

SIGNAL GENETICS, INC.

Form S-1/A

February 13, 2015

**As filed with the Securities and Exchange Commission
on February 13, 2015**

Registration No. 333-201533

**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**

SIGNAL GENETICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

8071
(Primary Standard Industrial
Classification Code Number)

47-1187261
(I.R.S. Employer
Identification No.)

**Signal Genetics, Inc.
5740 Fleet Street
Carlsbad, California
(760) 537-4100**

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

**Samuel D. Riccitelli
President and Chief Executive Officer
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5740 Fleet Street Carlsbad, California
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(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: As soon as practicable after this Registration Statement is declared 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, as amended, check the following box: x

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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, 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(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 smaller reporting company)

Smaller reporting company

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Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price ⁽¹⁾	Amount of Registration Fee ⁽²⁾
Common Stock, par value \$0.01 per share ⁽²⁾⁽³⁾ Representative s Warrant ⁽⁴⁾	\$ 8,625,000	\$ 1,002.23
Shares of Common Stock underlying Representative s Warrants ⁽²⁾⁽⁵⁾	\$ 468,750	\$ 54.47
Total	\$ 9,093,750	\$ 1,056.70 ⁽⁶⁾

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

(2) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional securities as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.

(3) Includes shares of common stock the underwriters have the option to purchase to cover over-allotments, if any.

(4) No fee pursuant to Rule 457(g) under the Securities Act of 1933, as amended.

(5) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act of 1933, as amended. The proposed maximum aggregate offering price of the representative s warrants is \$468,750, which is equal to 125% of \$375,000 (5% of \$7,500,000).

(6) The Registrant previously paid this amount in connection with the filing of this Registration Statement on January 15, 2015.

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 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to Section 8(a), may determine.

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The information in this preliminary 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 preliminary prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION DATED FEBRUARY 13, 2015

**2,884,615 Shares
Common Stock**

We are offering 2,884,615 shares of our common stock pursuant to this prospectus.

Our common stock is listed on The NASDAQ Capital Market under the symbol SGNL . On January 27, 2015, the last reported sale price of our common stock on The NASDAQ Capital Market was \$2.60 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	\$	\$
Underwriting discounts and commissions ⁽¹⁾	\$	\$
Proceeds, before expenses, to us	\$	\$

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 144,230 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 432,692 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 , 2015.

Joint Book-Running Managers

Aegis Capital Corp

Chardan Capital Markets, LLC
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 hematological malignancies. 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 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 Disperenziari 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 3,782,629 shares of common stock outstanding as of the date of this prospectus, which does not include 25,934 shares of our common stock to be issued to an employee upon the settlement of restricted stock units that vested January 1, 2015.

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.

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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.

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.

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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.

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

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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 apply to private companies.

We have elected to avail ourselves of this extended transition period for adopting new or revised accounting standards. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

Corporate Information

We were founded in New York as a Delaware limited liability company in January 2010 under the name Myeloma Health LLC. Signal Genetics LLC was formed as a Delaware limited liability company in December 2010. Effective January 1, 2011, substantially all of the member interests in Myeloma Health LLC were exchanged for member interests in Signal Genetics LLC and Myeloma Health LLC became a subsidiary of the Company. Immediately prior to the pricing of our initial public offering, on June 17, 2014, Signal Genetics LLC converted from a Delaware limited liability company to a Delaware corporation. We refer to this as the corporate conversion. In connection with the corporate conversion, each unit of Signal Genetics LLC was converted into a share of common stock of Signal Genetics, Inc., the members of Signal Genetics LLC became stockholders of Signal Genetics, Inc. and Signal Genetics, Inc. succeeded to the business of Signal Genetics LLC and its consolidated subsidiaries.

Our principal executive offices are located at 5740 Fleet Street, Carlsbad, California 92008, and our telephone number is (760) 537-4100. Our website address is *www.signalgenetics.com*. Information contained in our website does not form part of the prospectus and is intended for informational purposes only.

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THE OFFERING

Issuer

Signal Genetics, Inc.

Common stock offered by us

2,884,615 shares (or 3,317,307 shares if the underwriters exercise their over-allotment option in full).

Over-allotment option

The underwriters have an option for a period of 45 days to purchase up to 432,692 additional shares of our common stock to cover over-allotments, if any.

Common stock to be outstanding immediately after this offering

6,693,178 shares. If the underwriters' over-allotment option is exercised in full, the total number of shares of common stock outstanding immediately after this offering would be 7,125,870.

Use of Proceeds

We intend to use the net proceeds received from this offering to fund continued clinical development of new products and services and for expansion of our commercialization efforts and working capital and general corporate purposes. Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments and U.S. government securities. See Use of Proceeds on page 48.

Representative's warrants

The registration statement of which this prospectus is a part also registers for sale warrants to purchase 144,230 shares of our common stock to the representative of the underwriters as a portion of the underwriting compensation payable to the underwriters in connection with this offering. The warrants will be exercisable for a four-year period commencing one year following the effective date of this offering at an exercise price equal to 125% of the public offering price of the common stock. Please see Underwriting Representative's Warrants for a description of these warrants.

Risk Factors

See Risk Factors beginning on page 14 and the other information included in this prospectus for a discussion of factors you should carefully consider before investing in our securities.

NASDAQ Capital Market Symbol

SGNL

The number of shares of our common stock that will be outstanding immediately after this offering is based on 3,782,629 shares of common stock outstanding as of September 30, 2014 plus 25,934 shares of our common stock to be issued to an employee upon the settlement of restricted stock units that vested January 1, 2015, for an aggregate of 3,808,563 shares, and excludes:

42,500 shares of our common stock issuable upon exercise of the warrants issued to Aegis Capital Corp. in connection with the closing of our initial public offering;

124,000 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2014, with a weighted average exercise price of \$4.96 per share, issued under our 2014 Stock Incentive Plan, or the Incentive Plan;

940,093 shares of our common stock reserved for issuance upon the vesting of restricted stock unit awards outstanding as of September 30, 2014 issued under our Incentive Plan;

an additional 181,306 shares of our common stock reserved for future issuance under our Incentive Plan; and

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144,230 shares of our common stock issuable upon exercise of the warrants to be granted to Aegis Capital Corp. in connection with this offering.

Except for historical financial information or as otherwise stated herein, the information in this prospectus:

assumes no exercise by the underwriters of their option to purchase up to an additional 432,692 shares of common stock to cover over-allotments, if any;

assumes a public offering price of \$2.60 per share, which was the latest reported sale price of our common stock on the NASDAQ Capital Market on January 27, 2015; and

assumes that all outstanding restricted stock unit awards, which may be settled in cash or stock in the board of directors sole discretion, will be settled solely in stock.

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The following table sets forth our summary historical consolidated financial data. The summary consolidated financial data for the nine months ended September 30, 2014 and 2013, and as of September 30, 2014, is derived from our unaudited consolidated financial statements appearing elsewhere in this prospectus and are not necessarily indicative of results to be expected for the full fiscal year. The summary consolidated statement of operations data for the fiscal years ended December 31, 2013 and 2012 is derived from our audited consolidated financial statements and related notes included elsewhere in this prospectus. The summary consolidated statement of operations data for the year ended December 31, 2011 is derived from our audited consolidated financial statements not contained herein. Our financial statements are prepared and presented in accordance with generally accepted accounting principles in the United States. The results indicated below are not necessarily indicative of our future performance. You should read this information together with the sections entitled Capitalization, Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes included elsewhere in this prospectus.

	Nine Months Ended September 30,		Year Ended December 31,		
	2014	2013	2013	2012	2011
Statement of Operations Data:					
Net revenue	\$3,665,484	\$3,225,881	\$4,316,484	\$4,406,042	\$1,915,627
Operating expenses:					
Cost of revenue	2,333,216	2,110,323	2,498,940	3,042,184	2,472,390
Selling and marketing	325,639	253,094	378,769	1,325,245	530,876
General and administrative	1,891,006	1,131,555	1,788,141	2,907,947	2,589,787
Stock Compensation	3,578,465				
Research and development	148,288	182,193	96,847	225,378	103,317
Lease abandonment				932,287	
Gain on legal settlement			(250,000)		
Total operating expenses	8,276,614	3,677,165	4,512,697	8,433,041	5,696,370
Operating loss	(4,611,130)	(451,284)	(196,213)	(4,026,999)	(3,780,743)
Interest expense	(1,020,801)	(1,505,198)	(1,963,456)	(1,591,341)	(561,029)
Loss from continuing operations	(5,631,931)	(1,956,482)	(2,159,669)	(5,618,340)	(4,341,772)
Net loss from discontinued operations, net of tax benefit of \$0				(1,592,945)	(8,492,722)
Net loss	(5,631,931)	(1,956,482)	(2,159,669)	(7,211,285)	(12,834,494)
Dividend to member unit holder of Myeloma Health LLC		(240,000)	(285,000)	(390,000)	(140,000)
Net loss attributable to stockholders of Signal Genetics, Inc.	\$(5,631,931)	\$(2,196,482)	\$(2,444,669)	\$(7,601,285)	\$(12,974,494)
Basic and diluted net loss per share:					
	\$(1.78)				

Net loss attributable to
stockholders of Signal Genetics,
Inc.

Weighted average shares outstanding basic and diluted	3,162,639		
Pro forma basic and diluted net loss per share ⁽¹⁾		\$ (0.85)	\$ (0.88)
Pro forma weighted average shares outstanding basic and diluted ^(d)		2,587,475	2,791,354

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	As of September 30, 2014	
	Actual	As Adjusted ⁽²⁾⁽³⁾
Balance Sheet Data:		
Cash and cash equivalents	\$ 6,388,358	\$ 13,363,358
Total assets	9,524,766	16,499,766
Total liabilities	1,995,078	2,332,578
Total stockholders' equity	7,529,688	14,167,188

- (1) The pro forma gives effect to (1) the Debt Conversion (as described under "Certain Relationships and Related Transactions") (based on debt outstanding as of December 31, 2013) and (2) the corporate conversion. The as adjusted balance sheet gives effect to our receipt of estimated net proceeds from the sale of shares of common stock that we are offering at an assumed public offering price of the common stock of \$2.60 per share, which was the latest reported sale price of our common stock on the NASDAQ Capital Market on January 27, 2015, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. A \$1.00 increase (decrease) in the assumed public offering price of \$2.60 per share would increase (decrease) each of cash and cash equivalents, working capital, total assets, and total stockholders' equity by approximately \$2,682,692, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions.
- (2) The as adjusted data is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.
- (3)

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RISK FACTORS

Any investment in our securities involves a high degree of risk. Investors should carefully consider the risks described below and all of the information contained in this prospectus before deciding whether to purchase our common stock. Our business, financial condition or results of operations could be materially adversely affected by these risks if any of them actually occur. This prospectus also contains forward-looking statements that involve risks and uncertainties.

Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks we face as described below and elsewhere in this prospectus.

Risks Related to our Financial Condition

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 have a limited commercial history. Substantially all of our revenue has been derived from our MyPRS® testing services, which were launched in 2011. We have historically incurred substantial net losses. We incurred losses attributable to stockholders of Signal Genetics, Inc. (or members of Signal Genetics LLC, as applicable) of \$5.6 million, \$2.4 million and \$7.6 million for the nine months ended September 30, 2014 and the fiscal years ended December 31, 2013 and 2012, respectively. Losses are continuing through the date of this prospectus. We expect our losses to continue as a result of ongoing research and development expenses, increased selling and marketing costs and increased general and administrative costs to support our planned growth. These losses have had, and will continue to have, an adverse effect on our working capital, total assets and stockholders' equity. Because of the numerous risks and uncertainties associated with our research, development and commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows.

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

Our independent registered public accounting firm has issued a going concern opinion on our December 31, 2013 financial statements, expressing substantial doubt that we can continue as an ongoing business for the next twelve months after issuance of their report, based on our having suffered recurring losses from operations and having a net capital deficiency, as discussed in Note 1 of our accompanying financial statements. Although we are forecasting continued losses and negative cash flows as we continue to fund our selling and marketing activities and research and development programs, we expect that, with the proceeds of this offering, we will have sufficient cash on hand to support operations for at least the next twelve months from the date of this prospectus. However, we expect to seek additional financing and/or strategic investments following the offering, depending on the proceeds generated by the offering. There can be no assurance that any additional financing or strategic investments will be available on acceptable terms, if at all. If events or circumstances occur such that we do not obtain additional funding, we will most likely be required to seek loans from our majority stockholder, LeBow Alpha (who is under no obligation to make any such loans to us), on similar terms as we have obtained in the past, seek additional debt or equity financing and/or reduce certain discretionary spending, which could have a material adverse effect on our ability to achieve our

intended business objectives. In the event that we are unable to obtain additional funding following this offering, we will most likely be required to reduce our plans and/or certain discretionary spending, which could have a material adverse effect on our ability to achieve our intended business objectives. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in us.

We will need to raise additional capital.

We will need to secure additional financing following this offering in order to support our operations. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all. Our forecast of the period of time through which our current financial resources will be adequate to

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support our operations and the costs to support our general and administrative, selling and marketing and research and development activities are forward-looking statements and involve risks and uncertainties.

