SIGNAL GENETICS LLC
Form S-1/A
May 27, 2014

As filed with the Securities and Exchange Commission on May 27, 2014

Registration No. 333-194668

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

AMENDMENT NO. 3
TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

SIGNAL GENETICS LLC

(to be converted as described herein to
a corporation named)

SIGNAL GENETICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	8071	27-4674207

(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

Signal Genetics LLC
667 Madison Avenue, 14th Floor
New York, New York 10065
212-486-0040

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

Samuel D. Riccitelli
President and Chief Executive Officer
Signal Genetics, Inc.
667 Madison Avenue, 14th Floor
New York, New York 10065
212-486-0040

(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

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: o

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: o

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: o

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

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CALCULATION OF REGISTRATION FEE

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]	$31,353,600	$ 4,039
Representative s Warrants[4]		
Shares of Common Stock underlying Representative s Warrants[2][5]	$1,704,000	$ 220
Total	$33,057,600	$ 4,259 [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 $1,704,000, which is equal to 125% of $1,363,200 (5% of $27,264,000).

(6) The Registrant previously paid this amount in connection with the filing of this Registration Statement on March 19, 2014.

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 MAY 27, 2014

909,090 Shares
Common Stock

This is a firm commitment initial public offering of 909,090 shares of common stock by Signal Genetics, Inc. No public market currently exists for our shares. We anticipate that the initial public offering price of our shares of common stock will be between $10.00 and $12.00 per share.

We have applied to list our common stock on The NASDAQ Capital Market under the symbol SGNL. No assurance can be given that our application will be approved.

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 13 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	$	$

(1) The underwriters will receive compensation in addition to the underwriting discount. The registration statement, of which this prospectus is a part, also registers for sale warrants to purchase 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 114 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 136,363 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 , 2014.

Aegis Capital Corp

, 2014

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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

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the United States who come into possession of this prospectus 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 Company refer to Signal Genetics LLC a consolidated subsidiaries for the periods prior to the consummation of the corporate conversion (as described below), and such terms refer to Signal Genetics, Inc. and its consolidated subsidiaries for the periods after the consummation of the corporate conversion. Except as disclosed in the prospectus, the consolidated financial statements and selected historical consolidated financial data and other financial information included in this registration statement are those of Signal Genetics LLC and its subsidiaries and do not give effect to the corporate conversion. 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 123 of this prospectus.

Immediately prior to the effectiveness of the registration statement of which this prospectus is a part, we will complete a number of transactions pursuant to which Signal Genetics, Inc. will succeed to the business of Signal Genetics LLC and its consolidated subsidiaries and the members of Signal Genetics LLC will become stockholders of Signal Genetics, Inc. In this prospectus, we refer to such transactions as the corporate conversion.

Signal Genetics, Inc.

Business Overview

We are an emerging commercial stage, molecular 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. We were founded in January 2010 and became the exclusive licensee in our licensed field to the renowned research on multiple myeloma performed at the University of Arkansas for Medical Sciences, or UAMS, in April 2010.

Multiple myeloma, or 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 immunoglobins, 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 myeloma 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 leukemia and represents approximately 15% of all hematomalignancies. According to the American Cancer Society, or ACS, approximately 22,350 new cases of MM are expected to be diagnosed in the United States in 2013 and approximately 10,710 deaths from MM are expected to occur in the United States in 2013. More Americans will die from MM this year 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 77,617 people currently living with MM in the United States. The five-year survival rate for people with MM is about 43%. The ACS estimates that the lifetime risk in the United States of getting MM is 1 in 149.

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

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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 determination of the course of treatment for a patient and that patient s outlook or prognosis for recovery. 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 myeloma, including when treatment should begin and what treatments to use, based upon a patient s individual risk for relapse. However, those experts caring for MM patients have been faced with a staging system that predates the current era and a large amount of new genomic information that could assist in the staging process. The traditional approach which utilizes cytogenetic techniques, such as karyotyping and fluorescent in-situ hybridization, or FISH, for staging has not been able to accurately stage MM patients or fully assess the risk of relapse and classify MM. A more comprehensive and systematic approach is necessary to meet this unmet medical need.

Our flagship diagnostic service is the Myeloma Prognostic Risk Signature, or MyPRS®. The MyPRS® test is a microarray-based gene expression profile, or GEP, assay that tests for presence of specific groups of genes that can predict low or high level risk of early relapse. The MyPRS® test provides a whole-genomic expression profile of a person s myeloma. 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 can help make personalized treatment possible, and our MyPRS® test is the first one to be developed for multiple myeloma according to the 2007 John Shaughnessy paper in the Journal Blood. MyPRS® can be used at the time of initial myeloma diagnosis or when the patient has experienced a relapse to aid physicians in selecting the optimal treatment regime for each patient s unique condition. Specifically, the test helps allow:

risk stratification to help distinguish patients with indolent myeloma 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 myeloma sub classification that may affect the specific choice of therapies.

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 has been certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, to perform high complexity testing. We are either licensed, or not subject to licensure, and can thus perform our test using specimens collected in 49 of the 50 states. We are currently seeking a license in New York for the MyPRS® test, which would enable us to perform MyPRS® testing for patients located in New York. 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 asymptomatic monoclonal gammopathies, or AMG, the precursor conditions to MM. There is, however, currently no projected timeline for our use of MyPRS® in AMG patients. For a discussion of MyPRS® in AMG 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 a

targeted next generation gene sequencing service to assist our physician customers in further characterizing their MM patients and assisting with identifying the potential to use targeted therapies based upon the specific genetic mutations of their patients tumors. It is our intent to add such complementary services to our proprietary MyPRS® franchise to provide a more comprehensive suite of tests for our oncologist customers and their patients.

Market Opportunity

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,

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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, and in other cases can be indolent. Unfortunately, identifying those patients who will likely die of something other than their particular cancer diagnosis 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, their use has not resulted in uniformly better outcomes, such as overall survival. In part, this is because MM is a disease with significant tumor heterogeneity at the molecular level. Specialists in MM have long recognized the need for diagnostic tests that accurately identify the mutations and genotype of each patient with MM in order to allow risk stratification, predict prognosis and response to treatment. 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 have used plasma cell labeling indices, chemical markers, imaging studies and genetic abnormalities at the chromosomal level (*e.g.*, cytogenetics) to improve their ability to 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.

Unlike many forms of cancer, multiple myeloma is often asymptomatic, even in advanced stages. MM begins as a precursor condition known as monoclonal gammopathy of undetermined significance, or 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 develop MM.

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

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 at approximately 33,500 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 to more than 130,000 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 an accuracy of up to 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 myeloma 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, ten (10) issued patents and twenty-six (26) pending patent applications, 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.

There are four 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

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classification for multiple myeloma using RNA from plasma cells, methods of identifying groups of genes that can distinguish normal and multiple myeloma plasma cells by isolating RNA from CD138 positive plasma cells and identifying differentially expressed genes, methods of diagnosing multiple myeloma by examining mRNA levels or chromosomal translocations of particular genes from plasma cells, and methods of determining the prognosis of a multiple myeloma 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 several pending patent applications in the U.S. and abroad directed to other aspects of the MyPRS® test. For example, one U.S. application, along with Canadian and European counterpart applications, describes 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 person 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, in March 2011 from the Arkansas Medicare Administrative Contractor, or MAC, which at the time was Pinnacle Medical Services for MyPRS®. 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 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.

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 currently consists of one employee;

Broadening the base of healthcare insurance companies that have approved reimbursements for MyPRS®

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Expanding the diagnostic indications for MyPRS® to include AMG, the precursor condition to MM;
Establishing partnerships with other reference laboratories to expand the market reach for MyPRS®;
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 conventional tests used by physicians who care for MM patients;
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.

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 13 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.

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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 our initial public offering or our third-party collaborators terminate their relationship with us, our business may be materially harmed.

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

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

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

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

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

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.

The NASDAQ Capital Market may not list our securities for quotation on its exchange which could limit investors ability to make transactions in our securities and subject us to additional trading restrictions.

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

We have identified a material weakness in our internal control over financial reporting. If our internal control over financial reporting is not effective, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.

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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 nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

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

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise 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. In connection with the corporate conversion and this offering, Myeloma Health LLC will become a wholly-owned subsidiary of the Company. Prior to the closing of this offering, Signal Genetics LLC will convert 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 will be converted into shares of common stock of Signal Genetics, Inc., the members of Signal Genetics LLC will become stockholders of Signal Genetics, Inc. and Signal Genetics, Inc. will

succeed to the business of Signal Genetics LLC and its consolidated subsidiaries. See Corporate Conversion for further information regarding the corporate conversion.

Our principal executive offices are located at 667 Madison Avenue, 14th Floor, New York, New York 10065, and our telephone number is (212) 486-0040. We currently intend to relocate our principal executive offices to the County of San Diego, California upon completion of this offering. 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

909,090 shares (or 1,045,453 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 136,363 additional shares of our common stock to cover over-allotments, if any.

Common stock to be outstanding immediately after this offering

3,511,241 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 3,647,604.

Use of Proceeds

We intend to use the net proceeds received from this offering to fund continued clinical development of AMG indication for our MyPRS® test and for expansion of our commercial organization, the establishment of our San Diego corporate headquarters, the hiring of an executive team to manage and grow our business, including a Chief Financial Officer with public company experience and a Chief Commercial Officer, the repayment of funds advanced to us by Mr. LeBow to pay certain offering expenses, 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 46.

Representative s warrants

The registration statement of which this prospectus is a part also registers for sale warrants to purchase 45,454 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 closing of this offering at an exercise price equal to 125% of the initial 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 13 and the other information included in this prospectus for a discussion of factors you should carefully consider before investing in our securities.

Proposed symbol and listing

We have applied for listing of our common stock on The NASDAQ Capital Market under the symbol SGNL.

Unless we indicate otherwise, the number of shares of our common stock outstanding after this offering is based on the following:

the conversion of approximately $26.6 million of debt owed to certain entities controlled by Bennett S. LeBow, the Chairman of our board of directors, or the LeBow Debt (including principal and interest as of the date of this prospectus), into an aggregate of 2,420,333 Class C units, or the debt conversion;

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the consummation of the corporate conversion, pursuant to which all of the outstanding Class A and Class C units of Signal Genetics LLC will be automatically converted into an aggregate of 2,602,151 shares of our common stock;
737,881 shares of our common stock reserved for issuance upon the vesting of certain restricted stock unit awards to be issued to certain employees of the Company immediately prior to or simultaneously with this offering (including 245,645 restricted stock units, which will be immediately vested upon grant, but the common stock will not be issued until January 1, 2015); and
excludes an additional 371,091 shares of our common stock reserved for future issuance under the new equity incentive plan we intend to adopt immediately prior to this offering.

Unless specifically stated otherwise, the information in this prospectus:

assumes completion of the corporate conversion and debt conversion;
assumes no exercise by the underwriters of their option to purchase up to an additional 136,363 shares of common stock to cover over-allotments, if any;
assumes no exercise of the warrants granted to Aegis Capital Corp. upon completion of this offering; and
assumes an initial public offering price of $11.00 per share, which is the midpoint of the range set forth on the front cover of this prospectus.
assumes that the 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.

To the extent additional principal and interest on the LeBow Debt is incurred after the date of this prospectus and prior to the closing of this offering, the number of shares to be issued in connection with the debt conversion and the number of shares reserved for the restricted stock unit awards and for future issuance under the new equity incentive plan shall be adjusted accordingly.

Assuming an initial public offering price of $11.00 per share, the maximum number of shares of our common stock which shall be issued pursuant to the corporate conversion and debt conversion, which shall underly the restricted stock unit awards to be issued immediately prior to or simultaneously with this offering and which shall be reserved for future issuance under the new equity incentive plan shall in no event exceed 3,711,122 total shares.

A $1.00 decrease in the initial public offering price would result in the issuance of 2,662,366 Class C units in the debt conversion and an aggregate of 2,862,366 shares issued in the corporate conversion, comprised of 200,000 shares issued upon the conversion of the outstanding Class A units and 2,662,366 shares issued upon the conversion of the outstanding Class C units. The maximum number of shares of our common stock which would be issued pursuant to the corporate conversion and debt conversion, which would underly the restricted stock unit awards to be issued immediately prior to or simultaneously with this offering and which would be reserved for future issuance under the new equity incentive plan would in no event exceed 4,082,235 total shares.

A $1.00 increase in the initial public offering price would result in the issuance of 2,218,639 Class C units in the debt conversion and an aggregate of 2,385,305 shares issued in the corporate conversion, comprised of 166,666 shares issued upon the conversion of the outstanding Class A units and 2,218,639 shares issued upon the conversion of the outstanding Class C units. The maximum number of shares of our common stock which would be issued pursuant to the corporate conversion and debt conversion, which would underly the restricted stock unit awards to be issued immediately prior to or simultaneously with this offering and which would be reserved for future issuance under the new equity incentive plan would in no event exceed 3,401,862 total shares.

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SUMMARY HISTORICAL CONSOLIDATED FINANCIAL DATA

The following table sets forth our summary statement of operations data for the fiscal years ended December 31, 2012 and 2013 derived from our audited consolidated financial statements and related notes included elsewhere in this prospectus. The summary consolidated financial data for the year ended December 31, 2011 is derived from our audited consolidated financial statements not contained herein. The summary consolidated financial data for the three months ended March 31, 2014 and 2013, and as of March 31, 2014, are 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 year. 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.

	Three Months Ended March 31,		Year Ended December 31,		
	2014	2013	2013	2012	2011
Statement of Operations Data:					
Net revenue	$1,090,923	$1,139,388	$4,316,484	$4,406,042	$1,915,627
Operating expenses:					
Cost of revenue	663,514	668,967	2,498,940	3,042,184	2,472,390
Selling and marketing	73,070	86,100	378,769	1,325,245	530,876
General and administrative	512,325	417,830	1,788,141	2,907,947	2,589,787
Research and development	8,707	45,743	96,847	225,378	103,317
Lease abandonment				932,287	
Gain on legal settlement			(250,000)		
Total operating expenses	1,257,616	1,218,640	4,512,697	8,433,041	5,696,370
Operating loss	(166,693)	(79,252)	(196,213)	(4,026,999)	(3,780,743)
Interest expense	(539,086)	(457,904)	(1,963,456)	(1,591,341)	(561,029)
Loss from continuing operations	(705,779)	(537,156)	(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	(705,779)	(537,156)	(2,159,669)	(7,211,285)	(12,834,494)
Dividend to member unit holder of Myeloma Health LLC		(90,000)	(285,000)	(390,000)	(140,000)
Net loss attributable to member of Signal Genetics LLC	$(705,779)	$(627,156)	$(2,444,669)	$(7,601,285)	$(12,974,494)

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	As of March 31, 2014		
	Actual	Pro Forma[1]	Pro Forma, As Adjusted[2][3]
Balance Sheet Data:			
Cash and cash equivalents	$105,105	$105,105	$8,155,096
Total assets	3,495,332	3,495,332	10,563,188
Total liabilities	28,088,146	1,869,889	887,754
Total members deficiency/stockholders equity	(24,592,814)	1,625,443	9,675,434

	As of December 31, 2013		
	Actual	Pro Forma[1]	Pro Forma, As Adjusted[2][3]
Balance Sheet Data:			
Cash and cash equivalents	$209,348	$209,348	$8,359,339
Total assets	3,672,626	3,672,626	11,167,599
Total liabilities	27,559,661	1,646,125	991,107
Total members deficiency/stockholders equity	(23,887,035)	2,026,501	10,176,492

(1) The pro forma gives effect to (i) the debt conversion (based on the debt outstanding as of March 31, 2014 and as of December 31, 2013, respectively) and (ii) the corporate conversion. Common stock with respect to the vested portion of the restricted stock unit awards will not be issued until January 1, 2015 and is therefore not considered outstanding.

(2) The pro forma, as adjusted balance sheet data reflects the items described in footnote (1) above and gives effect to (i) the conversion of an additional $423,271 of LeBow Debt incurred between March 31, 2014 and the date of this prospectus for March 31, 2014 and an additional $1,055,108 of LeBow Debt incurred between January 1, 2014 and the date of this prospectus for December 31, 2013 and (ii) our receipt of estimated net proceeds from the sale of shares of common stock that we are offering at an assumed initial public offering price of the common stock of $11.00 per share, the midpoint of the price range on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. A $1.00 increase (decrease) in the assumed initial public offering price of $11.00 per share would increase (decrease) each of cash and cash equivalents, working capital, total assets, and total stockholders equity by approximately $836,000, 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.

(3) The pro forma as adjusted data is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

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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 a member of Signal Genetics LLC of $0.7 million, $2.4 million and $7.6 million for the three months ended March 31, 2014 and the fiscal years ended December 31, 2013 and 2012, respectively. From our inception in April 2010 through March 31, 2014, we had a members deficiency of $24.6 million. Losses are continuing through the date of this prospectus. We expect our losses to continue as a result of ongoing research and development expenses and increased selling and marketing costs. These losses have had, and will continue to have, an adverse effect on our working capital, total assets and members 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.

As described in Note 1 of our accompanying financial statements, our auditors have 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. 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 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 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. We may be unable to raise sufficient additional financing on terms that are acceptable to us, if at all. Our failure to raise additional capital and in sufficient amounts may significantly impact our ability to expand our business. 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 .

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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 Medicine & Medicaid Services, or CMS, which administers the Medicare program, has taken the position that the algorithm portion of multi-analyte algorithmic assays, or MAAAs, 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 polices 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 trend toward cost containment as government and private insurers seek to control health care costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Therefore, we cannot be certain that our services will be reimbursed at a level that is sufficient to meet our costs.

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 79% of our revenue for the three months ended March 31, 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 March 31, 2014, December 31, 2013 and 2012 accounted for approximately 64%, 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.

