SIGNAL GENETICS, INC.
Form 424B4
February 19, 2015

Filed pursuant to Rule 424(b)(4)
Registration No. 333-201533

PROSPECTUS

3,214,285 Shares
Common Stock

We are offering 3,214,285 shares of our common stock pursuant to this prospectus.

Our common stock is listed on The NASDAQ Capital Market under the symbol SGNL . On February 13, 2015, the last reported sale price of our common stock on The NASDAQ Capital Market was $3.91 per share.

We are an emerging growth company under applicable Securities and Exchange Commission rules and will be eligible for reduced public company disclosure requirements. See Summary Implications of Being an Emerging Growth Company.

Our business and an investment in our securities involves a high degree of risk. See Risk Factors beginning on page 14 of this prospectus for a discussion of information that you should consider before investing in our securities.

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 Share	Total
Public offering price	$ 2.80	$ 8,999,998
Underwriting discounts and commissions(1)	$ 0.196	$ 629,999.86
Proceeds, before expenses, to us	$ 2.604	$ 8,369,998.14

(1) The underwriters will receive compensation in addition to the underwriting discount. The registration statement, of which this prospectus is a part, also registers for sale warrants to purchase 160,714 shares of our common stock to be issued to the representative of the underwriters. We have agreed to issue the warrants to the representative of the underwriters as a portion of the underwriting compensation payable to the underwriters in connection with this offering. See Underwriting beginning on page 122 of this prospectus for a description of compensation payable to the underwriters, including a description of the warrants.

We have granted a 45-day option to the underwriters to purchase up to 482,142 additional shares of common stock solely to cover over-allotments, if any.

The underwriters expect to deliver the shares against payment therefor on or about February 20, 2015.

Joint Book-Running Managers

Aegis Capital Corp **Chardan Capital Markets, LLC**

February 17, 2015

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You should rely only on the information contained in this prospectus or in any free writing prospectus that we may specifically authorize to be delivered or made available to you. We have not, and the underwriters have not, authorized anyone to provide you with any information other than that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus may only be used where it is legal to offer and sell our securities. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the underwriters are not, making an offer of these securities in any jurisdiction where the offer is not permitted.

For investors outside the United States: We have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside must inform themselves about, and observe any restrictions relating to, the offering of securities and the distribution of this prospectus outside the United States.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We believe that the data obtained from these industry publications and third-party research, surveys and studies are reliable. The Company is ultimately responsible for all disclosure included in this prospectus.

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PROSPECTUS SUMMARY

This summary highlights 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 and the information set forth under the headings Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations in each case included elsewhere in this prospectus. In this prospectus, unless the context otherwise requires, the terms we, us, our, Signal Genetics and the Company refer to Signal Genetics, Inc. and its consolidated subsidiaries. We have provided definitions for some of the terms we use to describe our business and industry and other terms used in this prospectus in the Glossary of Terms beginning on page 131 of this prospectus.

Signal Genetics, Inc.

Business Overview

We are a commercial stage, molecular genetic diagnostic company focused on providing innovative diagnostic services that help physicians make better-informed decisions concerning the care of their patients suffering from cancer. Our mission is to develop, validate and deliver innovative diagnostic services that enable better patient-care decisions. The patient-care decisions we impact include the field of personalized medicine, wherein diagnostic tests guide treatment decisions with genetically-targeted therapies as well as traditional chemotherapy regimens. We were founded in January 2010 and hold an exclusive license in our licensed field to the intellectual property stemming from the renowned research on multiple myeloma, or MM, performed at the University of Arkansas for Medical Sciences, or UAMS.