We will also need to raise additional capital to expand our business to meet our long-term business objectives. Additional financing, which is not in place at this time, may be from the sale of equity or convertible or other debt securities in a public or private offering, from an additional credit facility or strategic partnership coupled with an investment in us or a combination of both.

If events or circumstances occur such that we are unable to obtain additional funding, we will most likely be required to reduce our plans and/or certain discretionary spending, which could have a material adverse effect on our ability to achieve our intended business objectives. For further discussion of our liquidity requirements as they relate to our long-term plans, see the section entitled Liquidity and Capital Resources Capital Resources and Expenditure Requirements .

Risks Related to our Business

If we are unable to obtain adequate coverage and reimbursement for our tests, it is unlikely that our tests will gain widespread acceptance.

Maintaining and growing revenues from MyPRS® depends on the availability of adequate coverage and reimbursement for our tests from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. Health care providers that order diagnostic services such as MyPRS® generally expect that those diagnostic services are covered and reimbursed by third-party payors for all or part of the costs and fees associated with the diagnostic tests they order. If such diagnostic tests are not covered and reimbursed then their patients may be responsible for the entire cost of the test, which can be substantial. Therefore, health care providers generally do not order tests that are not covered and reimbursed by third-party payors in order to avoid subjecting their patients to such financial liability. The existence of adequate coverage and reimbursement for the procedures performed with MyPRS® by government and private insurance plans is central to the acceptance of MyPRS® and any future services we provide. During the past several years, third-party payors have undertaken cost-containment initiatives including different payment methods, monitoring health care expenditures, and anti-fraud initiatives. In addition, the Centers for Medicare & Medicaid Services, or CMS, which administers the Medicare program, has taken the position that the algorithm portion of multi-analyte algorithmic assays, or MAAs, such as MyPRS® is not a clinical laboratory test and is therefore not reimbursable under the Medicare program. Although this position is only applicable to tests with a CMS determined national payment amount, it is possible that the local MACs, who make coverage and payment determinations for tests like MyPRS® may adopt this policy and reduce payment for MyPRS®. If that were to happen, reimbursement might be made for each gene used in the MyPRS® test and coverage and the amount of reimbursement for the genes we use in MyPRS® would be uncertain. We may not be able to achieve or maintain profitability if third-party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels. Further, many private payors use coverage decisions and payment amounts determined by CMS as guidelines in setting their coverage and reimbursement policies. Future action by CMS or other government agencies may diminish payments to clinical laboratories, physicians, outpatient centers and/or hospitals. Those private payors that do not follow the Medicare guidelines may adopt different coverage and reimbursement policies for MyPRS® and coverage and the amount of reimbursement under those policies is uncertain. For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state, and some state Medicaid programs may not pay an adequate amount for MyPRS® or may make no payment at all. As the portion of the U.S. population over the age of 65 and eligible for Medicare continues to grow, we may be more vulnerable to coverage and reimbursement limitations imposed by

CMS. Furthermore, the health care industry in the United States has experienced a general trend toward cost containment as government and private insurers seek to control health care costs through various mechanisms, including imposing limitations on payment rates and negotiating reduced contract rates with service providers, among other things. Therefore, we cannot be certain that our services will be reimbursed at a level that is sufficient to meet our costs.

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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.

Due to the early stage nature of our business and our limited selling and marketing activities to date, we have historically derived a significant portion of our revenue from a limited number of test ordering sites. In particular, the most significant portion of our revenue is generated from our MyPRS® test services provided at our clinical laboratory in Little Rock, Arkansas for UAMS. Revenue sourced either from or through UAMS accounted for approximately 81% of our revenue for the nine months ended September 30, 2014, 83% of our revenue for the year ended December 31, 2013 and 86% of our revenue for the year ended December 31, 2012. Accounts receivable sourced from or through UAMS at September 30, 2014, December 31, 2013 and 2012 accounted for approximately 70%, 62% and 85%, respectively.

Our test ordering sites are largely hospitals and cancer centers. Oncologists and pathologists at these sites order the tests on behalf of their oncology patients or as part of a clinical trial sponsored by a pharmaceutical company in which the patient is enrolled. We generally do not enter into formal written agreements with such test ordering sites and, as a result, we may lose the business of any of these test ordering sites at any time.

There is a scarcity of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite technical skills, we may be unable to successfully execute our business strategy.

The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field. Our future success depends upon our ability to attract and retain highly skilled personnel (including medical, scientific, technical, commercial, business, regulatory and administrative personnel) necessary to support our anticipated growth, develop our business and perform certain contractual obligations. Given the scarcity of professionals with the scientific knowledge that we require and the competition for qualified personnel among life science businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations. The loss of a key employee, the failure of a key employee to perform in his or her current position or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy.

We will need to generate significant revenues to become and remain profitable.

We intend to increase our operating expenses substantially as we add sales representatives to increase our geographic sales coverage, increase our marketing capabilities, conduct clinical trials and increase our general and administrative functions to support our growing operations. We will need to generate significant sales to achieve and maintain profitability and we might not be able to do so. Even if we do generate significant sales, we might not be able to become profitable or sustain or increase profitability on a quarterly or annual basis in the future. If our sales grow more slowly than we anticipate or if our operating expenses exceed our expectations, our financial performance will likely be adversely affected.

If we are unable to increase sales of our laboratory tests and services or to successfully develop and commercialize other indications for our proprietary tests, our revenues will be insufficient for us to achieve profitability.

Our revenue is derived primarily from our laboratory testing services. We currently offer our MyPRS® test through our state-of-the-art CLIA-certified and state licensed laboratory in Little Rock, Arkansas. MyPRS® is not assigned a specific CPT code, but our local MAC and Blue Cross Blue Shield, or BCBS, of Arkansas have established a specific payment amount for the test, which is billed under a nonspecific code. We are in varying stages of research and development for other diagnostic tests that we may offer. We do not currently offer any other testing services. If we are unable to increase sales of MyPRS® or to successfully develop and commercialize other diagnostic tests, we will not produce sufficient revenues to become profitable. Our laboratory testing services are expensive and may be a negative factor for reimbursement.

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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.

Our current business strategy focuses on discovering, developing and commercializing molecular diagnostic tests and services. We believe the success of our business depends on our ability to fully commercialize our existing diagnostic tests and services and to develop and commercialize new diagnostic tests. In particular, it is essential to our business strategy that we expand the indications for use of MyPRS®. The first additional indications for which we hope MyPRS® will be used include MGUS and SMM. Collectively, these precursor conditions are referred to as AMG.

However, we may be unsuccessful and MyPRS® may never be used for these indications. We may not succeed because it may never be accepted by the oncologist community, third-party payors may not pay for it, and the recent peer-reviewed publication that could support these indications for MyPRS® may not be sufficient to drive adoption support coverage and reimbursement and the results may not be duplicated in additional studies.

In addition, prior to commercializing our diagnostic tests, we must undertake time-consuming and costly development activities, sometimes including clinical studies, and may be required to obtain regulatory clearance or approval, which may be denied. This development process involves a high degree of risk, substantial expenditures and will occur over several years. Our development efforts may fail for many reasons, including:

failure of the tests at the research or development stage;
difficulty in accessing archival tissue samples, especially tissue samples with known clinical results; or
lack of clinical validation data to support the effectiveness of the test.

Tests that appear promising in early development may fail to be validated in subsequent studies, and even if we achieve positive results, we may ultimately fail to obtain the necessary regulatory clearances, approvals or coverage and reimbursement. There is substantial risk that our research and development projects will not result in commercially viable tests, and that success in early clinical trials will not be replicated in later studies. At any point, we may abandon development of a test or be required to expend considerable resources repeating clinical trials, which would adversely impact our ability to generate revenues from that test. In addition, as we develop tests, we will have to make significant investments in research, development and marketing resources. If a clinical validation study of a particular test fails to meet its endpoint, we might choose to abandon the development of that test. Further, our ability to develop and launch diagnostic tests will likely depend on our receipt of additional funding beyond that obtained through this offering. If our discovery and development programs yield fewer commercial tests than we expect, we may be unable to execute our business plan, which may adversely affect our business, financial condition and results of operations.

We may acquire other businesses or form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our offerings or distribution. For example, we may seek to purchase or license proprietary tests for other cancer indications or tests that complement our current offering for MM patients. We have limited experience with acquiring other companies and limited experience with forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all.

Our business depends on our ability to successfully develop and commercialize novel cancer diagnostic tests and s

If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a

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cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

To finance any acquisitions or joint ventures, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

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.

We currently offer our proprietary laboratory services in our CLIA-certified laboratory. Because we currently offer these tests and services solely for use within our laboratory, we believe we may market the tests as LDTs. Under current FDA enforcement policies and guidance, LDTs generally do not require FDA pre-market clearance or approval before commercialization, and we have marketed our LDTs on that basis. The FDA may, in the future, change this regulatory policy and require pre-market approvals, or PMAs, for LDTs. We may be unable to obtain PMAs for our tests, which could make it impossible for us to legally market our services, which would mean that our business may not be viable. See the risk factor below *If the 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 for our tests.*

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 are an early-stage company and have engaged in only limited selling and marketing activities for MyPRS®. There is not currently widespread awareness or adoption of our MyPRS® testing system. Although we believe that MyPRS® represents a promising commercial opportunity, it may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or profits for us. This is also true for any additional diagnostic tests we may market. We will need to establish a market for our diagnostic tests and build that market through physician education and awareness programs. Gaining acceptance in medical communities requires publication in leading peer-reviewed journals of results from studies using our tests. The process of publication in leading medical journals is subject to a peer review process and peer reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our studies published in peer-reviewed journals would limit the adoption of our tests and future coverage and reimbursement decisions for our tests could be negatively affected.

Our ability to successfully market the diagnostic tests that we may develop will depend on numerous factors, including:

whether health care providers believe our diagnostic tests are clinically useful;
whether the medical community accepts that our diagnostic tests are sufficiently sensitive and specific to be meaningful in patient care and treatment decisions; and
whether health insurers, government health programs and other third-party payors will cover and pay for our diagnostic tests and, if so, whether they will adequately reimburse us.

If we are unable to obtain regulatory clearance or approvals in the United States or if we experience delays in receiving

If any of these do not occur, we could fail to achieve widespread market acceptance of our diagnostic tests and our business would be materially harmed, as would our financial condition and results of operations.

If we cannot develop tests to keep pace with rapid advances in technology, medicine and science, our operating results and competitive position could be harmed.

In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. There are several new cancer drugs under development that may increase patient survival time. There have also been advances in methods used to analyze very large amounts of genomic information.

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We must continuously develop new tests and enhance our existing tests to keep pace with evolving standards of care. Our tests could become obsolete unless we continually innovate and expand them to demonstrate benefit in patients treated with new therapies. New cancer therapies typically have only a few years of clinical data associated with them, which limits our ability to perform clinical studies and correlate sets of genes to a new treatment's effectiveness. We plan to use part of the proceeds to fund continued clinical development of new products and services. We may experience research and development, regulatory, market or other difficulties that could delay or prevent our introduction of new or enhanced tests. The research and development process generally takes a significant amount of time from design stage to product launch, and we may have to abandon a test in which we have devoted substantial resources and time. We cannot be certain that any tests we seek to develop will prove to be effective; that we will be able to obtain, in a timely manner or at all, necessary regulatory approvals; that the tests we develop can be provided at acceptable costs, with appropriate quality or that they will be covered or reimbursed; or that, if developed, these tests will be successfully marketed and achieve community acceptance. If we cannot adequately demonstrate the applicability of our tests to new treatments, sales of our tests and services could decline, which would have a material adverse effect on our business, financial condition and results of operations.

If our tests do not continue to perform as expected, our operating results, reputation and business will suffer.

Our success depends on the market's confidence that we can continue to provide reliable, high-quality diagnostic tests. We believe that our customers are likely to be particularly sensitive to test defects and errors, such as false positive or false negative results which could affect the patient's eventual diagnosis and/or treatment. As a result, the failure of our tests or services to perform as expected would significantly impair our reputation and the public image of our tests and services, and we may be subject to legal claims arising from any defects or errors.

We may implement a product recall or voluntary market withdrawal of MyPRS® due to test defects or enhancements and modifications, which would significantly increase our costs.

The marketing of MyPRS® and any future diagnostic tests that we may develop involves an inherent risk that such tests may prove to be defective. In that event, we may voluntarily implement a market withdrawal of such tests or may be required to do so by a regulatory authority. A recall of MyPRS® or one of our future diagnostic tests, or a similar product or service offered by another provider, could impair sales of the services we market as a result of confusion concerning the scope of the recall or as a result of the damage to our reputation for quality and safety.

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.

We rely on third parties for the manufacture and supply of all of our laboratory instruments, equipment and materials, such as reagents, microarray chips and disposable test kits, that we need to perform our specialized diagnostic services, and rely on a limited number of suppliers for certain laboratory materials and some of the laboratory equipment with which we perform our diagnostic services. We do not have long-term contracts with our suppliers and manufacturers that commit them to supply equipment and materials to us. Certain of our suppliers provide us with analyte specific reagents, or ASRs, which serve as building blocks in the diagnostic tests we conduct in our laboratory.

