Group. Mr. Carbeau began his career serving in various sales, marketing and manufacturing roles with Eli Lilly and Company. He holds a B.S. in Industrial Engineering from Penn State University and an M.B.A. from the Wharton School of the University of Pennsylvania. Our Board of Directors has concluded that Mr. Carbeau’s role as Chief Executive Officer as well as his extensive experience across a range of senior management positions with life science companies make him uniquely suited to serve on the Board. Mr. Carbeau has not served on any other public company boards in the past five years.

KENNETH S. KORNMAN, DDS, Ph.D. is Interleukin's co-founder and serves as our President and Chief Scientific Officer. Dr. Kornman also served as our Chief Executive Officer from August 2012 through April 2015. He has also been a member of our Board of Directors since August 2012 and previously served as a director from August 2006 through April 2010. Prior to founding Interleukin in 1986, Dr. Kornman was a Department Chairman and Professor at The University of Texas Health Center at San Antonio. He has also been a consultant and scientific advisor for several major oral care and pharmaceutical companies. Dr. Kornman currently retains academic appointments at Harvard University and the University of Michigan. He holds multiple patents in the molecular diagnostics area, has published three books and more than 125 scientific papers and has lectured and consulted worldwide on the transfer of technology to clinical practice. Dr. Kornman also holds an MS (Periodontics) and Ph.D. (Microbiology-Immunology) from the University of Michigan. Our Board of Directors has concluded that Dr. Kornman should serve as a director because of his prior executive management experience, his scientific expertise and his knowledge of the dental and biotechnology industries. Dr. Kornman has not served on any other public company boards in the past five years.

STEPHEN DIPALMA has been our Interim Chief Financial Officer since September, 2014. Mr. DiPalma is Managing Director at Danforth Advisors, LLC, where he has served since April 2014. He brings more than 25 years of experience in life sciences and healthcare, including founding two start-ups, working with venture-backed companies, subsidiaries of Fortune 100 firms and publicly traded companies, and his work with Danforth Advisors clients. Previously, he served as the CFO of two public companies, and as CFO, COO, CEO or Director of eight privately held companies, in addition to his consulting clients. Mr. DiPalma participated in the successful reorganization of Cambridge Biotech from Chapter 11 bankruptcy protection into Aquila BioPharmaceuticals, led the effort to take RXi Pharmaceuticals public, and has extensive experience in international fund raising and corporate structuring. He was formerly Chairman of the Board of Cognoptix Inc., and is on the Board of Directors of Phytera, Inc. Mr. DiPalma received his M.B.A. from Babson College and his B.S. from the University of Massachusetts-Lowell.

JAMES M. WEAVER initially joined the Board of Directors in July 2007 as a designee of Pyxis. He served as Chairman of our Board from September 2007 until March 11, 2014, when he announced that he was resigning as a director due to his resignation from Alticor Corporate Enterprises (an affiliate of Pyxis) to pursue other interests. On March 31, 2014, Mr. Weaver was re-elected as an independent director and was also re-appointed as Chairman of the Board. He is the former Vice President of Alticor Corporate Enterprises, a member of the Alticor Inc. family of companies, which is engaged in the principal business of offering products, business opportunities, and manufacturing and logistics services in more than 80 countries and territories worldwide. In this role, Mr. Weaver was responsible for managing the current portfolio of Alticor's companies and directs its acquisition and growth. Prior to joining Alticor in June 2007, Mr. Weaver worked for X-Rite Inc. where he held various leadership positions, including Senior Vice President and General Manager, Vice President of marketing and software development, Vice President of marketing and product development, as well as lead executive on several acquisitions. Mr. Weaver also founded and held the position of President and Chief Executive Officer of Bold Furniture Inc, and has held various leadership positions at Steelcase Inc. and Bissell Inc. Mr. Weaver received a Bachelor's degree in general studies from the University of Michigan in Ann Arbor and serves on several non-profit and private company boards. Our Board of Directors has concluded that Mr. Weaver should serve as a director because of his prior senior management experience and judgment and his extensive sales and marketing experience in the consumer product industry. Mr. Weaver has not served on any other public company boards in the past five years.

LIONEL CARNOT joined the Board of Directors in May 2013. Mr. Carnot is Managing Director at Bay City Capital LLC, a leading, global life sciences investment firm, and has been extensively involved in the firm's activities since he joined The Pritzker Organization in 2000. Prior to The Pritzker Organization, Mr. Carnot was a Principal at Oracle Partners, a healthcare hedge fund. He also held several positions in the pharmaceutical industry, including Product Manager for Prozac at Eli Lilly as well as several sales and marketing positions at Rhone-Poulenc Rohrer (now Sanofi). Mr. Carnot was also a strategy and management consultant to the biopharmaceutical industry while at Booz Allen & Hamilton and Accenture Strategic Services. Mr. Carnot is a member of the Board of Directors of Merus B.V., Madrigal Pharmaceuticals and Tallikut Pharmaceuticals, and is a former member of the board of Reliant Pharmaceuticals, Pathway Diagnostics, BioSeek and Nexus Dx. Mr. Carnot holds an MBA with Distinction from INSEAD and an MS with honors in Molecular Biology from the University of Geneva. Our Board of Directors has concluded that Mr. Carnot should serve as a director because of his prior management, consulting and board experience in the biotechnology and diagnostic industries, coupled with scientific, technical, sales and marketing, finance, and business development expertise. Mr. Carnot has not served on any other public company boards in the past five years.