MM is a hematologic, or blood, cancer that develops in the bone marrow and specifically affects the plasma cells of the bone marrow. Normal plasma cells produce immunoglobulins, otherwise known as antibodies, which help the body fight infection and disease. In MM, the normal plasma cells become malignant and inhibit the production of normal blood cells and antibodies, including red blood cells, white blood cells and blood platelets, and crowd the bone marrow with malignant plasma cells, which produce an abnormal antibody called a monoclonal protein, or M protein. The hallmark characteristic of MM is a high level of M protein in the blood. MM can also cause soft spots in the bone known as osteolytic lesions. MM is the second most common blood cancer after non-Hodgkin s lymphoma (NHL) and represents approximately 15% of all hematomalignancies. According to the American Cancer Society and the National Cancer Institute, approximately 24,050 new cases of MM were expected to be diagnosed in the United States in 2014 and approximately 11,090 deaths from MM occurred in the United States in 2013. More Americans died from MM in 2014 than from any other blood cancer. Although a relatively rare disease, MM is responsible for 2% of all cancer deaths in the United States each year and will kill more Americans than melanoma, the deadliest form of skin cancer. There are an estimated 83,360 people currently living with MM in the United States. The five-year survival rate for people with MM is about 45%. The American Cancer Society estimates that the lifetime risk in the United States of getting MM is 1 in 143.

To date, there are no known causes of MM. The most significant risk factor for developing MM is age. According to Nature: International Weekly Journal of Science s supplement on MM published on December 15, 2011 in volume 480, page S-33 through S-80, or Nature s MM supplement, 96% of MM cases are diagnosed in people older than 45 years of age, and more than 63% are diagnosed in people older than 65 years of age. There are usually no early stage symptoms of MM and a suspicion of a MM diagnosis is often made incidentally through routine blood tests which

reveal low numbers of red blood cells and high levels of protein. Once diagnosed, MM is classified into one of three categories in a process known as staging. Staging is the process of determining how widespread or advanced the cancer is. Under the International Staging System, or ISS, MM is classified into three stages based upon the presence of serum beta-2 microglobulin and serum albumin, which are blood proteins that are measured through a blood test. Staging is the key factor in a physician s choice of treatment for a patient and that patient s outlook or prognosis, often framed as progression free survival (PFS) or overall survival (OS). Prognosis is typically based on the existence of different signs, symptoms and circumstances. Certain laboratory and clinical findings, or prognostic indicators, provide important information for MM, including when treatment should begin and what treatments to use, based upon a patient s individual prognosis and risk for relapse. However,

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the experts caring for MM patients have been burdened by a staging system that predates and thus fails to capture the rich body of new genomic information that has been shown to assist in the staging process. Similar genetic information has proven transformational in a number of solid tumor types, including breast, colon and lung cancer. In each case, specific genetic determinants enable doctors to identify patients who are likely to respond to genetically targeted therapies, resulting in better outcomes for these patients, including a higher rate of survival. According to the National Cancer Institute, these benefits have not yet been recognized in MM treatment. The traditional approach in MM treatment which utilizes cytogenetic techniques, such as karyotyping and fluorescent in-situ hybridization, or FISH, for staging may not accurately stage MM patients or accurately assess the risk of relapse. Perhaps the greatest shortcoming of the current staging system for MM is its inability to classify MM patients into high and low risk prognosis groups. A tool that can further define risk-stratification by classifying MM patients in this manner would better inform physicians when to treat and what drugs to treat patients with, potentially improving health outcomes in MM patients. We believe a more comprehensive, systematic approach utilizing current genetic technologies is necessary to meet this unmet medical need.

Our flagship diagnostic service is the Myeloma Prognostic Risk Signature, or MyPRS® test. The MyPRS® test is a microarray-based gene expression profile, or GEP, assay that measures the expression level of specific genes and groups of genes that are designed to predict an individual s long-term clinical outcome/prognosis, giving a basis for personalized treatment options and helping physicians classify MM patients into either high or low risk groups. The MyPRS® test provides a whole-genomic expression profile of a patient s MM. The GEP is a genetic fingerprint of a cancer, with each cancer being unique, just as each fingerprint is unique. Many recent studies show that the GEP of cancerous tumors makes personalized treatment possible, and our MyPRS® test is the first genetic test to be developed specifically for MM according to the 2007 John Shaughnessy paper in the journal *Blood (A validated gene expression model of high-risk multiple myeloma is defined by deregulated expression of genes mapping to chromosome 1. Mar 15;109(6):2276-84. Epub 2006 Nov 14).* MyPRS® is designed to be used at the time of initial MM diagnosis and also when the patient has experienced a relapse as an aid to physicians in selecting the optimal treatment regimen for each patient s unique condition. Specifically, the test helps allow:

risk stratification to help distinguish patients with indolent MM that may not need treatment from those patients with aggressive MM that requires more aggressive treatment; and
identification of important genomic alterations that allow for MM sub-classification that may affect the therapy selection, and potentially enable a personalized medicine approach.