A small number of test ordering sites account for most of the sales of ourtests and services. If any of these sites orc

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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 CLIA-certified and state licensed laboratory. MyPRS® is not assigned a specific CPT code, but our local MAC and 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.

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 AMM. 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;

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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 by this IPO. 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. 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 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.

If we are unable to obtain regulatory clearance or approvals in the UnitedStates or if we experience delays in receiv

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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 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. 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 the AMG indication for our MyPRS® test. 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

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

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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 regents, or ASRs, which serve as building blocks in the diagnostic tests we conduct in our laboratory. 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, 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,

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

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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.

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 and workers compensation insurance. We intend to obtain 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.

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

If we cannot compete successfully with our competitors, we may be unable toincrease or sustain our revenues or ac

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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 recently 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 recent FDA approvals are only 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), Clarient, 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. 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.

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 three months ended March 31, 2014, our research and development expenses were $9,000, which was 0.8% of our net revenue, and our selling and marketing expenses were $73,000, which was 6.7% 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.

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

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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 after we complete our initial public offering 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 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 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. The collective

efforts of each of these persons working as a team will be 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, and our key employee, Ryan Van Laar, Ph.D., 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. We do not maintain key person insurance on any of our employees except our President and Chief Executive Officer.

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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.

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 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 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.

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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 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 continues to deteriorate, 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

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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. 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 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 the recent sequestration signed into law 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. For claims submitted with dates of service or dates of discharge after April 1, 2013, these cuts will result in Medicare payments to health care providers, health care plans and drug plans being reduced by 2%.

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

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.

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, PPACA, which makes a number of substantial changes in the way health care is financed by both governmental and private insurers. Among other things, PPACA:

Requires each medical device manufacturer to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices, beginning in 2013. This tax may apply to some or all of the current tests that we offer and other tests which are in development.

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Mandates 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 includes a productivity adjustment that reduces the Consumer Price Index, or CPI, market basket update beginning in 2011. These changes in payments apply to some or all of the clinical laboratory test services we furnish to Medicare beneficiaries.

Establishes 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 PPACA is unknown, it is likely to be extensive and may result in significant changes to coverage and reimbursement of our tests. Most of the law s provisions have already gone into effect or will go into effect in 2014. Congress has also proposed a number of legislative initiatives, including possible repeal of PPACA. At this time, it remains unclear whether there will be any changes made to PPACA, whether to certain provisions or its entirety.

PPACA, among other things, imposed cuts to the Medicare reimbursement for clinical laboratories. Medicare updates laboratory payment rates for inflation based on the CPI. PPACA includes a productivity adjustment that will reduce the CPI update. For 2014, the productivity adjustment for the CLFS is -0.8%. In addition, PPACA includes an additional 1.75 percentage points reduction in the CPI update for clinical laboratories for the years 2011 through 2015. The annual update for 2014 in CLFS rates following the productivity adjustment and reduction of 1.75 percentage points is -0.75%.

Other legislative changes have been proposed and adopted since PPACA was enacted. On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions in Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers and suppliers of 2%, starting in 2013. Subsequent annual reductions, currently scheduled for each year through 2021, are limited to 2% per fiscal year. The full impact on our business of PPACA and the new law is uncertain.

In addition, on February 22, 2012, the President signed the Middle Class Tax Relief and Job Creation Act of 2012, or MCTRJCA, 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 will serve as the base for payment rates in subsequent years.

Due to changes in the CLFS rates required by PPACA and MCTRJCA and because of sequestration, payment for clinical laboratory services have gone down by 4.89% from 2012 to 2013. In addition, unless Congress acts to end sequestration or make other changes to applicable law, payments for clinical laboratory tests will continue to be subject to reductions in 2014 and beyond. MACs have the authority to apply these cuts to locally determined payments for tests, such as MyPRS®, that are reported using unlisted CPT codes. 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.

If any of our laboratory services are paid under the Medicare Physician Fee Schedule, under the current statutory formula, the rates for these services would be updated annually. For the past several years, the application of the statutory formula would have resulted in substantial payment reductions if Congress had failed to intervene. In the

Health care policy changes, including recently enacted legislation reforming the U.S. health care system, may have

past, Congress has passed interim legislation to prevent the decreases. On November 27, 2013, CMS issued its 2014 Physician Fee Schedule Final Rule, or the 2014 Final Rule. In the 2014 Final Rule, CMS called for a reduction of approximately 20.1% in the 2014 conversion factor that is used to calculate physician reimbursement. This legislatively required reduction in physician payments was postponed until March 31, 2014, when President Obama signed into law on December 26, 2013 H.J. Res. 59,

Health care policy changes, including recently enacted legislation reforming the U.S. health care system, may have

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the Bipartisan Budget Act of 2013, which included the Pathway for the SGR Reform Act of 2013. This provided a short-term reprieve from the Medicare Physician Fee Schedule cut. The Protecting Access to Medicare Act of 2014, which was signed into law on April 1, 2014, further extended this reprieve until December 31, 2014 and provided for a zero percent update through March 31, 2015. In order to pay for the cost of eliminating or delaying the required payment reduction, Congress would have to cut spending for other programs or raise revenues. In addition, there may be unrelated legislation (e.g., resulting from budget and debt ceiling negotiations) that may require spending cuts. In either case (e.g., offsetting the cost of maintaining physician payments at their current level and/or overall Medicare payment cuts due to budget negotiations), Medicare Physician Fee Schedule payments for clinical laboratory services could be reduced. We cannot predict whether such payments cuts will occur or whether other reductions in Medicare or Medicaid spending will be enacted. If any of our tests are paid under the Medicare Physician Fee Schedule and Congress fails to act to offset legislatively required reductions in Physician Fee Schedule payments, the resulting decrease in payment could adversely impact our revenues and results of operations.

In addition, many of the CPT codes that we may use to bill our tests were recently revised by the AMA, effective January 1, 2013. The adoption of analyte specific codes will allow payors to better identify tests being performed. This could lead to limited coverage or non-coverage decisions or payment denials. In the 2014 Final Rule, CMS announced that it has decided to keep the new molecular codes on the CLFS. CMS has also announced that it will 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, it 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 given itself the authority to revise payment rates for all tests paid under the CLFS. It is anticipated that CMS will use this new authority to reduce payment for many clinical laboratory services. 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. There can be no guarantees that Medicare and other payors will establish positive or adequate coverage policies or reimbursement rates.

The Protecting Access to Medicare Act of 2014, which was signed into law on April 1, 2014, contains 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 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

Health care policy changes, including recently enacted legislation reforming the U.S. health care system, may have

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

Health care policy changes, including recently enacted legislation reforming the U.S. health care system, may have

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utilization of clinical test services. Moreover, Congress has proposed on several occasions to impose a 20% coinsurance on patients for clinical laboratory tests reimbursed under the CLFS, which would require us to bill patients for these amounts.

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

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 three months ended March 31, 2014, we derived approximately 19% of our total revenue from private insurance, including managed care organizations and other health care insurance providers, 16% from government

payor programs, most of which was derived from Medicare, and 65% from direct-bill customers, including hospitals and other laboratories. In addition, for the year ended December 31, 2013, we derived approximately 13% 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 73% 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 depend on Medicare and a limited number of private payors for asignificant portion of our revenues and if these

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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. 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. Some of our tests may be reimbursed by Medicare under the Physician Fee Schedule, which is subject to adjustment on an annual basis. Medicaid reimbursement varies by state and is subject to administrative and billing requirements and budget pressures. PPACA 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 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

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

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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.

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.

Although 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. 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 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 FDA s current policies and guidance that FDA does not require that we 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 FDA regulation but is currently exempt from pre-market review by FDA. While we believe that we are currently in material compliance with applicable laws and regulations, we cannot assure you that 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, 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, FDA announced a public meeting to discuss the agency s oversight of LDTs

Complying with numerous regulations pertaining to our business is anexpensive and time-consuming process, and

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. 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 FDA adopts. The public meeting was held in July 2010 and further public comments were submitted to FDA through September 2010. FDA has stated it is continuing to develop draft guidance in this area. Section 1143 of the Food and Drug Administration Safety and Innovation Act, signed by

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the U.S. President on July 9, 2012, requires FDA to notify U.S. Congress at least 60 days prior to issuing a draft or final guidance regulating LDTs and provide details of the anticipated action.

We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our tests, whether through additional guidance issued by FDA, new enforcement policies adopted by FDA or new legislation enacted by Congress. We believe it is possible that legislation will be enacted into law or guidance could be issued by 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 Health and Human Services, or 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. FDA could require that we stop selling our tests pending pre-market clearance or approval. If 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 FDA or if the labeling claims 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 FDA. If 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 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 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

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

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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 PPACA, 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 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 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, PPACA 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, PPACA narrowed the public disclosure bar under the False Claims Act, allowing increased opportunities for

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

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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. PPACA 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. PPACA 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 healthcare 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 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 PPACA, 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

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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.

HIPAA includes a health care fraud provision prohibiting knowingly and willfully executing a scheme or artifice to defraud any healthcare 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

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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, (i) establishing an affirmative obligation to provide patient data breach notification in the event of the unauthorized acquisition, access, use or disclosure of unsecured PHI; (ii) elaborating upon the standard for minimum necessary uses and disclosures of PHI by a covered entity (iii) restricting certain uses of PHI for marketing purposes (by expanding the definition of marketing activities requiring authorization); (iv) prohibiting certain sales of PHI; (v) establishing an affirmative obligation to provide an accounting of disclosures made for payment, treatment and health care operations (up to 3 years made through an electronic health record); (vi)

requiring covered entities to agree to individuals requests to restrict disclosure of PHI in certain circumstances; (vii) applying the security regulations and certain provisions of the privacy regulations to business associates; and (viii) modifying an individuals 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 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

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3 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, of 10 issued U.S. patents and 26 pending patent applications, which include both U.S. and foreign patent applications, relating to various aspects of our technology. Of the 26 pending patent applications, six are owned outright by Signal Genetics, LLC. Our exclusive field of use covers, inter alia, therapeutic, diagnostic, 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

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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 . 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. 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 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 rights to use technologies licensed from third parties are not fully within our control, and we may not be able to

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

Our rights to use technologies licensed from third parties are not fully within our control, and we may not be able to

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we cannot obtain such licensed rights on reasonable terms. In particular, we in-license a portfolio of issued U.S. patents and pending U.S. and foreign 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, (i) these licenses terminate; (ii) 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; (iii) if the licensed patents or other intellectual property rights are found to be invalid or (iv) 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.

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 may be subject to claims by third parties asserting that our employees orwe have misappropriated their intellect

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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

Following the offering, we will be classified as a controlled company, and will qualify for exemptions from certain corporate governance requirements. Despite the availability of these exemptions, we have agreed with the underwriters that we will not rely on these exemptions for a period of two years following the offering. 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, will continue to control more than 50% of the outstanding voting power of our common stock following the offering, we will be classified as a controlled company within the meaning of the applicable stock exchange corporate governance standards. Under the rules of the NASDAQ Global Select Market, or NASDAQ, 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.

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Our majority stockholder will have the ability to control significant corporate activities after the completion of this offering and 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.

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 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:

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

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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 initial public offering price of our common stock will be substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. To the extent additional shares of common stock are subsequently issued, you will incur further dilution. Based on an assumed initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of $8.24 per share, representing the difference between our pro forma net tangible book value per share, after giving effect to this offering, and the assumed initial public offering price. In addition, purchasers of common stock in this offering will have contributed approximately 25.9% of the aggregate price paid by all purchasers of our stock but will own only approximately 25.9% of our common stock outstanding after this offering.

The NASDAQ Capital Market may not list our securities for quotation on its exchange which could limit investors ability to make transactions in our securities and subject us to additional trading restrictions.

We anticipate that our securities will be listed on The NASDAQ Capital Market, a national securities exchange, upon consummation of this offering. Although, after giving effect to this offering, we expect to meet, on a pro forma basis, The NASDAQ Capital Market s minimum initial listing standards, which generally mandate that we meet certain requirements relating to stockholders equity, market capitalization, aggregate market value of publicly held shares and distribution requirements, we cannot assure you that we will be able to meet those initial listing requirements. If The NASDAQ Capital Market does not list our securities for trading on its exchange, we could face significant material adverse consequences, including:

a limited availability of market quotations for our securities;

reduced liquidity with respect to our securities;

a determination that our shares of common stock are penny stock which will require brokers trading in our shares of common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our shares of common stock;

a limited amount of news and analyst coverage for our company; and

a decreased ability to issue additional securities or obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as covered securities. Because we expect that our common stock will be listed on The NASDAQ Capital Market, our common stock will be covered securities. Although the states are preempted from regulating the sale of covered securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. 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.

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

If after listing 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

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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 bid price requirement or prevent future non-compliance with NASDAQ s listing requirements.

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 drops to less than $5.00, our common stock will be deemed penny stocks. 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 (i) the purchaser s written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) 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 this offering, there has been no public market for our common stock. The initial public offering price for our common stock will be determined through negotiations with the underwriters. Although we have applied to have our common stock approved for listing on The NASDAQ Capital Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult for you to sell shares you purchase in this offering 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 initial public offering price. The market price for our common stock may be influenced by many factors, including:

- 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.

The price of our common stock may be volatile and fluctuate substantially,which could result in substantial losses fo

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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 180 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.

All of the 2,602,151 shares of common stock may be sold in the public market by existing stockholders on or about 181 days after , 2014, subject to volume and other limitations imposed under the federal securities laws. Sales of substantial amounts of our common stock in the public market after the completion of this offering, or the perception that such sales could occur, could adversely affect the market price of our common stock and could materially impair our ability to raise capital through offerings 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;

reduced disclosure obligations regarding executive compensation; and

exemptions from the requirements of holding a nonbinding 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

We are an emerging growth company, and the reduced disclosurerequirements applicable to emerging growth co

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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.

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.

We will incur increased costs as a result of operating as a public company, particularly once we cease to be an emerging growth company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will 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 will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. 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. 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 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.

We will incur increased costs as a result of operating as a public company,particularly once we cease to be an eme

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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, if any, to finance the growth and development of our business. In addition, the terms 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.

We have identified a material weakness in our internal control over financial reporting. If our internal control over financial reporting is not effective, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.

In connection with the audit of the Company s consolidated financial statements as of and for the years ended December 31, 2013 and 2012 and our expanded reporting requirements related to this filing, we identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weakness identified was due to a lack of accounting and finance personnel and the reliance on outside consultants. As such, our controls over financial reporting were not designed or operating effectively, and as a result there were adjustments required in connection with closing our books and records and preparing our December 31, 2013 and 2012 consolidated financial statements that were made by outside consultants.

In response to this material weakness, we plan to hire additional personnel with public company financial reporting expertise to build our financial management and reporting infrastructure, and further develop and document our accounting policies and financial reporting procedures. However, we cannot assure you that we will be successful in pursuing these measures or that these measures will significantly improve or remediate the material weakness described above. We also cannot assure you that we have identified all of our existing material weaknesses, or that we will not in the future have additional material weaknesses. We have not yet remediated our material weakness, and the remediation measures that we intend to implement may be insufficient to address our existing material weakness or to identify or prevent additional material weaknesses.

Neither we nor our independent registered public accounting firm has performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. It is possible that, had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, material weaknesses or significant control deficiencies may have been identified. However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with

the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

If we fail to remediate the material weakness or to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results, or report them within the timeframes required by law or stock exchange regulations. Failure to comply with Section 404 of the Sarbanes-Oxley Act could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. There is no assurance that we will be able to remediate the material weakness in a timely manner, or at all, or that in the future, additional material weaknesses will not exist or otherwise be discovered. If our efforts to remediate a material weakness are not successful, or if other material weaknesses or other deficiencies occur, our ability to accurately and timely report our financial position could be impaired, which could result in late filings of our annual and quarterly reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, restatements of our consolidated financial statements, a decline in our stock price, suspension or delisting of our common stock from the NASDAQ Capital Market, and could adversely affect our reputation, results of operations and financial condition.

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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 oth 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 $7.9 million, (or approximately $9.3 million if the underwriters exercise their over-allotment option in full), assuming an initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and after repaying or redeeming the $1.0 million of debt or preferred stock, as the case may be, to be delivered to LeBow Alpha in connection with the debt conversion, and pursuant to the terms of the Exchange Agreement, as consideration for the $1.0 million previously advanced to the Company to pay for certain offering expenses. See Certain Relationships and Related Transactions for additional information regarding the Exchange Agreement.

A $1.00 increase (decrease) in the assumed initial public offering price of $11.00 per share, would increase (decrease) the net proceeds from this offering by approximately $0.8 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 $1.4 million to fund continued clinical development of AMG indication for our MyPRS® test;
approximately $2.3 million to expand our commercialization efforts;
approximately $1.2 million to establish our San Diego corporate headquarters;
approximately $1.4 million to enhance our executive team to manage and grow our business, including a Chief Financial Officer with public company experience and a Chief Commercial Officer; 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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DIVIDEND POLICY

We do not anticipate paying dividends on our common stock. We currently intend to retain all of our future earnings, if any, 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.

CORPORATE CONVERSION

In connection with this offering, our board of directors and the holder of a majority of our outstanding units will elect to convert Signal Genetics LLC from a Delaware limited liability company to a Delaware corporation. In order to consummate such a conversion, a certificate of conversion will be filed with the Secretary of State of the State of Delaware prior to the effectiveness of the registration statement of which this prospectus is a part. In connection with the corporate conversion, all outstanding Class A and Class C units of Signal Genetics LLC will be automatically converted into an aggregate of 2,602,151 shares of common stock of Signal Genetics, Inc. No U.S. federal taxable income or taxable gain is expected to be recognized by Signal Genetics, Inc. as a result of our conversion from a limited liability company to a corporation.

A $1.00 decrease in the initial public offering price would result in an aggregate of 2,862,366 shares being issued in the corporate conversion. A $1.00 increase in the initial public offering price would result in an aggregate of 2,385,305 shares being issued in the corporate conversion.