If we cannot develop tests to keep pace with rapid advances in technology, medicine and science, our operating res

These suppliers are subject to regulation by the FDA, and must comply with federal regulations related to the manufacture and distribution of ASR products. Because we cannot ensure the actual production or manufacture of such critical equipment and materials, or the ability of our suppliers to comply with applicable legal and regulatory requirements, we may be subject to significant delays caused by interruption in production or manufacturing. If any of our third-party suppliers or manufacturers were to become unwilling or unable to provide this equipment or these materials in required quantities or on our required timelines, we would need to identify and acquire acceptable replacement sources on a timely basis. While we have developed alternate sourcing strategies for the equipment and materials we use, we cannot be certain that these strategies will be effective and even if we were to identify other suppliers and manufacturers for the equipment and materials we need to perform our specialized diagnostic services,

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there can be no assurance that we will be able to enter into agreements with such suppliers and manufacturers or otherwise obtain such items on a timely basis or on acceptable terms, if at all. If we encounter delays or difficulties in securing necessary laboratory equipment or materials, including consumables, we would face an interruption in our ability to perform our specialized diagnostic services and experience other disruptions that would adversely affect our business, results of operations and financial condition.

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 currently derive substantially all of our revenues from our laboratory testing services. We do not have any clinical reference laboratory facilities other than our facility in Little Rock, Arkansas. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including fire, flooding and power outages, which may render it difficult or impossible for us to perform our tests or provide laboratory services for some period of time. The inability to perform our tests or the backlog of tests that could develop if our facility is inoperable for even a short period of time may result in the loss of customers or harm to our reputation or relationships with collaborators, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facilities and the equipment we use to perform our research and development work could be costly and time-consuming to repair or replace, which could further delay our ability to provide our testing services.

Additionally, a key component of our research and development process involves using biological samples and the resulting data sets and medical histories, as the basis for our diagnostic test development. In some cases, these samples are difficult to obtain. If the parts of our laboratory facility where we store these biological samples are damaged or compromised, our ability to pursue our research and development projects, as well as our reputation, could be jeopardized. We carry insurance for damage to our property and the disruption of our business, but this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

Further, if our laboratory became inoperable, we may not be able to license or transfer our proprietary technology to a third party, with established state licensure and CLIA certification under the scope of which our diagnostic tests could be performed following validation and other required procedures, to perform the tests. Even if we find a third party with such qualifications to perform our tests, such party may not be willing to perform the tests for us on commercially reasonable terms. We may have to reapply for state licensure and CLIA certification if we are unable to find a third party with such qualifications.

If we fail to properly manage our anticipated growth, our business could suffer.

Our growth has placed, and will continue to place, a significant strain on our management and on our operational and financial resources and systems. Failure to manage our growth effectively could cause us to over-invest or under-invest, and result in losses or weaknesses. Additionally, our anticipated growth will increase the demands placed on our suppliers, resulting in an increased need for us to carefully monitor for quality assurance. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

If our sole laboratory facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to

Fluctuations in insurance cost and availability could adversely affect our profitability or our risk management profile.

We hold a number of insurance policies, including product liability insurance, property insurance, workers compensation insurance, and directors and officers liability insurance. If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results and cash flow could be materially adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. If we operate our business without insurance, we could be responsible for paying claims or judgments against us that would have otherwise been covered by insurance, which could adversely affect our results of operations or financial condition.

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If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenues or achieve and sustain profitability.

Our principal competition comes from the existing mainstream diagnostic methods that pathologists and oncologists use and have used for many years. It may be difficult to change the methods or behavior of the referring pathologists and oncologists to incorporate our molecular diagnostic testing in their practices. However, we believe that we can introduce our diagnostic tests successfully due to their clinical utility and the desire of pathologists and oncologists to find solutions for more accurate diagnosis, prognosis and personalized treatment options for MM and AMG patients.

But this is not certain and if the health care providers who are in a position to order our tests do not adopt them, it could adversely affect our business.

We also face competition from companies that currently offer or are developing products to profile genes, gene expression or protein biomarkers in various cancers. Personalized genetic diagnostics is a new area of science, and we cannot predict what tests others will develop that may compete with or provide results superior to the results we are able to achieve with the tests we develop. Our competitors include public companies such as NeoGenomics, Inc., Quest Diagnostics, Abbott Laboratories, Inc., Johnson & Johnson, Roche Molecular Systems, Inc., bioTheranostics, Inc. (part of bioMérieux SA), Genomic Health, Inc., Myriad Genetics Inc., Qiagen N.V., Foundation Medicine, Inc., Response Genetics, Inc., Cancer Genetics, Inc., and many private companies, including Agendia B.V. Another source of competition comes from other scientific teams attempting to develop GEP signatures utilizing other genes or a subset of the genes utilized in our MyPRS® test. Two groups of note include the French IFM-15 gene signature and the Netherlands EMC-92 gene signature which have been studied by independent groups and compared to the UAMS GEP test, or MyPRS®.

We provide services in a segment of the health care industry that is highly fragmented and extremely competitive. Any failure to respond to technological advances and emerging industry standards could impair our ability to attract and retain clients. This industry is characterized by rapid technological change. It is anticipated that competition will continue to increase due to such factors as the potential for commercial applications of biotechnology and the continued availability of investment capital and government funding for cancer-related research. Our competitors may succeed in developing diagnostic tests and/or services that are superior to our tests and technologies, including our pipeline tests. This could render our tests obsolete and, as a result, they might not be ordered, thus impairing the viability of our business.

We expect that pharmaceutical and biopharmaceutical companies will increasingly focus attention and resources on the personalized diagnostic sector as the potential and prevalence increases for molecularly targeted oncology therapies approved by the FDA along with companion diagnostics. For example, the FDA has approved two such agents Xalkori crizotinib from Pfizer Inc. along with its companion anaplastic lymphoma kinase FISH test from Abbott Laboratories, Inc. and Zelboraf vemurafenib from Genentech USA Incorporated and Daiichi-Sankyo Inc. along with its companion B-RAF kinase V600 mutation test from Roche Molecular Systems, Inc. These two FDA approvals are the second and third instances of simultaneous approvals of a drug and companion diagnostic, the first being the 1998 approval of Genentech, Inc.'s Herceptin trastuzumab for HER2 positive breast cancer along with the HercepTest from partner Dako A/S.

We also face competition from companies such as Genoptix, Inc. (a Novartis AG company), Clariant, Inc. (a division of GE Healthcare, a unit of General Electric Company), Bio-Reference Laboratories, Inc., Intergrated Genetics (a LabCorp Specialty Testing Group) and Foundation Medicine, Inc., which offer products or services or have conducted research to develop genetic profiles, or genetic or protein biomarkers for various cancers. Additionally, projects related to cancer genomics have received increased government funding, both in the United States and internationally.

If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenues or a

As more information regarding cancer genomics becomes available to the public, we anticipate that more products and services aimed at predicting patient outcome as well as identifying targeted treatment options will be developed and that these products and services may compete with the services we offer. In addition, competitors may develop their own versions of our tests in countries where we did not apply for patents or where our patents have not issued and compete with us in those countries, including promoting the use of their test(s) by physicians or patients in other countries.

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Many of our present and potential competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced, less complex tests that payors, pathologists and oncologists could view as functionally equivalent to our tests, which could force us to lower the list price of our tests and impact our operating margins and our ability to achieve profitability. In addition, technological innovations that result in the creation of enhanced diagnostic tools may enable other clinical laboratories, hospitals, physicians or medical providers to provide specialized diagnostic services similar to ours in a more patient-friendly, efficient or cost-effective manner than is currently possible. If we cannot compete successfully against current or future competitors, we may be unable to increase market acceptance and sales of our tests, which could prevent us from increasing or sustaining our revenues or achieving or sustaining profitability.

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.

In recent years, we have incurred significant costs in connection with the development of our diagnostic tests. For the nine months ended September 30, 2014, our research and development expenses were \$148,000, which was 4.0% of our net revenue, and our selling and marketing expenses were \$326,000, which was 8.9% of our net revenue. For the year ended December 31, 2013, our research and development expenses were \$97,000, which was 2.2% of our net revenue, and our selling and marketing expenses were \$379,000, which was 8.8% of net revenue. For the year ended December 31, 2012, our research and development expenses were \$225,000, which was 5.1% of our net revenue, and our selling and marketing expenses were \$1.3 million, which was 30.1% of net revenue. We expect our expenses to continue to increase, in absolute dollars, for the foreseeable future as we seek to expand the clinical utility of our diagnostic tests, and work to drive adoption of and reimbursement for our diagnostic tests and develop new tests. As a result, we will need to generate significant revenues in order to achieve sustained profitability.

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

To increase awareness and adoption of our molecular diagnostic tests and services, we will need to educate oncologists and pathologists on the clinical utility, benefits and value of each type of test we provide through published papers, presentations at scientific conferences and one-on-one education sessions by members of our sales force. In addition, we will need to assure oncologists and pathologists of our ability to obtain and maintain adequate reimbursement coverage from third-party payors. We may need to hire additional commercial, scientific, technical, selling and marketing and other personnel to support this process. If our educational efforts fail and medical practitioners do not order our diagnostic tests or other tests we may develop, utilization of our tests in sufficient volume for us to achieve sustained profitability or, perhaps, viability may not be possible.

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

Under standard clinical practice in the United States, tumor biopsies removed from patients are chemically preserved, embedded in paraffin wax and stored. Our clinical development relies on our ability to access these archived tumor

We expect to continue to incur significant expenses to develop and market our diagnostic tests, which could make it

biopsy samples, as well as information pertaining to their associated clinical outcomes. Other companies often compete with us for access. Additionally, the process of negotiating access to archived samples is lengthy, because it typically involves numerous parties and approvals to resolve complex issues such as usage rights, institutional review board approval, privacy rights, publication rights, intellectual property ownership and research parameters.

UAMS and other institutions provide us with tissue samples and other biological materials that we use in developing and validating our tests. We do not have written agreements with some of these third parties, and, in many of the cases in which the agreements are in writing, our relationships with such third parties are terminable on 30 days' notice or less. Disagreements or disputes might cause delays or termination of the research, development or commercialization of testing systems or additional test indications, might lead to additional responsibilities or costs to us or might result in litigation or arbitration, any of which could divert

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management attention and resources and be time-consuming and expensive. If one or more of these suppliers terminate their relationship with us, we will need to identify other third parties to provide us with tissue samples and biological materials, which could result in a delay in our research and development activities and negatively affect our business. In addition, as we grow, research and academic institutions may begin to seek financial contributions from us, which may negatively affect our results of operations. Potential suppliers may elect not to work with us based on their assessment of our financial, regulatory or intellectual property position. Even if we establish new agreements, this may not result in the successful development of future testing systems or additional test indications.

The loss of our Chairman or key members of our executive management team could adversely affect our business.

Our success in implementing our business strategy depends largely on the skills, experience and performance of the Chairman of our board of directors, Bennett S. LeBow, key members of our executive management team and others in key management positions, including Samuel D. Riccitelli, our President and Chief Executive Officer, and Tamara A. Seymour, our Chief Financial Officer. The collective efforts of each of these persons working as a team are critical to us as we continue to develop our technologies, tests and research and development and sales programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies and implementing our business strategy. Our President and Chief Executive Officer, Samuel D. Riccitelli, our Chief Financial Officer, Tamara A. Seymour, our Senior Vice President of Commercial Strategy and Business Development, Michael C. Cerio, our Chief Information Officer, Sudipto Sur, Ph.D., and our Vice President of Research and Operations, Ryan Van Laar, Ph.D. each have employment agreements with us. However, the existence of an employment agreement does not guarantee retention of members of our executive management team or our key employees and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

As we continue to grow our business, we may find it necessary to hire additional management or other personnel, either on a full-time or part-time basis, as employees or as consultants. Any new personnel that we hire may not be as familiar with our business or operations as our current employees, which means that we may incur expenses and inefficiencies related to training new employees and/or consultants. For example, we recently hired a Senior Vice President of Commercial Strategy and Business Development and Chief Information Officer. We expect that it will take time for these officers to become fully integrated into their new roles.

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 products we may develop.

Our success in selling our clinical laboratory services, diagnostic tests and any other tests or products that we are able to develop will require us to expand our sales force in the United States and internationally by recruiting additional

The loss of our Chairman or key members of our executive management team could adversely affect our ~~47~~ business.

sales representatives with extensive experience in oncology and close relationships with medical oncologists, surgeons, pathologists and other hospital personnel. To achieve our marketing and sales goals, we will need to substantially expand our sales and commercial infrastructure, with which to date we have had little experience. Sales professionals with the necessary technical and business qualifications are in high demand, and there is a risk that we may be unable to attract, hire and retain the number of sales professionals with the right qualifications, scientific backgrounds and relationships with decision-makers at potential customers needed to achieve our sales goals. We may face competition from other companies in our industry, some of whom are much larger than us and who can pay greater compensation and benefits than we

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can, in seeking to attract and retain qualified selling and marketing employees. If we are unable to hire and retain qualified selling and marketing personnel, our business will suffer.