Our Services

We offer our MyPRS® test in our approximately 2,800 square foot state-of-the-art laboratory located in Little Rock, Arkansas, which is certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, to perform high complexity testing. We received clearance under the New York State Department of Health (NYSDOH) process in 2014, and are currently licensed to sell our test in all 50 states. We are dedicated to making our extensively validated diagnostic services available to all patients who need them.

In addition, we are exploring, and peer-review studies are being conducted on, the use of our MyPRS® test as an indicator of progression to MM in patients with either smoldering multiple myeloma, or SMM, or monoclonal gammopathies of unknown significance, or MGUS, the precursor conditions to MM. There is, however, currently no projected timeline for our use of MyPRS® in these patients. For a discussion of MyPRS® in these patients see Market Opportunity, below.

Over the next 12 to 18 months, we intend to expand our test menu by adding tests that are used to help manage MM patients. There is a broad array of molecular and cytogenetic testing modalities that are utilized in the management of

patients with MM, such as conventional cytogenetics, FISH, molecular tests, M protein serum test and flow cytometry (especially in the context of minimum residual disease testing for MM therapy response). We also plan to launch both RNA sequencing and next generation DNA sequencing services to assist our physician customers in further characterizing their MM patients and enabling them to make better informed decisions regarding their use of targeted therapies based upon the specific genetic profile of their patients tumors. It is our intent to complement our proprietary MyPRS® franchise with these emerging next generation solutions to provide a best in class suite of tests for our physician customers and their patients.

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Market Opportunities

Over the past several decades, improved awareness and diagnostic testing technologies have led to an increase in the early diagnosis of cancer. Although the goals of these efforts were to decrease cancer mortality, national data demonstrate significant increases in early-stage disease, without a proportional decline in later-stage disease. What has emerged amongst clinicians and researchers has been an appreciation of the complexity of cancer. Cancers are heterogeneous and do not follow a uniform course. In some cases, cancer can lead to severe disease and death, while in other cases it is indolent. Unfortunately, identifying those patients who will likely succumb to non-cancer related causes, or comorbidities, is difficult.

Before 1990, treatment of MM was limited to the use of melphalan (a chemotherapeutic agent) and prednisone (a steroid), which were of marginal effectiveness. In 1986, high dose dexamethasone (a corticosteroid), which is used to induce plasma cell lysis, was introduced and in the early 1990s, induction therapy with vincristine, doxorubicin (a chemotherapeutic agent) and dexamethasone, followed by stem cell transplant after high dose melphalan was introduced and resulted in longer term remissions but patients always relapsed. Then, in 1999, thalidomide was added to existing regimens for MM. The first clinicians to attempt the use of thalidomide in the treatment of MM were at the UAMS. The initial use of thalidomide ultimately led to the development of Revlimid®, Celgene s blockbuster drug that is now part of most front-line therapies for the treatment of MM. In 2006, Velcade® was approved and added to existing regimens. Thalomid®, Revlimid® and Velcade® are now considered cornerstones of therapy in addition to stem cell transplant after bone marrow ablation.