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CAPITALIZATION

The following table sets forth our capitalization, as of March 31, 2014:

on an actual basis;
on a pro forma basis to give effect to the debt conversion and the corporate conversion as if they had occurred on March 31, 2014; and
on a pro forma as adjusted basis after giving effect to the debt conversion, the corporate conversion and the vesting of 245,645 restricted stock units issued to certain employees of the Company simultaneously with this offering as if they had occurred on March 31, 2014, as adjusted for (i) the conversion of an additional $423,271 of LeBow Debt incurred between March 31, 2014 and the date of this prospectus and (ii) the sale of the shares of our common stock in this offering at the assumed public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. Common stock with respect to the vested portion of the restricted stock unit awards will not be issued until January 1, 2015 and is therefore not considered outstanding.

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 pro forma financial information and related notes thereto included elsewhere in this prospectus.

	As of March 31, 2014 (unaudited)		
	Actual	Pro Forma	Pro Forma, As Adjusted[1]
Total Indebtedness	$27,226,777	$1,008,520	$26,385
Class A units, no par value; 100,000 authorized and 72,500 issued and outstanding, actual; no Class A Units issued and outstanding, pro forma; and no shares issued and outstanding, pro forma as adjusted.	2,000,000 [2]		
Class B units, no par value; 50,000 authorized and 41,088 issued and outstanding, actual; no Class B units issued and outstanding, pro forma; and no Class B units issued and outstanding, pro forma as adjusted.			
Common Stock, $0.01 par value, 50,000,000 shares authorized, no shares issued and outstanding, actual; 2,565,296 shares issued and outstanding, pro forma; 3,511,241 shares issued and outstanding, pro forma, as adjusted.		25,653	35,112
Additional paid in capital		28,192,604	39,208,502
Accumulated deficit		(26,592,814)	(29,568,180)
Members deficiency (excluding Class A Units)	(26,592,814)		
Total members deficiency/stockholders equity	(24,592,814)	1,625,443	9,675,434
Total capitalization	$2,633,963	$2,633,963	$9,701,819

(1) A $1.00 increase or decrease in the assumed initial public offering price of $11.00 per share would increase or decrease total stockholders equity and total capitalization on a pro forma as adjusted basis by approximately $836,000, 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.

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(2) This amount represents the capital contribution made by LeBow Alpha LLLP for Class A units, which has been broken out separately for the purposes of the capitalization table; however it is a component of the Company s members deficiency.

The number of shares of common stock that will be outstanding immediately after this offering is based on the number of shares of common stock outstanding immediately prior to this offering after giving effect to the debt conversion and the corporate conversion. The number excludes:

737,881 shares reserved for the restricted stock unit awards to be issued to certain employees immediately prior to or simultaneously with the offering (including 245,645 restricted stock units, which will be immediately vested upon grant, but the common stock will not be issued until January 1, 2015);

371,091 shares of our common stock reserved for future issuance under the new equity incentive plan we intend to adopt immediately prior to this offering; and

45,454 shares of our common stock issuable upon exercise of the warrants granted to Aegis Capital Corp. upon completion of this offering.

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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 pro forma net tangible book value per share of our common stock after giving effect to this offering.

Our historical net tangible book value as March 31, 2014 was $(24,592,814). Historical net tangible book value per share as of March 31, 2014 has not been provided due to the fact that at March 31, 2014 we were a limited liability company and did not have shares of Common Stock outstanding.

Our pro forma net tangible book value as of March 31, 2014 was $1,625,443, or $0.63 per share of our common stock. Pro forma net tangible book value per share represents the amount of our total tangible assets less our total liabilities, divided by the pro forma number of shares of our common stock outstanding as of March 31, 2014, which includes 2,565,296 shares after giving effect to the corporate conversion and debt conversion.

After giving effect to (i) the conversion of an additional $423,271 of LeBow Debt incurred between March 31, 2014 and the date of this prospectus and (ii) the sale of the shares in this offering at the assumed initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us, our pro forma as adjusted net tangible book value at March 31, 2014 would have been approximately $9,675,434, or $2.76 per share. This represents an immediate increase in pro forma net tangible book value of approximately $2.13 per share to our existing stockholders, and an immediate dilution of $8.24 per share to investors purchasing shares of common stock in this offering.

Dilution in pro forma 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 pro forma 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 initial public offering price per share		$ 11.00
Pro forma net tangible book value per share as of March 31, 2014	$ 0.63	
Increase in pro forma net tangible book value per share attributable to new investors	2.13	
Pro forma as adjusted net tangible book value per share after this offering		2.76
Dilution per share to new investors		$ 8.24

If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value will increase to $3.03 per share, representing an immediate dilution of $7.97 per share to new investors, assuming that the initial public offering price will be $11.00 per share, which is the midpoint of the range set forth on the cover page of this prospectus.

A $1.00 increase (decrease) in the assumed initial public offering price of $11.00 per share would increase (decrease) the pro forma as adjusted net tangible book value by approximately $836,000, the pro forma as adjusted net tangible book value per share by $0.23 per share, and the dilution in pro forma as adjusted net tangible book value per share to investors in this offering by $0.77 per share, 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.

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The following table summarizes, on a pro forma as adjusted basis as of March 31, 2014 (taking into account the conversion of the additional $423,271 of LeBow Debt incurred between March 31, 2014 and the date of this prospectus), the differences between the number of shares of common stock purchased from us, the total consideration and the average price per share paid by existing stockholders and by investors participating in this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses, at an assumed public offering price of $11.00 per share, the midpoint of the estimated price range of this prospectus.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	%	Amount	%	
Existing stockholders	2,602,151	74.1 %	$ 28,623,661	74.1 %	$ 11.00
New investors	909,090	25.9	9,999,990	25.9	11.00
Total	3,511,241	100.0 %	$ 38,623,651	100.0 %	$ 11.00

The number of shares of common stock that will be outstanding immediately after this offering is based on 2,602,151 shares of common stock outstanding immediately prior to this offering after giving effect to the debt conversion and the corporate conversion. The number excludes:

737,881 shares reserved for the restricted stock unit awards to be issued to certain employees immediately prior to or simultaneously with the offering;

371,091 shares of our common stock reserved for future issuance under the new equity incentive plan we intend to adopt immediately prior to this offering; and

45,454 shares of our common stock issuable upon exercise of the warrants granted to Aegis Capital Corp. upon completion of this offering.

If the underwriters exercise their over-allotment option in full, the number of shares held by new investors will increase to 1,045,453, or 28.7% of the total number of shares of common stock outstanding after this offering and the shares held by existing stockholders will be 2,602,151 but the percentage of shares held by existing stockholders will decrease to 71.3% of the total shares outstanding.

To the extent that the underwriters over-allotment option is exercised or any warrants or options are exercised, there will be further dilution to new investors.

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

The following discussion and analysis should be read together with our financial statements and the related notes appearing elsewhere in this prospectus. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. See Forward-Looking Statements for a discussion of the uncertainties, risks and assumptions associated with these statements. Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under Risk Factors and elsewhere in this prospectus.

Overview

We are an emerging commercial stage, molecular 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.

We were founded in January 2010 and became the exclusive licensee in our licensed field to the renowned research on multiple myeloma performed at UAMS in April 2010. Our flagship service offering is the Myeloma Prognostic Risk Signature, or MyPRS®, test. The MyPRS® test is a microarray-based gene expression profile, or GEP, assay that tests for presence of specific groups of genes that can predict low or high level risk of early relapse in patients suffering from MM. The information provided by the MyPRS® test aids physicians in selecting the optimal treatment regime for each patient s unique MM condition.

To our knowledge, we are the only company marketing a GEP test for assessing the status of MM in the United States. The MyPRS® test is protected by a substantial patent portfolio of issued and pending patents. Our proprietary estate consists of 10 issued patents and 26 pending patent applications, many of which protect and defend our exclusive ability to market the MyPRS® test as well as additional proprietary tests and treatments.

According to the American Cancer Society, ACS, and the National Cancer Institute, NCI, MM represents 1% of all cancers, 2% of all cancer related deaths and is the second most common blood cancer after leukemia representing approximately 15% of all hematomalignancies. Approximately 22,350 new cases of MM are expected to be diagnosed in the United States in 2013 and there are an estimated 77,617 people currently living with MM in the United States. The five-year survival rate for people with MM is about 43%. Additionally, MM begins as a precursor condition known as monoclonal gammopathy of undetermined significance, or MGUS. It is estimated that more than 3% of the population of the United States 50 years of age or older have MGUS. MGUS is not itself harmful to health. But every year, 1% of MGUS patients will develop MM. Aside from the precursor condition MGUS, MM exists on a spectrum from asymptomatic or smoldering multiple myeloma, or AMM, to full-blown MM. Collectively, these precursor conditions, MGUS and AMM are referred to as asymptomatic monoclonal gammopathy or AMG. Today it is not possible to accurately predict which of the more than 3 million patients with an AMG diagnosis will convert to full blown MM. The risk of AMG progressing to MM is between 1% to 10% per year. A recent peer-reviewed publication demonstrated that our MyPRS® test was an independent predictor of the risk of progression from AMG to clinical MM. Further clinical study replicating these results will likely be necessary to enable broad market acceptance for the use of MyPRS® in MM precursor conditions. Nonetheless, the applicability of our test for use in predicting MM

progression from AMG could potentially create a substantial increase in the patient population eligible for MyPRS® testing and as such represents an important pillar of our growth strategy. We estimate the total MM testing market at approximately 33,500 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 to more than 130,000 patients per year. *[Multiple Myeloma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up , Annals of Oncology, Moreau et al, 00:1-5, 2013 doi:10.1093/annonc/mdt297]*

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Our growth strategy includes the following key elements:

Expand the U.S. market penetration of our MyPRS® test by increasing the geographic coverage of our sales force which currently consists of one employee.

Broaden the base of health care insurance companies that have approved reimbursements for MyPRS®.

Expand the diagnostic indications for MyPRS® to include AMG, the precursor condition to MM.

Establish partnerships with other reference laboratories to expand the market reach for MyPRS®.

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

Expand our information technology infrastructure to further improve our customer service experience.

Continue to leverage our relationship with UAMS via our exclusive license agreement.

Expand our test offering with the addition of conventional tests used by physicians who care for MM patients.

Pursue additional collaborations and in-licensing to expand our service offering.

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

Our revenue is derived primarily from our laboratory testing services, and in particular from our MyPRS® testing services. We also derive a significant portion of our revenues from payments or reimbursements received from various payors, including Medicare, contracted insurance companies, directly billed customers (UAMS, pharmaceutical companies, reference laboratories and hospitals) and non-contracted insurance companies.

We believe a key challenge to achieving our growth strategy will be our ability to become contracted with additional payors beyond Medicare and Arkansas Blue Cross Blue Shield. In order to broaden our coverage policy approval to include a majority of the major health care insurance providers in the United States, we plan to hire experienced managed care professionals who can assist us with gaining contractual agreements with third-party payors. MyPRS® has been studied extensively and there are more than 30 peer-reviewed scientific publications that describe the validity and utility of the test. MyPRS® is one of the most extensively validated genomic assays available today. The MyPRS® assay has been validated on patient cohorts totaling over 4,500 patients, detailed in 17 peer-reviewed publications. Please visit our website at *www.signalgenetics.com* in the Publications section under the Physician Resources tab for a list of these publications. We intend to use these publications to create the clinical dossier that supports reimbursement approval by the majority of health care payors.

Other challenges to our growth strategy include: (1) the acceptance of our tests by the oncology community. For example, if medical oncologists do not adopt the use of MyPRS® to evaluate the risk of developing MM in patients with AMG, our growth strategy could be adversely affected, (2) if other tests that more accurately predict the severity of MM, the risk of progression of AMG to MM or the likelihood of response to therapy, are developed, physicians could stop ordering MyPRS®, adversely affecting our ability to generate revenue, and (3) payors, including our currently contracted payors, could reduce payment for MyPRS®.

Sources of Revenues and Expenses

Revenues

We generate revenues primarily from the completion of assays processed through our CLIA certified laboratory under a specified contractual protocol. During the three months ended March 31, 2014 and the years ended December 31, 2013 and 2012, the Company had one major customer, UAMS. Revenue sourced either from or through UAMS accounted for approximately 79%, 83% and 86%, respectively, of net revenue.

A significant portion of our revenues consist of payments or reimbursements received from various payors, including Medicare, contracted insurance companies, directly billed customers (UAMS, pharmaceutical

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companies, reference laboratories and hospitals) and non-contracted insurance companies. We report revenues from contracted payors and directly billed customers based on the contractual rate. Revenues from non-contracted payors are reported based on the amount expected to be collected, which is based on the historical collection experience of each payor or payor group, as appropriate. Our estimates of net revenue are subject to change based on the contractual status and payment policies of 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.

Cost of Revenue

Our cost of revenue consists primarily of the cost of materials, direct labor, costs associated with processing specimens including pathological review, quality control analyses, delivery charges necessary to render an individualized test result and depreciation and amortization expense. Costs associated with performing tests are recorded as the tests are processed.

Selling and marketing expenses

Our selling and marketing expenses consist primarily of sales commissions and support costs, salaries and related employee benefits, travel, license fees and marketing costs.

General and administrative expenses

Our general and administrative expenses consist primarily of salaries and related employee benefits, professional service fees and associated travel costs.

Research and development expenses

Our research and development expenses primarily include laboratory supplies, reagents, and consulting costs associated with developing and validating new testing services.

Interest expense

Interest expense primarily reflects interest on the notes payable to the related party.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosures in the financial statements. Critical accounting policies are those accounting policies that may be material due to the levels of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change, and that have a material impact on financial condition or operating performance. While we base our estimates and judgments on our experience and on various other factors that we believe to be reasonable under the circumstances, actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies used in the preparation of our financial statements require significant judgments and estimates. For additional information relating to these and other accounting policies, see Note 2 to our audited financial statements, appearing elsewhere in this prospectus.

Revenue Recognition

We recognize revenue from testing services in accordance with the Financial Accounting Standards Board Accounting Standards Codification, or FASB ASC, 605, *Revenue Recognition*, which requires that four basic criteria be met before revenue can be recognized: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred and title and the risks and rewards of ownership have been transferred to the client or services have been rendered; (3) the price is fixed or determinable; and (4) collectability is reasonably assured. The Company records revenues when the tests have confirmed results which are evidence that the services have been performed. Revenues are recorded on an accrual basis as the contractual obligations are completed and as a set of assays is processed through our laboratory under a specified contractual protocol. Revenues are billed to various payors, including Medicare, contracted insurance companies, directly billed customers (UAMS, pharmaceutical companies, reference laboratories and hospitals) and non-contracted insurance companies. The Company reports revenues from Medicare, contracted insurance companies and directly billed customers based on the contractual rate. The contractual rate is based on established, agreed

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upon rates between the Company and the respective payor and is the price invoiced by the Company. The Company reports revenues from non-contracted payors based on the amount expected to be collected which is based on the historical collection experience of each payor or payor group, as appropriate. The difference between the amount billed and the amount estimated to be collected from non-contracted payors is recorded as a contractual allowance at the same time the revenue is recognized, to arrive at reported net revenue. We do not record revenue from individuals for billings, deductibles or co-pays until cash is collected as collectability is not assured at the time services are provided, therefore there are no accounts receivable from self-payors. Gross revenues from individuals have been immaterial.

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. We regularly review our historical collection experience for non-contracted payors and adjust our expected revenues for current and subsequent periods accordingly. During the year ended December 31, 2012, we did not make any adjustments to our original revenue estimates for 2011, our first year of operations. During the year ended December 31, 2013 we recorded a change in estimate related to non-contracted revenues recorded during 2012 of $57,000 which caused a decrease in overall net revenue in 2013. This represented 6% of total non-contracted revenues during 2012 and 1% of our total net revenue for 2012. Results for the three months ended March 31, 2014 were similar to the year ended December 31, 2013. If we have a similar percentage reduction of 6% in our estimated amount to be collected from non-contracted payors on the uncollected accounts receivable from non-contracted payors at March 31, 2014 of $594,000, this could result in a $36,000 change in our financial position and results of operations.

Accounts Receivable and Allowance for Doubtful Accounts

We record accounts receivable net of an alowance for doubtful accounts. We estimate an allowance for doubtful accounts based on the aging of the accounts receivable and our historical collection experience for each type of payor. We have not had any bad debts from any of our contracted customers or noncontracted insurance companies, therefore there is no allowance for doubtful accounts recorded as of March 31, 2014, December 31, 2013 and 2012.