Some of our future contract manufacturers and distributors may be located outside of the United States, which may subject us to increased complexity and costs.

In the future we may need to rely on manufacturing or laboratory facilities located outside the United States for our tests. Our MyPRS® and future test sales may be subject to certain risks, including:

- difficulty in obtaining, maintaining or enforcing intellectual property rights in some countries;
 - local business and cultural factors that differ from our normal standards and practices;
 - foreign currency exchange fluctuations;
 - additional U.S., and new foreign regulatory requirements;
 - impediments to the flow of foreign exchange capital payments and receipts due to exchange controls instituted by certain foreign governments and the fact that local currencies of some countries are not freely convertible;
 - geopolitical and economic instability and military conflicts;
 - difficulties in managing international partners;
 - burdens of complying with a variety of foreign laws and treaties and changes in local laws and regulations, including tax laws;
 - increased financial accounting and reporting burdens;
 - difficulty in enforcing agreements, judgments and arbitration awards in foreign jurisdictions; and
 - adverse economic conditions in any jurisdiction.
- These factors could harm our business or results of operations.

If we were sued for product liability or professional liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of our tests could lead to the filing of product liability claims were someone to allege that our tests failed to perform as designed. We may also be subject to liability for errors in the test results we provide to pathologists and oncologists or for a misunderstanding of, or inappropriate reliance upon, the information we provide.

A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

Although we believe that our existing product and professional liability insurance is adequate, our insurers may fail to defend us or our insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could damage our reputation, or cause current clinical partners and collaborators to terminate existing agreements and potential clinical partners to seek other partners, cause customers to terminate their relationship with us and potential customers to seek alternative testing solutions, any of which could impact our results of operations.

**If we use biological and hazardous materials in a manner that causes injury,
we could be liable for damages.**

Our activities currently require the controlled use of potentially harmful biological materials and hazardous materials and chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject to, on an ongoing basis, federal, state and local laws and regulations governing the use, storage, handling and disposal of these

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materials and specified waste products. The cost of compliance with these laws and regulations may become significant and could have a material adverse effect on our financial condition, results of operations and cash flows. In the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines.

If we cannot support demand for our tests, including successfully managing the evolution of our technology and manufacturing platforms, our business could suffer.

As our test volume grows, we will need to increase our testing capacity, implement increases in scale and related processing, customer service, billing, collection and systems process improvements and expand our internal quality assurance program and technology to support testing on a larger scale. We will also need additional certified laboratory scientists and other scientific and technical personnel to process these additional tests. Any increases in scale, related improvements and quality assurance may not be successfully implemented and appropriate personnel may not be available. As additional tests are commercialized, we will need to bring new equipment on line, implement new systems, technology, controls and procedures and hire personnel with different qualifications. Failure to implement necessary procedures or to hire the necessary personnel could result in a higher cost of processing or an inability to meet market demand. We cannot assure that we will be able to perform tests on a timely basis at a level consistent with demand, that our efforts to scale our commercial operations will not negatively affect the quality of our test results or that we will respond successfully to the growing complexity of our testing operations. If we encounter difficulty meeting market demand or quality standards for our tests, our reputation could be harmed and our future prospects and business could suffer, which may have a material adverse effect on our financial condition, results of operations and cash flows.

Declining general economic or business conditions may have a negative impact on our business.

Continuing concerns over United States health care reform legislation and energy costs, geopolitical issues, the availability and cost of credit and government stimulus programs in the United States and other countries have contributed to increased volatility and diminished expectations for the global economy. These factors, combined with low business and consumer confidence and high unemployment, precipitated an economic slowdown and recession. If the economic climate does not improve or deteriorates, our business, including our access to patient samples and the addressable market for diagnostic tests that we may successfully develop, as well as the financial condition of our suppliers and our third-party payors, could be adversely affected, resulting in a negative impact on our business, financial condition and results of operations.

We depend on our information technology and telecommunications systems, and any failure of these systems could harm our business.

We depend on information technology and telecommunications systems for significant aspects of our operations. In addition, our third-party billing and collections provider depends upon telecommunications and data systems provided by outside vendors and information we provide on a regular basis. These information technology and telecommunications systems support a variety of functions, including test processing, sample tracking, quality control, customer service and support, billing and reimbursement, research and development activities and our general and administrative activities. Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters.

If we cannot support demand for our tests, including successfully managing the evolution of our technology and ma

Moreover, despite network security and back-up measures, some of our systems are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from processing tests, providing test results to pathologists, oncologists, billing payors, processing reimbursement appeals, handling patient or physician inquiries, conducting research and development activities and managing the administrative aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business. Furthermore, we depend on FedEx as our courier. Any disruption in any of our mail services or transportation logistics could result in spoiled or lost samples, which

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could reduce revenue. Moreover, we are required to comply with laws governing the transmission, security and privacy of health information that require significant compliance costs, and any failure to comply with these laws could result in material criminal and civil penalties and civil liabilities.

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.

Billing for laboratory tests is complicated and is subject to extensive and non-uniform rules and administrative requirements. Missing or incorrect information on requisitions adds complexity to and slows the billing process, creates backlogs and increases the aging of accounts receivable and bad debt expenses. Failure to timely or correctly bill may lead to our not being reimbursed for our services or an increase in aging of our accounts receivable. In addition, failure to comply with applicable federal and state laws relating to billing, including, but not limited, to the federal False Claims Act may lead to various penalties including civil and criminal fines and penalties, recoupment efforts, and exclusion from participation in Medicare and other federal health care programs. We rely heavily on a single third party to provide us with key software and services for our billing. If that third party is unable or unwilling to provide these services to us for any reason, fails to perform billing services accurately and completely, or violates the law, we may not be able to submit claims promptly or at all and we may be subject to an investigation and potential civil and criminal penalties. Delays in invoicing can lead to delays in revenue recognition, and inaccuracies in our billing could result in lost revenue. If we fail to adapt quickly and effectively to changes affecting our costs, pricing and billing, our profitability and cash flow will be adversely affected.

Regulatory Risks Relating to Our Business

Our business may be adversely impacted by sequestration in the United States.

On March 1, 2013, most agencies of the federal government automatically reduced their budgets according to an agreement made by Congress in 2012 known as sequestration. Originally devised as an incentive to force Congressional agreement on budget issues, the sequestration order was approved on March 1, 2013 by the President of the United States. Reimbursement under the CLFS continues to be reduced by 2% as a result of federal government sequestration.

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

Government payors, such as Medicare and Medicaid, have taken steps and can be expected to continue to take steps to control the cost, utilization and delivery of health care services, including clinical laboratory test services.

In March 2010, U.S. President Barack Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, which made a number of substantial changes in the way health care is financed by both governmental and private insurers. Among other things, the ACA:

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

Required each manufacturer of a taxable medical device to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices, beginning in 2013. Our MyPRS® test is not currently subject to this tax, but it or other tests we may offer in the future could be affected if they are ultimately required to be listed as a device with the FDA, under applicable FDA requirements.

Mandated a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule, or CLFS, of 1.75% for the years 2011 through 2015 and included a productivity adjustment that reduced the Consumer Price Index, or CPI, market basket update beginning in 2011.

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Established an Independent Payment Advisory Board to reduce the per capita rate of growth in Medicare spending. The Independent Payment Advisory Board has broad discretion to propose policies, which may have a negative impact on payment rates for services, including clinical laboratory services, beginning in 2016, and for hospital services beginning in 2020. These proposals will automatically be implemented unless Congress enacts alternative proposals that achieve the same saving targets.

While the ultimate impact of the ACA remains unclear, it is likely to be extensive and may result in significant changes to coverage and reimbursement of our tests. Congress has also proposed a number of legislative initiatives in response to the ACA, including possible repeal of the ACA. At this time, it remains unclear whether there will be any changes made to the ACA, whether to certain provisions or its entirety.

The ACA, among other things, imposed cuts to Medicare reimbursement for clinical laboratories. Medicare updates laboratory payment rates for inflation based on the CPI. The ACA included a productivity adjustment that will reduce the CPI update. For 2015, the productivity adjustment for the CLFS is -0.6 percent. In addition, the ACA included an additional 1.75 percent reduction in the CPI update for clinical laboratories for the years 2011 through 2015. The annual update for 2015 in CLFS rates following the productivity adjustment and reduction of 1.75 percentage points is -0.3 percent.

In addition, on February 22, 2012, the President signed the Middle Class Tax Relief and Job Creation Act of 2012, or MCTRJA, which, among other things, mandated an additional change in Medicare reimbursement for clinical laboratory services. This legislation required CMS to rebase payment amounts under the Medicare CLFS, reducing them by 2% in 2013. The reduced 2013 amount served as the base for payment rates in 2014, and subsequent years.

Such legislative changes have negatively impacted payments for clinical laboratory services since 2012. MACs have the authority to apply these cuts to locally determined payments for tests, such as MyPRS®, that are reported using unlisted CPT codes. Thus, even though we use an unlisted CPT code to bill for MyPRS® and reimbursement is determined by the local MAC, these changes could affect our reimbursement. The full impact on our business of these legislative initiatives is uncertain.

In addition, many of the CPT codes that we may use to bill our tests in the future are periodically revised by the AMA. The adoption of analyte specific codes allows payors to better identify tests being performed, resulting in changes to coverage and reimbursement. In the 2014 Final Rule, CMS announced that it has decided to keep the new molecular codes on the CLFS. CMS also announced that it would price the new codes using a gapfilling process by which it will refer the codes to the MACs to allow them to determine an appropriate price. In addition, CMS has also stated that it will not separately reimburse the algorithm portion of certain of the new codes for MAAAs, because it does not believe the algorithm qualifies as a clinical laboratory test. MACs are issuing payment and coverage decisions but the payment levels and the methodology for determining payment by Medicare and commercial health plans still remain largely unresolved. Our reimbursement could be adversely affected by any final CMS action in this area. Furthermore, CMS has the authority to revise payment rates for all tests paid under the CLFS, including imposing payment reductions. Even though we use an unlisted CPT code to bill for MyPRS® and reimbursement is determined by the local MAC, this authority could affect our reimbursement in the future. If CMS reduces reimbursement for new test codes or does not pay for the algorithmic portion of our MAAA tests, then our revenues will be adversely affected.

Whether Medicare and other payors will establish positive or adequate coverage policies or reimbursement rates remains uncertain.

The Protecting Access to Medicare Act of 2014, which was signed into law on April 1, 2014, contained provisions that significantly affect Medicare payment for tests that are reimbursed under the CLFS. Starting in 2017, Medicare payment for each test will be based on the amount of payment being made by private payors for that test. Private payor payment amounts, adjusted for discounts and other price concessions, will be collected by laboratories, starting

in 2016, and submitted to CMS so that market-based payment rates can be calculated. New tests will generally be paid using the crosswalk or gapfilling methodology described elsewhere in this prospectus. However, some new tests, termed Advanced Diagnostic Laboratory Tests, will be paid based on the laboratory's actual list charge for a brief period of time until private payor payment data is available. Furthermore, in order to facilitate implementation of the new payment

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methodology, starting in 2016, CMS is required to assign specific billing codes to many CLFS tests existing at the time of enactment and to all new CLFS tests. The Secretary of HHS has discretion in determining which labs will be required to collect private payor payment information, which tests may be designated as Advanced Diagnostic Laboratory tests, and which existing laboratory tests will be assigned new billing codes; therefore, the impact of this law, if any, on Medicare payment for MyPRS® or any test we might develop and commercialize in the future is unclear.

We cannot predict whether future health care initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. The taxes imposed by the new federal legislation and the expansion of government's role in the U.S. health care industry as well as changes to the reimbursement amounts paid by payors for diagnostic tests may reduce our profits and have a materially adverse effect on our business, financial condition, results of operations and cash flows. We expect continuing efforts on the part of payors to reduce reimbursement, to impose more stringent cost controls, and to reduce utilization of clinical test services.

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.

Pathologists and oncologists may not order our molecular diagnostic tests unless third-party payors, such as managed care organizations and government payors such as Medicare and Medicaid, pay a substantial portion of the test price.

Coverage and reimbursement by a third-party payor may depend on a number of factors, including a payor's determination that tests using our technologies are:

- experimental or investigational;
- not medically necessary;
- not appropriate for the specific patient;
- not cost-effective;
- not supported by peer-reviewed publications; and/or
- not included in clinical practice guidelines.

Uncertainty surrounds third-party payor reimbursement of any test incorporating new technology, including tests developed using microarrays. Technology assessments of new medical tests and devices conducted by research centers and other entities may be disseminated to interested parties for informational purposes. Third-party payors and health care providers may use such technology assessments as grounds to deny coverage for a test or procedure. To our knowledge, no technology assessments have been performed on our tests to date. However, if any technology assessments on our tests are performed, they could conclude that our tests are not clinically useful and this could result in payor non-coverage decisions, which would adversely affect our business.