Although new treatments for patients with MM have become available over the last 10 years, we do not believe that these treatments have provided any significant benefits in overall survival especially in the high risk patient population. In part, this is because MM is a disease with significant tumor heterogeneity at the genetic level. Specialists in MM have long recognized the need for diagnostic tests that accurately identify the mutations and overarching genotype of each patient to inform risk stratification, prognosis and choice of therapy. Because it is impossible to use classic staging modalities such as clinical factors and cell morphology (the microscopic review of tumor material by a pathologist) to classify MM, physicians use plasma cell labeling indices, chemical markers, imaging studies and genetic abnormalities at the chromosomal level (*e.g.*, cytogenetics) to better predict prognosis. Unfortunately, these tests provide limited information as to a particular MM patient s prognosis and response to treatment. With the use of MyPRS® GEP, it has become possible to go beyond morphological and chromosomal level analysis and identify the individual MM genomic profile of each individual patient.

Like many forms of cancer, MM can present as asymptomatic, even in advanced stages. MM begins as the precursor condition, MGUS. It is estimated that more than 3% of the population of the United States 50 years of age or older have MGUS. Characterized by an excess of particular immunoglobulins or M proteins in the serum or urine with less than 10% plasma cells in the bone marrow, MGUS is not itself harmful to health. But every year, 1% of MGUS patients will progress to MM.

Aside from the precursor condition, MGUS, MM exists on a spectrum from asymptomatic or SMM to full-blown MM. Collectively, these precursor conditions, MGUS and SMM, are referred to as AMG. Preventative treatment of every AMG patient is not a viable option. As noted in The Disperenzieri paper (*Blood* October 2013), along with the prohibitive expense, many doctors worry that they could do more harm than good if they treat otherwise healthy people, the vast majority of whom will never develop MM. A 1988 clinical study discussed in *Nature s* MM supplement, using the best treatments available at the time, concluded that treating patients even at the smoldering stage caused unnecessary side effects with no survival benefit.

The applicability of our test for use in predicting MM progression from AMG could create a substantial increase in the potential patient population eligible for MyPRS® testing and as such represents an important pillar of our growth strategy. We estimate the total potential MM testing market in the United States at approximately 36,000 patients per year, including newly diagnosed and relapsed patients. We believe we currently service just over 2% of this market. We estimate that the addition of an AMG progression indication feature for the MyPRS® test could expand the MyPRS® addressable market in the United States to more than 135,000 patients per year. As a specialty focused diagnostic laboratory company, we hope for such opportunities to expand our service offerings for the benefit and convenience of physicians and patients.

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Our Competitive Strengths

Differentiated value proposition of the MyPRS® test

We believe the MyPRS® test is one of the most extensively validated molecular prognostic assays on the market today. There are more than 30 peer-reviewed scientific publications that substantiate the clinical validity and utility of the MyPRS® test. MyPRS® is the only GEP-based prognostic assay commercially available in the United States which may be used to determine which patients have a high-risk form of MM.

Additionally, the MyPRS® test provides oncologists with the molecular subtype of each patient s particular form of MM. Molecular subtypes can be used to further stratify the level of risk severity of a patient s MM as well as assist the physician in choosing the most appropriate therapy while potentially avoiding therapies that may be less beneficial or harmful.

Furthermore, MyPRS® provides a virtual karyotype (a characterization of the chromosomal complement of an individual or a species, including number, form and size of the chromosomes), that can identify cytogenetic abnormalities in patients with MM. The accuracy of this method was validated against a range of conventional cytogenetic techniques and was shown to have a concordance of 89%. Certain cytogenetic abnormalities are commonly used, along with clinical and cell biology parameters in the traditional work up of MM patients for determining disease stage and to help guide therapy decisions for patients. The virtual karyotype algorithm in MyPRS® was designed to be an alternative to conventional methods that can be time consuming, expensive, subjective and can often fail to provide results due to the difficulties encountered when attempting to culture myeloma cells.

Relationship with University of Arkansas, leader in the study and treatment of MM

We are the exclusive licensee to the intellectual property developed at UAMS s Myeloma Institute for Research and Therapy, or MIRT, in our licensed field. MIRT is one of the largest centers in the world dedicated solely to MM and related diseases as well as to prevention and management of treatment-related consequences, including myelodysplastic syndrome (MDS) and acute myelogenous leukemia (AML). UAMS developed a novel Total Therapy approach, designed as a first line treatment for MM that includes a full array of treatment modalities. This approach is considered, by many in the oncology community, to have achieved positive results, particularly in patients diagnosed with low-risk MM who are treated at UAMS MIRT. A number of treatment improvements for MM patients were first discovered at MIRT. The physicians at MIRT routinely utilize our MyPRS® test to identify patients who may be eligible for the provision of Total Therapy.