The following tables present our gross accounts receivable from customers outstanding by aging category reduced by total contractual allowances to arrive at the net accounts receivable balance at March 31, 2014 and December 31, 2013. Other than our direct bill customers, all of our receivables were pending approval by third-party payors as of the date that the receivables were recorded:

	March 31, 2014				
	0-30 Days	31-60 Days	61-90 Days	Over 90	Total
Medicare	$ 33,713	$ 29,967	$ 6,606	$ 105,299	$ 175,585
Contracted insurance companies	24,000	16,000		84,693	124,693
Direct bill	283,969	18,470			302,439
Non-contracted insurance companies	129,402	96,603	104,950	1,416,215	1,747,170
	471,084	161,040	111,556	1,606,207	2,349,887
Less: Contractual allowances	68,533	52,140	57,604	997,887	1,176,164
Accounts receivable, net	$ 402,551	$ 108,900	$ 53,952	$ 608,320	$ 1,173,723

	December 31, 2013				
	0-30 Days	31-60 Days	61-90 Days	Over 90	Total
Medicare	$ 20,602	$ 41,204	$ 19,799	$ 86,876	$ 168,481
Contracted insurance companies	20,000	10,000	14,000	54,352	98,352
Direct bill	185,064	13,220	19,570		217,854
Non-contracted insurance companies	67,150	114,550	126,400	1,245,367	1,553,467
	292,816	178,974	179,769	1,386,595	2,038,154
Less: Contractual allowances	35,952	70,426	73,886	863,880	1,044,144
Accounts receivable, net	$ 256,864	$ 108,548	$ 105,883	$ 522,715	$ 994,010

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	December 31, 2012				
	0-30 Days	31-60 Days	61-90 Days	Over 90	Total
Medicare	$ 4,148	$ 4,158	$ 8,607	$ 48,576	$ 65,489
Contracted insurance companies	4,750	6,320	1,580	147,296	159,946
Direct bill	293,682	282,287	45,090	30,624	651,683
Non-contracted insurance companies	75,050	103,375	57,369	691,154	926,948
	377,630	396,140	112,646	917,650	1,804,066
Less: Contractual allowances	54,197	65,247	42,046	446,977	608,467
Accounts receivable, net	$ 323,433	$ 330,893	$ 70,600	$ 470,673	$ 1,195,599

The days sales outstanding for the three months ended March 31, 2014 and the years ended December 31, 2013 and 2012 was 89, 89 and 101 days, respectively. The decrease in the number of days during 2013 is primarily due to an improvement in our internal billing processes as well as the collection rates from third-party providers. During 2013, we discovered inefficiencies in our communication processes with third-party payors which related to revenues from non-contracted insurance companies during 2012 and early 2013. Once discovered, we corrected these inefficiencies and delivered a large quantity of requested documents to our third-party payors which we now believe will result in our ability to fully collect on those revenues. In addition, now that these processes have been improved we do not anticipate this type of delay in our future collections from third-party payors.

Equity Incentive Compensation

We recognize compensation expense in an amount equal to the estimated grant date fair value of each stock award over the estimated period of service and vesting. This estimation of the fair value of each stock-based grant or issuance on the date of grant involves numerous assumptions by management. The use of different values by management in connection with these assumptions could produce substantially different results.

Impairment of Long-Lived Assets

Our management reviews our long-lived assets with finite useful lives for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. We recognize an impairment loss when the sum of the future undiscounted net cash flows expected to be realized from the asset is less than its carrying amount. If an asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value. Considerable judgment is necessary to estimate the fair value of the assets and accordingly, actual results could vary significantly from such estimates. Our most significant estimates and judgments relating to the long-lived asset impairments include the timing and amount of projected future cash flows.

Accounting for Income Taxes

Deferred income taxes result primarily from temporary differences between financial and tax reporting. Deferred tax assets and liabilities are determined based on the difference between the financial statement basis and tax basis of assets and liabilities using enacted tax rates. Future tax benefits are subject to a valuation allowance when management is unable to conclude that our deferred tax assets will more-likely-than-not be realized from the results of operations. Our estimate for the valuation allowance for deferred tax assets requires management to make significant estimates and judgments about projected future operating results. If actual results differ from these projections or if management s expectations of future results change, it may be necessary to adjust the valuation allowance.

Recent Accounting Pronouncements

We have reviewed all recently issued standards and have determined they will not have a material impact on our financial statements or do not apply to our operations.

Future Accounting Pronouncements

Section 107 of the JOBS Act provides that an emerging growth company, such as our company, can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would

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otherwise apply to private companies. Although to date, we have not yet taken advantage of this delay, we have elected to avail ourselves of this extended transition period for adopting new or revised accounting standards in the future. 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. In the future, we may elect to opt out of the extended period for adopting new or revised accounting standards. If we do so, we will be required to disclose such decision, which will be irrevocable.

Results of Operations

Three Months Ended March 31, 2014 Compared to Three Months Ended March 31, 2013

Revenue

Revenue was $1,090,923 for the three months ended March 31, 2014, a decrease of $48,465 or 4.3% compared to $1,139,388 for the same period in 2013. The decrease in revenue was due to a combination of the following:

- A $72,415 decrease in revenue sourced either from or through our major customer, UAMS. This revenue consisted of a 19% decrease in tests performed during the three months ended March 31, 2014 as compared to the same period in 2013 (741 tests performed in 2014 versus 910 tests performed in 2013). The average sales price per test also increased by $136.37 primarily due to the mix in both the type of test being performed (research versus clinical) and the type of payor category.

An increase of $19,755 in revenue sourced from non-UAMS customers that included a 62% decrease in revenue from pharmaceutical companies due to the completion of a clinical study in 2013 ($32,313 decrease) and an increase from other hospitals outside of UAMS of 33% ($52,068 increase). These revenues resulted from a 23% increase in the number of tests performed during the three months ended March 31, 2014 as compared to the same period in 2013 (125 tests performed in 2014 versus 102 tests performed in 2013). This increase in volume also included a decrease of 13 tests for pharmaceutical companies due to the completion of the clinical study in 2013. Additionally, we experienced a decrease in average selling price per test of $219.95. The decrease in average selling price is primarily due to completion of the clinical study in 2013 which had a higher average selling price per test.

Cost of revenue

Cost of revenue was $663,514 (61% of sales) for the three months ended March 31, 2014, a decrease of $5,453 or 0.8%, compared to $668,967 (59% of sales) for the same period in 2013. The primary reason for the increased percentage of sales was due to fixed costs that do not vary with revenue.

Selling and marketing expenses

Selling and marketing expenses were $73,070 for the three months ended March 31, 2014, a decrease of $13,030, or 15.1%, compared to $86,100 in the same period in 2013. The primary reason for the decrease in selling and marketing expenses was due to a reduction of our sales staff. As discussed below under the caption Business Our Growth Strategy, we plan to expand our sales force and marketing expenditures once we complete this offering.

General and administrative expenses

General and administrative expenses were $512,325 for the three months ended March 31, 2014, an increase of $94,494, or 22.6%, compared to $417,830 in the same period in 2013. The primary reasons for the increase were due to $46,000 which resultead from a change in estimate due to a termination agreement signed with the landlord for a previously abandoned lease and $25,000 of additional consulting fees.

Research and development expenses

Research and development expenses were $8,707 for the three months ended March 31, 2014, a decrease of $37,036, or 81.0%, compared to $45,743 in the same period in 2013. The primary reason for the decrease in research and development expenses was due to the abandonment of certain research projects that were deemed to not be viable.

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In the future, we expect research and development expenses to increase as we work to develop additional diagnostic tests and add indications to our MyPRS® test. We cannot estimate the amounts we will need to invest in order to achieve the new indications or new tests, nor do we know if we will be successful in these endeavors.

Interest expense

Interest expense was $539,086 for the three months ended March 31, 2014, compared to $457,904 in the same period in 2013. The primary reason for the increase was due to increased borrowings on our note payable to the related party.

Net loss attributable to member of Signal Genetics LLC

For the foregoing reasons, we had a net loss attributable to member of Signal Genetics LLC of $(705,779) for the three months ended March 31, 2014 compared to a net loss attributable to member of Signal Genetics LLC of $(627,156) for the three months ended March 31, 2013.

Year Ended December 31, 2013 Compared to Year Ended December 31, 2012

Revenue

Revenue was $4,316,484 for the year ended December 31, 2013, a decrease of $89,558 or 2.0% compared to $4,406,042 for the same period in 2012. The decrease in revenue was due to a combination of the following:

A $186,137 decrease in revenue sourced either from or through our major customer, UAMS. This revenue consisted of a 2% decrease in tests performed during the year ended December 31, 2013 as compared to the same period in 2012 (3,435 tests performed in 2013 versus 3,492 tests performed in 2012). The average sales price per test also decreased by $36.27 primarily due to the mix in both the type of test being performed (research versus clinical) and the type of payor category.

An increase of $96,579 in revenue sourced from non-UAMS customers that included a 63% decrease in revenue from pharmaceutical companies due to the completion of a clinical study in 2013 ($190,813 decrease) and an increase from other hospitals outside of UAMS of 86% ($287,392 increase). These revenues resulted from a 10% increase in the number of tests performed during the year ended December 31, 2013 as compared to the same period in 2012 (383 tests performed in 2013 versus 349 tests performed in 2012). This increase in volume also included a decrease of 70 tests for pharmaceutical companies due to the completion of the clinical study in 2013. Additionally, we experienced an increase in average selling price per test of $90.52. The increase in average sales price is primarily due to improvement in collection rates from third-party payors and better acceptance of our tests by insurance companies.

Cost of revenue

Cost of revenue was $2,498,940 (58% of sales) for the year ended December 31, 2013, a decrease of $543,244 or 17.9%, compared to $3,042,184 (69% of sales) for the same period in 2012. The primary reason for the decrease in costs was a reduction in the cost of materials after re-negotiating with our supplier and the reduction of operating costs through efficiencies at our laboratory. In addition, costs of revenue include a number of fixed costs that do not vary with revenue.

Selling and marketing expenses

Selling and marketing expenses were $378,769 for the year ended December 31, 2013, a decrease of $946,476, or 71.4%, compared to $1,325,245 in the same period in 2012. The primary reason for the decrease in selling and

marketing expenses was due to reduction of our sales staff. As discussed below under the caption Business Our Growth Strategy, we plan to expand our sales force and marketing expenditures once we complete this offering.

General and administrative expenses

General and administrative expenses were $1,788,141 for the year ended December 31, 2013, a decrease of $1,119,806, or 38.5%, compared to $2,907,947 in the same period in 2012. The primary reason for the

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decrease was due to decreased legal costs primarily related to a tortuous interference case that was initiated in 2012 and eventually settled in August 2013 and the termination and settlement agreements of several management level employees during 2012.

Research and development expenses

Research and development expenses were $96,847 for the year ended December 31, 2013, a decrease of $128,531, or 57.0%, compared to $225,378 in the same period in 2012. The primary reason for the decrease in research and development expenses was due to the abandonment of certain research projects that were deemed to not be viable.

In the future, we expect research and development expenses to increase as we work to develop additional diagnostic tests and add indications to our MyPRS® test. We cannot estimate the amounts we will need to invest in order to achieve the new indications or new tests, nor do we know if we will be successful in these endeavors.

Lease abandonment

During the year ended December 31, 2012, we recorded approximately $932,000 as lease abandonment expense for costs associated with an operating lease that we are not using and have been unsuccessful in subleasing. There is a termination clause in the lease that we intend to exercise whereby we can terminate after August 2015.

Gain on legal settlement

In August 2013, we settled a suit in which we were the plaintiff for a tortuous interference claim regarding a potential acquisition and agreed to settle for a payment of at least $350,000. As of December 31, 2013, we have recorded a gain of $250,000 for the first payment we received in January 2014. We have not recorded the remaining future payments as either a receivable or a gain as of December 31, 2013 due to the uncertainty surrounding the gain contingency. The remaining gain will be recorded when the cash is collected.

Interest expense

Interest expense was $1,963,456 for the year ended December 31, 2013, compared to $1,591,341 in the same period in 2012. The primary reason for the increase was due to increased borrowings on our note payable to the related party.

Discontinued operations

We had a net loss from discontinued operations of $1,592,945 for the year ended December 31, 2012. The primary reason for this loss was due to fact that all operations related to CC Health LLC were classified as discontinued operations, and this division was completely shut down by July 2012, as management determined that the expense of developing the division s technology would be better spent on the Company s core business.

Net loss attributable to member of Signal Genetics LLC

For the foregoing reasons, we had a net loss attributable to member of Signal Genetics LLC of $(2,444,669) for the year ended December 31, 2013 compared to a net loss attributable to member of Signal Genetics LLC of $(7,601,285) for the year ended December 31, 2012.

Liquidity and Capital Resources

We had cash of $105,105 at March 31, 2014 compared to $209,348 at December 31, 2013, and total current liabilities of $27,932,461 at March 31, 2014 compared to $27,300,316 at December 31, 2013. As of March 31, 2014 we had a working capital deficit of approximately $26,346,000.

Our principal sources of cash have included borrowings on our note payable to the related party. We expect that as our revenues grow, our operating expenses will continue to grow and, as a result, we will need to generate significant additional net revenue to achieve profitability.

The Company has no material commitments for capital expenditures at this time.

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

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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. Our ability to successfully continue is primarily dependent upon continued support from the majority member. The Company expects to seek additional financing and/or strategic investments prior to the offering or following the offering, depending on the proceeds generated by the offering. However, 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 the Company does not obtain additional funding, the Company will most likely be required to seek loans from its majority member who will become our majority stockholder (who is under no obligation to make any such loans to the Company) on similar terms as the Company has obtained in the past, seek additional debt or equity financing and/or reduce certain discretionary spending, which could have a material adverse effect on the Company s ability to achieve its 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.

Operating activities

The following table sets forth our net cash provided by (used in) operations for the periods indicated:

	Three Months Ended March 31, 2014	Year Ended December 31, 2013	2012
Net loss from continuing operations	$ (705,779)	$(2,159,669)	$(5,618,340)
Non-cash adjustments	613,673	1,835,196	2,656,672
Changes in operating assets and liabilities	177,294	(649,445)	1,608,322
Net cash used in operating activities of discontinued operations		(193,875)	(1,654,812)
Net cash provided by (used in) operations	$ 85,188	$(1,167,793)	$(6,224,802)

We generated $85,188 of cash from operating activities in the three months ended March 31, 2014. Non-cash adjustments primarily reflect non-cash accrued interest on the note to the related party of $531,838 and additional expense recorded of $45,724 which resulted from a change in estimate due to a termination agreement signed with the landlord for a previously abandoned lease. Changes in operating assets and liabilities primarily reflect decreases in inventory of $232,405 and prepaid expenses and other current assets of $311,384 offset by increases in accounts receivable of $179,713 and a decrease in lease termination/abandonment payable of $149,384. The decrease in inventory was due primarily to the timing of the receipt of supplies as we did not have any new receipts during 2014. The decrease in prepaid expenses and other current assets is primarily due to the receipt of the $250,000 litigation settlement recorded during 2013. The increase in accounts receivable was due to increased revenues to our direct billed customers in the prior 30 days of $100,000 as well as increased revenues to our non-contracted customers which take longer to pay. Our days sales outstanding for both the three months ended March 31, 2014 and the year ended December 31, 2013 were 89 days. We do not know if collections will continue to improve or remain at these levels. Moreover, future collections may depend upon our ability to obtain in-network contracts with additional insurance providers. The decrease in the lease termination/abandonment payable was due to payments on the now terminated lease.

We used $1,167,793 of net cash in operating activities in the year ended December 31, 2013. Non-cash adjustments primarily reflect non-cash accrued interest on the note to the related party of $1,936,881 offset by a $250,000 gain in legal settlement that was received subsequent to year end. Changes in operating assets and liabilities primarily reflect decreases in accounts receivable of $201,589 offset by an increase in inventory of $187,102, decreases in accounts

payable and other accrued expenses of $279,734 and lease abandonment payable of $319,454. The primary reason for the decrease in accounts receivable was due to an improvement in our internal billing processes and the collection rate from third-party providers. Our days sales outstanding for the years ended December 31, 2013 and 2012 were 89 and 101 days, respectively. We do not know if collections will continue to improve or remain at these levels. Moreover, future collections may depend upon our ability to obtain in-network contracts with additional insurance providers. The increase in inventory was

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due primarily to the timing of the receipt of supplies during 2013 as compared to 2012. The decreases in accounts payable and accrued expenses were due to payments and reductions in fees for legal and consulting services and the decrease in lease abandonment payable was due to payments on the abandoned lease. The net cash used in operating activities of discontinued operations was due to payments for remaining liabilities of the CC Health business.

We used $6,224,802 of net cash in operating activities in the year ended December 31, 2012. Non-cash adjustments primarily reflect non-cash accrued interest on the note to the related party of $1,560,270 and lease abandonment charges of $932,287. Changes in operating assets and liabilities primarily reflect a decrease in inventory of $166,392 offset by an increase in accounts receivable of $369,579 and a decrease in accounts payable and other accrued expenses of $1,294,809. The primary reason for the increase in accounts receivable is due to the increased revenues in 2012. The decrease in accounts payable and other accrued expenses was primarily due to cash inflow from operations primarily beginning in 2012. The net cash used in operating activities of discontinued operations was primarily due to the net loss incurred for discontinued operations of $1,592,945 during the year.

Investing activities

We had only $19 of cash used in investing activities during the three months ended March 31, 2014 due to the increase in our restricted cash account for interest earned during the period.

We had $5,685 of net cash provided by investing activities in the year ended December 31, 2013 due primarily to decreases in security deposits.

We used $119,433 of net cash in investing activities in the year ended December 31, 2012 primarily due to purchases of property and equipment.

As of this time, we plan to focus on our growth strategies and do not plan on using a material amount of the net proceeds from this offering in investing activities.

Financing activities

We used $189,412 of net cash in financing activities during the three months ended March 31, 2014 due to the payments of $273,751 in deferred issuance costs offset by $100,000 proceeds on our note payable to the related party.

We generated $1,258,922 of net cash from financing activities during the year ended December 31, 2013, primarily due to the net proceeds of $2,105,731 on our note payable to the related party offset by $285,000 paid in distributions and $500,422 paid for deferred issuance costs.

We generated $5,805,573 of net cash from financing activities during the year ended December 31, 2012, primarily due to proceeds of $6,635,000 on our note payable to the related party offset by $720,000 paid in distributions.

Description of Indebtedness

We have borrowed money to support operations from Mr. LeBow and from various entities owned by him. As of March 31, 2014, the aggregate amount payable under such notes is $27.2 million. The notes bear interest at 8% compounded monthly and are due on demand. Interest expense has been accrued and is included in the balance reflected on the balance sheet. The notes are collateralized by substantially all of the assets of the Company.

In addition, we acquired certain property and equipment through the issuance of a note payable totaling approximately $182,000 of which the balance at March 31, 2014 is approximately $26,000. The note is payable in thirty-six monthly installments of $5,320 through August 2014. The effective interest rate of the notes is 3.4%. The related equipment is collateral for the note.