Because each payor generally determines for its own enrollees or insured patients whether to cover or otherwise establish a policy to reimburse our diagnostic tests, seeking payor approvals is a time-consuming and costly process. We cannot be certain that coverage for our tests will be provided in the future by additional third-party payors or that existing contracts, agreements or policy decisions or reimbursement levels will remain in place or be fulfilled under existing terms and provisions. If we cannot obtain coverage and reimbursement from private and governmental payors such as Medicare and Medicaid for our current tests, or new tests or test enhancements that we may develop in the future, our ability to generate revenues could be limited, which may have a material adverse effect on our financial condition, results of operations and cash flow. Further, we have experienced in the past, and will likely experience in the future, delays and temporary interruptions in the receipt of payments from third-party payors due to missing

Our commercial success could be compromised if third-party payors, including managed care organizations and Medicare

documentation and other issues, which could cause delay in collecting our revenue.

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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.

For the nine months ended September 30, 2014, we derived approximately 16% of our total revenue from private insurance, including managed care organizations and other health care insurance providers, 14% from government payor programs, most of which was derived from Medicare, and 70% from direct-bill customers, including hospitals and other laboratories. In addition, for the years ended December 31, 2013 and 2012, respectively, we derived approximately 13% and 23% of our total revenue from private insurance, including managed care organizations and other health care insurance providers, 14% and 11% from government payor programs, most of which was derived from Medicare, and 73% and 66% from direct-bill customers, including hospitals and other laboratories. Medicare and other third-party payors may withdraw their coverage policies or cancel their contracts with us at any time, review and adjust the rate of reimbursement or stop paying for our tests altogether, which would reduce our total revenues.

We face efforts by payors to control the cost, utilization and delivery of health care services including clinical laboratory tests. In the past, measures have been undertaken to reduce payment rates for and decrease utilization of the clinical laboratory industry generally. Because of the cost-trimming trends, third-party payors that currently cover and provide reimbursement for our tests may suspend, revoke or discontinue coverage at any time, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues, which may have a material adverse effect on our financial condition, results of operations and cash flows. As discussed above, from time to time, Congress has, and may in the future, legislated reductions in or frozen updates to the Medicare CLFS. In addition, Congress may adopt policies limiting or excluding coverage for tests that we perform. Medicaid reimbursement varies by state and is subject to administrative and billing requirements and budget pressures. The ACA includes several provisions that are intended to control utilization and payment, including provisions that reduce payments for services paid under the CLFS.

The health care industry has experienced a trend of consolidation among health insurance plans.

We are currently considered a non-contracting provider by a number of private third-party payors because we have not entered into a specific contract to provide our specialized diagnostic services to their insured patients at specified rates of reimbursement. If we were to become a contracting provider in the future, the amount of overall reimbursement we would receive is likely to decrease because we would be reimbursed less at a contracted rate than we would be at a non-contracted rate, which could have a negative impact on our revenues. Further, we may be unable to collect payments from patients beyond that which is paid by their insurance and will continue to experience lost revenue as a result.

Because of certain Medicare billing rules, we may not receive reimbursement for all tests provided to Medicare patients.

Under current Medicare billing rules, claims for our tests performed on Medicare beneficiaries who were hospital patients when the tumor tissue samples were obtained and whose tests were ordered less than 14 days from discharge must be included in the payment that the hospital receives for the patient services provided. Accordingly, we must bill individual hospitals for tests performed on Medicare beneficiaries during these timeframes in order to receive payment for our tests. Because we generally do not have a written agreement in place with these hospitals that purchase these

tests, we may not be paid for our tests or may have to pursue payment from the hospital on a case-by-case basis. This could be especially problematic for us if the hospital does not receive separate payment from Medicare for our test.

Because a portion of our revenues is from third-party payors with whom we are not currently contracted, we may be required to make positive or negative adjustments to accounting estimates with respect to contractual allowances, which may adversely affect our results of operations, our credibility with financial analysts and investors, and our stock price.

We record revenues net of contractual allowances. We estimate contractual allowances for non-contracted insurance companies based on our historical collection experience for each type of payor. In the event that the actual amount of payment received differs from the previously recorded estimate, an adjustment to revenue is

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made in the current period at the time of final collection and settlement. Our estimates of net revenue for non-contracted insurance companies are subject to change based on the contractual status and payment policies of the third-party payors with whom we deal. We regularly refine our estimates in order to make our estimated revenue as accurate as possible based on our most recent collection experience with each third-party payor. There can be no assurances that we will not be required to make similar adjustments to estimates with respect to contractual allowances in the future, which could adversely affect our results of operations, our credibility with financial analysts and investors, and our stock price.

Complying with numerous regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

We are subject to CLIA, a federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. Our clinical laboratory must be certified under CLIA in order for us to perform testing on human specimens. In addition, our proprietary tests must also be categorized as part of our CLIA certification so that we can offer them in our laboratory.

CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We have a current certificate under CLIA to perform high complexity testing. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make periodic inspections of our clinical reference laboratory outside of the renewal process.

The law also requires us to maintain a state laboratory license to conduct testing. Our laboratory is located in Arkansas and must have an Arkansas state license. Arkansas laws establish standards for day-to-day operation of our clinical reference laboratory, including the training and skills required of personnel and quality control. In addition, several other states require that we hold licenses to test specimens from patients in those states. Other states may have similar requirements or may adopt similar requirements in the future. Finally, we may be subject to regulation in foreign jurisdictions as we seek to expand international distribution of our tests.

If we were to lose our CLIA certificate or Arkansas laboratory license, whether as a result of a revocation, suspension or limitation, we would no longer be able to offer our tests, which would limit our revenues and harm our business. If we were to lose our license in other states where we are required to hold licenses, we would not be able to test specimens from those states.

In connection with the recent corporate conversion, we have been corresponding with state licensing authorities to ensure they have current information about our company and its operations and ownership structure. In connection with those efforts, we received a notice of intent to deny for change of ownership from the Florida Agency for Health Care Administration (AHCA) dated January 8, 2015. AHCA's notice alleges that we failed to timely notify them of a change of ownership. We are in the process of appealing this notice and believe the likelihood that we will lose our Florida license is remote. If we were to lose our license in Florida, we would not be able to test specimens from that state, which would limit our revenues and harm our business.

If the 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

Because a portion of our revenues is from third-party payors with whom we are not currently contracted, we may be

demand for, or reimbursement for our tests.

Although the FDA maintains that it has authority to regulate the development and use of LDTs, such as ours, as medical devices, it has not exercised its authority with respect to most LDTs as a matter of enforcement discretion. The FDA does not generally extend its enforcement discretion to reagents or software provided by third parties used to perform LDTs, and therefore these products must typically comply with the FDA medical device regulations, which are wide-ranging and govern, among other things: product design and development, product testing, product labeling, product storage, pre-market clearance or approval, advertising and promotion and product sales and distribution.

We believe that our MyPRS® test, as utilized in our laboratory testing, is an LDT. As a result, we believe that pursuant to the FDA's current policies and guidance that the FDA does not currently require that we

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obtain regulatory clearances or approvals for our LDT. The container we provide for collection and transport of tumor samples from a pathology laboratory or hospital to our clinical reference laboratory may be a medical device subject to the FDA regulation but is currently exempt from pre-market review by the FDA. While we believe that we are currently in material compliance with applicable laws and regulations, we cannot assure you that the FDA or other regulatory agencies would agree with our determination, and a determination that we have violated these laws, or a public announcement that we are being investigated for possible violations of these laws, could adversely affect our business, prospects, and the results of operations or financial condition.

Moreover, FDA guidance and policy pertaining to diagnostic testing is continuing to evolve and is subject to ongoing review and revision. A significant change in any of the laws, regulations or policies may require us to change our business model in order to maintain regulatory compliance. At various times since 2006, the FDA has issued guidance documents or announced draft guidance regarding initiatives that may require varying levels of FDA oversight of our tests. For example, in June 2010, the FDA announced a public meeting to discuss the agency's oversight of LDTs prompted by the increased complexity of LDTs and their increasingly important role in clinical decision-making and disease management, particularly in the context of personalized medicine. The FDA indicated that it was considering a risk-based application of oversight to LDTs and that, following public input and discussion, it might issue separate draft guidance on the regulation of LDTs, which ultimately could require that we seek and obtain either pre-market clearance or approval of LDTs, depending upon the risk-based approach the FDA adopts. The public meeting was held in July 2010 and further public comments were submitted to the FDA through September 2010. The FDA has stated it is continuing to develop draft guidance in this area.

On July 31, 2014, the FDA notified Congress (as required by Section 1143 of the Food and Drug Administration Safety and Innovation Act, signed by the U.S. President on July 9, 2012) of its intent to publish a proposed risk-based framework for LDTs, which are designed, manufactured, and used within a single laboratory. The notice to Congress provides the anticipated details of the draft guidance through which the FDA would propose to establish an LDT oversight framework, including premarket review for higher-risk LDTs, such as those that have the same intended use as FDA-approved or cleared companion diagnostics currently on the market. On October 3, 2014, the FDA published a proposed risk-based framework for LDTs, which are tests that are designed, manufactured, and used within a single laboratory. This draft guidance indicates that FDA would like to establish an LDT oversight framework, including premarket review for higher-risk LDTs, such as those that have the same intended use as FDA-approved or cleared companion diagnostics currently on the market. FDA's notice states that FDA does not consider devices to be LDTs if they are designed or manufactured completely, or partly, outside of the laboratory that offers and uses them. Such guidance, if and when finalized, may significantly impact the sales of our products and how customers use our products, and may require us to change our business model in order to maintain compliance with these laws. We cannot predict the ultimate timing or form of any FDA guidance or regulation on LTDs.

Additionally, on November 25, 2013, the FDA issued Final Guidance Distribution of In Vitro Diagnostic Products Labeled for Research Use Only. The guidance emphasizes that the FDA will review the totality of the circumstances when it comes to evaluating whether equipment and testing components are properly labeled as research use only. The final guidance states that merely including a labeling statement that the product is for research purposes only will not necessarily render the device exempt from the FDA's clearance, approval, and other regulatory requirements if the circumstances surrounding the distribution of the product indicate that the manufacturer knows its product is, or intends for its product to be, offered for clinical diagnostic uses. These circumstances may include written or verbal marketing claims or links to articles regarding a product's performance in clinical applications and a manufacturer's provision of technical support for clinical applications. If the FDA imposes significant changes to the regulation of LDTs, it could reduce our revenue or increase our costs and adversely affect our business, prospects, results of operations or financial condition.

If the FDA were to begin requiring approval or clearance of our tests, we could incur substantial costs and the delay

We may be required to proactively achieve compliance with certain FDA regulations and to conform our diagnostic service operations to the FDA's good manufacturing practice regulations for medical devices, known as the Quality System Regulation (QSR). In addition, we may voluntarily seek to conform our diagnostic service operations to QSR requirements. For clinical diagnostic products that are regulated as

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medical devices, the FDA enforces the QSR through pre-approved inspections and periodic unannounced inspections of registered manufacturing facilities. If we are subject to QSR requirements, the failure to comply with those requirements or take satisfactory corrective action in response to an adverse QSR inspection could result in enforcement actions, including a public warning letter or an untitled letter, a delay in approving or clearing, or a refusal to approve or clear, our products, a shutdown of diagnostic service operations, a product recall, civil or criminal penalties or other sanctions, which could in turn cause our sales and business to suffer.

We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our tests, whether through final guidance issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. We believe it is possible that legislation will be enacted into law or a final guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new tests. Given the attention Congress continues to give to these issues, legislation affecting this area may be enacted into law and may result in increased regulatory burdens on us as we continue to offer our tests and to develop and introduce new tests.

In addition, the Secretary of the U.S. Department of HHS, requested that its Advisory Committee on Genetics, Health and Society make recommendations about the oversight of genetic testing. A final report was published in April 2008. If the report's recommendations for increased oversight of genetic testing were to result in further regulatory burdens, they could negatively affect our business and delay the commercialization of tests in development.

Any requirement of pre-market review could negatively affect our business until such review is completed and clearance to market or approval is obtained. The FDA could require that we stop selling our tests pending pre-market clearance or approval. If the FDA allows our tests to remain on the market but there is uncertainty about the validity of our tests, if they are labeled investigational by the FDA or if the labeling claims the FDA allows us to make are very limited, orders or reimbursement may decline. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and making a 510(k) submission, or filing a PMA application with the FDA. If the FDA requires pre-market review, our tests may not be cleared or approved on a timely basis, if at all. We may also decide voluntarily to pursue FDA pre-market review of our tests if we determine that doing so would be appropriate.

Additionally, should future regulatory actions affect any of the reagents we obtain from vendors and use in conducting our tests, our business could be adversely affected in the form of increased costs of testing or delays, limits or prohibitions on the purchase of reagents necessary to perform our testing.

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 LDTs, those trials could lead to delays or failure to obtain necessary regulatory approval, which could cause significant delays in commercializing any future products and harm our ability to achieve sustained profitability.

