

SIGNAL GENETICS, INC.

Form S-1/A

February 13, 2015

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

**Registration No. 333-201533**

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

**AMENDMENT NO. 2  
TO  
FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

**SIGNAL GENETICS, INC.**

*(Exact name of registrant as specified in its charter)*

Delaware  
(State or other jurisdiction of  
incorporation or organization)

8071  
(Primary Standard Industrial  
Classification Code Number)

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

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

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

**Samuel D. Riccitelli  
President and Chief Executive Officer  
Signal Genetics, Inc.  
5740 Fleet Street Carlsbad, California  
(760) 537-4100**

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

## **Copies to:**

Daniel I. Goldberg, Esq.  
Reed Smith LLP  
599 Lexington Avenue  
New York, NY 10022  
Telephone: (212) 521-5400  
Facsimile: (212) 521-5450

**Brad L. Shiffman, Esq.  
Blank Rome LLP  
405 Lexington Avenue  
New York, NY 10174  
Telephone: (212) 885-5000  
Facsimile: (212) 885-5001**

**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

Edgar Filing: SIGNAL GENETICS, INC. - Form S-1/A

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if smaller reporting company)

Smaller reporting company

---

TABLE OF CONTENTS**CALCULATION OF REGISTRATION FEE**

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

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

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

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

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

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

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

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

---

TABLE OF CONTENTS

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

**PRELIMINARY PROSPECTUS      SUBJECT TO COMPLETION      DATED FEBRUARY 13, 2015**

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

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

Our common stock is listed on The NASDAQ Capital Market under the symbol SGNL . On January 27, 2015, the last reported sale price of our common stock on The NASDAQ Capital Market was \$2.60 per share.

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

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

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

	Per Share	Total
Public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Proceeds, before expenses, to us	\$	\$

The underwriters will receive compensation in addition to the underwriting discount. The registration statement, of which this prospectus is a part, also registers for sale warrants to purchase 144,230 shares of our common stock to be issued to the representative of the underwriters. We have agreed to issue the warrants to the representative of the underwriters as a portion of the underwriting compensation payable to the underwriters in connection with this offering. See Underwriting beginning on page 122 of this prospectus for a description of compensation payable to the underwriters, including a description of the warrants.

We have granted a 45-day option to the underwriters to purchase up to 432,692 additional shares of common stock solely to cover over-allotments, if any.

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

*Joint Book-Running Managers*

**Aegis Capital Corp**

**Chardan Capital Markets, LLC**  
2015

---

TABLE OF CONTENTS**TABLE OF CONTENTS**

	Page
<u>PROSPECTUS SUMMARY</u>	<u>1</u>
<u>THE OFFERING</u>	<u>10</u>
<u>SUMMARY HISTORICAL CONSOLIDATED FINANCIAL DATA</u>	<u>12</u>
<u>RISK FACTORS</u>	<u>14</u>
<u>CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	<u>47</u>
<u>USE OF PROCEEDS</u>	<u>48</u>
<u>MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS</u>	<u>49</u>
<u>CAPITALIZATION</u>	<u>50</u>
<u>DILUTION</u>	<u>51</u>
<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	<u>52</u>
<u>BUSINESS</u>	<u>64</u>
<u>MANAGEMENT</u>	<u>95</u>
<u>EXECUTIVE COMPENSATION</u>	<u>101</u>
<u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT</u>	<u>110</u>
<u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS</u>	<u>112</u>
<u>MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK</u>	<u>114</u>
<u>DESCRIPTION OF SECURITIES</u>	<u>118</u>
<u>UNDERWRITING</u>	<u>122</u>
<u>LEGAL MATTERS</u>	<u>130</u>
<u>EXPERTS</u>	<u>130</u>
<u>WHERE YOU CAN FIND ADDITIONAL INFORMATION</u>	<u>130</u>
<u>GLOSSARY OF TERMS</u>	<u>131</u>
<u>INDEX TO FINANCIAL STATEMENTS</u>	<u>F-1</u>

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

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

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

i

---



TABLE OF CONTENTS

## PROSPECTUS SUMMARY

*This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our securities, you should carefully read this entire prospectus, including our financial statements and the related notes and the information set forth under the headings Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operations in each case included elsewhere in this prospectus. In this prospectus, unless the context otherwise requires, the terms we, us, our, Signal Genetics and the Company refer to Signal Genetics, Inc. and its consolidated subsidiaries. We have provided definitions for some of the terms we use to describe our business and industry and other terms used in this prospectus in the Glossary of Terms beginning on page 131 of this prospectus.*

### Signal Genetics, Inc.

#### Business Overview

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

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

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

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

1

---

## TABLE OF CONTENTS

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

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

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

### **Our Services**

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

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

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

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

TABLE OF CONTENTS

## Market Opportunities

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

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

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

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

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

The applicability of our test for use in predicting MM progression from AMG could create a substantial increase in the potential patient population eligible for MyPRS® testing and as such represents an important pillar of our growth strategy. We estimate the total potential MM testing market in the United States at approximately 36,000 patients per year, including newly diagnosed and relapsed patients. We believe we currently service just over 2% of this market.

We estimate that the addition of an AMG progression indication feature for the MyPRS® test could expand the MyPRS® addressable market in the United States to more than 135,000 patients per year. As a specialty focused diagnostic laboratory company, we hope for such opportunities to expand our service offerings for the benefit and convenience of physicians and patients.

TABLE OF CONTENTS

## **Our Competitive Strengths**

### **Differentiated value proposition of the MyPRS® test**

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

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

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

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

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

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

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

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

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

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



## TABLE OF CONTENTS

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

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

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

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

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

### **Early success in establishing positive reimbursement coverage for MyPRS®**

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

## **Experienced oncology-centered laboratory and clinical trial services**

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

5

---

TABLE OF CONTENTS

## **Our Growth Strategy**

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

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

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

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

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

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

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

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

Expanding and leveraging our capabilities into additional blood cancer indications;

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

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

## **Recent Developments**

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

Tests from our largest customer, UAMS, totaled 3,671 resulting in net revenue of approximately \$3.6 million, net of unfavorable changes in estimates of \$0.2 million recorded in the current year as an adjustment to prior year revenues. Tests from our non-UAMS hospital customers totaled 509, a 50% increase over the prior year, resulting in net revenue of approximately \$0.7 million, net of unfavorable changes in estimate of \$0.2 million recorded in the current year as an adjustment to prior year revenues.

Management also estimates cash of approximately \$5.1 million at December 31, 2014. There are 3,782,629 shares of common stock outstanding as of the date of this prospectus, which does not include 25,934 shares of our common stock to be issued to an employee upon the settlement of restricted stock units that vested January 1, 2015.

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

TABLE OF CONTENTS

## Risks

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## TABLE OF CONTENTS

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

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

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

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

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

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

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

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

## **Implications of Being an Emerging Growth Company**

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

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

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

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

reduced disclosure obligations regarding executive compensation; and

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

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than \$1.0 billion in annual revenues, have more than \$700.0 million in market value of our capital stock held by non-affiliates or issue more than \$1.0 billion of non-convertible debt over a three-year period. We may choose



TABLE OF CONTENTS

to take advantage of some, but not all, of the available exemptions. We have taken advantage of some reduced reporting burdens in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

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

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

## **Corporate Information**

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

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

TABLE OF CONTENTS

## THE OFFERING

Issuer

Signal Genetics, Inc.

Common stock offered by us

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

Over-allotment option

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

Common stock to be outstanding immediately after this offering

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

Use of Proceeds

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

Representative's warrants

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

Risk Factors

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

NASDAQ Capital Market Symbol

SGNL

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

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

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

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

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



TABLE OF CONTENTS

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

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

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

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

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

11

---

TABLE OF CONTENTS**SUMMARY HISTORICAL CONSOLIDATED FINANCIAL DATA**

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

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

Net loss attributable to  
stockholders of Signal Genetics,  
Inc.

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

12

---

TABLE OF CONTENTS

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

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

13

TABLE OF CONTENTS

## RISK FACTORS

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

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

### **Risks Related to our Financial Condition**

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

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

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

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

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

### **We will need to raise additional capital.**

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

## TABLE OF CONTENTS

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

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

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

## **Risks Related to our Business**

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

Maintaining and growing revenues from MyPRS® depends on the availability of adequate coverage and reimbursement for our tests from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. Health care providers that order diagnostic services such as MyPRS® generally expect that those diagnostic services are covered and reimbursed by third-party payors for all or part of the costs and fees associated with the diagnostic tests they order. If such diagnostic tests are not covered and reimbursed then their patients may be responsible for the entire cost of the test, which can be substantial. Therefore, health care providers generally do not order tests that are not covered and reimbursed by third-party payors in order to avoid subjecting their patients to such financial liability. The existence of adequate coverage and reimbursement for the procedures performed with MyPRS® by government and private insurance plans is central to the acceptance of

MyPRS® and any future services we provide. During the past several years, third-party payors have undertaken cost-containment initiatives including different payment methods, monitoring health care expenditures, and anti-fraud initiatives. In addition, the Centers for Medicare & Medicaid Services, or CMS, which administers the Medicare program, has taken the position that the algorithm portion of multi-analyte algorithmic assays, or 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 policies is uncertain. For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state, and some state Medicaid programs may not pay an adequate amount for MyPRS® or may make no payment at all. As the portion of the U.S. population over the age of 65 and eligible for Medicare continues to grow, we may be more vulnerable to coverage and reimbursement limitations imposed by

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



TABLE OF CONTENTS

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

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

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

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

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

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

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

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

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

TABLE OF CONTENTS

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

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

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

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

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

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

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

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

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

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

TABLE OF CONTENTS

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

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

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

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

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

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

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

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

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

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

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

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

TABLE OF CONTENTS

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

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

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

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

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

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

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

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

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



TABLE OF CONTENTS

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

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

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

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

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

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

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

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

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

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

TABLE OF CONTENTS

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

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

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

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

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

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

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

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

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

TABLE OF CONTENTS

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

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

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

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

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

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

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

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

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

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

TABLE OF CONTENTS

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

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

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

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

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

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

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

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

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



TABLE OF CONTENTS

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

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

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

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

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

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

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

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

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

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

TABLE OF CONTENTS

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

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

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

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

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

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

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

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

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

TABLE OF CONTENTS

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

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

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

## **Regulatory Risks Relating to Our Business**

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

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

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

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

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

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

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

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

26

---

## TABLE OF CONTENTS

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

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

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

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

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

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

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

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

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



TABLE OF CONTENTS

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

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

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

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

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

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

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

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

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

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

TABLE OF CONTENTS

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

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

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

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

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

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

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

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

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

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

TABLE OF CONTENTS

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

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

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

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

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

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

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

**If the FDA were to begin requiring approval or clearance of our tests, we could incur substantial costs and time delays associated with meeting requirements for pre-market clearance or approval or we could experience decreased**

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

## **demand for, or reimbursement for our tests.**

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

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

TABLE OF CONTENTS

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

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

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

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

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

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



TABLE OF CONTENTS

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

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

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

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

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

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

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

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

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

TABLE OF CONTENTS

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

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

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

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

the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, in return for, to induce or to arrange for the referral of an individual for, or the purchase, order or recommendation of, any items or services for which payment may be made under a federal health care program such as the Medicare and Medicaid programs;

the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of designated health services with whom the physician or a member of the physician's immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which establishes federal crimes for knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services;

the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

the federal Physician Payment Sunshine Act requirements under the ACA, which require manufacturers of drugs, devices, biologics and medical supplies to report to HHS information related to payments and other transfers of value made to or at the request of covered recipients, such as physicians and teaching hospitals, and physician ownership and investment interests in such manufacturers. Payments made to physicians and research institutions for clinical trials are included within the ambit of this law; and

state law equivalents of each of the above federal laws, such as anti-kickback, physician self-referral and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

We seek to comply with these laws. However, it is possible that we could be the subject of a government investigation regarding our compliance with these laws and that the government could take the position that we are not in compliance with one or more of them. In such case, we may be judged to be in violation of those laws and subject to

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

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

## TABLE OF CONTENTS

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

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

### **Anti-Kickback Statutes**

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

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

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

### **False Claims Act and Related Criminal Provisions**

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

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

## TABLE OF CONTENTS

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

### **Civil Monetary Penalties Law**

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

### **Stark Law**

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

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

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

**The Health Insurance Portability and Accountability Act of 1996**

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



## TABLE OF CONTENTS

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

### **Other Fraud and Abuse Laws**

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

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

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

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

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

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

## TABLE OF CONTENTS

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

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

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

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

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

### **Intellectual Property Risks Related to Our Business**

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

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

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

Currently, we are the worldwide exclusive licensee, in our licensed field, or the owner of 12 issued patents (11 issued U.S. patents and one issued Japanese patent) and 21 pending patent applications (one of which was allowed by the USPTO on December 9, 2014), which include both U.S. and foreign patent applications, relating to various aspects of our technology. Of the 21 pending patent applications, five are owned outright by Signal Genetics, Inc. Our exclusive field of use covers, inter alia, therapeutic, diagnostic,

TABLE OF CONTENTS

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

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

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

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

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

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

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

TABLE OF CONTENTS

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

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

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

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

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

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

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

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

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

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



## TABLE OF CONTENTS

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

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

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

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

## **Risks Related to our Common Stock and this Offering**

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

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

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

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

TABLE OF CONTENTS

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

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

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

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

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

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

other acquisitions or dispositions of businesses or assets;  
incurrence of indebtedness and the issuance of equity securities;  
repurchase of stock and payment of dividends; and  
the issuance of shares to management under our equity incentive plans.

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

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

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

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

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

TABLE OF CONTENTS

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

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

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

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

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

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

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

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

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

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

TABLE OF CONTENTS

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

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

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

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

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

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

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

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



TABLE OF CONTENTS

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

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

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

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

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

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

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

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

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

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

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

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

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

TABLE OF CONTENTS

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

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

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

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

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

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

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

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

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

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

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

TABLE OF CONTENTS

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.

TABLE OF CONTENTS

## **CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

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

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

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

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

TABLE OF CONTENTS

## **USE OF PROCEEDS**

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

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

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

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

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

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

TABLE OF CONTENTS**MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS**

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

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

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

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

 **Holders**

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

**Dividend Policy**

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



TABLE OF CONTENTS**CAPITALIZATION**

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

on an actual basis; and

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

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

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

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

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

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

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

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

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

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

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



TABLE OF CONTENTS

**DILUTION**

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

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

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

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

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

Assumed public offering price per share		\$ 2.60
Net tangible book value per share as of September 30, 2014	\$ 1.99	
Increase per share attributable to new investors	\$ 0.13	
As adjusted net tangible book value per share after this offering		2.12
Dilution per share to new investors		\$ .48

If the underwriters exercise their over-allotment option in full, the as adjusted net tangible book value will increase to \$2.14 per share, representing an immediate dilution of \$0.46 per share to new investors, assuming that the public offering price will be \$2.60 per share, which was the latest reported sale price of our common stock on the NASDAQ Capital Market on January 27, 2015.

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.

TABLE OF CONTENTS

# 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 a commercial stage, molecular genetic diagnostic company focused on providing innovative diagnostic services that help physicians make better-informed decisions concerning the care of their patients suffering from cancer. Our mission is to develop, validate and deliver innovative diagnostic services that enable better patient-care decisions.