We are the exclusive provider of GEP-based testing to UAMS. UAMS has a thirty-year history of clinical and research knowledge and experience. UAMS has treated more than 10,000 patients since the program s inception in 1989. UAMS has amassed more than 10,000 gene array samples, many of which were used to discover and validate the MyPRS® test. More than 90% of patients who are treated at UAMS continue to be actively followed by UAMS over the course of their lifetime many patients have been followed for more than 20 years.

Because of our exclusive relationship with UAMS, we are uniquely positioned to benefit from the breadth of clinical research and expertise developed at UAMS. We intend to continue to use this relationship to improve our MyPRS® test and develop additional indications for the MyPRS® test, as well as additional tests. Our relationship with UAMS

also provides us with credibility within the oncology community beyond that related to the MyPRS® validation we have received in published articles, and we benefit from this association in our pursuit of additional collaborations with leading universities and research institutions.

Our substantial proprietary estate that protects our exclusive access to the MyPRS® test

We currently license, or own outright, 12 issued patents (11 issued U.S. patents and one issued Japanese patent) and 21 pending patent applications (one of which was allowed by the USPTO on December 9, 2014), many of which protect and defend our exclusive ability to market the MyPRS® test as well as additional proprietary tests and treatments. We also have six registered U.S. trademarks to further differentiate our products and services in the marketplace.

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There are five issued U.S. patents related to the MyPRS® test, which form the basis of our right to exclude others from practicing the MyPRS® test. The patents claim methods of gene expression-based classification for MM using RNA from plasma cells, methods of identifying groups of genes that can distinguish normal and MM plasma cells by isolating RNA from CD138 positive plasma cells and identifying differentially expressed genes, methods of diagnosing MM by examining mRNA levels or chromosomal translocations of particular genes from plasma cells, methods of determining the prognosis of a human multiple myeloma patient by measuring gene expression levels of multiple genes from plasma cells, and methods of determining the prognosis of a MM patient by determining the copy number of the CKS1B gene in plasma cells. CKS1B is one of the genes in the 70 gene signature.

In addition to the issued U.S. patents, we have one issued Japanese patent and several pending patent applications in the United States and abroad directed to other aspects of the MyPRS® test. For example, the Japanese patent provides methods for examining the susceptibility of a subject for transformation from a low-risk to a high-risk MM by measuring gene expression levels of multiple genes expressed from plasma cells isolated from the subject. Canadian and European counterpart applications of one of the five issued U.S. patents (U.S. Patent No. 8,843,320) describe the full 70 gene signature used in the MyPRS® test. Another pending U.S. application provides methods of prognosing subjects with MGUS using the 70 gene signature. We fully expect that additional advances will come out of our ongoing work and form the basis of additional intellectual property to protect and refine the MyPRS® test, through new patent filings, trademarks, trade secrets, and copyrights.

Focus on the leading academic hospitals in the United States where a large portion of MM patients are treated

We currently focus our sales efforts exclusively on leading academic research hospitals and clinics throughout the United States. Given our limited selling and marketing capabilities, focusing our sales efforts on these academic research hospitals and clinics provides an efficient way to reach the largest segment of MM patients with our limited resources. Selling into academic research hospitals and clinics is a complex process that requires technical knowledge and the ability to engage in discourse to convince technical and administrative stakeholders to adopt new diagnostic tests or therapies. Our current sales force is well versed in the science and technology behind our MyPRS® test. We will continue to grow our sales force with expertise necessary to interface successfully with these institutions.