If FDA decides to require that we obtain clearance or approvals to commercialize our proprietary genetic-based tests, we may be required to conduct additional pre-market clinical testing prior to submitting a regulatory notification or application for commercial sales. Clinical trials must be conducted in compliance with FDA regulations or FDA may take enforcement action or reject the data. The data collected from these clinical trials may ultimately be used to support market clearance or approval for our tests. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our test claims or that FDA or foreign authorities will agree with our conclusions

If we were required to conduct additional clinical trials prior to continuing to offer our proprietary MyPRS® test or any

regarding our test results. Success in early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and studies. If we are required to conduct pre-market clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our test development costs and delay commercialization. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. 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, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial. Moreover, the clinical trial process may fail to

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demonstrate that our tests are effective for the proposed indicated uses, which could cause us to abandon a test candidate and may delay development of other tests.

We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the trials properly. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests or to achieve sustained profitability.

We are subject to federal and state health care fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

We are subject to health care fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. These health care laws and regulations include, for example:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, in return for, to induce or to arrange for the referral of an individual for, or the purchase, order or recommendation of, any items or services for which payment may be made under a federal health care program such as the Medicare and Medicaid programs;
 - the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of designated health services with whom the physician or a member of the physician's immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies;
 - the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which establishes federal crimes for knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services;
 - the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
 - the federal Physician Payment Sunshine Act requirements under the ACA, which require manufacturers of drugs, devices, biologics and medical supplies to report to HHS information related to payments and other transfers of value made to or at the request of covered recipients, such as physicians and teaching hospitals, and physician ownership and investment interests in such manufacturers. Payments made to physicians and research institutions for clinical trials are included within the ambit of this law; and
 - state law equivalents of each of the above federal laws, such as anti-kickback, physician self-referral and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers.
- We seek to comply with these laws. However, it is possible that we could be the subject of a government investigation regarding our compliance with these laws and that the government could take the position that we are not in compliance with one or more of them. In such case, we may be judged to be in violation of those laws and subject to

We are subject to federal and state health care fraud and abuse laws and regulations and could face substantial pe

civil and criminal penalties. In addition, many of these laws and regulations are vague or indefinite and have not been interpreted by the courts or regulatory agencies. These laws and

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regulations may be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that could subject us to liability and/or require us to make changes in our operations.

We believe that federal and state governments continue to strengthen their enforcement efforts against health care fraud. In addition, the ACA increases the funding, power, penalties and remedies to pursue suspected cases of fraud and abuse and provides the government with expanded opportunities to pursue actions under the federal Anti-Kickback Statute, the False Claims Act, and the Stark Law. For example, the ACA narrowed the public disclosure bar under the False Claims Act, allowing increased opportunities for whistleblower litigation. In addition, the legislation modified the intent standard under the federal Anti-Kickback Statute, making it easier for prosecutors to prove that alleged violators had met the requisite knowledge requirement. The ACA also requires providers and suppliers to report any Medicare or Medicaid overpayment and return the overpayment on the later of 60 days of identification of the overpayment or the date the cost report is due (if applicable), or all claims associated with the overpayment will become false claims. The ACA also provides that any claim submitted from an arrangement that violates the Anti-Kickback Statute is a false claim. Any action brought against us for violation of these laws or regulations, even if we 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 our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, and/or exclusion from participation in Medicare, Medicaid or other state or federal health care programs, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business, our financial condition and results of operations.

Anti-Kickback Statutes

The federal Anti-Kickback Statute establishes criminal prohibitions against and civil penalties for the knowing and wilful solicitation, receipt, offer or payment of any remuneration, whether direct or indirect, in return for, to induce, or to arrange for the referral of patients or the ordering or purchasing of items or services payable in whole or in part under Medicare, Medicaid or other federal health care programs. Sanctions for violations of the Anti-Kickback Statute include criminal and civil penalties, such as imprisonment and/or criminal fines of up to \$25,000 per violation, and civil penalties of up to \$50,000 per violation and up to three times the amount received from the health care program, and exclusion from the Medicare, Medicaid and other federal health care programs.

The Office of Inspector General, or OIG, has the authority to promulgate regulations referred to as "safe harbors" that define certain business relationships and arrangements that would not be subject to civil sanction or criminal enforcement under the Anti-Kickback Statute. Failure to comply with a safe harbor provision does not make the activity illegal. Rather, the safe harbors set forth specific criteria that, if fully met, will assure the entities involved of not being prosecuted criminally or civilly for the arrangement under the Anti-Kickback Statute.

Many states also have enacted statutes similar to the Anti-Kickback Statute, which may include criminal penalties, applicable to referrals of patients regardless of payor source, and may contain exceptions different from state to state and from the exceptions to the federal Anti-Kickback Statute.

False Claims Act and Related Criminal Provisions

The False Claims Act, imposes civil penalties for knowingly making or causing to be made false claims with respect to governmental programs, such as Medicare and Medicaid, for services billed but not rendered, or for misrepresenting actual services rendered, in order to obtain higher reimbursement. Under the interpretation of certain courts, claims submitted for services furnished in violation of the Anti-Kickback Statute or Stark Law could also

violate the False Claims Act. Moreover, private individuals may bring *qui tam* or whistle blower suits against providers under the False Claims Act, which authorizes the payment of a portion of any recovery to the individual bringing suit. Such actions are initially required to be filed under seal pending their review by the Department of Justice. The False Claims Act generally provides for the imposition of civil penalties of \$5,500 to \$11,000 per claim and for treble damages, resulting in the possibility of substantial financial penalties for small billing errors that are replicated in a large number of claims, as each individual claim could be deemed to be a separate violation of the False Claims Act. Some states also

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have enacted statutes similar to the False Claims Act which may include criminal penalties, substantial fines, and treble damages. The Social Security Act provides financial incentives to states that enact state false claims acts that meet specified requirements. The OIG, in consultation with the Attorney General of the United States and the Department of Justice, determines whether a state false claims act meets these enumerated requirements to qualify for the added financial incentive. Due to certain changes in the law, including the enactment of the ACA, the OIG's specified requirements for obtaining financial incentives were revised effective March 2013. Because of these changes, states that formerly were approved for financial incentives were given until March 31, 2013 to bring their false claims acts up to date to conform with the changes to the law. Currently, the OIG's website indicates that the false claims acts of 28 states have been reviewed. Of those 28 states, OIG has determined that the state false claims acts of 15 states (California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Iowa, Massachusetts, Minnesota, Montana, New York, Rhode Island, Tennessee, Texas, and Washington) meet the OIG's revised requirements.

Civil Monetary Penalties Law

Individuals or entities who have among other things (1) directly submitted, or caused to be submitted, claims which are improper or false; (2) arranged or contracted with an individual or entity that the person knows or should know is excluded from participation in federal health care programs; or (3) offered or received kickbacks may also be subject to monetary penalties or exclusion under the Civil Monetary Penalties Law, or the CMPL, at the discretion of the OIG. Penalties are generally not more than \$10,000 for each item or service. However, under the CMPL, violators of the federal Anti-Kickback Statute provisions may also be subject to additional civil money penalties of \$50,000 per violation. Violators are also subject to an assessment of up to three times the amount claimed for each item or service in lieu of damages sustained by the United States or a state agency because of such claim, or damages of up to three times the total amount of remuneration offered, paid, solicited, or received. In addition, any person or entity who violates this section may be excluded from participation in the federal or state health care programs.

Stark Law

The original Ethics in Patient Referrals Act of 1989, commonly referred to as the Stark Law, was enacted as part of the Omnibus Budget Reconciliation Act, or OBRA, of 1989, and prohibited a physician from referring Medicare patients for clinical laboratory services to entities with which the physician (or an immediate family member) has a financial relationship, unless an exception applies. Sanctions for violations of the Stark Law may include denial of payment, refund obligations, civil monetary penalties and exclusion of the provider from the Medicare and Medicaid programs. In addition, the Stark Law prohibits the entity receiving the referral from filing a claim or billing for services arising out of the prohibited referral.

Provisions of OBRA 1993, known as Stark II, amended the Stark Law to revise and expand upon various statutory exceptions, expanded the services regulated by the statute to a list of Designated Health Services, and expanded the reach of the statute to the Medicaid program. Although CMS published Phase III of the Stark regulations on September 5, 2007, intending Phase III to be the final phase of the Stark rulemaking process, CMS continues to address the Stark Law as part of its annual rulemaking process for reimbursement under the Medicare Part B Physician Fee Schedule or under the Inpatient Prospective Payment System.

Finally, many states in which we operate have enacted self-referral statutes similar to the Stark Law. Such state self-referral laws may apply to referrals of patients regardless of payor source and may contain exceptions different from each other and from those contained in the Stark Law.

The Health Insurance Portability and Accountability Act of 1996

HIPAA expanded federal fraud and abuse laws by increasing their reach to all federal health care programs, establishing new bases for exclusions and mandating minimum exclusion terms, creating an additional statutory exception to the Anti-Kickback Statute for risk-sharing arrangements, requiring HHS to issue advisory opinions, increasing civil money penalties to \$10,000 per item or service and assessments to three times the amount claimed, creating a specific health care fraud offense and related health fraud crimes, and expanding investigative authority and sanctions applicable to health care fraud. HIPAA also prohibits a provider from offering anything of value which the provider knows or should know would be likely to induce a federal health care program beneficiary to select or continue with the provider.

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HIPAA includes a health care fraud provision prohibiting knowingly and willfully executing a scheme or artifice to defraud any health care benefit program, which includes any public or private plan or contract affecting commerce under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract. Penalties for violating this statute include criminal penalties, exclusion from the Medicare and Medicaid programs, freezing of assets and forfeiture of property traceable to commission of a health care fraud.

Other Fraud and Abuse Laws

Our operations are also subject to a variety of other federal and state fraud and abuse laws, principally designed to ensure that claims for payment to be made with public funds are complete, accurate and fully comply with all applicable program rules, and to prevent remuneration in exchange for referrals or purchases of items which may be reimbursed by the government or which may lead to overutilization, corruption of health care provider judgment, or a lack of transparency in costs or charges. Failure to remain in compliance with any of these rules could result in a material adverse effect on our business, financial condition or results of operations.

We are required to comply with laws governing the transmission, security and privacy of health information that require significant compliance costs, and any failure to comply with these laws could result in material criminal and civil penalties.

Under the administrative simplification provisions of HIPAA, HHS has issued regulations which establish uniform standards governing the conduct of certain electronic health care transactions and protecting the privacy and security of Protected Health Information, or PHI, used or disclosed by health care providers and other covered entities. Three principal regulations with which we are currently required to comply have been issued in final form under HIPAA: privacy regulations, security regulations and standards for electronic transactions.

The privacy regulations cover the use and disclosure of PHI by health care providers. It also sets forth certain rights that an individual has with respect to his or her PHI maintained by a health care provider, including the right to access or amend certain records containing PHI or to request restrictions on the use or disclosure of PHI. We have also implemented policies, procedures and standards to comply appropriately with the final HIPAA security regulations, which establish requirements for safeguarding the confidentiality, integrity and availability of PHI, which is electronically transmitted or electronically stored. The HIPAA privacy and security regulations establish a uniform federal floor and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI. As a result, we are required to comply with both HIPAA privacy regulations and varying state privacy and security laws. Almost all U.S. states now require notification to affected individuals and state authorities, as well as the media in certain cases, in the event of a breach of the security of personal information (including PHI in a few states), often with significant financial penalties for noncompliance.

The Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, enacted pursuant to the American Recovery and Reinvestment Act of 2009, or the ARRA, made sweeping changes to the health information privacy and security regulations of HIPAA by expanding the scope and application of the statute. These changes include, among other things, (1) establishing an affirmative obligation to provide patient data breach notification in the event of the unauthorized acquisition, access, use or disclosure of unsecured PHI; (2) elaborating upon the standard for minimum necessary uses and disclosures of PHI by a covered entity; (3) restricting certain uses of PHI for marketing purposes (by expanding the definition of marketing activities requiring authorization); (4)

prohibiting certain sales of PHI; (5) establishing an affirmative obligation to provide an accounting of disclosures made for payment, treatment and health care operations (up to three years made through an electronic health record); (6) requiring covered entities to agree to individuals' requests to restrict disclosure of PHI in certain circumstances; (7) applying the security regulations and certain provisions of the privacy regulations to business associates; and (8) modifying an individual's right to access PHI in an electronic format. HHS issued modifications to the HIPAA Regulations, effective March 26, 2013, implementing some of these changes including the obligation to provide patient data

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breach notifications, which subject the Company to additional administrative requirements in the U.S. With regard to the accounting of disclosures, the HITECH Act provides for removing the exception in the existing HIPAA privacy regulations accounting of disclosures of PHI requirement for disclosures of PHI for payment, treatment, and health care operations purposes made through an electronic health record (within the past three years). HHS issued proposed regulations to implement this provision of the HITECH Act in May 2011, but those regulations have not been finalized.

The HITECH Act also implemented measures to strengthen enforcement of HIPAA and increased applicable penalties for HIPAA violations. Penalties are now tiered and range from \$100 to \$50,000 per violation with an annual cap for the same violations of \$25,000 to \$1,500,000. The Office for Civil Rights of the HHS, or OCR, has increased enforcement activities and has recently levied large penalties for violations. In addition, as mandated by the HITECH Act, OCR has begun an audit program to assess compliance by covered entities and their business associates with the HIPAA privacy and security rules and breach notification standards.