We were founded in January 2010 and hold an exclusive license in our licensed field to the intellectual property stemming from the renowned research on MM performed at UAMS. Our flagship service offering is the MyPRS® test, which is a microarray-based GEP assay that tests for the 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 our MyPRS® test aids physicians in selecting the optimal treatment regimen 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 12 issued patents and 21 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 and the National Cancer Institute, MM represents 1% of all cancers, 2% of all cancer-related deaths and is the second most common blood cancer after NHL representing approximately 15% of all hematolymphomas. Approximately 24,050 new cases of MM were diagnosed in the United States in 2014 and there are an estimated 83,360 people currently living with MM in the United States. The five-year survival rate for people with MM is about 45%. 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 SMM, to full-blown MM. Collectively, these precursor conditions, MGUS and SMM, 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 studies 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 in the United States at approximately 36,000 patients per year, including newly diagnosed and relapsed patients. We believe we currently service just over 2% of this market. We estimate that the addition of an AMG progression indication feature for the MyPRS® test could expand the MyPRS® addressable market in the United States to more than 135,000 patients per year. [ *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]

## TABLE OF CONTENTS

Our growth strategy includes the following key elements:

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

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

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

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

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

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

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

Expanding and leverage our capabilities into additional blood cancer indications.

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

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

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 hired our Vice President of Managed Care and Payor Relations to 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. Further, 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](http://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 justifies reimbursement approval by the majority of health care payors.

Other challenges to our growth strategy include: (1) 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) if payors, including our currently contracted payors, decide to 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 and test results are delivered to ordering physicians. During the nine months ended September 30, 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 81%, 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 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

## TABLE OF CONTENTS

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 and supplies, 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 personnel costs, 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.

Revenues are recorded on an accrual basis when the contractual obligations are completed as a set of assays is processed through our laboratory and test results are delivered to ordering physicians. 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. We report revenues from Medicare, contracted insurance companies and directly billed customers based on the contractual rate. The contractual rate is based on established agreed upon rates between the Company and the respective payor and is the price invoiced by the Company. We report revenues from non-contracted insurance companies 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

TABLE OF CONTENTS

amount billed and the amount estimated to be collected from non-contracted insurance companies 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-payers. Gross revenues from individuals have been immaterial.

Our estimates of net revenue from 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 revenues in 2013. This represented 6% of the total non-contracted revenues for 2012 and 1% of our total net revenues for 2012. During the nine months ended September 30, 2014, we recorded an unfavorable change in estimate related to non-contracted revenues previously recorded during 2012 and 2013 of \$65,000 and \$79,000, respectively. This represented 7% of the total non-contracted revenues for 2012 and 14% of the total non-contracted revenues for 2013. If we have a similar cumulative percentage reduction of 14% in our estimated amount to be collected from non-contracted payors on the uncollected accounts receivable from non-contracted payors at September 30, 2014 of \$611,000, this could result in an \$85,000 unfavorable change in our financial position and results of operations.

**Accounts Receivable and Allowance for Doubtful Accounts**

We record accounts receivable net of an allowance 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. During the nine months ended September 30, 2014, the Company determined that approximately \$78,000 of insurance reimbursements were sent directly to patients, in error, and identified approximately \$66,000 of older Medicare claims that may be past the due date requirements. Although the Company will attempt to recover these funds, an allowance for doubtful accounts of approximately \$144,000 was set up at September 30, 2014 due to the uncertainty of these collections. There was no bad debt expense or allowance for doubtful accounts recorded as of 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 September 30, 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:

	September 30, 2014					Total
	0	30 Days	31 60 Days	61 90 Days	Over 90	
Medicare	\$ 34,530	\$ 47,579	\$ 27,916	\$ 164,825	\$ 274,850	
Contracted insurance companies	10,000	16,000	10,921	104,036	140,957	
Direct bill	300,927	331,832			632,759	
Non-contracted insurance companies	134,300	114,945	122,930	1,890,277	2,262,452	
Individual reimbursements				77,903	77,903	
	479,757	510,356	161,767	2,237,041	3,388,921	

Edgar Filing: SIGNAL GENETICS, INC. - Form S-1/A

Less: Contractual allowances	84,543	71,232	80,053	1,458,603	1,694,431
Less: Allowance for doubtful account				144,492	144,492
Accounts receivable, net	\$ 395,214	\$ 439,124	\$ 81,714	\$ 633,946	\$ 1,549,998

---

55

TABLE OF CONTENTS

	December 31, 2013				
	0	31	61	90	
	Days	Days	Days	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

	December 31, 2012				
	0	31	61	90	
	Days	Days	Days	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 nine months ended September 30, 2014 and the years ended December 31, 2013 and 2012 was 93, 89 and 101 days, respectively. The increase in the number of days from December 31, 2013 to September 30, 2014 is primarily due to increased revenues from our non-contracted insurance companies, which have historically taken longer to pay. The increase in the aging of our non-contracted insurance companies is also the result of inefficiencies we discovered in 2013 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 believe will enable us to collect significant portions of these 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. Revenues from non-contracted insurance companies represented 13%, 13% and 23% of our total revenues during the nine months ended September 30, 2014 and the years ended December 31, 2013 and 2012, respectively. Since these customers are slower to pay, our accounts receivable over 90 days will increase if revenues from these customers increase.

**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.

## TABLE OF CONTENTS

### **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 that other than as disclosed in Note 2 to the consolidated financial statements included herein, such standards will not have a material impact on our consolidated financial statements or do not otherwise 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 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**

#### **Nine Months Ended September 30, 2014 Compared to Nine Months Ended September 30, 2013**

##### **Revenue**

Net revenue was \$3,665,484, net of an unfavorable change in estimate of \$144,065 recorded in the current period as an adjustment to prior year revenues, for the nine months ended September 30, 2014, an increase of \$439,603, or 14%, compared to \$3,225,881 for the same period in 2013. The increase in net revenue was due to a combination of the following factors:

A \$257,909 increase in net revenue sourced either from or through our major customer, UAMS. Despite a 1% decrease in UAMS tests performed during the nine months ended September 30, 2014 as compared to the same period in 2013 (2,682 tests performed in 2014 versus 2,714 tests performed in 2013), the average sales price per test increased by \$137, or 14%, primarily due to the mix in the type of testing being performed (research versus clinical). The increase was offset by a change in estimate of \$76,374 recorded in the current period for prior year revenues.

A \$181,694 increase in net revenue sourced from non-UAMS customers. Despite a 66% decrease in net revenue from pharmaceutical companies due to the completion of a clinical study in 2013 (\$66,545 decrease), net revenue from other hospitals outside of UAMS increased by 62% (a \$248,239 increase). The increase in net revenues resulted from a 44% increase in the number of tests performed during the nine months ended September 30, 2014 as compared to the same period in 2013 (387 tests performed in 2014 versus 268 tests performed in 2013) despite the fact that we performed 27 fewer tests for pharmaceutical companies due to the completion of the clinical study in 2013. Additionally, we experienced an increase in average sales price per test of \$67, or 4%. The increase was offset by a change in estimate of \$67,691 recorded in the current period for prior year revenues.

57

---

## TABLE OF CONTENTS

### **Cost of revenue**

Cost of revenue was \$2,333,216 (64% of revenues) for the nine months ended September 30, 2014, an increase of \$222,893, or 11%, compared to \$2,110,323 (65% of revenues) for the same period in 2013. The increase was primarily attributable to: (1) \$88,000 in increased personnel costs primarily related to a one-time bonus paid to a key operations employee in July 2014 and costs associated with an accrued incentive plan offset by a decrease in other personnel costs and (2) \$158,000 in increased material and supply costs due to increases in costs from our suppliers and increases in the usage of certain materials to support the increased number of tests performed offset by (3) a \$40,000 decrease in IT-related consulting costs.

### **Selling and marketing expenses**

Selling and marketing expenses were \$325,639 for the nine months ended September 30, 2014, an increase of \$72,545, or 29%, compared to \$253,094 for the same period in 2013. The increase in selling and marketing expenses was primarily attributable to an increase in personnel and other operating expenses related to establishing a marketing and commercial strategy and business development functions for the Company. We plan to further expand our sales force and marketing expenditures in the future.

### **General and administrative expenses**

General and administrative expenses were \$1,891,006 for the nine months ended September 30, 2014, an increase of \$759,541, or 67%, compared to \$1,131,555 for the same period in 2013. The increase was primarily attributable to: (1) \$241,000 in personnel costs and recruiting fees related to the hiring of our Chief Financial Officer, Controller and administrative staff in August and September of 2014; (2) \$270,000 of legal, accounting, insurance and other expenses related to our becoming a publicly-traded company; (3) \$144,000 of bad debt expense related to our establishing an allowance for doubtful accounts; and (4) \$85,000 in management consulting services.

### **Stock Compensation**

Stock compensation expense was \$3,578,465 for the nine months ended September 30, 2014, compared to no expense for the same period in 2013. Stock compensation expense in 2014 related to the restricted stock units and stock options that were granted to certain individuals in connection with our initial public offering as well as to new employees and members of the board of directors and, in particular, the portion of certain restricted stock units that vested upon the consummation of our initial public offering in June 2014.

### **Research and development expenses**

Research and development expenses were \$148,288 for the nine months ended September 30, 2014, a decrease of \$33,905, or 19%, compared to \$182,193 for the same period in 2013. The primary reason for the decrease was our 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.



**Interest expense**

Interest expense was \$1,020,801 for the nine months ended September 30, 2014, compared to \$1,505,198 for the same period in 2013. The decrease was primarily attributable to the Debt Conversion (as described under Certain Relationships and Related Transactions ) that occurred on June 17, 2014. We expect that interest expense going forward will decrease significantly.

**Net loss attributable to stockholders**

For the foregoing reasons, we had a net loss attributable to stockholders of Signal Genetics, Inc. of \$(5,631,931) for the nine months ended September 30, 2014, compared to a net loss attributable to stockholders of Signal Genetics, Inc. of \$(2,196,482) for the nine months ended September 30, 2013.

TABLE OF CONTENTS

**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 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 \$91. 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, cost of revenue includes 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 further 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 decrease was due to decreased legal costs primarily related to a tortious 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.

## TABLE OF CONTENTS

### **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 tortious 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. 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 \$6,388,358 at September 30, 2014 compared to \$209,348 at December 31, 2013, and total current liabilities of \$1,995,078 at September 30, 2014 compared to \$27,300,316 at December 31, 2013. As of September 30, 2014, we had working capital of \$6,660,480.

Prior to our initial public offering in June 2014, our principal sources of cash consisted primarily of borrowings on our note payable to the related party. We received net proceeds of \$6,144,325 from the initial public offering (after the payment of underwriter commissions and offering expenses). We expect that as our revenues grow, our operating expenses will grow and, as a result, we will need to generate significant additional net revenues to achieve profitability.

We have 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 business for the next twelve months after issuance of their report based on our having suffered recurring losses from operations and having a net capital deficiency, as discussed in Note 1 of our accompanying financial statements. Although we are forecasting continued losses and negative cash flows as we continue to fund our selling and marketing activities and research and development programs, we expect that, with the proceeds of this offering, we will have sufficient cash on hand to support operations for at least the next twelve months from the date of this prospectus. However, we expect to seek additional financing and/or strategic investments following the offering, depending on the proceeds generated by the offering. There can be no assurance that any additional financing or strategic investments will be available on acceptable terms, if at all. In the event that we are unable to obtain additional funding, we will most likely be required to seek loans from our majority stockholder, LeBow Alpha (who is under no obligation to make any such loans to us), on similar terms as we have obtained in the past, seek additional debt or equity financing and/or reduce certain discretionary spending, which could have a material adverse effect on our ability to achieve our

TABLE OF CONTENTS

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

**Operating activities**

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

	Nine Months Ended September 30, 2013	Year Ended December 31, 2012 2014	
Net loss from continuing operations	\$(5,631,931)	\$(2,159,669)	\$(5,618,340)
Non-cash adjustments	4,882,826	1,835,196	2,656,672
Changes in operating assets and liabilities	(467,145 )	(649,445 )	(1,608,322)
Net cash used in operating activities of discontinued operations		(193,875 )	(1,654,812)
Net cash used in operations	\$(1,216,250)	\$(1,167,793)	\$(6,224,802)

We used \$1,216,250 of net cash in operating activities in the nine months ended September 30, 2014. Non-cash adjustments primarily reflect stock compensation expense of \$3,578,465 and non-cash accrued interest on the note to the related party of \$1,007,733. Changes in operating assets and liabilities primarily reflect an increase in accounts receivable of \$700,480 and a decrease in lease termination/abandonment payable of \$305,069, partially offset by a decrease in inventory of \$124,577 and an increase in accounts payable and accrued expenses of \$404,360. The decrease in inventory was primarily due to the timing of the receipt of supplies. The increase in accounts payable and accrued expenses was primarily due to increased operating expenses incurred during the period. The increase in accounts receivable was primarily due to increased revenues in 2014 from our non-contracted customers, who have historically taken longer to pay, as well as the timing of collections from our direct-billed customers. Our days sales outstanding, or DSO, for the nine months ended September 30, 2014 also increased to 93 days from 89 days for the year ended December 31, 2013, due to the increased revenues from non-contracted customers, which have historically taken longer to pay. We do not know if collections will 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 made 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 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

## TABLE OF CONTENTS

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 \$12,616 of net cash used in investing activities in the nine months ended September 30, 2014 due primarily to purchases of property and equipment as well as the funding of the security deposit for our new corporate headquarters facility lease in California.

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 generated \$7,407,876 of net cash from financing activities during the nine months ended September 30, 2014, primarily due to gross proceeds of \$8,500,000 received from our initial public offering and \$795,000 received from our note payable to the related party, offset by \$1,855,675 paid for deferred issuance costs.

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**

Prior to our initial public offering, we borrowed money from our majority stockholder and various entities owned by him to support our operations. The majority of these borrowed amounts were converted into equity as part of the Debt Conversion (as described under *Certain Relationships and Related Transactions* ), which occurred prior to the corporate conversion. As of September 30, 2014, the aggregate amount payable to the related party was \$1,045,000, which amount is non-interest bearing and due on demand.

In addition, we acquired certain property and equipment through the issuance of a note payable totaling approximately \$182,000 of which the balance at September 30, 2014 was approximately \$11,000. The note was payable in thirty-six monthly installments of \$5,320 and the final payment was made in October 2014. The effective interest rate of the note was 3.4%. The related equipment was collateral for the note.



## **Related Party Transactions**

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

## **Off-Balance Sheet Arrangements**

As of each of September 30, 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 laboratory lease termination agreement. 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.

TABLE OF CONTENTS

## **Commitments and Contingencies**

As of each of September 30, 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.