Related Party Transactions

See above for a description of our note payable to the related party.

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Off-Balance Sheet Arrangements

As of each of March 31, 2014, December 31, 2013 and 2012, we were contingently liable for a standby letter of credit for $50,000 issued as a security deposit on a lease. We have approximately $50,000 cash in a restricted account that is held as collateral for this letter of credit. Otherwise, we have no off-balance sheet arrangements.

Commitments and Contingencies

As of each of March 31, 2014, December 31, 2013 and 2012, other than our office and laboratory lease, employment agreements with key executive officers, a license agreement with UAMS and a services agreement with a third party to assist with collections from customers we had no material commitments other than the liabilities reflected in our financial statements.

The JOBS Act

In April 2012, the JOBS Act, was enacted. Section 107 of 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. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company has elected to avail itself of the 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.

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BUSINESS

General

We are an emerging commercial stage, molecular 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. We were founded in January 2010 and became the exclusive licensee in our licensed field to the renowned research on multiple myeloma performed at UAMS in April 2010.

Multiple myeloma, or 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 immunoglobins, 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 myeloma 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 leukemia and represents approximately 15% of all hematomalignancies. According to the American Cancer Society, or ACS, and the National Cancer Institute, NCI, approximately 22,350 new cases of MM are expected to be diagnosed in the United States in 2013 and approximately 10,710 deaths from MM are expected to occur in the United States in 2013. More Americans will die from MM this year 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 77,617 people currently living with MM in the United States. The five-year survival rate for people with MM is about 43%. The ACS estimates that the lifetime risk in the United States of getting MM is 1 in 149. *[American Cancer Society: www.cancer.org and National Cancer Institute: www.seer.cancer.gov]*

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 determination of the course of treatment for a patient and that patient s outlook or prognosis for recovery. 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 myeloma, including when treatment should begin and what treatments to use, based upon a patient s individual risk for relapse. However, those experts caring for MM patients have been faced with a staging system that predates the current era and a large amount of new genomic information that could assist in the staging process. The traditional approach which utilizes cytogenetic analysis (*i.e.*, karyotyping) and FISH, for staging has not been able to accurately stage MM patients or fully assess the risk of relapse and classify MM. A more comprehensive and systematic approach is necessary to meet this unmet medical need. *[IMWG Consensus on Risk Stratification in Multiple Myeloma , Leukemia, Chng et al, advance online publication, 20 September 2013; (2013) doi: 10.1038/leu.2013.247*

Myeloma Classification & Risk Assessment , Seminars in Oncology, Fonseca and Monge, Vol. 40, No. 5, October 2013, pg. 554.]

Our flagship service is the Myeloma Prognostic Risk Signature, or MyPRS®. The MyPRS® test is a microarray-based gene expression profile, or GEP, assay that tests for presence of specific groups of genes that can predict low or high level risk of early relapse. The MyPRS® test provides a whole-genomic expression profile of a person s myeloma. 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 can help make personalized treatment possible, and our MyPRS® test is the first one to be developed for multiple myeloma

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according to the 2007 Shaughnessy paper in the Journal Blood. MyPRS® can be used at the time of initial myeloma diagnosis or when the patient has experienced a relapse to aid physicians in selecting the optimal treatment regime for each patient s unique condition. Specifically the test allows:

risk stratification to help distinguish patients with indolent myeloma 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 myeloma sub classification that may affect the specific choice of therapies.

In each of the three months ended March 31, 2014 and 2013, we had total revenues of $1.1 million, in the year ended December 31, 2013, we had total revenue of $4.3 million compared to $4.4 million in 2012.

Our Proprietary Genomic Tests and Services

Background

The last two decades have brought significant changes in the management of patients with MM. More effective therapies have improved the outlook for patients and progress in analytical genomics has made it clear that MM is a heterogeneous condition with a variety of genomic alterations. However, we believe those experts caring for MM patients have been faced with an antiquated staging system that does not utilize new genomic information. We believe the traditional approach utilizing staging based on cytogenetic analysis (*i.e.*, karyotyping) and FISH testing has not been adequate to fully assess risk and classify MM, and that a more comprehensive and systematic approach is necessary to optimize treatment of MM patients.

Our MyPRS® GEP signatures test enables physicians to obtain more complete information than has heretofore been available for the purposes of allowing optimal treatment and care due to the ability to more accurately predict a patient s outcome and severity of disease. The ability to better predict patient outcomes is a valuable tool for physicians and patients to use to help establish an appropriate course of treatment for patients with MM. Both new patients and those with relapses of MM may benefit from our test. We believe the ability to better predict a patient s outcome through the GEP signature could also enhance the ability of pharmaceutical and biotech companies to develop personalized treatments for MM.

Researchers at the UAMS developed a genomic profile test for patients with MM, which has been exclusively licensed for use by us. The test is a microarray-based test that predicts the prognosis of patients with MM and which provides guidance as to optimal patient management both at the time of initial diagnosis and at the time of relapse after treatment. The MyPRS® test took over 10 years to develop and its accuracy, validity and clinical utility have been demonstrated in over 4,500 patients and have been documented in 17 articles published in peer-reviewed U.S. and international medical journals. Based on the published medical literature, many experts in MM have concluded that the MyPRS® test should be used as part of routine patient management. *[Complete remission in multiple myeloma examined as time-dependent variable in terms of both onset and duration in Total Therapy protocols , Hoering et el; Blood 2009 114: 1299-1305, The molecular characterization and clinical management of multiple myeloma in the post-genome era ; Zhou et al, Leukemia, advance online publication, 6 August 2009; doi: 10.1038/leu.2009.160, Myeloma Classification & Risk Assessment ; Fonseca & Monge; Seminars in Oncology; Vol. 40, No. 5, October 2013, pp. 554-566.]*

The MyPRS® test is performed on cells obtained from MM patients and involves isolating malignant plasma cells from the bone marrow and extracting their RNA. Through the use of state-of-the-art microarray technology and the application of proprietary software to analyze raw genetic data, the MyPRS® test is able to determine the specific

subtype of MM present and to predict the prognosis and risk of relapse after treatment.

We believe the published data supports performance of the MyPRS® GEP testing on patients with myeloma at the time of diagnosis and at the time of relapse after therapy. Even in patients without clinical symptoms, the altered expression levels of specific genes involved in bone destruction or cellular proliferation may be able to forecast prognosis. In clinically apparent myeloma, the test can help stratify patients according to survival probability with more accuracy than other available tests. In addition, when MyPRS® is performed at the time of relapse, it can help predict whether a patient has progressed to a high-risk gene profile. Thus, we advocate that newly diagnosed MM patients should obtain MyPRS® GEP analysis. Approximately 15% to 25% of this patient group will have a MyPRS® GEP profile that predicts relapse within a relatively short

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period of time. *[Myeloma Classification & Risk Assessment ; Fonseca & Monge; Seminars in Oncology; Vol. 40, No. 5, October 2013, pp. 554-566.]* Those patients who relapse may be reassessed with the MyPRS® test at the time of relapse to help determine whether their MyPRS® GEP signature has changed. If this reassessment reveals a conversion to a high-risk gene profile, more aggressive therapeutic options may be warranted because a conversion to high-risk MM is correlated with a significant reduction in post-relapse survival.

Our Technology

The MyPRS® test is performed on RNA extracted from CD138 positive plasma cells obtained from the bone marrow of MM patients. This allows the precise determination of the percentage of CD138 positive plasma cells in the specimen and ensures sufficient genetic material will be available for GEP analysis. The purified RNA from the isolated plasma cells is fluorescently labeled and hybridized (or crossbred) to a whole-genome GeneChip® platform, containing over 54,000 complimentary genetic sequences. After all unbound RNA is washed away, the chip is scanned and the florescence intensity of each probe is quantified, resulting in a whole-genome expression profile. The MyPRS® assay utilizes the Affymetrix GeneChip® 3000Dx v.2 system, a state-of-the-art whole-genome microarray platform, specifically designed for clinical applications. The GeneChip® system has been extensively validated across thousands of publications and is an internationally recognized standard for microarray-based profiling of RNA from human tissues. The Affymetrix platform has been FDA cleared and CE marked by the European Commission for marketing within the European Union for a number of *in vitro* diagnostic uses.

Each patient s bone marrow aspirate, isolated RNA and their normalized gene expression profile, undergoes a series of quality control checks throughout the process to ensure the integrity of the results generated. The final step in the MyPRS® test involves the use of proprietary statistical and bioinformatic algorithms that are the product of more than two decades of research at the Myeloma Institute for Research and Therapy, or MIRT, at UAMS. After generation of a whole genome profile that passes quality assurance testing, MyPRS® algorithms are applied to generate a series of informative results:

Prognosis: Quantification of the expression of 70 genes to help predict the patient s prognosis and overall risk for relapse and survival. This can aid in the selection of the most appropriate therapeutic regime for each patient.
Molecular Subtype: Interrogation of 700 genes for the presence of specific alterations that may allow classification of MM into seven disease subtypes. This can further stratify a patient s risk profile and has the potential to further identify the best therapeutic option for many patients. *[The molecular classification of multiple myeloma ; Zhan et al, Blood journal, September 15, 2006; 108:6, 2020-2028.]*
Virtual Karyotype: Identification of MM cytogenetic abnormalities, or CA, through the MyPRS® virtual karyotype. MyPRS® virtual karyotype, based upon the expression levels of 816 genes, has an accuracy rate up to 89% when compared with conventional methods for assessing CA (*e.g.*, metaphase karyotype and array-based comparative genomic hybridization). *[Prediction of cytogenetic abnormalities with gene expression profiles ; Zhou et al, Blood journal, prepublished online as Blood First Edition paper, April 10, 2012; D01 10.1182/blood-2011-10-388702.]*
This high rate of agreement with conventional karyotyping means that physicians may be able to use MyPRS® in cases where, for example, conventional karyotyping is not possible.
The final result of the MyPRS® analysis process is a readily interpretable, well-referenced, gene expression profiling report which can aid the physician s ability to offer truly personalized treatment options.

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 has been certified under CLIA, to perform high complexity testing. Our laboratory is licensed to sell

our test in 49 of the 50 states. We are currently seeking a license in New York for the MyPRS® test, which would enable us to perform MyPRS® testing for patients located in New York. We are dedicated to making our extensively validated diagnostic services available to all patients who need them.

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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 AMG, a precursor condition to MM. There is, however, currently no projected timeline for our use of MyPRS® in AMG patients. For a discussion of MyPRS® in AMG patients see Market Opportunity, below.

Over the next 12 to 18 months, we intend to expand our test menu by adding tests that are needed to 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 a targeted next generation gene sequencing service to assist our physician customers in further characterizing their MM patients and assisting with identifying the potential to use targeted therapies based upon the specific genetic mutations of their patients tumors. It is our intent to add such complimentary services to our proprietary MyPRS® franchise to provide a more comprehensive suite of tests for our oncologist customers and their patients.

Market Opportunity

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, in other cases can be indolent and in other cases patients die from non-cancer related causes irrespective of the aggressiveness of their disease. Unfortunately, identifying those patients who will likely die of something other than their particular cancer diagnosis is difficult. *[Overdiagnosis and Overtreatment in Cancer: An Opportunity for Improvement ; Esserman et al; JAMA, Published Online: July 29, 2013. Doi.10.1001/jama.2013.108415.]*

One of the main goals in the care of those individuals diagnosed with cancer is to accurately predict the clinical course of the patient and the progression of the disease. Accurate predictions could provide physicians with the ability to predict more personalized therapeutic options for their cancer patients. The choice of therapy can change depending on many variables such as age, stage of disease, comorbidities and specific genetic mutations. According to Nature s MM supplement, this is particularly true for MM patients whose therapeutic options can range from watchful waiting for those with low risk disease, to an intense regimen involving multimodality chemotherapies, one or more bone marrow or stem cell transplantations and experimental protocols through enrollment in new drug and new drug combination clinical trials for those with high risk disease.

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 steroid), 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, a process whereby the human bone marrow cells are eliminated in preparation for a bone marrow transplant, performed using high-intensity chemotherapy and total body irradiation. *[The Future of Drug Development and Therapy in Myeloma ; Seminars in Oncology, Lonial and Boise, Vol. 40, No. 5,*

October 2013.]

Although new treatments for patients with MM have become available over the last 10 years, their use has not resulted in uniformly better outcomes, such as overall survival. In part, this is because MM is a disease with significant tumor heterogeneity at the molecular level. Specialists in MM have long recognized the need for diagnostic tests that accurately identify the mutations and genotype of each patient with MM in

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order to allow risk stratification, predict prognosis and response to treatment. Because classic staging modalities such as clinical factors and cell morphology (the microscopic review of tumor material by a pathologist) have very limited ability to classify MM, physicians have used plasma cell labeling indices, chemical markers, imaging studies and genetic abnormalities at the chromosomal level (*e.g.*, cytogenetics) to improve their ability to predict prognosis. Unfortunately, even these tests provide limited information as to a particular MM patient s prognosis and response to treatment. *[Introduction: Recent Advances in the Understanding and Management of Multiple Myeloma ; Seminars in Oncology, Jakubowiak: Vol. 40, No. 5, October 2013, pp. 535-536, Myeloma Classification & Risk Assessment ; Fonseca & Monge; Seminars in Oncology; Vol. 40, No. 5, October 2013, pp. 554-566.]*

Medical practitioners in the myeloma field agree that there is a critical need to utilize genetic risk stratification methods at the time of initial diagnosis because of the potential to enhance the ability to define and discriminate patients at high risk for early relapse from those at low risk for relapse in order to better personalize treatment of these patients according to their levels of risk and relapse. Armed with such a stratification algorithm, physicians could have a greater ability to individualize treatment options, improve therapeutic efficacy and clinical outcomes, minimize adverse effects, perform fewer diagnostic tests, decrease unnecessary treatments, and reduce the clinical and financial burden to health care systems and individual patients. Now, with the use of MyPRS® GEP, it has become possible to go beyond morphological and chromosomal level analysis and better identify the individual MM genomic profile of each individual patient. *[Smoldering multiple myeloma requiring treatment: time for a new definition? ; Dispenzieri et al, Blood Prepublished online October 21, 2013; doi: 10.1182/blood-2013-08-520890.]*

Unlike many forms of cancer, multiple myeloma is often asymptomatic, even in advanced stages. MM begins as a precursor condition known as MGUS. It is estimated that more than 3% of the population of the United States 50 years of age or older have MGUS. *[Prevalence of Monoclonal Gammopathy of Undetermined Significance: A Systematic Review ; Wadhera et al, Mayo Clin Proc. 2010; 85(10): 933-942.]* 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 according to the ACS and NCI, every year, 1% of MGUS patients will develop MM. According to Nature s MM supplement, there is no way to identify those MGUS patients that will convert to MM; but due to the high mortality rate and speed of disease progression, clinicians are eager to identify those patients so they can start treating them as soon as is appropriate.

Aside from the precursor condition MGUS, MM exists on a spectrum from AMM to full-blown MM. Collectively, these precursor conditions, MM and AMM are referred to as AMG. Preventative treatment of every AMG patient is not a viable option. 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 impact on survival time. According to Nature s MM Supplement, many researchers would like to test newer therapies on MGUS patients as well as those with early forms of MM but they agree that this should only be done if there is a way of accurately stratifying patients based on their risk of progression from the AMG state into the symptomatic stages of disease. This ability could allow them to avoid unnecessary treatment in AMG patients who will not progress to MM.

Recently, a scientific abstract was presented at the 2013 American Society of Clinical Oncology, or ASCO, meeting that demonstrated, for the first time, the ability of our MyPRS® test to predict risk of progression from AMG to MM. The work was part of a multi-center, prospective, clinical study sponsored by the National Cancer Institute Southwest Oncology Group. The study was accepted for peer-reviewed publication in the journal Blood and was published online on October 21, 2013. The study demonstrated that the MyPRS® test was an independent predictor of the risk of progression from AMG to clinical MM. Further clinical study replicating these results will likely be necessary to enable broad market acceptance for the use of MyPRS® in MM precursor conditions. Nonetheless, the applicability of

our test for use in predicting MM progression from AMG could potentially create a substantial increase in the patient population eligible for MyPRS® testing and as such represents an important pillar of our growth strategy. We estimate the total MM testing market at approximately 33,500 patients per year, including newly diagnosed and relapsed patients. We

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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 to more than 130,000 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.

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 taking the following actions:

Expand the U.S. market penetration of our MyPRS® test by increasing the geographic coverage of our sales force which currently consists of one employee

We intend to expand the user base of clinicians using our MyPRS® test through direct marketing and sales to academic hospitals and their out-patient clinics. To do this, we will expand our direct sales force. Our current selling and marketing efforts in the United States are handled by one sales person. We currently have relationships with a number of physicians at several of the large academic centers, other than UAMS, who use our MyPRS® test on their MM patients. By increasing our sales personnel we believe we can further penetrate the academic market and increase the number of physicians who use our test. Additionally we plan to further develop our marketing materials and increasingly utilize new forms of communication via the internet, in addition to more traditional methods of communication such as educational seminars to support our marketing efforts and to provide awareness about the clinical validity and clinical utility of MyPRS® for use in MM and hopefully in AMG.

Broaden the base of health care insurance companies that have approved reimbursement for MyPRS®

Currently, Medicare has approved coverage and reimbursement for MyPRS® through a LCD promulgated by the Jurisdiction H MAC, which includes Arkansas, where the Company s laboratory is located. Accordingly, Medicare will pay for the tests we provide to Medicare patients if those tests are performed in accordance with the LCD coverage requirements. Blue Cross Blue Shield of Arkansas also has an approved coverage policy for MyPRS®. In order to broaden our coverage policy approval to include a majority of the major health care insurance providers in the United States, we plan to hire experienced managed care professionals who can assist us with gaining contractual agreements with third-party payors. MyPRS® has been studied extensively and there are more than 30 peer-reviewed scientific publications that describe the validity and utility of the test. We intend to use these publications to create the clinical dossier that supports reimbursement approval by the majority of health care payors. However, there is no assurance that our efforts will succeed and it is even possible that payors currently covering MyPRS® could withdraw their coverage.