We seek to comply with HIPAA privacy regulations and state privacy laws. In addition, we are in the process of taking necessary steps to comply with HIPAA's standards for electronic transactions, which establish standards for common health care transactions. Given the complexity of HIPAA, the HITECH Act and state privacy restrictions, the possibility that the regulations may change, and the fact that the regulations are subject to changing and potentially conflicting interpretation, our ability to comply with HIPAA, the HITECH Act and state privacy requirements is uncertain and the costs of compliance are significant. To the extent that we or our third-party billing company submit electronic health care claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and the HITECH Act, payments to us may be delayed or denied. Additionally, the costs of complying with any changes to HIPAA, the HITECH Act and state privacy restrictions may have a negative impact on our operations. We could be subject to criminal penalties and civil sanctions for failing to comply with HIPAA, the HITECH Act and state privacy restrictions, which could result in the incurrence of significant monetary penalties.

Changes in, or interpretations of, tax rules and regulations may adversely affect our effective tax rates.

We are subject to income and other taxes in the United States. Significant judgment is required in evaluating our provision for income taxes. During the ordinary course of business, there are many transactions for which the ultimate tax determination is uncertain. For example, there could be changes in the valuation of our deferred tax assets and liabilities or changes in the relevant tax, accounting, and other laws, regulations, principles and interpretations. Although we believe our tax estimates are reasonable, the final determination of tax audits and any related litigation could be materially different from our historical income tax provisions and accruals. The results of an audit or litigation, or the effects of a change in tax policy in the United States, could have a material effect on our operating results in the period or periods for which that determination is made.

Intellectual Property Risks Related to Our Business

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

Our ability to protect our proprietary discoveries and technologies affects our ability to compete and to achieve sustained profitability. Currently, we rely on a combination of issued U.S. patents, U.S. and foreign patent

applications, copyrights, trademarks and trademark applications, confidentiality or non-disclosure agreements, material transfer agreements, licenses, work-for-hire agreements and invention assignment agreements to protect our intellectual property rights. We also maintain certain company know-how, trade secrets and technological innovations designed to provide us with a competitive advantage in the market place as trade secrets.

Currently, we are the worldwide exclusive licensee, in our licensed field, or the owner of 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), which include both U.S. and foreign patent applications, relating to various aspects of our technology. Of the 21 pending patent applications, five are owned outright by Signal Genetics, Inc. Our exclusive field of use covers, inter alia, therapeutic, diagnostic,

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prognostic, and personalized medicine applications worldwide, excluding applications using fluorescence in situ hybridization, or FISH, and some claims directly covering DKK1 inhibitors and their uses.

While we intend to pursue additional patent applications, it is possible that our pending patent applications and any future applications may not result in issued patents. Even if patents are issued, third parties may independently develop similar or competing technology that avoids the claims of our patents or may challenge the validity of our patents. Further, we cannot be certain that the steps we have taken will prevent the misappropriation of our trade secrets and other confidential information as well as the misuse of our patents and other intellectual property, particularly in foreign countries where we have not filed for patent protection.

From time to time the U.S. Supreme Court, other federal courts, the U.S. Congress or the U.S. Patent and Trademark Office, or USPTO, as well as counterpart agencies and bodies in corresponding foreign jurisdictions, may change the standards of patentability and any such changes could have a negative impact on our business.

For instance, on October 30, 2008, the Court of Appeals for the Federal Circuit issued a decision that methods or processes cannot be patented unless they are tied to a machine or involve a physical transformation. The U.S. Supreme Court later reversed that decision in *Bilski v. Kappos*, or *Bilski*, finding that the machine-or-transformation test is not the only test for determining patent eligibility. The Court, however, declined to specify how and when processes are patentable. On March 20, 2012, in *Mayo v. Prometheus*, or *Mayo*, the U.S. Supreme Court reversed the Federal Circuit's application of *Bilski* and invalidated a patent focused on a diagnostic process because the patent claim embodied a law of nature. On July 30, 2012, the USPTO released a memorandum entitled "2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature", with guidelines for determining patentability of diagnostic or other processes in line with the *Mayo* decision. On June 13, 2013, in *Association for Molecular Pathology v. Myriad Genetics*, or *Myriad*, the Supreme Court held that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring. The Supreme Court's decision reversed in part and affirmed in part the earlier decision of the Federal Circuit that both isolated genes and cDNA were patent eligible, however, the Supreme Court specifically did not address the patentability of any method claims involving the use of such isolated genes. On March 4, 2014, the USPTO released a memorandum entitled "2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products", which we refer to as the March 4, 2014 memorandum. This memorandum provides guidelines for the USPTO's new examination procedure for subject matter eligibility under 35 U.S.C. §101 for claims embracing natural products or natural principles. On December 16, 2014, the USPTO issued a "2014 Interim Guidance on Patent Subject Matter Eligibility", which we refer to as the 2014 Interim Guidance, for use by USPTO personnel in determining subject matter eligibility in view of recent decisions by the U.S. Supreme Court, which supercedes the March 4, 2014 memorandum and includes a request for public comment on the 2014 Interim Guidance. Although the guidelines do not have the force of law, patent examiners have been instructed to follow them.

Some aspects of our technology involve products and/or processes that may be subject to this evolving standard and we cannot guarantee that any of our pending claims will be patentable as a result of such evolving standards or that issued patents will be held valid, if challenged under these changing standards.

In addition, on February 5, 2010, the Secretary's Advisory Committee on Genetics, Health and Society voted to approve a report entitled "Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests." That report defines patent claims on genes broadly to include claims to isolated nucleic acid molecules as well as methods of detecting particular sequences or mutations. The report also contains six recommendations, including the creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale or selling a test developed under the patent for patient care purposes, or for anyone using the

patent-protected genes in the pursuit of research. The report also recommended that the Secretary should explore, identify and implement mechanisms that will encourage more voluntary adherence to current guidelines that promote nonexclusive in-licensing of diagnostic genetic and genomic technologies. It is unclear whether the HHS will act upon these recommendations, or if the

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recommendations would result in a change in law or process that could negatively impact our patent portfolio or future research and development efforts.

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

Our ability to market certain of our tests and services, domestically and/or internationally, is in part derived from licenses to intellectual property which is owned by third parties. As such, we may not be able to continue selling our tests and services if we lose our existing licensed rights or sell new tests and services if we cannot obtain such licensed rights on reasonable terms. In particular, we in-license a portfolio of issued U.S. and foreign patents, and pending U.S. and foreign patent applications as the worldwide exclusive licensee in our licensed field from UAMS.

We may also need to license other technologies to commercialize future diagnostic tests that we may offer. As may be expected, our business may suffer if, for example, (1) these licenses terminate; (2) if the licensors fail to abide by the terms of the license, properly maintain the licensed intellectual property or fail to prevent infringement of such intellectual property by third parties; (3) if the licensed patents or other intellectual property rights are found to be invalid or (4) if we are unable to enter into necessary licenses on reasonable terms or at all. In return for the use of a third party's technology, we may agree to pay the licensor royalties based on sales of our products as well as other fees. Such royalties and fees are a component of cost of product revenues and will impact the margins on our tests.

We may face intellectual property infringement claims that could be time-consuming and costly to defend, and could result in our loss of significant rights and the assessment of treble damages.

From time to time we may face intellectual property infringement, misappropriation, or invalidity/non-infringement claims from third parties. Some of these claims may lead to litigation. The outcome of any such litigation can never be guaranteed, and an adverse outcome could affect us negatively. For example, were a third party to succeed on an infringement claim against us, we may be required to pay substantial damages (including up to treble damages if such infringement were found to be willful). In addition, we could face an injunction, barring us from conducting the allegedly infringing activity. The outcome of the litigation could require us to enter into a license agreement which may not be under acceptable, commercially reasonable, or practical terms or we may be precluded from obtaining a license at all.

It is also possible that an adverse finding of infringement against us may require us to dedicate substantial resources and time in developing non-infringing alternatives, which may or may not be possible. In the case of diagnostic tests, we would also need to include non-infringing technologies which would require us to re-validate our tests. Any such re-validation, in addition to being costly and time consuming, may be unsuccessful.

Finally, we may initiate claims to assert or defend our own intellectual property against third parties. If one or more of our patents were held to be invalid or not infringed, we might not be able to exclude others from offering similar or identical tests to ours. Any intellectual property litigation, irrespective of whether we are the plaintiff or the defendant, and regardless of the outcome, is expensive and time-consuming, and could divert our management's attention from our business and negatively affect our operating results or financial condition.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Although we try to ensure that we, our employees, and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we, our employees, or independent contractors have used or disclosed intellectual property in violation of others' rights. These claims may cover a range of matters, such as challenges to our trademarks, as well as claims that our employees or independent contractors are using trade secrets or other proprietary information of any such employee's former employer or independent contractors.

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In addition, while it is our policy to require our employees and independent contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

We or our suppliers and/or manufacturers may be subject to litigation relating to, among other things, payor and customer disputes, regulatory actions, professional liability, intellectual property, employee-related matters, product liability and other potential claims, which could adversely affect our business.

We or our suppliers and/or manufacturers may become subject in the ordinary course of business to material litigation related to things, payor or customer disputes, professional liability, regulatory actions, intellectual property, employee-related matters, product liability and other potential claims, as well as investigations by governmental agencies and governmental payors relating to the specialized diagnostic services we provide. Responding to these types of claims, regardless of their merit, could result in significant expense and divert the time, attention and resources of our management. Legal actions could result in substantial monetary damages as well as significant harm to our reputation with our oncologist customers and with payors, which could adversely affect our business, financial condition and results of operations. Our laboratory directors and other laboratory professionals may be sued, or may be added as an additional party, under physician liability or other liability law for acts or omissions by our lab directors, laboratory personnel, and other employees and consultants, including but not limited to being sued for misdiagnoses or liabilities arising from the professional interpretations of test results. We may periodically become involved as defendants in medical malpractice and other lawsuits, and are subject to the attendant risk of substantial damage awards, in particular in connection with our MyPRS® test. Our laboratory directors are insured for medical malpractice risks on a claims-made basis under traditional professional liability insurance policies. We also maintain general liability insurance that covers certain claims to which we may be subject. Our general insurance does not cover all potential liabilities that may arise, including governmental fines and penalties that we may be required to pay, liabilities we may incur under indemnification agreements and certain other uninsurable losses that we may suffer. It is possible that future claims will not be covered by or will exceed the limits of our insurance coverage or that our insurers will refuse to defend us against claims. The suppliers and manufacturers of the diagnostic tests we perform, which are critical to the performance of our specialized diagnostic services, may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that their diagnostic tests infringe the intellectual property rights of these third parties. In such event, we could no longer have access to, or we may be prohibited from marketing or performing, such diagnostic tests unless we obtained a license from such third party. A license may not be available to us on acceptable terms, if at all. If we are unable to license diagnostic tests that are important to our specialized diagnostic services, our business, financial condition and results of operations may be adversely affected.

Risks Related to our Common Stock and this Offering

We or our suppliers and/or manufacturers may be subject to litigation relating to, among other things, payor and customer

We are classified as a controlled company, and qualify for exemptions from certain corporate governance requirements. Despite the availability of these exemptions, we agreed with Aegis Capital Corp., as underwriter of our initial public offering, that we will not rely on these exemptions for a period of two years following our initial public offering, or until after June 23, 2016.

However, to the extent we still qualify, we may in the future elect to rely on these exemptions, and to the extent we do, our stockholders will not have the same protections afforded to stockholders of companies that are subject to such requirements.

Because Bennett S. LeBow, our Chairman, through his control of LeBow Alpha, LLLP, or LeBow Alpha, currently controls more than 50% of the outstanding voting power of our common stock, we are classified as

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a controlled company under the corporate governance rules of the NASDAQ Stock Market, or NASDAQ, and to the extent Mr. LeBow continues to control more than 50% of the outstanding voting power of our common stock following this offering, we will continue to be classified as a controlled company following this offering. Under NASDAQ rules, a company of which more than 50% of the outstanding voting power is held by an individual, group or another company is a controlled company and may elect not to comply with certain stock exchange corporate governance requirements, including:

the requirement that a majority of the board of directors consists of independent directors;
the requirement that director nominees be selected, or recommended for the board of director s selection, either by a majority of the board s independent directors or a nominations committee comprised solely of independent directors;
and

the requirement to have a compensation committee comprised solely of independent directors.
Despite the availability of these exemptions, we agreed with Aegis Capital Corp., as underwriter of our initial public offering, that we will not rely on these exemptions until after June 23, 2016. However, to the extent we still qualify, we may in the future elect to rely on these exemptions, and to the extent we do, our stockholders will not have the same protections afforded to stockholders of companies that are subject to such requirements.

Our majority stockholder has the ability to control significant corporate activities and will continue to have significant control over our corporate activities after the completion of this offering. Our majority stockholder s interests may not coincide with yours.