TABLE OF CONTENTS

## **BUSINESS**

### **General**

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

MM, is a hematologic, or blood, cancer that develops in the bone marrow and specifically affects the plasma cells of the bone marrow. Normal plasma cells produce immunoglobulins, otherwise known as antibodies, which help the body fight infection and disease. In MM, the normal plasma cells become malignant and inhibit the production of normal blood cells and antibodies, including red blood cells, white blood cells and blood platelets, and crowd the bone marrow with malignant plasma cells, which produce an abnormal antibody called a monoclonal protein, or M protein. The hallmark characteristic of MM is a high level of M protein in the blood. MM can also cause soft spots in the bone known as osteolytic lesions. MM is the second most common blood cancer after NHL and represents approximately 15% of all hematological malignancies. According to the American Cancer Society and the National Cancer Institute, approximately 24,050 new cases of MM were diagnosed in the United States in 2014 and approximately 11,090 deaths from MM occurred in the United States in 2013. More Americans died from MM in 2014 than from any other blood cancer. Although a relatively rare disease, MM is responsible for 2% of all cancer deaths in the United States each year and will kill more Americans than melanoma, the deadliest form of skin cancer. There are approximately 83,360 people currently living with MM in the United States. The five-year survival rate for people with MM is about 45%. The American Cancer Society estimates that the lifetime risk in the United States of getting MM is 1 in 143. *[American Cancer Society: [www.cancer.org](http://www.cancer.org) and National Cancer Institute: [www.seer.cancer.gov](http://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 choice of treatment for a patient and that patient's outlook or prognosis, often framed as progression free survival (PFS) or overall survival (OS). Prognosis is typically based on the existence of different signs, symptoms and circumstances. Certain laboratory and clinical findings, or prognostic indicators, provide important information for MM, including when treatment should begin and what treatments to use, based upon a patient's individual prognosis and risk for relapse. However, the experts caring for MM patients have been burdened by a staging system that predates and thus fails to capture the rich body of new genomic information that has been shown to assist in the staging process. Similar genetic information has proven transformational in a number of solid tumor types, including breast, colon and lung cancer. In each case, specific genetic determinants enable doctors to identify patients who are likely to respond to genetically targeted therapies resulting in better outcomes for these

patients, including a higher rate of survival. According to the National Cancer Institute, these benefits have not yet been recognized in MM treatment. The traditional approach in MM treatment, which utilizes cytogenetic analysis (*i.e.*, karyotyping) and FISH for staging, may not accurately stage MM patients or accurately assess their risk of relapse. We believe the greatest shortcoming of the current staging system for MM is its inability to classify MM patients into high and low risk prognosis groups. A tool that can further define risk-stratification by classifying MM patients in this manner would better inform physicians when to treat and what drugs to treat

## TABLE OF CONTENTS

patients with, potentially improving health outcomes in MM patients. We believe a more comprehensive, systematic approach utilizing current genetic technologies is necessary to meet this unmet medical need. [ *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; *Effectiveness of Targeted Therapy in Patients with Previously Untreated Metastatic Breast Cancer: A Systematic Review and Meta-Analysis* , *Clinical. Breast Cancer*, Kawalec et al, 2014 Oct 22; *Targeted Therapies in Metastatic Colorectal Cancer: A Systematic Review and Assessment of Currently Available Data* , *Oncologist*, Kirstein et al, 2014 Nov; 19(11): 1156-1168; *The Next Generation of Epidermal Growth Factor Receptor Kinase Inhibitors in the Treatment of Lung Cancer* , Steuer et al, *Cancer*, 2014 Dec 17.]

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

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

During the nine months ended September 30 2014, we recognized \$3.7 million in total revenue compared to \$3.2 million for the same period in 2013. During the year ended December 31, 2013, we recognized 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 the rich and rapidly growing body of new genomic information. We believe the traditional approach, which is dependent on cytogenetic analysis (*i.e.*, karyotyping) and FISH testing, may not accurately assess risk nor can it classify a MM patient's risk of relapse, and that a more comprehensive and systematic approach is necessary to optimize treatment of MM patients.

Our MyPRS® GEP signatures test gives physicians a comprehensive set of genetic information, which they may use to assist them in selecting optimal treatments for their patients and personalizing their patients' care. These benefits stem from the robust genetic prediction of a patient's prognosis and the severity of the disease. The ability to predict a patient's prognosis is a valuable tool for physicians and patients to use to help determine the appropriate course of

treatment for patients with MM. We believe that both new patients and those who have had MM relapses may benefit from our test. We believe the ability to predict a patient's prognosis through the GEP signature could also enhance the ability of pharmaceutical and biotechnology companies to develop personalized treatments for MM. To this end, we have and will continue to engage in dialogues with pharmaceutical and biotechnology companies developing MM therapies, with the intent of forming alliances. We envision potential partnerships deriving from clinical trial testing services (CTS), wherein we capture fee for service revenue and seek to embed MyPRS® and our overarching GEP signatures

## TABLE OF CONTENTS

into the partner's drug development program. We are contemplating potential companion diagnostic opportunities emerging from CTS partnerships in the long term, a natural evolution of the use of our genetic test to better guide trial design, patient recruitment and identify potential responders to therapies in development.

Researchers at the UAMS developed a genomic profile test for patients with MM, which they have exclusively licensed to us. The test is a gene expression 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 validate in the academic setting 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 al; *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.] We plan to pursue inclusion of our test in key cancer treatment guidelines, including the National Cancer Center Network (NCCN) guidelines and other influential standard of care flowcharts typically followed by cancer physicians.

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 identifies and distinguishes between high and low risk MM patients and predicts the prognosis and risk of relapse after treatment.

We believe the published data supports performance of MyPRS® GEP testing on patients with MM 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 MM, 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 strongly believe 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 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 complementary genetic sequences. After all unbound RNA is washed away, the chip is scanned and the fluorescence 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.



## TABLE OF CONTENTS

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 survival prognosis and overall risk for relapse. This can aid in the selection of the most appropriate therapeutic regimen 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, as individual genes and groups of genes diagnostic of the disease subtype may overlap with targets or pathways relevant to currently marketed therapies or those in development. [ *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 a concordance rate of approximately 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; DOI

10.1182/blood-2011-10-388702.] This high rate of concordance with conventional karyotyping means that physicians may be able to use MyPRS® in cases where, for example, conventional karyotyping is not possible. Worth noting is that the medical community is in broad agreement that conventional testing methods are leaky [ *Using RNA-Seq, SNP-CN, and Targeted Deep Sequencing to Improve the Diagnostic Paradigm in MM* , Rossi et al, *ASH 2013*, abstract #1856], and prove discordant across sites and even individual pathologists within the same practice. We believe a significant market opportunity exists for a molecular genetic solution that ameliorates the extant shortcomings of traditional pathology analyses. In light of the shortcomings of the conventional methods, we are striving to develop a novel, next generation virtual karyotyping solution leveraging emerging RNA sequencing platforms. We believe such a solution may potentially displace conventional karyotyping and FISH by eliminating the interoperator and other sources of variability inherent to conventional methods, and we are taking a holistic approach to clinical utility, commercial strategy and optimal reimbursement of this potentially transformative product.

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 is certified under CLIA to perform high complexity testing. We received clearance under the New York State Department of Health (NYSDOH) process in 2014, and are currently licensed to sell our test in all 50 states. We are dedicated to making our extensively validated diagnostic services available to all patients who need them.

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

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

67

---

## TABLE OF CONTENTS

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

## **Market Opportunities**

### **Prognosis/Risk of Progression**

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 is an appreciation of the complexity of cancer. Cancers are heterogeneous and do not follow a uniform course. In some cases, cancer can lead to severe disease and death, while in other cases it is indolent. In some cases patients die from non-cancer related causes (called comorbidities) irrespective of the aggressiveness of their cancer. Unfortunately, identifying those patients who will likely succumb to comorbidities 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 select more personalized therapeutic options for their cancer patients. The choice of therapy is influenced by many variables such as age, stage of disease, comorbidities and specific genetic mutations or gene expression levels. 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 multimodal chemotherapies, to one or more bone marrow or stem cell transplantations and most often as a last resort experimental protocols through enrollment in clinical trials for those with high risk disease.

### **Pharmaceutical and Biotechnology Alliances: Advancing Personalized Medicine and Companion Diagnostics**

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. 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. 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 via high-intensity chemotherapy and total body irradiation in preparation for a bone marrow transplant. [ *The Future of Drug Development and Therapy in Myeloma* ; Seminars in Oncology, Lorial and Boise, Vol. 40, No. 5, October 2013.]

Although new treatments for patients with MM have become available over the last 10 years, we do not believe that these treatments have provided any significant benefits in overall survival especially in the high risk patient population. In part, this is because MM is a disease with significant tumor heterogeneity at the genetic level. Specialists in MM have long recognized the need for diagnostic tests that accurately identify the mutations and overarching genotype of each patient to inform risk stratification, prognosis and choice of therapy. Because classic staging modalities such as clinical factors and cell morphology (the microscopic review of tumor material by a pathologist) are suboptimal and subjective, physicians use plasma cell labeling indices, chemical markers, imaging studies and genetic abnormalities at the chromosomal level

## TABLE OF CONTENTS

(e.g., cytogenetics) to better 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.*] We believe that novel therapies in development – in particular those with a novel mechanism of action – will benefit from a rich body of genetic and biological data. These data will add value in the following ways:

*in support of regulatory dossiers with FDA and comparable agencies in Europe and Asia:* pharmaceutical and biotechnology companies developing novel MM therapies may improve their chances of regulatory approval if the dossier captures salient information on genetic determinants of on-target, off-target and pathway effects;

*for optimal market positioning and lifecycle management:* identification of patient subgroups or other responder populations may better target drugs for improved outcomes and result in more cost effective patient management. Novel therapies are often more costly and are likely to be best suited to patient subgroups that represent specific market segments, thus abandoning the archaic one size fits all approach to cancer treatment. This smart marketing is likely to be driven by genetic diagnostics, including companion diagnostics that underpin premium pricing for novel, targeted therapies; and

*feedback to research and translational medicine:* many novel therapies fail during the transition into clinical trials in human subjects (typically referred to as the Investigational New Drug, or IND stage). This critical inflection point is increasingly managed by translational medicine groups within the pharmaceutical and biotechnology industry. Translational medicine teams are increasingly successful in navigating the IND stage as a result of the rich body of genetic data that now exists on most common solid tumors. There is a dearth of similar data in the field of MM, although this is changing. We seek to be in the vanguard of genetic diagnostic services that will enable pharmaceutical and biotechnology partners to design informed development programs. An ancillary, long term benefit is that our genetic signatures may be put on the path to potential companion diagnostics at this critical early juncture. Medical practitioners in the MM 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 optimally define and discriminate patients at high risk for early relapse from those at low risk for relapse, and in turn help to personalize treatment based on individual risk of relapse. Armed with a robust genetic classifier like MyPRS®, physicians could better personalize treatment options, improve therapeutic efficacy and survival, minimize adverse effects, perform fewer diagnostic tests, significantly decrease costly unnecessary treatments, and ultimately reduce the clinical and financial burden to health care systems and individual patients. Now, with the use of MyPRS® GEP, it is possible to supplant traditional pathology analyses and classify each MM patient based on their unique genetic fingerprint. [ *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.*] We see the high risk MM patient population – the target of a number of clinical trials and novel therapies therein – as an ideal field of deployment for MyPRS® and other genetic signatures we are developing.

### **Large Patient Populations with Precursor Conditions to MM**

Like many forms of cancer, MM can present as 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 American Cancer Society and the National Cancer Institute, every year, 1% of MGUS patients will progress to MM. The MM diagnostic community concurs that there is currently no way to identify those MGUS patients that will progress to MM; this represents a significant unmet need. Due to the high mortality rate and

speed of

69

---

## TABLE OF CONTENTS

progression inherent to MM, we believe there is demand for a diagnostic test that accurately identifies patients at high risk of progression from MGUS to MM and as potential candidates for early intervention.

Aside from the precursor condition, MGUS, MM exists on a spectrum from SMM to full-blown MM. Collectively, these precursor conditions, MGUS and SMM, are referred to as AMG. Preventative treatment of every AMG patient is not a viable option. Along with the prohibitive expense, many doctors worry that they could do more harm than good if they treat otherwise healthy people, the vast majority of whom will never develop MM. A 1988 clinical study discussed in *Nature's* MM supplement, using the best treatments available at the time, concluded that treating patients even at the smoldering stage caused unnecessary side effects with no survival benefit. Current thinking suggests 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 MGUS state to symptomatic MM. This ability could allow them to avoid unnecessary treatment in AMG patients who will not progress to MM.

Our progress toward a commercial diagnostic for AMG progression was recognized in a scientific paper published in *Blood* in January 2014 and an abstract presented at the 2014 American Society for Hematology (ASH) annual meetings. These publications recognized the ability of our MyPRS® test and other related, emerging signatures currently in development at UAMS to predict the risk of progression from AMG to MM. The work captured in the 2014 paper in the journal *Blood* was part of a multi-center, prospective, clinical study sponsored by the National Cancer Institute Southwest Oncology Group. The study validated our MyPRS® test as an independent predictor of the risk of progression from AMG to clinical MM. Further clinical studies validating these results in independent patient cohorts are likely necessary to drive broad market acceptance for the use of MyPRS® in MM precursor conditions.

Nonetheless, the clinical utility of our test and emerging genetic signatures we have the option to license exclusively for use in predicting MM progression from AMG could significantly expand the target market for MyPRS® testing. As such, validation of this work represents an important pillar of our growth strategy. We estimate the total MM testing market in the United States at approximately 36,000 patients per year, including newly diagnosed and relapsed patients. We believe we currently service just over 2% of this market. We estimate that the addition of an AMG progression indication feature for the MyPRS® test could expand the MyPRS® addressable market in the United States to more than 135,000 patients per year.

## **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 via the following commercial strategies and tactics:

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

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 grow our direct sales force by hiring additional Territory Sales Managers. Our current sales and marketing efforts in the United States are affected by three Territory Sales Managers and one National Sales Director. We currently have relationships with a number of physicians at several of the 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 centers and increase the number of physicians who use our test. Additionally we plan to enhance our marketing materials and leverage high traffic, high visibility channels via the internet, in addition to more traditional methods of communication such as educational seminars to

increase awareness of the clinical validity and utility of MyPRS® for use in MM and its precursor conditions.

***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 consistently with the LCD coverage requirements. Blue Cross Blue Shield of Arkansas also has an approved

70

---



## TABLE OF CONTENTS

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 have hired a Vice President of Managed Care and Payor Relations who leads our efforts to augment our roster of 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 a Health Economic Outcomes Research (HEOR) 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 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 recognized our test as an independent predictor of progression to MM in AMG patients. More recently, an abstract was presented at the 2014 annual meeting of the American Society for Hematology (ASH) on a related gene signature in development by UAMS. This novel signature demonstrates similar promise for predicting AMG patients at high risk of progression to MM. Our current exclusive license agreement with UAMS grants us an option to an exclusive license to this novel signature. We intend to fund additional retrospective and prospective clinical studies that we hope will independently validate these findings and as a near term goal 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 outcomes for those 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 over 30 pharmaceutical and biotechnology companies actively developing 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 and the second was completed in 2014). We intend to invest in business development and scientific resources in order to pursue additional collaborations with pharmaceutical companies.

This line of business is targeted to a defined number of pharmaceutical and biotechnology customers, and success is driven by competitive advantages in clinical validation, proprietary assets and experience selling to industry clients. The focus is on robust assay services provided in lockstep with a client's clinical trials to enable development of novel therapeutics or repositioning existing therapies. We believe the longer term value play manifests in companion diagnostic (CDx) opportunities, a natural outcome once MyPRS® or our related GEPs have been embedded in specific trials designed to drive regulatory approval, a new indication or a first line approval or other repositioning of

an existing drug.

## TABLE OF CONTENTS

### **Clinical Trial Services**

We anticipate building demand for clinical trial services (CTS) by leveraging two key marketing strategies:

1. Robust clinical validation of a proprietary anchor asset we believe the body of clinical validation data on our MyPRS® test is a significant barrier to competition. A suite of publications in high impact peer review journals buttresses our position. We have a robust portfolio of issued and pending patents that exclude competitors from duplicating our services. We believe we can leverage our best in class validation and strong intellectual property portfolio to position ourselves as the partner of choice for pharma and biotech companies seeking MM testing services.

2. Defined sales pitch to limited number of clients clinical trial services are typically sold under a master template agreement that can be deployed serially across partnerships. This enables a defined sales pitch and common set of metrics (e.g., size of trial, timeline) that typically results in a straightforward deal process and rapid close once the client has chosen a service provider. This fee for service model ameliorates the need for complex business development negotiations arising from sophisticated deal terms and splits of intellectual property rights. Finally, the limited number of potential pharma and biotech clients in the MM space gives rise to a concentrated market that can be targeted with a limited number of business development professionals. In August 2014, we hired a Senior Vice President of Commercial Strategy and Business Development to lead our pharmaceutical and biotechnology partnering efforts, and in the fourth quarter of 2014, we opened dialogues with multiple pharma and biotech targets.