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

In June 2013, an ASCO meeting abstract demonstrated for the first time the ability of our MyPRS® test to predict the risk that a patient with AMG would progress to develop MM. The research was based upon a clinical study sponsored by the Southwest Oncology Group, or SWOG. The study, which began in 2002 and stopped enrolling patients in April 2011, was designed, in part, to develop biomarkers that would inform physicians as to which AMG patients were more likely to progress to MM. A peer-reviewed publication based on this research recently issued in the January 2014 issue of the journal Blood. The paper demonstrated that our test was an independent predictor of progression to MM in AMG patients. We intend to fund additional retrospective and prospective clinical studies that we hope will replicate this finding and enable us to petition health care payors to expand the covered indications for our MyPRS® test to include AMG patients. Because patients are typically not diagnosed or treated for MM until they become symptomatic, we hope the ability to test AMG patients for risk of progression to MM will better allow physicians to make earlier therapeutic interventions with the hope of improving the long-term outcome of those patients.

Establish partnerships with other reference laboratories to expand the market reach for MyPRS®

Although a large fraction of MM patients are managed and treated in the academic hospital setting, we believe only a small fraction of AMG patients are seen and cared for in this setting. Due to the relative lack

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of severity of the disease, the majority of AMG patients are diagnosed and followed in the community oncology setting. In order to reach this potentially large AMG patient population, we intend to develop partnerships with a select group of reference laboratories whose principal business includes calling upon the community oncologist. This could result in wider market access for us while providing our select reference laboratory partners with a more differentiated test portfolio (*i.e.*, which includes MyPRS®) that will appeal to community oncologists treating AMG patients.

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

There are a number of new molecular entities for the treatment of MM in various phases of clinical development. According to the website of the International Myeloma Foundation, there are more than 240 new therapies for MM in pre-clinical and phase I development. There are also a number of pharmaceutical companies with development programs for MM therapies. A study published by the International Myeloma Working Group in 2009 recommended that all clinical trials for drugs intended to treat MM consider incorporation of GEP into the correlative science studies to identify subgroups of high-risk disease. Historically, we have performed our MyPRS® testing for some of the major MM drug developers. We believe our expertise and diagnostic testing services can assist pharmaceutical companies in their clinical development efforts. We have secured two pharmaceutical company collaboration arrangements as of the date of this prospectus (one of which was completed in 2013). We intend to invest in business development and scientific resources in order to pursue additional collaborations with pharmaceutical companies.

Expand our information technology infrastructure to further improve our customer service experience

Diagnostic testing is, at its core, an information service. As such, we require a robust information technology infrastructure to facilitate and expedite the receipt of orders, transmission of results, payor benefit and coverage information and a better understanding of how our test is being used by physicians. We currently maintain an information technology infrastructure that supports our operations, including a physician web portal, ResultsPX, which is a secure online environment for viewing patient results that includes a MyPRS® gene expression heatmap showing individual patient s prognosis in relation to the database of those patients used to develop the test. An individual patient s results can be viewed over time if the patient has had more than one test. We intend to add additional differentiated features to ResultsPX to enhance its capabilities. We plan to facilitate direct interfacing with our clients electronic medical record systems by building electronic medical record interfaces to enable paperless ordering and reporting. We also plan to invest in systems and processes to monitor the performance of our business operations and assess the quality levels of the services we provide to ensure we are meeting our commitments to our external customers.

Continue to leverage our relationship with UAMS via our exclusive license agreement

We entered into a license agreement, or the License Agreement, with UAMS on April 1, 2010, as amended on September 1, 2010, September 14, 2010, October 2011 and December 1, 2011. Pursuant to the License Agreement, UAMS granted us a worldwide exclusive license, for our licensed field, with, *inter alia*, the right to sublicense, or assign the license in connection with a sale or transfer, including, until April 2020, the exclusive option to license the inventions, within our licensed field, conceived and reduced to practice in whole or in part by Drs. Bart Barlogie or John Shaughnessy. Our licensed field includes applications to malignant and nonmalignant human or animal

pathologies, including but not limited to determining and/or identifying the presence, predisposition, effect of treatment, mode or type of treatment, type of patient susceptibility to treatment or prevention, progress of treatment, current and predicted clinical outcome, and/or therapeutic or prophylactic treatment and/or regimen. These uses, patent, and technology rights exclude using FISH, which is licensed to a third party. Our licensed patent rights also exclude certain claims directly covering DKK1 inhibitors and/or their uses. The License Agreement provides access to the clinical trial samples, such as biological material and annotated clinical outcome data associated with such clinical samples.

In consideration for this License Agreement, we agreed to pay UAMS $30,000 in annual minimum royalty fees on net sales to customers other than UAMS, of our diagnostic services that make use of licensed products, unless net sales exceed certain thresholds, in which case the additional royalty fee would range from 2% to 4% percent. Royalty fee expense, included in the selling and marketing section of the accompanying

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consolidated statements of operations, for the three months ended March 31, 2014 and the years ended December 31, 2013 and 2012 was $7,500, $30,000 and $85,000, respectively.

We will continue to leverage our relationship with UAMS to advance our position in our licensed field, including diagnostic technology. For instance, the license grants us rights to certain clinical data as well as an exclusive option to license new inventions. Through the License Agreement, we are also able to control the maintenance of patents and prosecution of pending applications exclusively in our licensed field, and, in the case of applications that encompass FISH technology, together with UAMS and a third party. We pay 100% of the prosecution costs for gene expression profiling only patent cases. If we elect not to pursue a particular patent application, the rights to that patent revert to UAMS, and UAMS can take the necessary steps to prosecute and maintain the patent. In certain circumstances, such as where we do not exercise our option to license new inventions, UAMS may pursue a license to the new invention with a third party. The License Agreement also grants us the right to prosecute infringement actions, where the University does not intend to prosecute the infringement. Together with UAMS, we bear full responsibility for enforcement of patent rights against all claims of infringement by third parties and the right, but not the obligation to bring action against any alleged infringement of the licensed patents by third parties, bearing all costs. UAMS has the right to pursue any offensive enforcement we choose not to pursue at its own expense and we may agree with UAMS to pursue such action jointly, sharing all related costs.

The License Agreement terminates on the first to occur of: (i) the date of the expiration of the last to expire of the patents issued in any country, or (ii) termination of the agreement pursuant to its terms. UAMS may terminate the agreement 90 days after written notice to us if we do not cure or initiate steps to cure, a material breach or default. UAMS may also terminate this agreement at any time upon notice to us, if we challenge the validity of any of the patent rights granted to us under the license agreement. We may terminate the agreement for any reason, upon written notice to UAMS. We are obligated to indemnify UAMS against all liabilities to third parties, from claims arising in connection with the agreement and our (or our sublicensee s) production, manufacture, use, sale, consumption or advertisement of licensed processes and licensed products, except claims that the licensed patent rights infringe third-party intellectual property rights and any claims arising out of negligent or willful misconduct of UAMS and its affiliates. We also are required to maintain comprehensive general liability insurance, appropriately covering these activities.

There are potential new diagnostic breakthroughs that may result from our collaboration with UAMS including next generation sequencing that may enable new understanding of MM and related disease and what treatments are most appropriate for each individual. However, there is no guarantee any such tests or services will ever be created or commercialized.

Expand our test offering with the addition of conventional tests used by physicians who care for MM patients

There are a number of conventional tests that oncologists use routinely in the care and staging of their MM and AMG patients. These include flow cytometry and cytogenetics. We anticipate ample opportunity for us to expand our testing menu to include some of these tests thus offering convenience to our customers (fewer patient sample draws, less sample splitting, less need for interacting with multiple diagnostic service providers) while providing additional growth opportunity for our company.

Targeted gene sequencing is of particular interest to physicians managing high-risk MM patients. These physicians are increasingly using non-conventional or targeted therapies on patients who fail (or develop resistance to) first line treatments. Many case studies are being published and presented at major conferences showing the importance of

looking for specific genetic mutations in tumor DNA that are known to respond to a specific treatment even if that treatment is indicated for use in another cancer type, not MM. While the clinical implications of detecting specific DNA mutations in patients with multiple myeloma is still being determined, the utility and demand for personal patient genetic information for these patient s tumors is growing rapidly. A number of major myeloma research groups, including UAMS, are applying whole-genome sequencing to patients with multiple myeloma in order to understand the genetic basis of disease development, progression and varying levels of treatment response.

Initially, it is our plan to offer commercially available targeted DNA sequencing panels. We will expand our offering as scientific research uncovers new genetic mutations important to cancer patients. UAMS has a

Expand our test offering with the addition of conventional tests used by physicians who care for MM patients

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greater than 20-year history of using the latest technology to identify gene expression signatures of MM patients, and increasingly, single gene mutations that are related to multiple myeloma. It is our expectation that through our exclusive licensing arrangement with UAMS we will eventually add proprietary content to our targeted gene-sequencing offering and further differentiate our services.

Pursue Additional Collaborations and In-licensing to Expand Our Business

We intend to pursue additional collaborations with leading universities and research institutions or in-licensing of services or technologies that could enable us to accelerate the implementation of our plans to expand the services we provide to oncologists. We expect to implement this plan by way of licensing of technology and know-how, investments in other companies, strategic collaborations, and other similar transactions. We expect these collaborations to provide us with early access to new technologies available for commercialization.

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

We intend to work closely with select key suppliers and partners to reduce the costs associated with key material components of our MyPRS® test. As we grow our business we anticipate achieving benefits of scale that will help to streamline our laboratory work processes and increase our purchasing power for instruments, reagents, laboratory supplies, logistical services and reimbursement services.

Our Competitive Strengths

We believe our competitive strengths include:

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 based on our knowledge that the test has been validated in 17 separate and distinct patient test databases. Please visit our website at *www.signalgenetics.com* in the Publications section under the Physician Resources tab for a list of publications describing the use of MyPRS® on patients with MM. 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 to help 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 avoiding therapies that may be less beneficial or harmful.

Furthermore, MyPRS® provides a virtual karyotype 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 an accuracy of up to 89%, as previously noted. This high rate of agreement with conventional karyotyping means that physicians may be able to use MyPRS® in cases where conventional karyotyping is not possible. 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, or MDS, and acute myelogenous leukemia, or 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

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MIRT. A number of treatment improvements for myeloma patients were first discovered at MIRT. The physicians at MIRT routinely utilize our MyPRS® test to identify patients who may be eligible for 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.

At this time, our business is dependent on our relationship with UAMS, our largest customer. UAMS pays us directly for tests they refer to us. They also refer patients whose private insurance reimburses us for the test(s) we perform for them. Revenue sourced either from or through UAMS accounted for approximately 79%, 83% and 86% of net revenue for the three months ended March 31, 2014 and the years ended December 31, 2013 and 2012, respectively. 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

As of October 4, 2013, we license, or own outright, 10 issued patents (with various expiration dates ranging from 2022 to 2029) and 26 pending patent applications, 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 US trademarks to further differentiate our products and services in the marketplace, including the marks MyPRS® (Reg. No. 4,230,011) and MyPRS Plus® (Reg. No. 4,230,010).

There are four issued U.S. patents related to the MyPRS® test, which form the basis of our right to exclude others from practicing the MyPRS® test. U.S. Patent No. 7,668,659 claims methods of gene expression-based classification for multiple myeloma that include extracting total RNA from plasma cells. U.S. Patent No. 7,894,992 provides methods of identifying groups of genes that can distinguish normal and multiple myeloma plasma cells by isolating RNA from CD138 positive plasma cells, hybridizing the RNA to a microarray, identifying differentially expressed genes, and applying hierarchical clustering to identify groups of genes capable of discriminating normal and multiple myeloma plasma cells. The broadest claims of these two patents are not limited to particular gene sets.

U.S. Patent No. 7,983,850 provides methods of diagnosing multiple myeloma by examining mRNA levels or chromosomal translocations of particular genes from isolated plasma cells, thereby classifying the MM molecular subtype of the individual.

U.S. Patent No. 7,741,035 broadly covers the 70 gene signature used to predict the patient s prognosis and overall risk for relapse and survival. Specifically, this patent provides methods of determining the prognosis of a multiple myeloma patient by determining the copy number of the CKS1B gene in plasma cells, where an increased level of this gene indicates a poor prognosis. CKS1B is one of the genes in the 70 gene signature.

In addition to the issued U.S. patents, above, we have several pending patent applications in the U.S. and abroad directed to other aspects of the MyPRS® test. For example, USSN 11/133,937 (published as US 20050260664), along with Canadian and European counterpart applications, describes the full 70 gene signature used in the MyPRS® test. USSN 14/039,728 provides methods of prognosing subjects with MGUS using the 70 gene signature. A new provisional application is directed to prognostic methods using an even smaller subset of only five genes, which can be used with limited numbers of plasma cells from either

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multiple myeloma or MGUS subjects (unpublished provisional application, USSN 61/825,396). Additionally, we have several other unpublished applications covering various other prognostic methods for use in multiple myeloma subjects.

Two U.S. patent applications are related to methods of detecting cytogenetic abnormalities using gene expression levels. USSN 13/810,705 (published as US 20130209446) recites methods of detecting cytogenetic abnormalities associated with multiple myeloma or MGUS by determining the gene expression level of certain genes that are copy number variant-dependent. USSN 13/524,589 (published as US 20130059746) provides methods of predicting the presence cytogenetic abnormalities associated with multiple myeloma by testing gene expression levels for subsets of genes in cells isolated from the subject. This application also claims software and systems for performing these methods.

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 hospitals provides an efficient way to reach the largest segment of MM patients with our limited resources. Selling into academic hospitals 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 person 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®

An important milestone in the development of any new molecular diagnostic test is the ability to achieve routine reimbursement for the novel service. One of the more important third-party payors from which to achieve approval is Medicare. We successfully achieved a positive LCD for MyPRS® with the Jurisdiction H MAC in March 2011, which includes Arkansas, where the Company s laboratory is located. Accordingly, Medicare will pay for the MyPRS® tests we provide to Medicare patients, if those tests are performed in accordance with the LCD coverage requirements. We have also received reimbursement approval with 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 with 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 are well-positioned to consult with our oncologist customers to help them derive maximum value from the diagnostic and prognostic data generated by our tests.

Selling and Marketing

We offer our MyPRS® test services through our CLIA certified laboratory in Little Rock, Arkansas. Our primary sales market includes academic hospitals and associated out-patient centers, community based oncologists and pharmaceutical companies. Selling diagnostic testing services for cancer requires a

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knowledgeable and skilled sales force that can help oncologists and their clinical care team members understand the value of our testing services. It is our aim that our sales representatives have previous sales experience in the oncology field, including pharmaceutical sales experience or experience in the sales of medical diagnostic services, and have knowledge of academic centers and oncology practices in research institutions. As we expand our sales force, our sales force will be compensated through a combination of salaries and commissions based upon actual sales performance and periodic incentives, all at levels commensurate with each individual s qualifications, performance and responsibilities.

As of March 31, 2014, our sales team was comprised of one member and our selling and marketing efforts were directly overseen by our President and Chief Executive Officer. We intend to continue to expand our sales team as appropriate. Our sales strategy focuses on expanding the MyPRS® test services while acquiring new customers. Our sales approach is designed to understand our current and potential customers needs and to provide the appropriate solutions from our expanding range of diagnostic services.

We have developed a set of marketing materials to support our sales efforts. Our marketing materials provide a summary of our MyPRS® test along with practical information regarding how to order our tests. When creating our marketing materials we have focused on establishing a distinctive corporate brand and plan on continuing to build upon our strong MyPRS® brand.

Information Technology

We have implemented a commercially available and supported laboratory information system to perform tracking, evaluation, and reporting of laboratory specimens as they are analyzed. Hardware and software used in conjunction with this system are commercially available items that can easily be procured. We also make use of commercial software applications that allow for biostatistical analysis of data generated.

Specimen storage equipment consists of freezers to store frozen tissue specimens. These freezers are monitored via computerized probes on a continuous basis to ensure that temperatures are maintained at levels necessary to keep these specimens frozen. Should temperatures in any of the freezers move out of range due to mechanical failure an emergency alert is sent to us for response. These freezers are also supported by a freestanding emergency backup generator that will engage in the event of a general power outage in order to maintain freezer temperatures at necessary levels.

Competition

The primary competition for our MyPRS® test stems from the use of older diagnostic technologies to assess patient prognosis and to define high risk and low risk MM patients. These older technologies include various serum markers, karyotype analysis and FISH probes. Several independent groups have assessed the use of GEP versus various conventional methodologies and these studies have been published in peer-reviewed journals. For a select list of these publications, please visit our website at *www.signalgenetics.com* in the Publications section under the Physician Resources tab. It is our experience that whenever MyPRS® is compared to conventional techniques, the MyPRS® test shows superior ability to predict patient outcome. We believe that an active educational-based marketing campaign and additional sales personnel to deliver the message to potential new clients is needed to drive MyPRS® adoption by educating physicians as to the limitations of conventional testing modalities and the added benefits of MyPRS® testing. Additionally, there are a number of independent clinical studies that are underway that continue to compare our MyPRS® test to various conventional techniques, and we believe these new studies will also demonstrate the superiority of our MyPRS® test to predict patient prognosis. However, we cannot be sure that the data will support the

superiority of MyPRS® and even if there is support, physicians may not adopt use of MyPRS® by incorporating it in to their molecular diagnostic work up of MM or AMG patients.