For so long as LeBow Alpha retains its ability to control over 50% of the voting power of our outstanding common stock following the offering, Mr. LeBow will retain the ability to control the outcome of matters submitted to a vote of stockholders and, through our board of directors, the ability to control decision-making with respect to our business direction and policies. Matters over which Mr. LeBow will, directly or indirectly, exercise control following this offering include:

the election of our board of directors and the appointment and removal of our officers;
mergers and other business combination transactions, including proposed transactions that would result in our stockholders receiving a premium price for their shares;

other acquisitions or dispositions of businesses or assets;
incurrence of indebtedness and the issuance of equity securities;
repurchase of stock and payment of dividends; and

the issuance of shares to management under our equity incentive plans.

Even if LeBow Alpha owns less than 50% of the voting power, for so long as it continues to hold a significant percentage of our voting power, Mr. LeBow will retain the ability to exert significant influence over these matters.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws that will become effective upon the closing of this offering may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These

Our majority stockholder has the ability to control significant corporate activities and will continue to have significant

provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

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the authorized number of directors can be changed only by resolution of our board of directors;
our bylaws may be amended or repealed by our board of directors or our stockholders;
stockholders may not call special meetings of the stockholders or fill vacancies on the board of directors;
our board of directors will be authorized to issue, without stockholder approval, preferred stock, the rights of which will be determined at the discretion of the board of directors and that, if issued, could operate as a poison pill to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our board of directors does not approve;
our stockholders do not have cumulative voting rights, and therefore our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors; and
our stockholders must comply with advance notice provisions to bring business before or nominate directors for election at a stockholder meeting.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

If you purchase shares of common stock in this offering, you will suffer immediate dilution of your investment.

The public offering price per share of our common stock will be substantially higher than the net tangible book value per share of our common stock immediately after the offering. At the assumed public offering price of \$2.60 per share, which was the last sale price of our common stock on The NASDAQ Capital Market on January 27, 2015, purchasers of our common stock will incur immediate dilution of \$0.48 per share in the net tangible book value of their purchased shares. Conversely, the shares of our common stock that our existing stockholders currently own will receive an increase in net tangible book value per share. See Dilution.

You may be diluted by exercises of outstanding options and warrants.

As of September 30, 2014, we had outstanding options to purchase an aggregate of 124,000 shares of our common stock at a weighted average exercise price of \$4.96 per share and warrants to purchase an aggregate of 42,500 shares of our common stock at an exercise price of \$12.50 per share. The exercise of such outstanding options and warrants will result in further dilution of your investment. In addition, you may experience additional dilution if we issue common stock in the future. As a result of this dilution, you may receive significantly less in net tangible book value than the full purchase price you paid for the shares in the event of liquidation.

Our failure to meet the continued listing requirements of The NASDAQ Capital Market could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of The NASDAQ Capital Market, such as the corporate governance requirements or the minimum closing bid price requirement, NASDAQ may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we would take actions to restore our compliance with NASDAQ's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the NASDAQ minimum

If you purchase shares of common stock in this offering, you will suffer immediate dilution of your investment.

bid price requirement or prevent future non-compliance with NASDAQ's listing requirements. Further, if we were to be delisted from The NASDAQ Capital Market, our common stock would cease to be recognized as covered securities and we would be subject to regulation in each state in which we offer our securities.

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If our shares become subject to the penny stock rules, this may make it more difficult to sell our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than \$5.00 (other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). The OTCBB does not meet such requirements and if the price of our common stock remains less than \$5.00 and we are no longer listed on a national securities exchange, our common stock may be deemed a penny stock. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that prior to effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive: (1) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (2) a written agreement to transactions involving penny stocks; and (3) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stock holders may have difficulty selling their shares.

An active trading market for our common stock may not develop.

Prior to our initial public offering in June 2014, there was no public market for our common stock. The listing of our common stock on the NASDAQ Capital Market does not assure that a meaningful, consistent and liquid trading market exists. Although our common stock is listed on The NASDAQ Capital Market, trading volume in our common stock has been limited and an active trading market for our shares may never develop or be sustained. If an active market for our common stock does not develop, it may be difficult for investors to sell their shares without depressing the market price for the shares or at all.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

Our stock price is likely to be volatile. The stock market in general and the market for smaller diagnostic services companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the offering price. The market price for our common stock may be influenced by many factors, including:

- issuances of new equity securities pursuant to a future offering, including issuances of preferred stock;
- the success of competitive products, services or technologies;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of health care payment systems;
- market conditions in the diagnostic services sector;

general economic, industry and market conditions; and
the other factors described in this Risk Factors section.

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Reports published by securities or industry analysts, including projections in those reports that exceed our actual results, could adversely affect our common stock price and trading volume.

Securities research analysts, including those affiliated with our underwriters, may establish and publish their own periodic projections for our business. These projections may vary widely from one another and may not accurately predict the results we actually achieve. Our stock price may decline if our actual results do not match securities research analysts' projections. Similarly, if one or more of the analysts who writes reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price could decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, our stock price or trading volume could decline. While we expect securities research analyst coverage, if no securities or industry analysts begin to cover us, the trading price for our stock and the trading volume could be adversely affected.

Future sales of our common stock, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.

Sales of substantial amounts of our common stock in the public market after this offering, or the perception that these sales may occur, could materially and adversely affect the price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. The shares of common stock sold in this offering will be freely tradable, without restriction, in the public market, except for any shares sold to our affiliates.

In connection with this offering, we, our officers and directors and holders of our outstanding common stock have agreed, subject to limited exceptions, not to issue, sell or transfer any shares of common stock for 90 days after the date of this prospectus without the consent of Aegis Capital Corp. However, Aegis Capital Corp. may release these shares from any restrictions at any time. We cannot predict what effect, if any, market sales of shares held by any stockholder or the availability of shares for future sale will have on the market price of our common stock.

We are an emerging growth company, and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain 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;

Reports published by securities or industry analysts, including projections in those reports that exceed our actual re

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 have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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We have elected to avail ourselves of the extended transition period for adopting new or revised accounting standards available to emerging growth companies under the JOBS Act and will, therefore, not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies, which could make our common stock less attractive to investors.

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 allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. The Company has elected to avail itself of this extended transition period for adopting new or revised accounting standards and therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We cannot predict whether investors will find our stock less attractive as a result of this election. If some investors find our common stock less attractive as a result of this election, there may be a less active trading market for our common stock and our stock price may be more volatile.

Since our initial public offering in June 2014, we have begun to incur significantly increased costs and our management has had to devote substantial time as a result of operating as a public company; and such costs are expected to further increase after we are no longer an emerging growth company.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The NASDAQ Capital Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel have had to devote a substantial amount of time to these compliance initiatives since becoming a public company. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made certain activities more time-consuming and costly.

Because we only recently became a public company, we cannot yet predict or estimate the costs we may incur in the future with respect to these compliance initiatives or the timing of such costs. In addition, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting with our second annual report to be filed with the SEC in 2016. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting

We have elected to avail ourselves of the extended transition period for adopting new or revised accounting standards.

firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We do not anticipate paying future dividends on our capital stock. We currently intend to retain all of our future earnings, as applicable, to finance the growth and development of our business. In addition, the terms

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of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We currently do not have any net operating loss carryforwards.

Net operating losses incurred by the Company as of December 31, 2013 have been used by the members to offset gains on other interests and are therefore not able to be carried forward to the Company.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements.

In some cases, you can identify forward-looking statements by terminology, such as expects, anticipates, intends, estimates, plans, believes, seeks, may, should, could, would, will or the negative of such terms or other expressions. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus.

You should read this prospectus and the documents that we reference herein and therein and have filed as exhibits to the registration statement, of which this prospectus is part, completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this prospectus is accurate as of the date on the front cover of this prospectus only. Because the risk factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements.

These risks and uncertainties, along with others, are described above under the heading Risk Factors. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of the information presented in this prospectus, and particularly our forward-looking statements, by these cautionary statements.

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USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of shares of our common stock in this offering will be approximately \$6.6 million, (or approximately \$7.7 million if the underwriters exercise their over-allotment option in full), assuming a public offering price of \$2.60 per share, which was the latest reported sale price of our common stock on the NASDAQ Capital Market on January 27, 2015, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A \$1.00 increase (decrease) in the assumed public offering price of \$2.60 per share, would increase (decrease) the net proceeds from this offering by approximately \$2.7 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We currently intend to use the net proceeds from this offering as follows:

approximately \$1.8 million to fund continued clinical development of new products and services;
approximately \$3.2 million to expand our commercialization efforts; and
approximately \$1.6 million for working capital and general corporate purposes.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments and U.S. government securities.

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MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Prior to our initial public offering, no public trades occurred in our common stock. Since June 18, 2014, our common stock has been listed on The NASDAQ Capital Market. The following table sets forth, for the periods indicated, our high and low sales prices on The NASDAQ Capital Market.

	High	Low
2015		
First Quarter ⁽¹⁾	\$ 3.88	\$ 2.29
2014		
Second Quarter ⁽²⁾	\$ 9.99	\$ 7.05
Third Quarter	\$ 9.05	\$ 4.12
Fourth Quarter	\$ 5.00	\$ 2.11

(1) From January 1, 2015 through January 28, 2015.

(2) From June 18, 2014 through June 30, 2014.

Holders

As of September 30, 2014, we had approximately four registered holders of record of our common stock. A substantially greater number of holders of our common stock are street name or beneficial holders, whose shares of record are held by banks, brokers, other financial institutions, and registered clearing agencies.

Dividend Policy

We do not anticipate paying dividends on our common stock. We currently intend to retain all of our future earnings, as applicable, to finance the growth and development of our business. We are not subject to any legal restrictions respecting the payment of dividends, except that we may not pay dividends if the payment would render us insolvent. Any future determination as to the payment of cash dividends on our common stock will be at our board of directors discretion and will depend on our financial condition, operating results, capital requirements and other factors that our board of directors considers to be relevant.

TABLE OF CONTENTS**CAPITALIZATION**

The following table sets forth our capitalization, as of September 30, 2014:

on an actual basis; and

on an as adjusted basis after giving effect to the sale of the shares of our common stock in this offering at the assumed public offering price of \$2.60 per share, which was the latest reported sale price of our common stock on the NASDAQ Capital Market on January 27, 2015, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.

You should consider this table in conjunction with Use of Proceeds, Management's Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and unaudited as adjusted financial information and related notes thereto included elsewhere in this prospectus.

	As of September 30, 2014 (unaudited)	
	Actual	As Adjusted ⁽¹⁾
Total indebtedness	\$10,597	\$10,597
Common Stock, \$0.01 par value, 50,000,000 shares authorized, 3,782,629 shares issued and outstanding, actual; 6,693,178 shares issued and outstanding, as adjusted.	37,826	66,931
Additional paid in capital	39,010,827	45,619,222
Accumulated deficit	(31,518,965)	(31,518,965)
Total stockholders' equity	7,529,688	14,167,188
Total capitalization	\$7,540,285	\$14,177,785

(1) A \$1.00 increase or decrease in the assumed public offering price of \$2.60 per share would increase or decrease total stockholders' equity and total capitalization on an as adjusted basis by approximately \$2,682,692, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions.

The number of shares of common stock that will be outstanding immediately after this offering is based on 3,782,629 shares of our common stock outstanding as of September 30, 2014 plus 25,934 shares of our common stock to be issued to an employee upon the settlement of restricted stock units that vested January 1, 2015, for an aggregate of 3,808,563 shares. The number excludes:

42,500 shares of our common stock issuable upon exercise of the warrants issued to Aegis Capital Corp. in connection with our initial public offering;

124,000 shares of our common stock issuable upon the exercise of stock options as of September 30, 2014, with a weighted average exercise price of \$4.96 per share, issued under our 2014 Stock Incentive Plan, or the Incentive Plan;

940,093 shares of our common stock reserved for issuance upon the vesting of restricted stock unit awards as of September 30, 2014 issued under our Incentive Plan;

an additional 181,306 shares of our common stock reserved for future issuance under our Incentive Plan;

144,230 shares of our common stock issuable upon exercise of the warrants to be issued to Aegis Capital Corp. in connection with this offering; and

excludes any shares of our common stock issuable upon exercise of the underwriters' over-allotment option.

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DILUTION

If you invest in our common stock in this offering, your interest will be immediately and substantially diluted to the extent of the difference between the public offering price per share of our common stock and the as adjusted net tangible book value per share of our common stock after giving effect to this offering.

Our historical net tangible book value as September 30, 2014 was \$7,529,688, or \$1.99 per share of our common stock. Net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding.

After giving effect to the sale of the shares in this offering at the assumed public offering price of \$2.60 per share, which was the latest reported sale price of our common stock on the NASDAQ Capital Market on January 27, 2015, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2014 would have been approximately \$14,167,188, or \$2.12 per share. This represents an immediate increase in as adjusted net tangible book value of approximately \$0.13 per share to our existing stockholders, and an immediate dilution of \$0.48 per share to investors purchasing shares of common stock in this offering.

Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of our common stock in this offering and the net tangible book value per share of our common stock immediately after this offering.

The following table illustrates the per share dilution to investors purchasing shares in the offering:

Assumed public offering price per share	\$ 2.60
Net tangible book value per share as of September 30, 2014	\$ 1.99
Increase per share attributable to new investors	\$ 0.13