### **Companion Diagnostic Opportunities**

We anticipate that embedding our technology in clinical trials will create potential companion diagnostic (CDx) opportunities for us, and CDx partnering is currently the only viable path for diagnostic companies to capture some part of the value stream from marketed MM therapeutics. The value drivers we believe deriving from MyPRS® and GEP CDx for pharmaceutical and biotechnology stakeholders are discussed in detail in the above section above titled *Pharmaceutical and Biotechnology Alliances: Advancing Personalized Medicine and Companion Diagnostics*.

We contemplate receiving fee for service revenue, potential development or regulatory milestones, and potential milestones or other payments based on the commercial success of our potential CDx partners therapeutics.

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

Diagnostic testing is, at its core, an information service. The informatics infrastructure that we have implemented generates, collects, manages and utilizes the data and information required for the optimal operation of our organization. From a customer service perspective, this infrastructure enables a robust and streamlined process for receipt of orders, tracking of samples as they progress through our laboratory and the transmission of results. The informatics system also implements the algorithmic basis for the analysis of diagnostic data which delivers the results.

We plan to further optimize our laboratory informatics for performance, robustness and scalability to support our business goals.

For our customers, we currently host ResultsPX™, which is a secure, online portal providing rich and contextual patient test results for viewing by physicians. Using the portal, physicians can gain additional insights including MyPRS® gene expression heat maps showing an individual patient's prognosis in relation to the database of those patients used to develop the test as well as a tracking of a patient's results over repeated tests. We intend to add features to this portal that allow more interaction by physicians with the data, with a focus on improving the utility and utilization of our test results, to gain a better understanding of how our results are currently being used and to engage

more directly with physicians.

From a reimbursement perspective, our informatics system collates payor, benefit and coverage information to expedite the billing process. Going forward we plan to implement direct interfaces with our clients' electronic medical records systems to enable paperless ordering and reporting. This will avoid multiple data re-entry steps making the process less prone to error as well as more efficient, with benefits for fast and accurate billing and follow-up on claims.

TABLE OF CONTENTS

We plan to extend our informatics systems and processes to measure and monitor our business operations and services so that we are able to continue to not only meet our quality commitments to our customers but to also continuously improve our performance.

**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 (with the right to sublicense) in our licensed field. Notably, we are unencumbered in our ability to assign the license in connection with a sale or transfer of our Company. Further, we have the exclusive option to license (within our licensed field) inventions conceived and reduced to practice in whole or in part by our licensor, UAMS. 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 consolidated statements of operations, for the nine months ended September 30, 2014 and the years ended December 31, 2013 and 2012 was \$22,500, \$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: (1) the date of the expiration of the last to expire of the patents issued in any country; or (2) 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.

73

---

## TABLE OF CONTENTS

There are potential new diagnostic breakthroughs that may result from our collaboration with UAMS including next generation sequencing, RNA sequencing, virtual karyotyping and genetic tests for MM precursor conditions 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 other molecular tests useful to 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 MM is still being determined, the utility and demand for personal patient genetic information for these patients' tumors is growing rapidly. A number of major MM research groups, including UAMS, are applying whole-genome sequencing to patients with MM 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 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 MM. 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.

### **Expand and leverage our capabilities into additional blood cancer indications**

We believe that the strategy and tactics we are employing in the MM market will be translatable to additional blood cancer or hematology oncology indications. For example, we see technology synergies, call-point synergies, similar HEOR dynamics, and congruent clinical utility/validity messaging between MM and many other hematology oncology, or Heme Onc, disease segments. These commonalities give rise to what we call verticals wherein we see replicable approaches deploying genetic diagnostics to diagnose precursor conditions, parse high and low risk patient subgroups, and identify patients likely to respond to novel therapies in other blood and bone marrow based cancers.

We contemplate entering one or more of these additional verticals in the next 24 to 36 months. In our experience, several characteristics are common across hematology oncology disorders, including:

*Markets can be captured by penetrating a manageable set of academic center call points.* The major Heme Onc markets include NHL and the constellation of acute and chronic leukemias. These markets are all niche indications with annual incidence in the United States of less than 75,000 patients per year. These cases are typically managed by leading academic centers, where expert Key Opinion Leaders (KOLs) lead a small practice group focused on the

specific disease. As a result, a relatively small sales force similar to the team we have deployed is sufficient to target the necessary call points required to access these markets. We believe that the geographic focus and specific sales tactics we have used to approach the MM market can be applied directly to other Heme Onc verticals. [*National*

*Cancer Institute: [www.seer.cancer.gov](http://www.seer.cancer.gov)]*

*Disease heterogeneity requires genetic analysis to inform optimal patient management.* As with MM, the course of disease is often vastly different across the patient populations in lymphoma and leukemia. Also consistent with MM, these disparities are genetically driven. An array of

74

---



TABLE OF CONTENTS

differentially expressed genes, specific mutations and abnormalities at a chromosomal level are known or suspected to underpin the breadth of indolent to aggressive diseases. These genetic determinants give rise to highly heterogeneous diseases and patient subgroups. To better manage these subgroups and make better informed treatment decisions, clinicians are relying on the growing body of genetic information for prognosis and prediction of drug response. Conventional karyotyping and FISH are widely used in the management of the various leukemias. We believe substantial demand exists for a more current approach that utilizes genetic analysis at the level of gene expression and mutational analysis. We see an opportunity to leverage our expertise with and in-house access to best in class platforms to provide a transformational, next generation platform for virtual karyotyping and FISH in these new verticals.

*Clinicians are receptive to emerging testing platforms.* It has been our experience that Heme Onc clinicians are generally forward thinking and technologically skilled. Given the treatment-heavy nature of the diseases they manage (blood cancers cannot be surgically debulked, for example) coupled with objectively poor outcomes (5 year survival rates in the 50% to 70% range; [National Cancer Institute: [www.seer.cancer.gov](http://www.seer.cancer.gov)]) a deep understanding of the biology and genetics of disease is required. This yields a clinician customer base that appreciates and, in our experience, demands diagnostic testing solutions that leverage emerging platforms. This dynamic obviates the initial resistance to disruptive technologies our team has experienced, for example, in past exposure to the solid tumor space. *Reimbursement thesis is replicable across indications.* We believe we are composing a cogent and compelling HEOR case that supports the clinical utility and cost effectiveness of our MyPRS® test in MM. Once finalized, we anticipate this model can be ported over to additional verticals: the core messages (in terms of improved outcomes and potential costs savings), overarching framework (financial model, utility and quality metrics) and industry networking will all be common elements. If we are able to successfully promulgate our HEOR thesis with payors in MM, we believe we can follow essentially the same model in other verticals.

*Major investment by pharma and biotech in development of novel drugs and targeted therapies that may benefit from genetic diagnostics.* Similar to MM, we believe there is significant demand for novel therapies in the lymphomas and leukemias. Long term survival, especially in high risk patient populations, remains relatively poor. As a result, the drug industry has committed considerable resources to developing novel therapies, manifesting in 2,184 clinical trials (active, Phase 0 to Phase III) in these Heme Onc indications ([<https://clinicaltrials.gov/ct2/home>]). By embedding our services and technologies in a partner's clinical trials we will seek to capture fee for service revenue that is not at risk under CMS reimbursement changes. We will also seek to position our tests as future companion diagnostics, a transformational milestone for those diagnostic companies that achieve it. We believe that close ties to emerging therapies will better position our tests and services as clinical diagnostics in additional Heme Onc verticals.

Given the commonalities spanning several near neighbor Heme Onc markets, we believe the vertical approach will allow us to successfully penetrate one or more of these additional indications. We anticipate that a leadership position can be established by actuating specific drivers, including:

*Leveraging a proprietary anchor asset.* We contemplate identifying and in-licensing promising assets backed by compelling initial data sets as proprietary anchors in new verticals. Our senior management team has extensive experience in identifying assets, forming relationships with leading academic centers and negotiating exclusive licenses to diagnostic inventions. These novel products and services would be patent protected and exclusive to us, and serve as the nucleus of the portfolio we seek to build in a new vertical.

*Building a best in class body of clinical data.* We anticipate allocating financial and other resources to augment the body of clinical data and specific uses of our services in the clinical diagnostic and

## TABLE OF CONTENTS

drug development settings. We plan to target data releases to highly visible peer reviewed journals and major industry conferences. Finally, we contemplate forming research collaborations with well-respected KOL clinicians to better position our work in the field and chart a course to inclusion in key guidelines.

*Promulgating robust HEOR case studies to support reimbursement.* We believe that the core model we are building to support use of our MyPRS® and GEP in MM can be applied in other Heme Onc verticals. As discussed above, we believe the core elements of the HEOR thesis and the actual approach to payors is portable across Heme Onc verticals.

*Partnering with pharma and biotech companies.* We plan to partner with pharma and biotech companies developing MM therapies to embed our services and technologies in clinical trials and put our assets on the path to be future companion diagnostics. If we are successful in forming clinical trial service and CDx partnerships with MM drug developers, we believe these relationships will position us as a partner of choice for genetic diagnostic services in additional Heme Onc verticals. Worth noting is that many pharma and biotech companies actively developing MM therapies are also actively developing novel drugs for lymphomas and leukemias thus we will already be known to the potential partner and can seek to leverage any existing relationships to de-risk due diligence, deal making and other stage gates that would be relative unknowns absent a prior partnership.

We believe that significant synergies and similarities exist across the spectrum of Heme Onc verticals. We anticipate that targeting these new verticals is a path of least resistance approach to additional markets, and that our strategies, tactics and key learnings from MM can be ported over to these markets to capture significant medium- to long-term growth opportunities.

### **Pursue Additional Collaborations and In-licensing to Expand Our Service Offering**

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](http://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.

## TABLE OF CONTENTS

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 a concordance of 89%, as previously noted. This high rate of concordance 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 pioneered a novel Total Therapy approach, designed as a first line treatment for MM that includes a full array of treatment modalities. This approach is considered by many in the oncology community to have achieved positive results, particularly in patients diagnosed with low-risk MM who are treated at UAMS MIRT. A number of treatment improvements for MM patients were first discovered at MIRT. The physicians at MIRT routinely utilize our MyPRS® test to identify patients who may be eligible for 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 81%, 83% and 86% of net revenue for the nine months ended September 30, 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 December 31, 2014 we license, or own outright, 12 issued patents (11 issued U.S. patents and one issued Japanese patent with various expiration dates ranging from 2022 to 2029) and 21 pending patent applications (one of which was allowed by the USPTO on December 9, 2014), many of which protect and defend our exclusive ability to market the MyPRS® test as well as additional proprietary tests and treatments. We also have six registered US trademarks to further differentiate our products and services in the marketplace, including the marks MyPRS® (Reg.

There are five issued U.S. patents related to the MyPRS® test, which form the basis of our right to exclude others from practicing the MyPRS® test. U.S. Patent No. 7,668,659 claims methods of gene expression-based classification for MM 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 MM plasma cells by isolating RNA from CD138 positive plasma cells, hybridizing the RNA to a microarray, identifying

TABLE OF CONTENTS

differentially expressed genes, and applying hierarchical clustering to identify groups of genes capable of discriminating normal and MM 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 MM 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 MM 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.

U.S. Patent No. 8,843,320 also covers the 70 gene signature used in the MyPRS® test. Specifically, this patent provides methods of determining the prognosis of a human MM patient by measuring gene expression levels of multiple genes from plasma cells.

In addition to the issued U.S. patents above, we have one issued Japanese patent and several pending patent applications in the U.S. and abroad directed to other aspects of the MyPRS® test. For example, the Japanese patent provides methods for examining the susceptibility of a subject for transformation from a low-risk to a high-risk MM by measuring gene expression levels of multiple genes expressed from plasma cells isolated from the subject. Canadian and European counterpart applications of U.S. Patent No. 8,843,320 also describe 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. International Application No. PCT/US2014/038,626, published as WO 2014/189,843 describes prognostic methods using an even smaller subset of only five genes, which can be used with limited numbers of plasma cells from either MM or MGUS subjects. Additionally, we may have other unpublished applications covering various other prognostic methods for use in MM subjects as we continue to pursue new patent filings.

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 MM 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 of cytogenetic abnormalities associated with MM 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. International Application No. PCT/US2013/070,149, published as WO 2014/078,571, describes methods for identifying a multiple myeloma patient that would benefit from a treatment that includes bortezomib by determining the presence of a chromosomal translocation, which is determined by measuring gene expression levels of multiple genes.

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 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 force is well versed in the science and technology behind our MyPRS® test. We will continue to grow our sales force with expertise necessary to interface successfully with these institutions.

The extensive scientific evidence that substantiates the MyPRS® test is a key enabler for our sales effort that affords us access to the thought leaders within these institutions. The relationships that we build with the thought leaders at leading academic hospitals is a direct result of the quality of our science and the quality of

## TABLE OF CONTENTS

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. Our efforts are now focused upon achieving 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 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, new hires 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 December, 2014, our sales team was comprised of four members. 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. The hardware for such systems is commercially available for purchase or as a cloud-based service. The deployment of LIS software typically requires some elements of customization to fit the processes, procedures and workflows followed in the laboratory. Analysis of the data generated by our instruments are carried out by well tested algorithms implemented using established software products and libraries. Given the trend in diagnostics instrumentation, we believe that the quantum of data generated which will need to be managed and analyzed will increase sharply. However, we believe that computational as well as networking technology will keep pace with these increased demands as well as availability of software and services to support our analytical needs.

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

## TABLE OF CONTENTS

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](http://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.

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

## TABLE OF CONTENTS

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), Clariant, 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.

## **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 \$148,000, \$97,000 and \$225,000 for the nine months ended September 30, 2014 and for the years ended December 31, 2013 and 2012, respectively, representing 1.8%, 2.1% and 2.7% of our total operating expenses for the nine months ended September 30, 2014 and 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 hematological malignancies 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.

81

---

## TABLE OF CONTENTS

First, we exclusively license, in our licensed field, a patent portfolio from UAMS with numerous issued U.S. patents and pending U.S., foreign 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 five 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 European and Japanese applications, provides methods of prognosing a MM 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 14/114,406 (published as US 20140079813) and a counterpart European application are directed to methods of predicting post-relapse survival of a relapsed MM patient by testing the level of gene expression of a group of particular MM genes.

The additional issued patents from the UAMS portfolio include U.S. Patent No. 7,308,364, which includes methods of diagnosing MM 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 MM 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 MM 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. Japanese Patent No. 5531360 provides claims to methods for examining the susceptibility of a subject for transformation from a low-risk to a high-risk multiple myeloma by measuring gene expression levels of multiple genes from plasma cells isolated from the subject.

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) which the USPTO allowed on December 9, 2014, together with corresponding Canadian and European applications, which provide 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

82

---

TABLE OF CONTENTS

other authorized parties (such as hospitals or independent laboratories) that order the testing service and pay us for performing the ordered service.

For the nine months ended September 30, 2014, we derived approximately 16% of our total revenue from private insurance, including managed care organizations and other health care insurance providers, 14% from government payor programs, most of which was derived from Medicare, and 70% from direct-bill customers, including hospitals and other laboratories. In addition, for the 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, despite our best efforts, resulting in possible 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. 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 assigned a new 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 believe the payment amount is not appropriate, we may request reconsideration of the payment amount. Currently, 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 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 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. 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, 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

## TABLE OF CONTENTS

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. Such contract typically 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 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. Regardless of whether we obtain a specific CPT code for MyPRS®, our reimbursement could change 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 MAAs. 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 changes with respect to the payments that we receive for our tests and affect coverage by Medicare or other payors. Whether Medicare and other payors will establish positive or adequate coverage policies or reimbursement rates is uncertain. 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.