Another source of competition for our MyPRS® test stems from other scientific teams attempting to develop GEP signatures utilizing other genes or a subset of the genes utilized in the MyPRS® test. Two signatures 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, MyPRS®. Based on previous head-to-head comparisons, we believe that the MyPRS® test is a superior predictor of patient outcome compared to any other published gene expression signature. However, there is no guarantee that in the future a GEP will not be commercially available that is superior to MyPRS®. If that happens, our commercialization efforts could be severely hampered.

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We are not currently aware of any company attempting to bring GEP based tests into the U.S. market. Additionally, we believe our intellectual property portfolio will provide protection for our exclusive ability to market GEP tests for MM in the U.S. Our success to date in establishing reimbursement coverage for our MyPRS® test may provide an additional competitive barrier to any new U.S. market entrant attempting to use GEP to predict prognosis in MM patients. This is because we believe any such test would have to be supported by evidence showing clinical validity and clinical utility that is of the same strength as the evidence supporting MyPRS®. Lastly, we are not aware of any pending clinical research utilizing a GEP to predict conversion from AMG to MM other than the SWOG study that used the MyPRS® test. However, there may be other academic or industry based scientists who are developing new genetic expression based predictive assays or other novel technology based assays that will be superior to MyPRS® test in predicting risk in patients with MM and/or AMG.

We compete largely on the basis of the quality of our tests, the significant number of peer-reviewed scientific publications that support the clinical validity and utility of our MyPRS® test, our turnaround time, the convenience of ordering our tests and the innovation of our results delivery platform.

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. Our actual and potential competitors in the United States and abroad may include biotechnology, genomic and diagnostic companies such as Novartis, Cancer Genetics, Inc. and NeoGenomics, Inc., large clinical laboratories, universities and other research institutions. Many of our potential competitors have considerably greater financial, technical, marketing, research and other resources than we do, which may allow these competitors to discover important information and develop technology before we do. 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 products that are superior to our tests and technologies, including our pipeline products. Also, our competitors may succeed in developing technologies, products or services that are more effective than those that will be developed by us or that would render our technology or product candidates less competitive or obsolete.

In addition, our goal is to develop diagnostic tests and other services that impact the treatment of MM and other cancers. If those treatments change, it is possible that the demand for our services and products could significantly decline or cease altogether. The development of new or superior competing technologies, products or services, or a change in the treatment of MM and other cancers, could affect our competitive position and harm our business. Moreover, these competitors may offer broader services and/or product lines and have greater name recognition than us and may offer discounts as a competitive tactic.

Additionally, competitors may succeed in developing products and/or services that are approved by the FDA and/or they may market technologies, products or services that are more effective or commercially attractive than our tests and services or that render our technologies and current or potential tests and other services obsolete. Competitors may also develop proprietary positions that may prevent us from commercializing, or continue to commercialize current and future product candidates.

We also face competition from companies such as Genoptix, Inc. (a Novartis AG company), Clarient, Inc. (a division of GE Healthcare, a unit of General Electric Company), Bio-Reference Laboratories, Inc., Integrated 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. As more information regarding cancer genomics becomes available to the public, we anticipate that more products

aimed at predicting patient outcome as well as identifying targeted treatment options will be developed and that these products may compete with ours. 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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Research and Development Program

Research and development is crucial to the Company s development as we seek to expand our series of diagnostic tests for use by physicians that treat MM and other cancer patients. Our research and development expenses were $9,000, $97,000 and $225,000 for the three months ended March 31, 2014 and for the years ended December 31, 2013 and 2012, respectively, representing 0.8%, 2.1% and 2.7% of our total operating expenses for the years ended December 31, 2013 and 2012, respectively. Major components of our research and development expenses include supplies and reagents for our research activities, personnel costs, occupancy costs, equipment warranties and service, insurance, consulting, clinical research sponsorship and sample procurement costs. We also plan to invest in clinical research studies to further validate the clinical utility of MyPRS® to predict the risk that a patient with AMG would progress to developing MM and to facilitate the development and clinical utility validation of additional genetic characterization of MM patients. We expect research and development expenses to increase as we work to develop additional diagnostic tests and services or add indications, including new testing modalities such as targeted next generation gene sequencing and to study additional diagnostic and prognostic indicators for patients suffering from MM and its precursor conditions AMG, other hematomalignancies and solid tumor cancers. In the future, we expect research and development expenses to increase as we work to develop additional tests and services and add indications to our MyPRS® test. We cannot estimate the amounts we will need to invest in order to achieve the new indications or new services, nor do we know if we will be successful in these endeavors.

Intellectual Property

We rely on a combination of patents, trade secrets, copyrights, trademarks, license agreements, nondisclosure and other contractual provisions and technical measures to protect our intellectual property rights in our tests and services, technology and processes. We have substantial intellectual proprietary rights in at least four areas.

First, we exclusively license, in our licensed field, a patent portfolio from UAMS with numerous issued U.S. patents and pending U.S. and international patent applications related to the MyPRS® test. For a more detailed discussion of our licensing agreement with UAMS, see note 9 to the consolidated financial statements. For a discussion of the four issued U.S. patents and pending U.S. and foreign applications included in this licensed portfolio that are most closely related to the MyPRS® test, see Risk Factors Risk Related to our Intellectual Property Our substantial proprietary estate that protects our exclusive access to the MyPRS® test , above.

Second, the in-licensed UAMS portfolio includes issued U.S. patents and pending patent applications in the U.S. and foreign jurisdictions in addition to those discussed above. USSN 13/138,099 (published as US 20120015906), together with counterpart Canadian, European, and Japanese applications, provides methods of prognosing a multiple myeloma subject using an 80 gene profile in isolated plasma cells from the subject. These methods can use plasma cells obtained from a subject before or after administration of a chemotherapeutic agent, such as bortezomib. USSN 13/068,008 (published as US 20110269638) is directed to methods of predicting post-relapse survival of a relapsed multiple myeloma patient by testing the level of gene expression of a group of particular multiple myeloma genes.

The additional issued patents from the UAMS portfolio include U.S. Patent No. 7,308,364, which includes methods of diagnosing multiple myeloma based on the expression levels of 14 genes in plasma cells. U.S. Patent Nos. 7,935,679, or the 679 patent, and 8,501,702, or the 702 patent, are directed to methods of treatment. The 679 patent is directed to methods of treating a subject with multiple myeloma by administering CKS1B antagonists, such as RNA-mediated interference, peptide nucleic acids, an antibody, or CKS1b antisense RNA. The 702 patent provides methods of preventing, repairing, reducing, or treating lytic bone lesions or inhibiting progression of a tumor in the bone of an individual with multiple myeloma by expressing a Wnt-3a ligand in the individual and blocking the activity of DKK1.

U.S. Patent No. 7,723,301 provides methods of inhibiting the teratogenicity of an anti-neoplastic agent by administering Noggin, an anti-DKK1 antibody, LiCl, or Gsk3-inhibitor IX. U.S. Patent Nos. 7,094,886 and 7,696,150 provide claims to an isolated nucleic acid encoding Evi27, a novel protein with homology to the IL-17 receptor (together with vectors and host cells containing this nucleic acid) and methods of inhibiting Evi27 biological activity in a cell by contacting the cell with a soluble isoform of Evi27, respectively.

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Third, we own outright patent applications that were developed internally at Signal Genetics or acquired. These include USSN 13/498,965 (published as US 20130023434), together with corresponding Canadian and European applications, which provides methods of classifying biological samples from a cancer sample, related computer systems, as well as a 200 gene signature for breast cancer.

Fourth, we have and will continue to pursue the registration of our trademarks in the United States and internationally.

Through our clinical laboratory, we provide clinical services that utilize our proprietary trade secrets. In particular, we maintain trade secrets with respect to specimen accessioning, sample preparation and certain aspects of technical analysis. All of our trade secrets are kept under strict confidence and we take all reasonable steps, including the use of non-disclosure agreements and confidentiality agreements, to ensure that our confidential information is not unlawfully disseminated. We also conduct training sessions on the importance of maintaining and protecting trade secrets with our scientific staff and laboratory directors and supervisors.

Third-party Payor Reimbursement

Revenues from our clinical laboratory tests are derived from several different sources. Depending on the billing arrangement and applicable law, parties that reimburse us for our services include but are not limited to:

- third-party payors that provide coverage to enrollees, such as commercial insurers, managed care organizations and governmental payor programs; and
- other authorized parties (such as hospitals or independent laboratories) that order the testing service and pay us for performing the ordered service.

For the three months ended March 31, 2014, we derived approximately 19% of our total revenue from private insurance, including managed care organizations and other health care insurance providers, 16% from government payor programs, most of which was derived from Medicare, and 65% from direct-bill customers, including hospitals and other laboratories. In addition, for the year ended December 31, 2013, we derived approximately 13% of our total revenue from private insurance, including managed care organizations and other health care insurance providers, 14% from Medicare, 73% from direct-bill customers, including hospitals, pharmaceutical companies and other laboratories.

Where there is a coverage policy, contract or agreement in place, we bill the third-party payor, the hospital or referring laboratory where applicable. We also bill patients for deductibles and coinsurance or copayments, where applicable in accordance with the insurance policy or contractual terms. Where there is no coverage policy, contract or agreement in place, we pursue reimbursement from patients on a case-by-case basis. In each case we bill according to applicable Federal and state law, contractual requirements and any other regulations and payor rules and guidance governing coding, coverage and payment. However, it is possible that we may not be in compliance with all the requirements listed above. If we are not in compliance with all requirements, it is possible we could be subject to criminal civil penalties as described below.

At present, the only test for which we are reimbursed is the MyPRS® test. Reimbursement under the Medicare program for MyPRS® is made under the CLFS and is determined by our local MAC. We report MyPRS® using a non-specific CPT code called an unlisted code. Per guidance from our local MAC, in 2013 we began using a new CPT code 81599, Unlisted multianalyte assay with algorithmic analysis. Before 2012 we used another unlisted CPT code per the instructions of the Jurisdiction H MAC. The amount we are reimbursed under this code is subject to change by the MAC without notice and may also change based on changes in the law (*e.g.*, annual payment updates for all laboratory codes).

If we are required to stop using an unlisted code and start using a CPT code that specifically describes MyPRS®, our payment rate may change because payment for codes that describe specific laboratory procedures are assigned national payment rates by CMS. If we are assigned such a code and believe the payment amount is not appropriate, at present, we have the ability to request reconsideration of any such payment amount once. Medicare can establish national payment amounts in one of two ways: (1) by crosswalking the payment amounts from one or more existing CPT codes to the new code (*e.g.*, 1 unit of

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Code A plus three units of Code B plus one half unit of Code C), or (2) by requesting the MACs to develop a payment amount for the new code. Under this second methodology, after the MAC payment amounts are developed, Medicare reviews all the payment amounts and determines the median. Medicare then sets the median as the national limitation amount, or NLA, which is a cap on payment for the test. Any MAC which had set a payment amount lower than the median continues to pay at the lower amount after the NLA is set. There is a one-time opportunity to request reconsideration of the CMS payment amount which must occur immediately following the establishment of the NLA. After the reconsideration process, the payment amount cannot change except that Congress can enact legislation providing for yearly updates in payment amounts for laboratory codes (*e.g.*, an increase or decrease of 0.5%). In billing Medicare for clinical laboratory services, we are required to accept, as payment in full, the lowest of our actual charge, the fee schedule amount for the state or local geographical area or the NLA. There are no Medicare patient coinsurance amounts for clinical laboratory tests. Notwithstanding its current policies, as described above, Medicare has proposed a new policy that would allow it to review the payment amounts for all tests paid under the CLFS. If this policy is finalized, CMS will begin reviewing all clinical laboratory tests on a rolling basis and, unlike today when clinical laboratory payments cannot be changed once established, payment amounts could be reduced periodically after the CMS review. If adopted, this policy could result in a decrease in reimbursement for any test we offer.

As previously noted, the Protecting Access to Medicare Act of 2014, which was signed into law on April 1, 2014, contains provisions that significantly affect Medicare payment for tests that are reimbursed under the CLFS. Specifically, Medicare payment amounts will be based on the amount of payment being made by private payors; many laboratories will be required to report private payor payment amounts to CMS; new tests will generally be paid using the existing crosswalk or gapfilling methodology for determining payment; 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; and, 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. Because the Secretary of HHS has discretion over many aspects of implementing these provisions, 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.

Medicare also has policies that limit when we can bill Medicare directly for our services and where we are required to bill another provider, such as a hospital which bills Medicare and makes payment to us under arrangement. When the testing that we perform is done on a specimen that was collected while the patient was in the hospital, as either an inpatient or outpatient, we are required with some possible exceptions, to bill the hospital for our services, rather than the Medicare program, if the service was ordered fewer than 14 days after the patient s discharge from the hospital. These requirements are complex and time-consuming and may affect our ability to collect for our services, especially if the hospital does not receive separate payment for our test.

With respect to commercial payors, our reimbursement rates can vary based on whether we are considered to be an in-network provider, a participating provider, a covered provider or an out-of-network provider. These definitions can vary from insurance company to insurance company, but we are generally considered an out of network or non-participating provider in the vast majority of cases. It is not unusual for a company that offers highly specialized or unique testing to be an out of network provider. An in-network provider usually has a contracted arrangement with the insurance company or benefits provider. This contract governs, among other things, service-level agreements and reimbursement rates. In certain instances an insurance company may negotiate an in-network rate for our testing rather than pay the typical out-of-network rate. An in-network provider usually has rates that are lower per test than those that are out-of-network , and that rate can vary from a single digit percentage deduction discount to upwards of 25% to 30% percent lower than an out-of-network provider. The discount rate varies based on a variety of factors including the insurance company, the testing type and the specifics of the patient s insurance plan.

In addition, as part of the MCTRJCA, Congress extended the special billing rule that allowed laboratories to bill Medicare for the technical component of certain pathology services furnished to patients of qualifying

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hospitals. Effective July 1, 2012, independent laboratories, like our laboratory, are required to bill for the technical component of these services when ordered by qualifying hospitals. Currently, none of our testing services are subject to this rule.

Billing Codes for Third-party Payor Reimbursement

CPT codes are the main code set used by physicians, hospitals, laboratories and other health care professionals to report separately-payable clinical laboratory tests for reimbursement purposes. The CPT coding system is maintained and updated on an annual basis by the American Medical Association. There is no specific code to report microarray tests for oncology, such as our MyPRS® test. As described previously, we use an unlisted non-specific code to report MyPRS®. At present, there is no requirement for us to obtain a specific CPT code for MyPRS®, although there may be such a requirement in the future. If we do obtain a specific CPT code for MyPRS®, our reimbursement could go down due to the establishment of a national payment amount. However, if we do not obtain a specific code, our reimbursement may also go down because the MAC with jurisdiction in Arkansas can change our reimbursement without notice.

If we do obtain a CPT code specific to MyPRS®, we would be assigned a code from a specific subset of codes for MAAAs. These tests typically use an algorithm applied to certain specific components to arrive at a score that is used to predict a particular clinical outcome. CMS has stated that it will not pay for the algorithmic portion of these tests, because the algorithm does not qualify as a clinical laboratory test. Instead, it will pay for only the specific analytes (*e.g.*, genes) that are performed as part of the MAAA. CMS also stated it has plans to seek additional information about these codes in the future and it is not clear what position CMS will take in the future with respect to making payment for the algorithmic portion of MAAA tests. Its decision could adversely affect future reimbursement for such tests, including MyPRS® and other tests we may develop. Currently 100% of our revenue is derived from MyPRS®, which is a MAAA.

Changes in coding and reimbursement as described above could have an adverse impact on our revenues going forward. If CMS decides not to reimburse for the algorithm included in the MAAA tests, then we would only be able to bill Medicare for the specific genetic examinations that we perform, without the algorithms, and coverage and reimbursement would be uncertain. The introduction of the new codes, in combination with the other action being considered by CMS with regard to pricing, could result in a reduction in the payment that we receive for our tests and make it more difficult to obtain coverage from Medicare or other payors. There is no guarantee that Medicare and other payors will establish positive or adequate coverage policies or reimbursement rates. Please see the section entitled Legislative and Regulatory Changes Impacting Clinical Laboratory Tests for further discussion of certain legislative and regulatory changes to these billing codes and the impact on our business.

Coverage and Reimbursement for MyPRS® Test and Future Service Offerings

Although MyPRS® is a relatively new test, some third-party payors have established coverage and reimbursement policies for it and we have been able to receive reimbursement for MyPRS® from some payors, including major commercial third-party payors.

The current landscape with payors is generally as follows:

Commercial Third-party Payors and Patient Pay. Where there is a coverage policy in place, we bill the payor and the patient in accordance with all applicable laws, regulations and payor policies. Where there is no coverage policy in place, we pursue reimbursement on behalf of each patient on a case-by-case basis. Our efforts in obtaining reimbursement based on individual claims, including pursuing appeals or reconsiderations of claims denials, take a substantial amount of time, and bills may not be paid for many months, if at all. Specifically, if a third-party payor denies coverage after final appeal, payment may not be received at all. We are working to decrease risks of nonpayment by pursuing contractual arrangements with the majority of third-party payors.

Medicare and Medicaid. There is a positive coverage policy from Medicare and we are paid for MyPRS® when performed in accordance with the coverage requirements. However, our coverage could be withdrawn or revised in a way that reduces the amount of our current coverage. Based upon our prior experience, we believe that in the future as much as 30% to 40% of the future market for our tests may be derived from patients covered by Medicare and Medicaid.

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We cannot predict whether, or under what circumstances, payors will reimburse MyPRS® or any of our future tests. Payment amounts can also vary across individual policies. Denial of coverage by payors, or reimbursement at inadequate levels, would have a material adverse impact on market acceptance of our tests.