The extensive scientific evidence that substantiates the MyPRS® test is a key enabler for our sales effort that affords us access to the thought leaders within these institutions. The relationships that we build with the thought leaders at leading academic hospitals is a direct result of the quality of our science and the quality of our services and helps to secure continued access to these accounts and the MM patients they treat. It also affords us the opportunity to expand our offerings as we add additional services to our test menu.

Early success in establishing positive reimbursement coverage for MyPRS®

We successfully obtained a positive Local Coverage Determination, or LCD, for MyPRS® in March 2011 from the Arkansas Medicare Administrative Contractor, or MAC, which at the time was Pinnacle Medical Services. The current MAC is Novitas Health Solutions. We have also received reimbursement approval from Blue Cross Blue Shield of Arkansas and we are an in-network provider to their patient population. We anticipate that with additional hiring of managed care professionals, we will be able to achieve positive coverage determinations from a majority of the major third-party payors in the United States. However, those efforts may take quite some time and may not be successful.

Experienced oncology-centered laboratory and clinical trial services

Our specimens are tested and interpreted by highly qualified oncology-focused laboratory professionals with more than 56 years of cumulative experience with gene expression-based diagnostic testing technology. Because our clinical staff is highly specialized in oncology, we believe we are better positioned to consult with our oncologist customers to help them derive maximum value from the diagnostic and prognostic data generated by our tests.

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Our Growth Strategy

Our goal is to deliver innovative diagnostic services that enable physicians to make better-informed treatment decisions regarding the care of their cancer patients. We intend to do this by:

Expanding the U.S. market penetration of our MyPRS® test by increasing the geographic coverage of our sales force, which was increased from one to four employees as of December 2014;

Broadening the base of health care insurance companies that have approved reimbursements for MyPRS®;

Expanding the diagnostic indications for MyPRS® to include AMG, the precursor conditions to MM;

Pursuing collaborations with pharmaceutical companies who focus on developing therapies to treat MM and its precursor disease;

Expanding our information technology infrastructure to further improve our customer service experience;

Continuing to leverage our relationship with UAMS via our exclusive license agreement;

Expanding our test offering with the addition of other molecular tests useful to physicians who care for MM patients;

Expanding and leveraging our capabilities into additional blood cancer indications;

Pursuing additional collaborations and in-licensing to expand our service offering; and

Continuing to reduce the costs associated with the development, manufacture and interpretation of our proprietary genomic tests and services.

Recent Developments

We are currently finalizing our financial results for the year ended December 31, 2014. While complete financial information and operating data as of and for such period are not available, our management preliminarily estimates that for the year ended December 31, 2014, we will report net revenue in the range of approximately $4.1 million to $4.5 million, net of unfavorable changes in estimates of $0.4 million recorded in the current year as an adjustment to prior year revenues. Net revenue includes the following:

Tests from our largest customer, UAMS, totaled 3,671 resulting in net revenue of approximately $3.6 million, net of unfavorable changes in estimates of $0.2 million recorded in the current year as an adjustment to prior year revenues.

Tests from our non-UAMS hospital customers totaled 509, a 50% increase over the prior year, resulting in net revenue of approximately $0.7 million, net of unfavorable changes in estimate of $0.2 million recorded in the current year as an adjustment to prior year revenues.

Management also estimates cash of approximately $5.1 million at December 31, 2014. There are 3,808,563 shares of common stock outstanding as of the date of this prospectus.

These estimates are preliminary and may change. We have not completed our normal closing procedures and our auditors have not completed their normal audit procedures for the year ended December 31, 2014, and there can be no assurance that our final results for this year will not differ from these estimates, including as a result of year-end closing procedures or audit adjustments, and such changes could be material. These estimates should not be viewed as a substitute for full audited financial statements prepared in accordance with GAAP or as a measure of our performance.

Risks

Our business and our ability to execute our business strategy are subject to a number of risks of which you should be aware before you decide to buy our common stock. In particular, you should carefully consider the following risks, which are discussed more fully in Risk Factors beginning on page 14 of this prospectus.

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We are an early stage company with a limited commercial history and a history of net losses; we expect to incur net losses in the future, and we may never achieve sustained profitability.