TABLE OF CONTENTS

## **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.

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. The ACA, among other things, imposed additional cuts to the Medicare reimbursement for clinical laboratories. Specifically, the ACA 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 2015, the productivity adjustment is -0.6%. In addition, the ACA 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 served as a base for 2014 and subsequent years. As such, reimbursement for clinical laboratory services have decreased since 2012, a trend that is likely to continue absent further legislative activity by Congress.

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.

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

## TABLE OF CONTENTS

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.

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**

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. In June 2014, following our initial public offering, we obtained the requisite approvals for our LDTs in New York.

TABLE OF CONTENTS

## **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 material compliance with their applicable licensing laws.

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

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

## TABLE OF CONTENTS

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 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. 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.

88

---

TABLE OF CONTENTS

**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 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

## TABLE OF CONTENTS

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 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 the ACA, 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. 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

TABLE OF CONTENTS

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 not been regulated by FDA to date.

The FDA has stated that it has the power to regulate LDTs such as the ones that we develop. Nevertheless, it has exercised enforcement discretion and not regulated most LDTs performed by high complexity CLIA certified laboratories. It is possible, perhaps likely, that FDA will decide to more actively regulate LDTs, which could lead to pre-market and post-market obligations. Section 1143 of the Food and Drug Administration Safety and Innovation Act, signed by the President on July 9, 2012, requires FDA to notify Congress at least 60 days prior to issuing a draft or final guidance regulating LDTs and provide details of the anticipated action.

Class II devices are subject to FDA's general controls, and any other special controls as deemed necessary by FDA to provide reasonable assurance of the safety and effectiveness of the device. Pre-market review and clearance by FDA for Class II devices are generally accomplished through the 510(k) pre-market notification procedure. Pre-market notification submissions are subject to user fees, unless a specific exemption applies. To obtain 510(k) clearance for a medical device (or for certain modifications to devices that have received 510(k) clearance), a manufacturer must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or to a pre-amendment device that was in commercial distribution before May 28, 1976, or a predicate device, for which FDA has not yet called for the submission of a PMA application. In making a determination that the device is substantially equivalent to a predicate device, FDA compares the proposed device to the predicate device or predicate devices and assesses whether the subject device is comparable to the predicate device or predicate devices with respect to intended use, technology, design and other features which could affect the safety and effectiveness. If FDA determines that the subject device is substantially equivalent to the predicate device or predicate devices, the subject device may be cleared for marketing. FDA's 510(k) clearance pathway generally takes from three to twelve months from the date the application is completed, but can take significantly longer. Moreover, in January 2011, FDA announced twenty-five specific action items it intended to take to improve transparency and predictability of the 510(k) program. We anticipate that the changes may also result in additional requirements with which manufacturers will need to comply in order to obtain or maintain 510(k) clearance for their devices. These additional requirements could increase the costs or time for manufacturers seeking marketing clearances through the 510(k) process. Moreover, the 510(k) process could result in a not-substantially equivalent determination, in which case the device would be regulated as a Class III device, discussed below.

Class III devices are those devices which are deemed by FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device. Reasonable assurance of the safety and effectiveness of Class III devices cannot be assured solely by the general controls and the other requirements described above. These devices are required to undergo the PMA process in which the manufacturer must demonstrate reasonable assurance of the safety and effectiveness of the device to FDA's satisfaction. A PMA application must provide extensive preclinical and clinical trial data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications (and supplemental PMA applications) are subject to significantly higher user fees than are 510(k) pre-market notifications. After approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process. The PMA process, including the gathering of clinical and nonclinical data and the submission to and review by FDA, can take several years.



A clinical trial may be required in support of a 510(k) submission and generally is required for a PMA application. These trials generally require an effective Investigational Device Exemption from FDA for a specified number of patients, unless the product is exempt from Investigational Device Exemption requirements or deemed a non-significant risk device eligible for more abbreviated Investigational Device Exemption requirements. The Investigational Device Exemption application must be supported by appropriate

TABLE OF CONTENTS

data, such as animal and laboratory testing results. Clinical trials may begin 30 days after the submission of the Investigational Device Exemption application unless FDA or the appropriate institutional review boards at the clinical trial sites place the trial on clinical hold.

After a device is placed on the market, regardless of the classification or pre-market pathway, it remains subject to significant regulatory requirements. Even if regulatory approval or clearance of a medical device is granted, FDA may impose limitations or restrictions on the uses and indications for which the device may be labeled and promoted. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the Quality Systems Regulations, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by FDA. FDA also may inspect foreign facilities that export products to the United States.

Failure to comply with applicable regulatory requirements can result in enforcement action by FDA, which may include any of the following sanctions: warning letters, fines, injunctions, civil or criminal penalties, recall or seizure of current or future products, operating restrictions, partial suspension or total shutdown of production, denial of 510(k) clearance or PMA applications for new products, or challenges to existing 510(k) clearances or PMA applications.

If they become regulated by FDA, we believe that our LDTs would likely be regulated as either Class II or Class III devices. It is also possible that some may fall into one Class and some into the other. Accordingly, some level of pre-market review either a 510(k) or a PMA would likely be required for each test. While the data requirements are typically greater for Class III devices, the data required for Class II devices has increased, and it is likely that some amount of clinical data (retrospective or prospective or both) would be required for either type of submission. Currently, FDA is undertaking a review of the adequacy of the 510(k) process. It is difficult to predict what changes may result, but it should be assumed that any changes will increase, not decrease, the regulatory requirements.

If the FDA decides to regulate MyPRS® or any future test of ours, it could classify the test as a Class II or Class III device. This would mean that we would have to invest substantial time and resources into obtaining FDA approval and we might have to withdraw the applicable test from the market. This could adversely affect our operations, revenues and our potential to be a profitable or viable entity.

The FDA has stated that it intends to regulate some LDTs as devices. On October 3, 2014, the FDA published a proposed risk-based framework for LDTs, which are tests that are designed, manufactured, and used within a single laboratory. This draft guidance indicates that FDA would like to establish an LDT oversight framework, including premarket review for higher-risk LDTs, such as those that have the same intended use as FDA-approved or cleared companion diagnostics currently on the market. FDA's notice states that FDA does not consider devices to be LDTs if they are designed or manufactured completely, or partly, outside of the laboratory that offers and uses them. The degree to which in-house tests are regulated by the FDA has also been the focus of recent Congressional attention, and Congress is considering the introduction of legislation that would subject at least some such tests to pre-market review or approval by the FDA.

MyPRS® and the other tests being developed by the Company include the use of genes and determine whether a patient falls into a high or low risk for disease recurrence or response to a particular chemotherapy. The Company plans to continue to develop and offer these tests as LDTs unless it becomes clearer that these tests are subject to regulation by the FDA. We will continue to monitor both the FDA and Congress and we intend to comply with any

new requirements that may apply.

## **Good Laboratory Practice, or GLP**

We are subject to various regulatory requirements designed to ensure the quality and integrity of our non-clinical testing processes. Our standard operating procedures are written in accordance with applicable regulations and guidelines for operating in the United States. The industry standards for conducting preclinical laboratory testing are embodied in GLP regulations promulgated by the FDA. In the United States, non-clinical studies intended for FDA submission must be conducted in accordance with GLP regulations;

## TABLE OF CONTENTS

foreign governments may require our North American clients to comply with certain regulatory requirements of other countries (in order to gain approval within these countries), such as regulations promulgated by the Japanese Ministry of Health, Labor and Welfare and Ministry of Agriculture, Forestry and Fisheries, and in Europe, the Organization for Economic Co-operation and Development. GLP regulations specify requirements for facilities, equipment, and professional staff and standardized procedures for conducting studies, including procedures for recording and reporting data and for managing study materials and records. We have established a required quality assurance program that monitors ongoing compliance with GLP regulations by auditing test data and reporting and conducting inspections of testing procedures.

Our business is also subject to regulation under state and federal laws regarding environmental protection and hazardous substances control, such as the Federal Occupational Safety and Health Act, or OSHA, the Environmental Protection Act, and the Toxic Substances Control Act. These regulations, among other things, require work practice controls, protective clothing and equipment, training and other measures designed to minimize exposure to chemicals and transmission of pathogens. We believe that we are in compliance with these and other applicable laws and that the costs of our ongoing compliance will not have a material adverse effect on our business. However, it is possible that the government will find that we are not in compliance with these requirements, which could have an adverse effect on our business and subject us to regulatory sanctions. In addition, statutes and regulations applicable to our business may be adopted which impose substantial costs to assure compliance or otherwise materially adversely affect our operations.

### **Regulation of Reimbursement and Coverage**

Revenues for clinical laboratory testing services come from a variety of sources and depend significantly on the availability of third-party reimbursement, including from the Medicare and Medicaid programs, commercial insurers and managed care organizations. We are currently a Medicare laboratory services provider and intend to become a Medicaid laboratory services provider. We also receive reimbursement from third-party payors for our testing services. As is the case with health care services generally, the majority of payors pay for our testing services at varying levels that may be significantly lower or otherwise differ from our list prices. Obtaining reimbursement from third-party payors is both time consuming and expensive. Payment from third-party payors may not be sufficient to allow us to sell our services on a profitable and competitive basis.

### **Corporate Practice of Medicine**

Numerous states have enacted laws prohibiting business corporations, such as us, from practicing medicine and employing or engaging physicians to practice medicine, generally referred to as the prohibition against the corporate practice of medicine. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed physician. Violation of these laws may result in civil or criminal fines, as well as sanctions imposed against us and/or the professional through licensure proceedings.

### **Other Regulatory Requirements**

Our laboratory is subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemical, biological agents and compounds, blood and bone marrow samples and other human tissue. Typically, we use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors are licensed or otherwise qualified to handle and dispose of such waste.

OSHA has established extensive requirements relating to workplace safety for health care employers, including requirements to develop and implement programs to protect workers from exposure to blood-borne pathogens by preventing or minimizing any exposure through needle stick or similar penetrating injuries.

## **Employees**

As of the date of this prospectus, we have 25 employees, all of whom were full time employees. None of our employees is represented by a labor union, and we consider our relationship with our employees to be good.

TABLE OF CONTENTS

## **Description of Property**

We currently lease approximately 2,800 square feet of space in Little Rock, Arkansas for use as a clinical reference laboratory. The monthly rent is approximately \$6,300. This lease will expire in March 2015, but we expect to renew the lease with terms similar to the current lease. Based on our current operational needs, we believe that such facilities are adequate for our laboratory operations for the near future.

In August 2014, we entered into a new lease for approximately 5,560 square feet of office space in California which we now use as our corporate headquarters. We began occupying the space on October 1, 2014. The lease term began in November 2014 and will continue for 36 months with monthly rent of approximately \$14,000, which will increase at a rate of 3% annually. The lease terms include three months of rent abatement during the first year and an option to renew the lease for one additional 36-month period. The newly leased space in Carlsbad, California, replaces the Company's previous headquarters which were located in New York, New York.

## **Legal Proceedings**

We are subject to claims and legal actions that arise in the ordinary course of business from time to time. However, we are not currently subject to any claims or actions that we believe would have a material adverse effect on our financial position or results of operations.

TABLE OF CONTENTS

**MANAGEMENT**

**Board of Directors and Executive Officers**

Our business and affairs are organized under the direction of our board of directors, which currently consists of five members. Set forth below are our directors and executive officers and their respective ages and positions as of the date of this prospectus:

Executive Officers and Directors	Age	Position(s) Held
Bennett S. LeBow	76	Chairman of the Board
Samuel D. Riccitelli	55	President, Chief Executive Officer and Director
Tamara A. Seymour	56	Chief Financial Officer
David A. Gonyer, R. Ph.	50	Director
Douglas A. Schuling	54	Director
Robin L. Smith, M.D.	49	Director

There are no family relationships among any of our directors or executive officers. The executive officers and directors named above may act as authorized officers of the Company when so deemed by resolutions of the Company. Set forth below is a summary of the business experience of each of our directors and executive officers identified above and our key employee:

**Bennett S. LeBow.** Mr. LeBow has served as the Chairman of our board of directors since our inception in January 2010 and was our founding member and the sole manager of Signal Genetics LLC, prior to the corporate conversion. Mr. LeBow is the sole partner and has sole voting and dispositive power, of our principal shareholder, LeBow Alpha. Mr. LeBow is a private investor and currently serves as the Chairman and Chief Executive Officer of BSL Capital, Inc. Mr. LeBow also serves as the Chairman of the board of directors of Vector Group, Ltd., where he has been a director since 1986 and where he served as Executive Chairman from January 2006 until his retirement in December 2008. Mr. LeBow served as the Chairman of the board of directors of Borders Group Inc. from May 2010 until January 2012 and Chief Executive Officer from June 2010 until January 2012. In February 2011, Borders Group Inc. filed a petition for protection under Chapter 11 of Title 11 of the United States Bankruptcy Code. Mr. LeBow received a B.A. in electrical engineering from Drexel University.

We selected Mr. LeBow to serve on our board of directors as Chairman due to the perspective and extensive experience he brings as our founder. Mr. LeBow brings to the board of directors significant executive leadership and operational experience in both the private and public sector.

**Samuel D. Riccitelli.** Mr. Riccitelli has served as our President and Chief Executive Officer and as a director on our board of directors since October 2012. From July 2011 to October 2012, Mr. Riccitelli was an independent consultant. From October 2001 to June 2011, Mr. Riccitelli served as the Executive Vice President and Chief Operating Officer of Genoptix, Inc., a publicly traded diagnostic services company focused on the needs of community hematologists and oncologists. From 1995 to 2001, Mr. Riccitelli served in a number of positions for Becton, Dickinson and Company, including most recently as a vice president and general manager and as a board member for BD Ventures, L.L.C., a venture capital fund. From 1989 to 1994, he served in a number of positions at Puritan-Bennett Corporation, including most recently as general manager. Mr. Riccitelli also served on the board of directors of Exagen Diagnostics, Inc., from October 2011 through September 2014. Mr. Riccitelli received a B.A. in Biology from Washington and Jefferson College and a M.S. Eng. degree from The University of Texas in Mechanical & Biomedical

Engineering.

We selected Mr. Riccitelli to serve on our board of directors because he brings to the board of directors extensive knowledge of the life sciences and biotechnology industries. He has served in senior corporate positions of companies in the biotechnology and diagnostic industries. Mr. Riccitelli has led the successful development and commercialization of a broad range of diagnostic services, medical devices, and information based product and services and is a named inventor on eight patents. His business experience provides him with a broad understanding of the operational, financial and strategic issues facing public companies.



TABLE OF CONTENTS

**Tamara A. Seymour.** Ms. Seymour has served as our Chief Financial Officer since August 4, 2014. Prior to joining the Company, Ms. Seymour served as Chief Financial Officer of HemaQuest Pharmaceuticals, Inc., a biotechnology company, beginning in November 2010. From July 2009 through November 2010, Ms. Seymour served as a financial consultant for various life sciences companies. From 2001 to 2009, Ms. Seymour served as Chief Financial Officer and Secretary for Favril, Inc. (now MMRGlobal, Inc.), a publicly traded biotechnology company focused on developing immunotherapies for hematological malignancies. While at Favril, she was responsible for various private and public equity and debt financings, including the initial public offering. From 1991 to 2001, Ms. Seymour served as consulting chief financial officer for a number of biotechnology companies. From 1988 through 1991, Ms. Seymour was Director of Finance and Controller with Agouron Pharmaceuticals, Inc. From 1980 and 1988, she worked with Deloitte & Touche LLP and PricewaterhouseCoopers LLP in various positions including audit manager from 1985 to 1988. Ms. Seymour is a Certified Public Accountant. Ms. Seymour received an M.B.A. with an emphasis in Finance from Georgia State University and a bachelor's degree in Business Administration with an emphasis in Accounting from Valdosta State University.