ROGER C. COLMAN joined the Board of Directors in March 2011. Mr. Colman is Vice President of Corporate Development for Alticor Corporate Enterprises a member of the Alticor family of companies. He joined Alticor in 1994 from Readi-Bake, Inc., where he held positions as an operations and distribution executive. Mr. Colman earned a Bachelor of Science degree and a Master's of Business Administration degree from Grand Valley State University in Allendale, Michigan. Our Board of Directors has concluded that Mr. Colman should serve as a director because of his prior executive management experience, including assisting Amway affiliate operations in over 30 countries in diverse roles which included business process improvement and strategic planning, and prior experience serving on corporate boards. Mr. Colman has not served on any other public company boards in the past five years.

JOSEPH M. LANDSTRA joined the Board of Directors on March 31, 2014. Mr. Landstra has been with Alticor Inc., a member of the Alticor family of companies, since May 2009, and is currently Director of Finance and Assistant Treasurer. Prior to his role with Alticor, Mr. Landstra was Controller for Dickinson Press Inc. from April 2008 to May 2009 and with X-Rite Inc. from 2003 to April 2008, completing his time with X-Rite as European Controller. Mr. Landstra also worked for Deloitte & Touche LLP supporting a broad range of audit clients. Mr. Landstra is Certified Public Accountant in the state of Michigan. Mr. Landstra also serves on the Board of Directors for Metagenics, Inc. which is in the Alticor family of companies. Mr. Landstra earned a Bachelor of Science degree in Accountancy from Calvin College in Grand Rapids, Michigan. The Board of Directors has concluded that Mr. Landstra should serve as a director because of his prior senior executive management experience, his background in the nutrigenomic medical foods and nutraceuticals business through his current position at Alticor, and his broad-based financial and business expertise. Mr. Landstra has not served on any other public company boards in the past five years.

WILLIAM C. MILLS III joined the Board of Directors in April 2010. He currently serves as Chairman of the Board of Directors and CEO of Stereotaxis, Inc. (NASDAQ: STXS), a medical device company that markets robotic cardiology instrument navigation systems designed to enhance the treatment of arrhythmias and coronary disease. He has over 35 years of venture capital experience, having held positions from 2004 until 2009 as a managing member of EGS Healthcare Capital Partners; from 1999-2004 as a Partner in the Boston office of Advent International; from 1988-1999 as a General Partner of The Venture Capital Fund of New England; and from 1981-1988 as a Managing General Partner of Ampersand Ventures/PaineWebber Ventures. Currently, he is Chairman of the Board of Managers of Ascension Health Ventures III, LLC. Mr. Mills received his A.B. in Chemistry, cum laude, from Princeton University, his S.M. in Chemistry from the Massachusetts Institute of Technology and his M.S. in Management from MIT's Sloan School of Management. Except as noted above, Mr. Mills has not served on any other public company boards in the past five years.

DAYTON MISFELDT joined the Board of Directors in May 2013. Mr. Misfeldt is a Managing Director at Bay City Capital LLC, a leading, global life sciences investment firm, and focuses on biopharmaceutical investment opportunities. Prior to joining Bay City Capital in May 2000, Mr. Misfeldt was a Vice President at Roth Capital Partners where he worked as a sell-side analyst covering the biopharmaceutical industry. Mr. Misfeldt has also worked as a Project Manager at LifeScience Economics. Mr. Misfeldt received a B.A. in Economics from the University of California, San Diego. Mr. Misfeldt currently serves on the Board of Directors of Sunesis Pharmaceuticals, Inc, a publicly traded biopharmaceutical company and several private company boards. Our Board of Directors has concluded that Mr. Misfeldt should serve as a director because he has financial expertise and strong

understanding of the biotechnology industry, which the Board believes makes him an important resource for the Board as it assesses both financial and strategic decisions. Except as noted above, Mr. Misfeldt has not served on any other public company boards in the past five years.

Director Independence

Our Board of Directors has determined that the following members qualify as independent directors under the definition promulgated by The NASDAQ Stock Market LLC: Lionel Carnot, Roger C. Colman, Joseph M. Landstra, William C. Mills III, Dayton Misfeldt and James Weaver.

EXECUTIVE AND DIRECTOR COMPENSATION

Summary Compensation Table

The following table sets forth the total compensation awarded or paid to, accrued or earned during the fiscal years ended December 31, 2014 and 2015 by our Chief Executive Officer, our former Chief Executive Officer (our current President and Chief Scientific Officer), our former Chief Marketing Officer and our Interim Chief Financial Officer (there were no other executive officers employed by us as of December 31, 2015). We refer to these individuals as our "Named Executive Officers."

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)(2)	Option Awards ($)(1)(2)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)(3)	Total ($)
Mark B. Carbeau Chief Executive Officer	2015	$ 259,712	$ 47,906	$ —	$ 1,972,964	$ —	$ —	$ —	$ 2,280,582
	2014	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —
Kenneth S. Kornman	2015	$ 360,000	$ 45,450	$ —	$ 503,680	$ —	$ —	$ 3,296	$ 912,426