We may need to raise additional financing to meet our liquidity requirements.

If our CLIA certificate or any other required license or certification is lost, suspended or restricted, we may not be able to perform or get paid for any lab tests, temporarily or permanently.

A small number of test ordering sites account for most of the sales of our tests and services. If any of these sites orders fewer tests from us for any reason, our revenues could decline.

Our business depends on our ability to successfully develop and commercialize novel cancer diagnostic tests and services, which is time consuming and complex, and our development efforts may fail.

If we are unable to obtain regulatory clearance or approvals in the United States or if we experience delays in receiving clearance or approvals, our growth strategy may not be successful and our business may not be viable.

If we are unable to execute our marketing strategy for our cancer diagnostic tests and are unable to gain acceptance in the market, we may be unable to generate sufficient revenue to sustain our business.

We rely on a limited number of third parties for manufacture and supply of all of our laboratory instruments, tests and materials, and we may not be able to find replacement suppliers or manufacturers in a timely manner in the event of any disruption, which could adversely affect our business.

If our sole laboratory facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to provide services and pursue our research and development efforts may be jeopardized.

We expect to continue to incur significant expenses to develop and market our diagnostic tests, which could make it difficult for us to achieve and sustain profitability.

If pathologists and oncologists decide not to order our diagnostic tests, we may be unable to generate sufficient revenue to sustain our business.

We depend on certain collaborations with third parties for the supply of certain tissue samples and biological materials that we use in our research and development efforts. If the costs of such collaborations increase after we complete this offering or our third-party collaborators terminate their relationship with us, our business may be materially harmed.

Our inability to attract, hire and retain a sufficient number of qualified sales professionals would hamper our ability to increase demand for our tests, to expand geographically and to successfully commercialize any other diagnostic tests or services we may develop.

We outsource our billing and collections to a third-party provider. Our provider may fail in its duties to us and thereby reduce our cash collections and harm our business.

Health care policy changes, including recently enacted legislation reforming the U.S. health care system, may have a material adverse effect on our financial condition, results of operations and cash flows.

Our commercial success could be compromised if third-party payors, including managed care organizations and Medicare, do not provide coverage and reimbursement, breach, rescind or modify their contracts or reimbursement policies or delay payments for our molecular diagnostic tests.

We depend on Medicare and a limited number of private payors for a significant portion of our revenues and if these or other payors stop providing reimbursement or decrease the amount of reimbursement for our tests, our revenues could decline.

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If the U.S. Food and Drug Administration, or FDA, were to begin requiring approval or clearance of our tests, we could incur substantial costs and time delays associated with meeting requirements for pre-market clearance or approval or we could experience decreased demand for, or reimbursement of, our tests.

If we were required to conduct additional clinical trials prior to continuing to offer our proprietary MyPRS® test or any other tests that we may develop as Laboratory Developed Tests, or LDTs, those trials could lead to delays or failure to obtain necessary regulatory approval, which could cause significant delays in commercializing any future tests and harm our ability to achieve sustained profitability.

If we are unable to maintain intellectual property protection, our competitive position could be harmed.

Our rights to use technologies licensed from third parties are not fully within our control, and we may not be able to sell our diagnostic tests and other services if we lose our existing rights or cannot obtain new rights on reasonable terms.

Our inability to meet the continued listing requirements of The NASDAQ Capital Market could result in a delisting of our common stock and have a negative effect on the price of our common stock, which could impair your ability to sell or purchase our common stock when you wish to do so.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

Implications of Being an Emerging Growth Company

As a company with less than $1.0 billion in revenue during our last fiscal year, we qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from specified disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced Management s Discussion and Analysis of Financial Condition and Results of Operations disclosure;

not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;

not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor s report providing additional information about the audit and the financial statements;

reduced disclosure obligations regarding executive compensation; and

exemptions from the requirements of holding a non-binding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.0 billion in annual revenues, have more than $700.0 million in market value of our capital stock held by non-affiliates or issue more than $1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of some reduced reporting burdens in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise

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