**David A. Gonyer, R. Ph.** Mr. Gonyer became a member of our board of directors immediately prior to the listing of our common stock on The NASDAQ Capital Market in June 2014. Mr. Gonyer is a co-founder of Evoke Pharma, Inc., a specialty pharmaceutical company focused primarily on the development of drugs to treat gastrointestinal diseases, and has served as its President and Chief Executive Officer and a member of its board of directors since March 2007. From January 2004 to June 2007, Mr. Gonyer served as Vice President, Strategic and Product Development of Medgenex, Inc., a subsidiary of Victory Pharma, Inc., a biopharmaceutical company focused on acquiring, developing and marketing products to treat pain and related conditions. From April 2000 to December 2004, Mr. Gonyer was a founder and Vice President of Sales and Marketing at Xcel Pharmaceuticals, Inc., a specialty pharmaceutical company focused on neurological disorders. From December 1996 to April 2000, Mr. Gonyer served as Director of Marketing at Elan/Dura Pharmaceuticals, Inc. From 1987 to 1996, Mr. Gonyer held a broad range of management positions in commercial operations, alliance/partnership management, and regional sales at Eli Lilly & Company, a global pharmaceutical company. Mr. Gonyer serves as a member of the board of directors of Neurelis, Inc., a privately held neurological specialty pharmaceutical company, a position he has held since May 2010. Mr. Gonyer is a Registered Pharmacist and holds a B.Sc. in Pharmacy from Ferris State University School of Pharmacy.

We selected Mr. Gonyer to serve on our board of directors because of his significant management experience, his extensive experience in the pharmaceutical industry and his substantial knowledge with respect to developing and marketing pharmaceutical products.

**Douglas A. Schuling.** Mr. Schuling became a member of our board of directors immediately prior to the listing of our common stock on The NASDAQ Capital Market in June 2014. From April 1999 through May 2011, when he retired, Mr. Schuling held the position of Executive Vice President and Chief Financial Officer for Genoptix, Inc., a publicly traded specialized laboratory service provider focused on delivering diagnostic services to hematologists and oncologists. Since May 2011, Mr. Schuling has acted as an independent consultant. From 1997 to March 1999, Mr. Schuling held the position of Chief Financial and Operating Officer for Point-of-Care Systems, a venture capital backed clinical information systems company. From 1985 to 1997, Mr. Schuling held various positions at Nellcor Puritan Bennett, a research, development and manufacturing company, specializing in medical equipment and supplies, most recently as Hospital Group Controller. Mr. Schuling received his B.S. degree in accounting from Drake University.

We selected Mr. Schuling to serve on our board of directors because of his extensive knowledge of the life sciences and biotechnology industries and his substantial financial and accounting background, having served as the chief financial officer of two other companies and controller of a third company.

***Dr. Robin L. Smith.*** Dr. Robin Smith became a member of our board of directors immediately prior to the listing of our common stock on The NASDAQ Capital Market in June 2014. Dr. Smith was named Executive Chairman January 2, 2015. She served as the Chief Executive Officer and Chairman of the board of directors of NeoStem, Inc. from June 2, 2006 to January 2, 2015, after first joining the company as Chairman of its Advisory Board in September 2005. She currently serves on the board of trustees of the NYU Langone

## TABLE OF CONTENTS

Medical Center and is past chairman of the board for the New York University Hospital for Joint Diseases where she headed up new development efforts and board member recruitment. Currently, Dr. Smith is the president and chairman of the board of The Stem for Life Foundation. She was also appointed to the board of directors, Science and Faith STOQ Foundation in Rome and the Capital Formation Committee of the Alliance for Regenerative Medicine.

From 2003 to 2006, Dr. Smith was a consultant for multiple privately and publicly held companies. From 2000 to 2003, Dr. Smith served as President and Chief Executive Officer of IP2M, a multi-platform media company specializing in health care, which was sold to a publicly-traded company in February 2003. Previously, from 1998 to 2000, she was Executive Vice President and Chief Medical Officer for HealthHelp, Inc., a National Radiology Management company. Dr. Smith received her M.D. degree from Yale University in 1992 and was presented with the Janet M. Glasgow Memorial Achievement Citation awarded by the American Medical Women's Association to women who graduate first in their class from medical school. She was also elected to Alpha Omega Alpha and chosen to be a Farr Scholar. She received her M.B.A. degree from the Wharton School of Business in the top 10% of her class in 1997.

We selected Dr. Smith to serve on our board of directors because of her expertise in business development and medicine, which includes her extensive and diversified experience serving in executive and board level capacities for various medical enterprises and health care-based entities. Dr. Smith has acted as a senior advisor to, and investor in, companies where she has played a significant role in restructuring and/or growth.

## **Key Employees**

***Michael Cerio.*** Mr. Cerio has served as our Senior Vice President of Commercial Strategy and Business Development since August 2014. Prior to joining us, Mr. Cerio served as an independent consultant building out commercial plans for oncology diagnostics startups with the life science venture capital firm, MPM Capital, Inc., since May 2013. From June 2012 to April 2013, Mr. Cerio served as Consulting Chief Executive Officer for Modulation Therapeutics, Inc., a company that was developing a novel mechanism of action MM drug. From April 2012 to April 2013, Mr. Cerio was the President and Chief Executive Officer of Oncolome Diagnostics, Inc., where he built out commercial plans for oncology diagnostics in myelodysplastic syndrome and non-small cell lung cancer. From 2005 through 2011, Mr. Cerio led the licensing, early commercial strategy and merger and acquisition teams at Genzyme Genetics Corp., the clinical diagnostics business unit of Genzyme Corporation. From 1999 through 2005, Mr. Cerio held business development and licensing roles at BG Medicine and Genaissance Pharmaceuticals Inc. Mr. Cerio holds a B.S. in biology from Syracuse University, a M.S. in microbiology from the University of Connecticut and a M.B.A. from Columbia University.

***Sudipto Sur. Ph.D.*** Dr. Sur has served as our Chief Information Officer since January 2014. Prior to joining us, Dr. Sur was President of Anssur Corp and Founder and Chief Executive Officer of Miralex Systems Incorporated from 2007 to 2014, firms involved in modeling, analysis and visualization services for large scale scientific, engineering, marketing and business data as well as in the development of complex engineering systems and algorithms in areas such as medical robotics and unstructured large scale imaging. From 2004 to 2007 he served as Director of R&D: Informatics and Systems for Sequenom, Inc. From 2001 to 2004 Dr. Sur was Associate Director, Control Systems and Software for Genoptix, Inc. Dr. Sur holds a Ph.D. in Control Systems and Robotics from the California Institute of Technology and a B.S. in Mechanical Engineering from the Indian Institute of Technology, Bombay.

***Ryan Van Laar, Ph.D.*** Dr. Van Laar has served as our Vice President of Research and Operations since August 2014 and as our Director of Bioinformatics from February 2012 through July 2014. Prior to joining us, Dr. Van Laar served as the Founder and Chief Scientific Officer of ChipDX from June 2008 to February 2012. From May 2008 to January 2012, Dr. Van Laar worked at Regeneron Pharmaceuticals, Inc. as a bioinformatics scientist, facilitated the expansion

of their oncology bioinformatics department and had the responsibility for identifying and developing oncology targets and biomarkers. From June 2005 to May 2008, Dr. Van Laar worked as a senior bioinformatician at Agendia where he developed novel diagnostic and prognostic multi-gene assays for breast and colon cancer, including the first FDA-cleared multi-gene oncology test, Mammaprint. Dr. Van Laar's work has been extensively published in more than 20 peer-reviewed journals and has more than 20 issued patents. Dr. Van Laar received his Ph.D. in molecular biology and bioinformatics from The University of Melbourne, Australia.

TABLE OF CONTENTS

## **Board Composition and Election of Directors**

Our board of directors consists of five members: Messrs. LeBow, Riccitelli, Gonyer and Schuling and Dr. Smith. Our board of directors has undertaken a review of its composition and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that each of Messrs. Gonyer and Schuling and Dr. Smith is independent under the applicable rules of the SEC and NASDAQ and that neither Messrs. LeBow, nor Riccitelli is independent as defined under the such rules. In making such determination, our board of directors considered the relationship that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his independence, including the beneficial ownership of our capital stock by each non-employee director. Mr. Riccitelli is not an independent director under these rules because he is our President and Chief Executive Officer and Mr. LeBow is not an independent director under these rules because of the payments that have been made by us to LeBow Alpha.

## **Corporate Governance**

### **Our Status as a Controlled Company**

Our Chairman, Mr. LeBow, is the sole partner of and has sole voting and dispositive power of the shares held by LeBow Alpha, our largest stockholder. Mr. LeBow, as a result of his ownership of LeBow Alpha, which holds greater than 50% of the voting power of our outstanding common stock, has the ability to control the outcome of matters submitted to our stockholders for approval, including the election of our directors, as well as the overall management and direction of our company. In addition, because LeBow Alpha controls over 50% of the voting power of our common stock, we are considered a controlled company under the corporate governance rules of NASDAQ and are, therefore, eligible to rely on exemptions from certain of these requirements including, without limitation, the requirement that a majority of our board of directors be independent and that we have a compensation committee and a nominating committee each comprised solely of independent directors. To the extent LeBow Alpha continues to control over 50% of the voting power of our common stock following the offering, we will continue to be a controlled company. Despite the availability of these exemptions, we agreed with Aegis Capital Corp., as underwriter in our initial public offering, that we will not rely on these exemptions until after June 23, 2016. However, to the extent we still qualify, we may in the future elect to rely on these exemptions, and to the extent we do, our stockholders will not have the same protections afforded to stockholders of companies that are subject to such requirements.

### **Board Committees**

Our board of directors has established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee.

#### **Audit Committee**

The members of our Audit Committee are Mr. Gonyer, Mr. Schuling and Dr. Smith, each of whom has been determined by our board of directors to be independent under applicable NASDAQ and SEC rules and regulations. Mr. Schuling is the chair of the Audit Committee. Our Audit Committee's responsibilities include, among others: appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;

overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from that firm;  
reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;  
    monitoring our internal control over financial reporting, disclosure controls and procedures;  
    overseeing our internal audit function;

98

---

## TABLE OF CONTENTS

discussing our risk management policies;  
establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;  
meeting independently with our internal auditing staff, if any, our independent registered public accounting firm and management;

reviewing and approving or ratifying any related person transactions; and  
preparing the Audit Committee report required by Securities and Exchange Commission, or SEC, rules.  
All audit and non-audit services, other than *de minimis* non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our Audit Committee.

Our board of directors has determined that Mr. Schuling is an audit committee financial expert as defined in applicable SEC rules.

### **Compensation Committee**

The members of our Compensation Committee are Mr. Gonyer, Mr. Schuling and Dr. Smith, each of whom has been determined by our board of directors to be independent under current NASDAQ and SEC rules and regulations. Dr. Smith is the chair of the Compensation Committee. Our Compensation Committee's responsibilities include, among others:

reviewing and approving annually the corporate goals and objectives applicable to the compensation of the Chief Executive Officer, evaluating at least annually the Chief Executive Officer's performance in light of those goals and objectives, and determining and approving the Chief Executive Officer's compensation level based on this evaluation;  
reviewing and approving the compensation of all other executive officers;  
reviewing and approving and, when appropriate, recommending to the board of directors for approval, incentive compensation plans and equity-based plans, and where appropriate or required, recommending for approval by the stockholders of the Company, the adoption, amendment or termination of such plans; and administering such plans;  
reviewing and approving the executive compensation information included in the Company's annual report on Form 10-K and proxy statement;  
reviewing and approving or providing recommendations with respect to any employment agreements or severance arrangements or plans; and  
reviewing director compensation and recommending any changes to the board of directors.

### **Nominating and Corporate Governance Committee**

The members of our Nominating and Corporate Governance Committee are Mr. Gonyer, Mr. Schuling and Dr. Smith, each of whom has been determined by our board of directors to be independent under current NASDAQ rules. Mr. Gonyer is the chair of the Nominating and Corporate Governance Committee. Our Nominating and Corporate Governance Committee's responsibilities include, among others:

identifying and recommending candidates to fill vacancies on the board of directors and for election by the stockholders;  
recommending committee and chairperson assignments for directors to the board of directors;  
developing, subject to the board of directors' approval, a process for an annual evaluation of the board of directors and its committees and to oversee the conduct of this annual evaluation;

## TABLE OF CONTENTS

overseeing the Company's corporate governance practices, including reviewing and recommending to the board of directors for approval any changes to the documents and policies in the Company's corporate governance framework, including its certificate of incorporation and bylaws; and monitoring compliance with the Company's Code of Business Conduct and Ethics, investigating alleged breaches or violations thereof and enforcing its provisions.

### **Board of Directors Leadership Structure**

Our principal stockholder also serves as the Chairman of our board of directors. Our board of directors does not have a lead independent director. Our board of directors has determined its leadership structure is appropriate and effective for us, given our stage of development.

### **Risk Oversight**

Our board of directors monitors our exposure to a variety of risks through our Audit Committee. Our Audit Committee charter gives the Audit Committee responsibilities and duties that include discussing with management, the internal audit department and the independent auditors our major financial risk exposures and the steps management has taken to monitor and control such exposures, including our risk assessment and risk management policies.

### **Code of Business Conduct and Ethics**

We have adopted a code of business conduct and ethics that applies to all of our employees, officers, and directors, including those officers responsible for financial reporting. These standards are designed to deter wrongdoing and to promote honest and ethical conduct. The code of business conduct and ethics and the written charter for the audit committee is available on our website. The information that appears on our website is not part of, and is not incorporated into, this prospectus.

None of our directors or executive officers, nor any associate of such individual, is involved in a legal proceeding adverse to us or any of our subsidiaries.



TABLE OF CONTENTS**EXECUTIVE COMPENSATION****Summary Compensation Table (2014 and 2013)**

The following table sets forth the information as to compensation paid to or earned by our President and Chief Executive Officer and our only other executive officer during the fiscal years noted below whose total compensation exceeded \$100,000. The persons listed in the following table are referred to herein as the named executive officers.

Name and Principal Position	Fiscal Year	Salary	Bonus	Stock Award(s) <sup>(1)</sup>	Option Award(s)	All Other Compensation	Total
Samuel D. Riccitelli <i>Chief Executive Officer</i>	2014	\$ 469,775	\$	\$ 7,455,110	\$	\$ 24,164	\$ 7,949,049
<i>and President</i>	2013	\$ 450,000	\$	\$	\$ <sup>(2)</sup>	\$ 114,947	\$ 564,947
Tamara A. Seymour <sup>(3)</sup> <i>Chief Financial Officer</i>	2014	\$ 144,712	\$	\$ 468,280	\$	\$ 1,398	\$ 614,390

(1) Represents the aggregate grant date fair value of awards computed in accordance with FASB ASC Topic 718.

(2) Mr. Riccitelli was granted 22,725 incentive units pursuant to his employment agreement. These incentive units were forfeited by Mr. Riccitelli in connection with our corporate conversion.

(3) Ms. Seymour has served as Chief Financial Officer since August 4, 2014.

**Riccitelli Employment Agreement**

We entered into an amended and restated employment agreement, or the CEO Agreement, with Samuel D. Riccitelli, on June 17, 2014 (the effective date of the CEO Agreement) in connection with our initial public offering. The CEO Agreement was subsequently amended on July 23, 2014, to bring the agreement into compliance with Section 409A of the Internal Revenue Code of 1986, as amended, and the Treasury Regulations and interpretive guidance issued thereunder. The CEO Agreement prohibits Mr. Riccitelli from engaging in any competitive activity, as described in the CEO Agreement, during his employment with us and for a period of one year following termination of his employment for any reason.