Legislative and Regulatory Changes Impacting Clinical Laboratory Tests

From time to time, Congress has revised the Medicare statute and the formulas it establishes for both the Medicare CLFS and the Physician Fee Schedule. The payment amounts under the Medicare fee schedules are important not only for our reimbursement under Medicare, but also because the schedule often is used as a basis for establishing the payment amounts set by other third-party payors. For example, state Medicaid programs are prohibited from paying more than the Medicare fee schedule limit for clinical laboratory services furnished to Medicaid recipients.

Under the statutory formula for CLFS amounts, increases are made annually based on the CPI for All Urban Consumers as of June 30 for the previous twelve-month period. As part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Congress eliminated the CPI for All Urban Consumers update from 2004 2008. In addition, for years 2009 through 2013, the Medicare Improvements for Patients and Providers Act of 2008, or MIPPA, mandated a 0.5% cut to the CPI for All Urban Consumers. Accordingly, the update for 2009 was reduced to 4.5% and negative 1.9% for 2010. PPACA, among other things, imposed additional cuts to the Medicare reimbursement for clinical laboratories. Specifically, PPACA replaced the 0.5% cut enacted by MIPPA with a productivity adjustment that will reduce the CPI update in payments for clinical laboratory tests. In 2011, the productivity adjustment was -1.2%. In addition, PPACA includes a separate 1.75% reduction in the CPI update for clinical laboratories for the years 2011 through 2015. The MCTRJCA mandated an additional change in reimbursement for clinical laboratory services payments. This legislation required CMS to reduce the Medicare CLFS by 2% in 2013, which in turn will serve as a base for 2014 and subsequent years. Due to changes in the law required by PPACA and the MCTRJCA and because of sequestration, payment for clinical laboratory services have gone down by 4.89% from 2012 to 2013. In addition, unless Congress acts to end sequestration or make other changes to applicable law, payments for clinical laboratory tests will be subject to additional reductions in 2014 and beyond. MACs have the authority to apply these cuts to locally determined payments for tests, such as MyPRS®, that are reported using unlisted CPT codes. 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.

MyPRS® is not paid under the Medicare Physician Fee Schedule. However, tests we may offer in the future may be paid under that fee schedule. If so, payment rates for such tests will continue to be subject to reductions based on the statutory formula unless Congress intervenes by implementing a temporary or permanent fix to prevent such reductions. For example, on November 27, 2013, CMS issued the 2014 Final Rule calling for a reduction of approximately 20.1% in the 2014 conversion factor that is used to calculate physician reimbursement. This legislatively required reduction in physician payments was postponed until March 31, 2014, when President Obama signed into law on December 26, 2013 H.J. Res. 59, the Bipartisan Budget Act of 2013, which included the Pathway for SGR Reform Act of 2013, providing a short-term reprieve from the Medicare Physician Fee Schedule cut. The Protecting Access to Medicare Act of 2014, which was signed into law on April 1, 2014, further extended this reprieve until December 31, 2014 and provided for a zero percent update through March 31, 2015. If Congress fails to act in future years to offset similar deductions, the resulting decrease in payment could adversely impact our revenues and results of operations. In addition, from time to time, CMS may request that the American Medical Association s Relative Value Scale Update Committee reexamine the relative values of certain pathology codes. The Relative Value Scale Update Committee is an expert panel that provides relative value recommendations to CMS for use in annual updates to the Medicare Physician Fee Schedule. These relative values are used by CMS to determine payments and

CMS seeks to assess whether such codes are misvalued and an adjustment is necessary. We cannot predict at this time whether the Relative Value Scale Update Committee will recommend any changes affecting payment for clinical laboratory services and/or whether CMS will accept those recommendations.

Further, with respect to the Medicare Program, Congress has proposed on several occasions to impose a 20% coinsurance on patients for clinical laboratory tests reimbursed under the CLFS, which would require us to bill patients for these amounts. Because we do not contact patients directly and because patients may never have heard of us, it may be difficult or even impossible to collect any coinsurance amounts. In the event that

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Congress were to ever enact such legislation, the cost of billing and collecting for these services could exceed the amount actually received from the patient and effectively increase our costs of billing and collecting.

If we open up new laboratory locations, some of our Medicare claims could be subject to policies issued by other MACs. For example, if we open a laboratory in California, we would be subject to the policies of Noridian Administrative Services, the current MAC for California, Nevada, Hawaii and certain U.S. territories. In addition, Noridian could issue a decision to non-cover MyPRS®.

Governmental Regulation

Our business is subject to extensive laws and regulations, the most significant of which are summarized below.

Clinical Laboratory Improvement Amendments

We are subject to CLIA, which is administered by CMS, and extends federal oversight to virtually all clinical laboratories by requiring certification by the federal government or by a federally-approved accreditation agency.

Under CLIA, a laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of, or assessment of health. CLIA also requires that we hold a certificate applicable to the type of work we perform and comply with certain standards. CLIA further regulates virtually all clinical laboratories by requiring compliance with various operational, personnel, facilities, administration, quality and proficiency requirements intended to ensure that their clinical laboratory testing services are accurate, reliable and timely. CLIA certification is also a prerequisite to be eligible to bill for services provided to governmental payor program beneficiaries. CLIA is user-fee funded. Therefore, all costs of administering the program must be covered by the regulated facilities, including certification and survey costs.

CLIA has specific conditions for certification. CLIA is intended to ensure the quality and reliability of clinical laboratories, including the accuracy, reliability and timeliness of patient test results performed in clinical laboratories in the United States, by mandating specific standards in the areas of personnel qualification, administration participation in proficiency testing, patient test management, quality control, quality assurance and inspections. CLIA regulations contain guidelines for the qualification, responsibilities, training, working conditions and oversight of clinical laboratory employees. In addition, specific standards are imposed for each type of test that is performed in a laboratory. The categorization of commercially marketed *in vitro* diagnostic tests under CLIA is the responsibility of the FDA. The FDA will assign commercially marketed test systems into one of three CLIA regulatory categories based on their potential risk to public health. Tests will be designated as waived, of moderate complexity or of high complexity. CLIA and the regulations promulgated thereunder are enforced through quality inspections of test methods, equipment, instrumentation, materials and supplies on a periodic basis. The sanction for failure to comply with CLIA requirements may be suspension, revocation or limitation of a laboratory s CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties. If a laboratory is certified as high complexity under CLIA, the laboratory is permitted to obtain analyte specific reagents, or ASRs, which are commercially marketed products that function as the building blocks of *in vitro* diagnostic tests and in-house diagnostic tests known as home brews. We received our CLIA certificate as a high complexity laboratory in 2011. To renew this certificate, we participate in periodic CLIA inspections approximately every two years. Our most recent CLIA inspection took place on January 18, 2013, and has resulted in certification for two years starting July 22, 2013, the date of expiration of the previous certification. Loss of our CLIA certification, change in CLIA or CLIA regulations or in the interpretation thereof, could have a material adverse effect on our business.

New York State Laboratory Licensing

We are in the process of obtaining a license for our laboratory from the New York State Department of Health. New York state laws and regulations also establish standards for the day-to-day operations of clinical laboratories, including physical facility requirements and equipment and quality control. New York standards include proficiency testing requirements, even for a laboratory not located within the state. In addition, the New York Department of Health separately approves certain LDTs offered in New York State. The Company expects to obtain the requisite approvals for its LDTs in New York.

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Other States Laboratory Testing

In addition to New York, certain other states, including, California, Florida, Maryland, Pennsylvania, and Rhode Island require that we hold licenses to test specimens from patients residing in those states even though we are physically located in Arkansas. We have obtained licenses in these states and believe we are in compliance with their applicable licensing laws.

From time to time, other states may require out of state laboratories to obtain licensure in order to accept specimens from such state. If we identify any other state with such requirements or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements.

Other Laboratory Regulations

Our clinical operations are also subject to regulation under state laws that may be more stringent than CLIA. State clinical laboratory laws generally require that laboratories and/or laboratory personnel meet certain qualifications. State clinical laboratory laws also generally require laboratories to specify certain quality controls and maintain certain records. For example, California requires that we maintain a state issued license and comply with California standards for our laboratory operations, including the standards for laboratory personnel and quality control. Additional states may require similar licenses in the future. Potential sanctions for violation of these state requirements include significant fines and the suspension or loss of various licenses, certificates and authorizations, which could adversely affect our business and results of operations. Finally, we may be subject to regulation in foreign jurisdictions, including in Europe and Asia, if we expand offering of our tests or distribution of our tests internationally.

HIPAA Compliance and Privacy Protection and the HITECH Act

HIPAA and its implementing regulations established comprehensive federal protection for the privacy and security of health information. The HIPAA standards apply to three types of organizations, or Covered Entities: health plans, health care clearing houses, and health care providers who conduct certain health care transactions electronically, or Standard Transactions. Covered Entities must have in place administrative, physical and technical safeguards to protect against the misuse of individually identifiable health information, or PHI. Additionally, some state laws impose privacy and security protections more stringent than HIPAA s and some states impose privacy and security obligations specifically applicable to clinical laboratories. Additionally, many states have implemented data breach laws requiring additional security measures for certain types of PHI and also public notification of the theft, breach or other loss of personal information. There are also international privacy laws, such as the European Data Directive and various national laws implementing the Data Directive, that impose restrictions on the access, use, and disclosure of health information and other types of identifiable personal information. All of these laws may impact our business. We are a Covered Entity subject to the HIPAA regulations because our testing services are reimbursable by insurance payors and we conduct Standard Transactions. We have an active program designed to address HIPAA regulatory compliance. This program will likely require periodic updating to comply with amendments to HIPAA. Regardless of our own Covered Entity status, HIPAA presently applies to many of the facilities and physicians with whom we do business and controls the ways in which we may obtain tissue specimens and associated clinical information from those facilities and physicians. We believe we have taken the steps required for us to comply with applicable health information privacy and confidentiality statutes and regulations under both federal and applicable state jurisdictions. However, we may not be able to maintain compliance in all jurisdictions where we do business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain tissue specimens and

associated patient information could significantly impact our business and our future business plans.

Additionally, the HITECH Act and the regulations promulgated thereunder by the HHS require HIPAA covered entities, including clinical laboratories, to provide notification to affected individuals and to the Secretary of HHS, following discovery of a breach of unsecured PHI. In some cases, the HITECH Act requires covered entities to provide notification to the media of breaches. In the case of a breach of unsecured PHI at or by a business associate of a covered entity, the HITECH Act requires the business associate to notify the covered entity of the breach. The HITECH Act requires the Secretary of HHS to post on the HHS website a list of covered entities that experience breaches of unsecured PHI involving more than 500

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individuals. The HITECH Act made other changes relating to the HIPAA privacy and security rules, including, among others, establishing that, effective February 17, 2010, the HIPAA security and certain privacy regulations apply directly to business associates and, consequently, that a business associate s violation of the HIPAA regulations may result in government enforcement action directly against the business associate or the covered entity with whom the business associate contracts depending upon the nature of that business relationship. The regulations implementing this portion of the HITECH Act, however, were not issued until January 25, 2013, with a compliance date of September 23, 2013. We contract with business associates to provide certain services regulated by the HIPAA regulations and therefore must comply with the HIPAA regulations governing those business relationships.

In summary, 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.

Federal and State Physician Self-referral Prohibitions

We are subject to the Stark Law, and restrictions under California s Physician Ownership and Referral Act, or PORA. These restrictions prohibit us from billing a patient or any governmental or private payor for any test when the physician ordering the test, or any member of such physician s immediate family, has an investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition.

Both the Stark Law and PORA contain an exception for referrals made by physicians who hold investment interests in a publicly traded company that has stockholders equity exceeding $75 million at the end of its most recent fiscal year or on average during the previous three fiscal years, and which satisfies certain other requirements. In addition, both the Stark Law and PORA contain an exception for compensation paid to a physician for personal services rendered by the physician. In the future we may develop compensation arrangements with other physicians for personal services, such as speaking engagements and specimen tissue preparation. We will structure these arrangements with terms intended to comply with the requirements of the personal services exception to Stark Law and PORA and other applicable laws.

However, we cannot be certain that regulators would find these arrangements to be in compliance with Stark Law, PORA or similar state laws. If we are deemed out of compliance by the applicable regulators, we would be required to refund any payments we receive pursuant to a referral prohibited by these laws to the patient, the payor or the Medicare program, as applicable.

Penalties for a violation of the Stark Law include: refunds of amounts collected by an entity in violation of the Stark Law, denial of payment for the services provided in violation of the prohibition, and civil penalties of up to $15,000 per service arising out of the prohibited referral. Additionally, a person who engages in a scheme to circumvent the Stark Law s prohibition may be subject to a civil penalty of up to $100,000. A violation of PORA is a misdemeanor and could result in civil penalties and criminal fines.

Other states have self-referral restrictions with which we have to comply that differ from those imposed by federal and California law.

While we have attempted to comply with these laws, it is possible that some of our financial arrangements with pathologist and other physicians could be subject to regulatory scrutiny at some point in the future, and we cannot provide assurance that we will be found to be in compliance with these laws following any such regulatory review.

Federal, State and Foreign Fraud and Abuse Laws

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under a governmental payor program. The definition of remuneration has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, waivers of co-payments, ownership interests and providing anything at less than its fair market value. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements

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within the health care industry, the HHS has issued a series of regulatory safe harbors. These safe harbor regulations set forth certain provisions, which, if met, will assure health care providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. For further discussion of the impact of federal and state health care fraud and abuse laws and regulations on our business, see the section entitled Risk Factors Risks Related to Our Business 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, or if a tribunal has determined that we do not fully comply with such laws.

In addition to the administrative simplification regulations discussed above, HIPAA also created two new federal crimes: health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from governmental payor programs such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from governmental payor programs.

Finally, another development affecting the health care industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act s whistleblower or qui tam provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal governmental payor program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has defrauded the federal government by submitting a false claim to the federal government and permit such individuals to share in any amounts paid by the entity to the government in fines or settlement. In addition, various states have enacted false claim laws analogous to the federal False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a governmental payor program. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties ranging from $5,500 to $11,000 for each false claim.

Additionally, in Europe various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines, for individuals and/or companies committing a bribery offence. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the Bribery Act 2010, which went into effect in July 2011, a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act 2010. Under the new regime, an individual found in violation of the Bribery Act 2010, faces imprisonment of up to 10 years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

There are federal and state laws prohibiting fraudulent billing and providing for the recovery of non-fraudulent overpayments, as a large number of laboratories have been forced by the federal and state governments, as well as by private payors, to enter into substantial settlements under these laws. In particular, if an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties ranging from $5,500 to $11,000 for each separate false claim. While there are many potential bases for liability under the federal False Claims Act, such liability primarily arises when an entity

knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. Submitting a claim with reckless disregard or deliberate ignorance of its validity could result in substantial civil liability. A current trend within the health care industry is the increased use of the federal False Claims Act and, in particular, actions under the False

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Claims Act s whistleblower or qui tam provisions to challenge providers and suppliers. Those provisions allow a private individual standing to bring actions on behalf of the government, alleging that the defendant has submitted a fraudulent claim for payment to the federal government. The government may join in the lawsuit, but if the government declines to do so, the individual may choose to pursue the lawsuit alone. The government must be kept apprised of the progress of the lawsuit. Whether or not the federal government intervenes in the case, it will receive the majority of any recovery. In addition, various states have enacted laws modeled after the federal False Claims Act.

Even though we believe we are in compliance with these laws and regulations, it is possible the government may determine that we are not in compliance, in which case we could be subject to civil and criminal penalties.

The Physician Payment Sunshine Act

The Physician Payment Sunshine Act, or the Sunshine Act, which was enacted as part of PPACA, requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare, Medicaid or the Children s Health Insurance Program, to report annually to HHS payments or other transfers of value made by that entity, or by a third party as directed by that entity, to physicians and teaching hospitals, or to third parties on behalf of physicians or teaching hospitals, during the course of the preceding calendar year. Similar reporting requirements have also been enacted on the state level in the United States, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with health care professionals. In addition, some states such as Massachusetts and Vermont impose an outright ban on certain gifts to physicians.

The final rule implementing the Sunshine Act, published on February 8, 2013, requires data collection on payments to begin on August 1, 2013. The first annual report, comprised of data collected from August 1, 2013 to December 31, 2013, is due March 31, 2014. Failure to comply with the reporting requirements can result in significant civil monetary penalties ranging from $1,000 to $10,000 for each payment or other transfer of value that is not reported (up to a maximum per annual report of $150,000) and from $10,000 to $100,000 for each knowing failure to report (up to a maximum per annual report of $1 million). We believe that our laboratory is not an applicable manufacturer as that term is defined in the final rule implementing the Sunshine Act, and, therefore, we are not required to collect data on and report these payments. However, we cannot be certain that regulators will agree with our position. If we are deemed to be an applicable manufacturer subject to the Sunshine Act, we could be subject to civil monetary penalties for failing to comply with the requirements.

These laws could affect our promotional activities by limiting the kinds of interactions we could have with hospitals, physicians or other potential purchasers or users of our tests. Both the disclosure laws and gift bans could impose administrative, cost and compliance burdens on us.

Food and Drug Administration

The FDA regulates the sale or distribution in interstate commerce, of medical devices, including *in vitro* diagnostic test kits. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls, including labeling, listing, registration, and reporting. It may also include pre-market notification and adherence to the FDA s quality system regulation, which are device-specific good manufacturing practices. Class II devices are subject to general controls and special controls, such as performance standards and post-market surveillance. Class III devices are subject to most of the previously identified requirements as well as to PMA. Most *in vitro* diagnostic kits are regulated as Class I or Class II devices.

Entities that fail to comply with FDA requirements can be liable for criminal or civil penalties, recalls, seizures, orders to cease manufacturing and restrictions on labeling and promotion.

The FDA presently requires clearance or approval of diagnostic test kits that are sold to laboratories, hospitals and doctors, considering them to be medical devices. However, diagnostic tests that are developed and performed by a CLIA-certified reference laboratory, known as home-brew, in-house or LDTs have