The CEO Agreement continues in effect until October 31, 2015, and automatically renews for additional one-year terms on each anniversary of the effective date of the CEO Agreement after October 31, 2015. The CEO Agreement provides for, among other things, an annual base salary of \$450,000, payable on a semi-monthly basis. It also provides that Mr. Riccitelli will be reimbursed for all reasonable business expenses, including travel and entertainment expenses incurred in the performance of his duties. During the term of his employment, Mr. Riccitelli is entitled to participate in any annual performance-based incentive compensation programs and any long-term incentive compensation programs that are established by the Company, on the terms established from time to time by the Compensation Committee or the board of directors of the Company. Mr. Riccitelli is also entitled to four weeks of paid vacation time and is eligible to receive the same employee benefits as are provided by the Company to other executive employees.

The CEO Agreement also provides for certain post-termination benefits. See [Payments Due Upon Termination of Employment or a Change in Control Riccitelli Employment Agreement](#) below for more information.

## **Seymour Employment Agreement**

We entered into an employment agreement, or the CFO Agreement, with Tamara A. Seymour, on August 4, 2014 (the effective date of the CFO Agreement). The CFO Agreement prohibits Ms. Seymour from engaging in any competitive activity, as described in the CFO Agreement, during her employment with us.

The CFO Agreement continues in effect until the one year anniversary of the effective date of the CFO Agreement, and automatically renews for additional one-year terms on each anniversary of such effective date. The CFO Agreement provides for, among other things, an annual base salary of \$350,000, payable on a semi-monthly basis. It also provides that Ms. Seymour will be reimbursed for all reasonable business expenses, including travel and entertainment expenses incurred in the performance of her duties. The CFO Agreement

## TABLE OF CONTENTS

also provides that at the end of each fiscal year of the Company, in addition to Ms. Seymour's base salary then in effect, she will be eligible to receive a bonus payment of up to 30% of her base salary then in effect, which bonus payment will be awarded in the sole discretion of the Compensation Committee based upon performance goals established by the Compensation Committee during the first ninety (90) days of each fiscal year, which goals shall be set after consultation with the Chief Executive Officer. Pursuant to the terms of the CFO Agreement, Ms. Seymour received an initial restricted stock unit award for 92,000 shares as of the Effective Date. Ms. Seymour is also entitled to four weeks of paid vacation time and is eligible to receive the same employee benefits as are provided by the Company to other executive employees.

The CFO Agreement also provides for certain post-termination benefits. See *Payments Due Upon Termination of Employment or a Change in Control* below for more information.

### **2014 Stock Incentive Plan**

Prior to our initial public offering, we adopted a stock incentive plan, the 2014 Plan. The following description of the 2014 Plan is qualified in its entirety by the full text of the plan.

*Purpose.* We believe that the 2014 Plan promotes our long-term growth and profitability by (1) providing key people with incentives to improve stockholder value and to contribute to our growth and financial success through their future services, and (2) enabling us to attract, retain and reward the best-available personnel.

*Eligibility.* Selected employees, officers, directors, and other individuals providing bona fide services to us or any of our affiliates, are eligible for awards under the 2014 Plan. The plan administrator may also grant awards to individuals in connection with hiring, retention, or otherwise before the date the individual first performs services for the Company or an affiliate. However, those awards will not become vested or exercisable before the date the individual first performs those services for us.

*Shares subject to the plan.* The number of shares of common stock that we may issue pursuant to awards under the 2014 Plan is 1,245,399; provided, however, that no more than 1,000,000 shares of common stock may be issued in the form of full-value awards, and no more than 600,000 shares of common stock may be issued pursuant to incentive stock options intended to qualify under section 422 of the Internal Revenue Code. The maximum number of shares of common stock subject to awards of any combination that may be granted under the 2014 Plan during any fiscal year to any one individual will be limited to 750,000 shares. These limits will be appropriately adjusted to reflect any stock dividends, split ups, recapitalizations, mergers, consolidations, share exchanges, and similar transactions. If any award, or portion of an award, under the 2014 Plan expires or terminates unexercised, becomes unexercisable, is settled in cash without delivery of shares, or is forfeited or otherwise terminated, surrendered or canceled as to any shares, or if any shares are repurchased by or surrendered to us in connection with any award, or if any shares are withheld by us, the shares subject to such award and the repurchased, surrendered and withheld shares will thereafter be available for further awards under the 2014 Plan other than incentive stock options.

*Administration.* The 2014 Plan is administered by our board of directors or by a committee or committees as the board may appoint from time to time. The plan administrator has the full authority and discretion to administer the 2014 Plan and to take any action that is necessary or advisable in connection with the administration of the plan, including without limitation the authority and discretion to interpret and administer the plan and any instrument or agreement relating to the plan or any award made thereunder. The plan administrator's determinations will be final and conclusive.

*Types of awards.* The 2014 Plan provides for grants of stock options (including incentive stock options qualifying under Code section 422 and nonstatutory stock options), stock appreciation rights, restricted or unrestricted stock awards, restricted stock units, performance awards, other stock-based awards, or any combination of the foregoing. As of December 31, 2014, 1,092,093 shares have been granted pursuant to awards under the 2014 Plan. Future benefits or amounts that will be allocated to any participant or group of participants are indeterminable at this time because participation and the types of awards (including options) available under the plan are subject to the discretion of the plan administrator.

102

---

TABLE OF CONTENTS

*Stock options.* The 2014 Plan allows the plan administrator to grant incentive stock options, as that term is defined in section 422 of the Internal Revenue Code, or nonqualified stock options. Only our employees or employees of our subsidiaries or any parent corporation may receive incentive stock option awards. Options must have an exercise price at least equal to the fair market value of the underlying shares (110% of the fair market value for incentive stock options if the grantee is a 10% holder within the meaning of Code section 422) on the date of grant. The option holder may pay the exercise price in cash or by check, by tendering shares of common stock, by a combination of cash and shares, or by any other means that the plan administrator approves. Generally, options granted under the 2014 Plan will have a 10 year term (five year term in the case of incentive stock options granted to a 10% holder), however, the options will expire earlier if the option holder's service relationship with us terminates.

*Stock appreciation rights.* The 2014 Plan allows the plan administrator to grant awards of stock appreciation rights, which entitle the holder to receive a payment in cash, in shares of common stock, or in a combination of both, having an aggregate value equal to the spread on the date of exercise between the fair market value of the underlying shares on that date and the base price of the shares specified in the grant agreement, multiplied by the number of shares specified in the award being exercised.

*Stock awards.* The 2014 Plan allows the plan administrator to grant stock awards to eligible participants in such amounts, on such terms and conditions, and for such consideration, including no consideration or minimum consideration as may be required by law. A stock award may be denominated in common stock or other securities, stock-equivalent units or restricted stock units, securities or debentures convertible into common stock, or any combination of the foregoing and may be paid in common stock or other securities, in cash, or in a combination of common stock or other securities and cash, all as determined in the sole discretion of the plan administrator.

*Performance awards.* The 2014 Plan allows the plan administrator to grant performance awards which become payable in common stock or other securities, in cash, or in a combination of common stock or other securities and cash, on account of attainment of one or more performance goals established by the plan administrator. The plan administrator may establish performance goals relating to any of the following, as it may apply to an individual, one or more business units, divisions or subsidiaries, or on a Company-wide basis, and in either absolute terms or relative to the performance of one or more comparable companies or an index covering multiple companies:

*Earnings or profitability metrics:* including, but not limited to, earnings/loss (gross, operating, net, or adjusted); earnings/loss before interest and taxes, or EBIT; earnings/loss before interest, taxes, depreciation and amortization, or EBITDA; profit margins; expense levels or ratios; in each case adjusted to eliminate the effect of any one or more of the following: interest expense, asset impairments, early extinguishment of debt, equity incentive compensation expense, changes in generally accepted accounting principles or critical accounting policies, or other extraordinary or non-recurring items, as specified by the plan administrator when establishing the performance goals;

*Return metrics:* including, but not limited to, return on investment, assets, equity or capital (total or invested);

*Cash flow metrics:* including, but not limited to, operating cash flow; cash flow sufficient to achieve financial ratios or a specified cash balance; free cash flow; cash flow return on capital; net cash provided by operating activities; cash flow per share; working capital;

*Liquidity metrics:* including, but not limited to, capital raising; debt reduction; extension of maturity dates of outstanding debt; debt leverage (debt to capital, net debt-to-capital, debt-to-EBITDA or other liquidity ratios) or access to capital; debt ratings; total or net debt; other similar measures approved by the plan administrator;

*Stock Price and Equity Metrics:* including, but not limited to, return on stockholders' equity; total stockholder return; revenue (gross, operating or net); revenues from sales; revenues from search model; revenue growth; stock price; stock price appreciation; market capitalization; earnings/loss per share (basic or diluted) (before or after taxes); price-to-earnings ratio;



TABLE OF CONTENTS

*Strategic Metrics:* including, but not limited to, number of users, site traffic, conversion ratios, product research and development; regulatory filings or approvals; patent application or issuance; manufacturing or process development; sales or net sales; geographic coverage; market share; market penetration; inventory control; growth in assets; key hires; business expansion; acquisitions, divestitures, affiliate agreements, collaborations, licensing or joint ventures; financing; resolution of significant litigation; legal compliance or risk reduction.

The plan administrator is authorized to make adjustments in the method of calculating attainment of performance measures and performance targets in recognition of: (1) extraordinary or non-recurring items; (2) changes in tax laws; (3) changes in generally accepted accounting principles or changes in accounting policies; (4) charges related to restructured or discontinued operations; (5) restatement of prior period financial results; and (6) any other unusual, non-recurring gain or loss that is separately identified and quantified in our financial statements; provided that the plan administrator's decision as to whether such adjustments will be made with respect to any covered employee, within the meaning of section 162(m) of the Internal Revenue Code, is determined when the performance targets are established for the applicable performance period. Notwithstanding the foregoing, the plan administrator may, at its sole discretion, modify the performance results upon which awards are based under the 2014 Plan to offset any unintended results arising from events not anticipated when the performance measures and performance targets were established; provided, that such modifications may be made with respect to an award granted to any covered employee, only to the extent permitted by Section 162(m) of the Internal Revenue Code if the award was intended to constitute qualified performance-based compensation within the meaning of Section 162(m) of the Internal Revenue Code.

*Change in control.* In the event of any transaction resulting in a change in control of the Company (as defined in the 2014 Plan), outstanding stock options and other awards that are payable in or convertible into our common stock will terminate upon the effective time of the change in control unless provision is made in connection with the transaction for the continuation, assumption, or substitution of the awards by the surviving or successor entity or its parent. In the event of such termination the holders of stock options and other awards under the 2014 Plan will be permitted immediately before the change in control to exercise or convert all portions of awards that are then exercisable or convertible or which become exercisable or convertible upon or prior to the effective time of the change in control. In the event that a change in control occurs after a performance-based stock award has been granted but before completion of the applicable performance period, a pro rata portion of such award will become payable (or a pro rata portion of the lapse restrictions will lapse, as applicable) as of the date of the change in control to the extent otherwise earned on the basis of achievement of the pro rata portion of the performance goals and performance targets relating to the portion of the performance period completed as of the date of the change in control.

*Amendment and termination.* The 2014 Plan became effective on June 17, 2014. No award will be granted under the 2014 Plan after the close of business on the day before the tenth anniversary of the effective date of the plan. Our board of directors may terminate, amend or modify the 2014 Plan, or any portion thereof, at any time. Shareholder approval will be required to reprice any options or SARs under the 2014 Plan.

*U.S. federal income tax consequences.* The following is a general summary of the U.S. federal income tax treatment of stock options and other awards that are authorized for issuance under the 2014 Plan, based upon the provisions of the Internal Revenue Code as of the date of this prospectus. This summary is not intended to be exhaustive and the exact tax consequences to any grantee will depend upon his or her particular circumstances and other facts. Participants must consult their tax advisors with respect to any state, local and non-U.S. tax considerations or particular federal tax implications of awards granted to them under the 2014 Plan.

*Treatment of Options.* The Code treats incentive stock options and nonstatutory stock options differently. However, as to both types of options, no income will be recognized to the optionee at the time of the grant of the options under the 2014 Plan.





TABLE OF CONTENTS

Generally, upon exercise of a nonstatutory (or non-qualified) stock option (including an option intended to be an incentive stock option but which has not continued to so qualify at the time of exercise), an optionee will recognize ordinary income tax on the excess of the fair market value of the stock on the exercise date over the option price. In general, if an optionee, in exercising a nonstatutory stock option, tenders shares of our common stock in partial or full payment of the option price, no gain or loss will be recognized on the tender. However, if the tendered shares were previously acquired upon the exercise of an incentive stock option and the tender is within two years after the date of grant or within one year after the date of exercise of the incentive stock option, the tender will be a disqualifying disposition of the shares acquired upon exercise of the incentive stock option.

For incentive stock options, there is no taxable income to an optionee at the time of exercise. However, the excess of the fair market value of the stock on the date of exercise over the exercise price will be taken into account in determining whether the alternative minimum tax will apply for the year of exercise. If the shares acquired upon exercise are held until at least two years from the date of grant and more than one year from the date of exercise, any gain or loss upon the sale of such shares, if held as capital assets, will be long-term capital gain or loss (measured by the difference between the sales price of the stock and the exercise price). Under current federal income tax law, a long-term capital gain will be taxed at a rate which is less than the maximum rate of tax on ordinary income. If the two-year and one-year holding period requirements are not met (a disqualifying disposition), an optionee will recognize ordinary income in the year of disposition in an amount equal to the lesser of (1) the fair market value of the stock on the date of exercise minus the exercise price or (2) the amount realized on disposition minus the exercise price. The remainder of the gain will be treated as long-term capital gain, depending upon whether the stock has been held for more than a year. If an optionee makes a disqualifying disposition, he or she will be obligated to notify us.

In general, if an optionee, in exercising an incentive stock option, tenders shares of our common stock in partial or full payment of the option price, no gain or loss will be recognized on the tender. However, if the tendered shares were previously acquired upon the exercise of another incentive stock option and the tender is within two years after the date of grant or within one year after the date of exercise of the other option, the tender will be a disqualifying disposition of the shares acquired upon exercise of the other option.

As noted above, the exercise of an incentive stock option could subject an optionee to the alternative minimum tax.

The application of the alternative minimum tax to any particular optionee depends upon the particular facts and circumstances which exist with respect to the optionee in the year of exercise. However, as a general rule, the amount by which the fair market value of the common stock on the date of exercise of an option exceeds the exercise price of the option will constitute an item of adjustment for purposes of determining the alternative minimum taxable income on which the alternative tax may be imposed. As such, this item will enter into the tax base on which the alternative minimum tax is computed and may therefore cause the alternative minimum tax to become applicable in any given year.

*Treatment of Stock Appreciation Rights.* Generally, the recipient of a stock appreciation right will not recognize any income upon grant of the stock appreciation right. Upon exercise of a stock appreciation right, the holder will recognize ordinary income equal to the fair market value of our common stock at that time.

*Treatment of Stock Awards.* Generally, absent an election to be taxed currently under Section 83(b) of the Code, or a Section 83(b) Election, there will be no federal income tax consequences to the recipient upon the grant of a restricted stock award. At the expiration of the restriction period and the satisfaction of any other restrictions applicable to the restricted shares, the recipient will recognize ordinary income equal to the fair market value of our common stock at that time. If a Section 83(b) Election is made within 30 days after the date the restricted stock award is granted, the recipient will recognize an amount of ordinary income at the time of the receipt of the restricted shares equal to the fair market value (determined without regard to applicable restrictions) of the shares of our common stock at such

time. If a Section 83(b) Election is made, no additional income will be recognized by the recipient upon the lapse of restrictions on the shares (and prior to the sale of such shares), but, if the shares are subsequently forfeited, the recipient may not deduct the income that was recognized pursuant to the Section 83(b) Election at the time of the receipt of the shares.

The recipient of an unrestricted stock award will recognize ordinary income equal to the fair market value of our common stock that is the subject of the award when the award is made.

TABLE OF CONTENTS

The recipient of a restricted stock unit will recognize ordinary income as and when the units vest. The amount of the income will be equal to the fair market value of the shares of our common stock issued at that time. The recipient of a restricted stock unit will not be permitted to make a Section 83(b) Election with respect to such award.

*Treatment of Performance Awards and Other Stock-Based Awards.* The federal income tax consequences of performance share awards, performance unit awards, other cash-based awards and other stock-based awards will depend on the terms and conditions of those awards.

*Tax Withholding.* We have the right to deduct or withhold, or require a participant to remit to us, the amount required to satisfy minimum statutory withholding requirements of federal, state and local tax laws and regulations (domestic or foreign) with respect to any taxable event arising as a result of the 2014 Plan.

*Inapplicability of Code Sections and ERISA.* Sections 401(a) and 401(k) of the Code and the provisions of the Employee Retirement Income Security Act of 1974 are not applicable to the 2014 Plan.

## Outstanding Equity Awards at Fiscal Year-End 2014

The following table provides information about the number of outstanding equity awards held by our named executive officers at December 31, 2014.

Name	Stock Awards		Equity Incentive Plan Awards: Number of Unearned Shares, Units Or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units Or Other Rights That Have Not Vested (\$)
	Number of Shares Or Units of Stock That Have Not Vested (#)	Market Value of Shares Or Units of Stock That Have Not Vested (\$)		
Samuel D. Riccitelli	497,008 <sup>(1)</sup>	1,262,380		
Tamara A. Seymour	92,000 <sup>(2)</sup>	233,680		

The shares underlying this award vest as follows: (1) 124,252 shares vested on January 1, 2015; (2) 124,252 shares vest on June 17, 2015; (3) 124,252 shares vest on December 17, 2015; and (4) 124,252 shares vest on June 17, 2016. In addition, 248,503 shares underlying this award vested on June 17, 2014, and will be issued to Mr. Riccitelli on or before December 31, 2015. These shares will be issued to Mr. Riccitelli in two tranches, the first of which will be issued sometime in 2015 (on a date to be mutually agreed upon by us and Mr. Riccitelli) and the second of which will be issued on or before March 15, 2016.

(2) 23,000 shares vest on August 4<sup>th</sup> in each of 2015, 2016, 2017 and 2018.

## Payments Due Upon Termination of Employment or a Change in Control

### Employment Agreement

Mr. Riccitelli's CEO Agreement and Ms. Seymour's CFO Agreement entitle each of them (each referred to herein as the Executive) to receive certain payments upon the termination of such person's employment under certain

circumstance as described below.

*Termination for Cause* In the event Executive's employment is terminated for Cause, Executive's sole remedy will be to collect all unpaid base salary, all accrued personal time off and all unreimbursed expenses payable for all periods through the effective date of termination, as well as any amount arising from his participation in, or benefits under, any employee benefit plan, program or arrangement, payable in accordance with the terms of such plan, program or arrangement.

Cause means (1) expiration of the term of the CEO Agreement or CFO Agreement (as applicable), (2) a material breach by Executive of his or her fiduciary duty to the Company that results in material harm to the Company; (3) a material breach by Executive of the terms of the CEO Agreement or CFO Agreement (as applicable) or any other agreement between Executive and the Company, which remains uncured for a period of 30 days following the receipt of written notice

TABLE OF CONTENTS

specifying the nature of the breach; (4) the willful commission by Executive of any act of embezzlement, fraud, larceny or theft on or from the Company; (5) substantial and continuing willful neglect or inattention by Executive of the duties of such person's employment, refusal to perform the lawful and reasonable directions of the board of directors or the willful misconduct or gross negligence of Executive in connection with the performance of such duties which remain uncured for a period of 30 days following the receipt of written notice specifying the nature of the breach; (6) the willful commission by Executive of any crime involving moral turpitude or a felony; and (7) Executive's performance or omission of any act which, in the judgment of the board of directors, if known to the customers, clients, stockholders or any regulators of the Company, would have a material adverse impact on the business of the Company.

*Termination Without Cause* In the event Mr. Riccitelli's employment is terminated without Cause, he will be entitled to receive all unpaid base salary, accrued annual bonus or incentive compensation (including any unpaid, accrued annual bonus or incentive compensation from the immediately preceding year), accrued personal time off, and all unreimbursed expenses payable for all periods through the effective date of termination (with such amounts to be paid on the date of termination).

In addition, Mr. Riccitelli will be entitled to receive a severance payment, calculated as follows:

should the termination occur on or prior to June 23, 2015, Mr. Riccitelli will be entitled to continue to receive his then-current base salary for a period of six months; and  
should the termination occur after June 23, 2015, Mr. Riccitelli will be entitled to continue to receive his then-current base salary for a period of twelve months.

In the event Ms. Seymour's employment is terminated without Cause, Ms. Seymour will be entitled to receive a severance payment calculated as follows:

should the termination occur during the initial one-year term of the CFO Agreement, Ms. Seymour will be entitled to continue to receive her then-current base salary for the greater of the number of months remaining in the initial one-year term or six months; and  
should the termination occur anytime during the employment period after the initial one-year term, Ms. Seymour will be entitled to continue to receive her then-current base salary for twelve months.

Neither Executive will be required to mitigate the amount of any severance payments received by seeking other employment during the term of the severance period. However, should the Executive obtain other employment during the term of the severance period, the Company will pay such person, for the remaining length of the severance period, only the difference between such person's new salary and base salary (as in effect at the time of termination), if the new salary is less than such person's base salary (*i.e.*, the Company will not be obligated to make any severance payments to Executive if such person's new salary is greater than such person's applicable base salary). The severance payment (less all applicable withholdings) will be paid in equal monthly installments over the applicable period immediately following the termination of Executive's employment. The Company will also reimburse Executive for premiums for COBRA coverage for Executive (and to the extent he or she has family coverage, his family), provided that Executive elects such coverage, during the applicable period when such person is receiving severance payments, until such time as Executive obtains other employment and is entitled to comparable health coverage from such employer.

*Termination After Disability or Death* In the event that Executive's employment is terminated due to disability (as described in the CEO Agreement or CFO Agreement (as applicable)) or on account of such person's death, then Executive (or such person's estate or personal representative, as applicable) will be entitled to receive all unpaid base salary, accrued annual bonus or incentive compensation (including any unpaid, accrued annual bonus or incentive compensation from the immediately preceding year), accrued personal time off, and all unreimbursed expenses payable for



TABLE OF CONTENTS

all periods through the effective date of termination. In the case of disability only, Executive will be entitled to receive, in addition to the amounts specified above, for a period of six months, a series of monthly payments equal to such person's then-current monthly base salary payments such person received during his or her employment if and only if Executive does not receive any payments as a result of the short-term and long-term disability insurance benefits that the Company obtains on such person's behalf pursuant to the CEO Agreement or CFO Agreement (as applicable), which payments will be paid in equal installments over the applicable period. If Executive is provided with such insurance payments, then such person will only be entitled to receive the difference between the insurance payments and such person's base salary, if the payments are less than such person's base salary.

*Termination by Executive for Good Reason* In the event that Executive's employment is terminated by such person for Good Reason, then Executive will be entitled to receive all unpaid base salary, accrued annual bonus or incentive compensation (including any such unpaid, accrued compensation from the immediately preceding year), accrued personal time off and all unreimbursed expenses payable for all periods through the effective date of such person's termination. In addition, Executive will be entitled to receive the same severance payment such person would be entitled to receive if his or her employment were terminated by the Company without Cause

Good Reason means (1) the Company has materially breached the CEO Agreement or CFO Agreement (as applicable) and the Company has failed to cure or remedy such breach after 30-days written notice from Executive (provided that Executive must resign within 30 days after expiration of the 30-day period following written notice without cure or remedy by the Company), (2) there has occurred any material and substantial diminution or reduction in duties, base salary, title, health care coverage (but only if such diminution is disproportionate to a diminution in health care coverage applicable to other employees of the Company), authority or responsibilities of Executive, whether is scope or nature, and the Company has failed to cure or remedy such breach after 30-days written notice from Executive; or (3) the Company has required that Executive perform any act or refrain from performing any act that would be in violation of applicable law.

*Termination by Executive without Good Reason* In the event Executive terminates his or her employment without Good Reason, such person will only be entitled to receive all unpaid base salary, all accrued personal time off and all unreimbursed expenses payable for all periods through the effective date of termination and Executive will not be entitled to any compensation or other amounts from the Company following the effective date of termination.

**Director Compensation**

Prior to our corporate conversion and our initial public offering, we did not pay compensation to our managers for their service on our board of managers. In connection with our initial public offering, our board of directors adopted the following compensation arrangement for our non-employee independent directors.

**Annual Compensation**

Board retainer/meeting fees	\$25,000 plus \$1,000 per meeting
Audit Committee Member Meeting Fees	\$500 per meeting
Audit Committee Chairman Retainer	\$10,000
Compensation Committee Member Meetings Fees	\$500 per meeting
Compensation Committee Chairman Retainer	\$5,000
Nominating and Corporate Governance Committee Member Meeting Fees	\$500 per meeting
Nominating and Corporate Governance Committee Chairman Retainer	\$5,000

TABLE OF CONTENTS**Equity Awards granted upon appointment to the Board of Directors**

Restricted Stock Unit Award 5,500 shares

Stock Option Award 6,000 shares

The table below sets forth the compensation of our non-employee directors for fiscal year 2014.

2014 Director Compensation<sup>(1)</sup>

Name	Fees earned or paid in cash (\$)	Stock Awards <sup>(2)</sup> (\$)	Option Awards <sup>(3)</sup> (\$)	Total (\$)
David A. Gonyer, R. Ph.	\$ 20,155	\$ 30,800	\$ 20,845	\$ 71,800
Douglas A. Schuling	22,847	30,800	20,845	74,492
Robin L. Smith, M.D.	20,155	30,800	20,845	71,800

Mr. Riccitelli, our President and Chief Executive Officer, is also a director on our board of directors. Mr.

Riccitelli's compensation for serving as our President and Chief Executive Officer is reported in the Summary

(1) Compensation Table and other compensation tables set forth under Executive Compensation. Mr. Riccitelli does not receive any additional compensation for his service on our Board, nor does Mr. LeBow, the Chairman of our board of directors.

Each of the directors was granted a restricted stock unit award for 5,500 shares of common stock on July 17, 2014.

(2) Each restricted stock unit represents a contingent right to receive the economic equivalent of one share of common stock, payable in shares of common stock, cash or some combination of both, as determined by the Company. The restricted stock units will become payable in four equal annual installments beginning on July 17, 2015. The values set forth in this column are based on the aggregate grant date fair value of the awards computed in accordance with FASB ASC Topic 718 (excluding the effect of estimated forfeitures).

(3) Each of the directors was granted a stock option to purchase 6,000 shares of common stock on July 17, 2014. The stock options vest in four equal annual installments beginning on July 17, 2015. The values set forth in this column are based on the aggregate grant date fair value of the awards computed in accordance with FASB ASC Topic 718 (excluding the effect of estimated forfeitures).

109



TABLE OF CONTENTS

# SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information with respect to the beneficial ownership of our common stock immediately prior to and immediately following the offering:

each person who is known by us to be the beneficial owner of more than 5% of our outstanding common stock;  
 each of our directors;  
 each of our named executive officers; and  
 all of our directors and executive officers as a group.

The pre-offering percentage ownership information shown in the table is based upon 3,808,563 shares of common stock outstanding immediately prior to the offering, which includes 25,934 shares of our common stock to be issued to an employee upon the settlement of restricted stock units that vested January 1, 2015. The post-offering percentage is based upon 6,693,178 shares of common stock outstanding after completion of this offering, assuming no exercise of the underwriters' over-allotment option.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options, warrants or other rights that are either immediately exercisable or exercisable on or before March 30, 2015, which is 60 days after the date of this prospectus. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for each of the individuals and entities listed in this table is c/o Signal Genetics, Inc., 5740 Fleet Street, Carlsbad, California 92008.

Name of Beneficial	Number of Shares Beneficially Owned	Percentage Ownership (Pre-Offering)	Percentage Ownership (Post-Offering)
<b>5% Holders</b>			
LeBow Alpha, LLLP <sup>(1)</sup>	2,232,629	58.6 %	33.4 %
LFIT-A Trust <sup>(2)</sup>	350,000	9.2 %	5.2 %
LeBow 2012 Nevada Trust <sup>(3)</sup>	350,000	9.2 %	5.2 %
<b>Executive Officers, Directors and Director Nominees</b>			
Bennett S. LeBow <sup>(1)</sup>	2,232,629	58.6 %	33.4 %
Samuel D. Riccitelli	372,755 <sup>(4)</sup>	8.9 %	5.3 %
Tamara A. Seymour		*	*
David A. Gonyer		*	*
Douglas A. Schuling		*	*
Dr. Robin L. Smith		*	*
All Executive Officers & Directors, as a group (six persons)	2,605,384	62.3 %	36.9 %

\*

Less than one percent.

Bennett S. LeBow is the sole partner of LeBow Alpha. By virtue of his position with LeBow Alpha, he is deemed (1) to be the beneficial owner of these shares and has sole voting and dispositive power over the shares. The address of LeBow Alpha is 667 Madison Avenue, 14<sup>th</sup> Floor, New York, New York 10065.

(2) Seth Kaplan is the trustee of this trust and has sole voting and dispositive power with respect to these shares. The address of the LFIT-A Trust is 667 Madison Avenue, 14<sup>th</sup> Floor, New York, New York 10065.

110

---

TABLE OF CONTENTS

Stephen Danner and Premier Trust, Inc. are the trustees of this trust and have sole voting and dispositive power (3) with respect to these shares. The address of the LeBow 2012 Nevada Trust is 667 Madison Avenue, 14<sup>th</sup> Floor, New York, New York 10065.

(4) These restricted stock units are fully-vested and currently issuable to Mr. Riccitelli, and will be issued on or before December 31, 2015.

111

---

TABLE OF CONTENTS

## **CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

The following is a summary of transactions since January 1, 2012 to which we have been a party in which the amount involved exceeded the lesser of \$120,000 or one percent of the average of our total assets at the end of the last two recent fiscal years and in which any of our executive officers, directors, director nominees or beneficial holders of more than five percent of our capital stock had or will have a direct or indirect material interest, other than compensation arrangements which are described under the section of this prospectus entitled Management Non-Employee Director Compensation and Management Executive Compensation.

### **Secured Demand Promissory Note**

We and our subsidiaries, as borrowers, entered into a Secured Demand Promissory Note, or the Original Promissory Note, in the amount of \$20,000,000 with LeBow Alpha, as lender, dated November 3, 2011. Any unpaid principal under the Original Promissory Note bore interest at a rate of 8% per annum, compounded quarterly. In addition, interest was payable on any overdue installment of principal for the period overdue, on demand, at a rate equal to 11% per annum, compounded quarterly as of the last day of each calendar quarter. The Chairman of our board of directors, Bennett LeBow, is the sole partner of LeBow Alpha, our principal stockholder, and has sole voting and dispositive power over this entity.

The Original Promissory Note was amended from time to time to increase the principal amount of the borrowings thereunder and to include additional amounts owed to other LeBow-controlled entities as lenders, namely LeBow Gamma Limited Partnership, or LeBow Gamma, and BSL Capital, Inc. (collectively, the LeBow Entities ), from whom we have also borrowed money, from time to time.

On December 31, 2013, we entered into an Amended and Restated Secured Demand Promissory Note, or the New Promissory Note, in the amount of \$25,000,000 with LeBow Alpha to include all of the principal and interest then owed to LeBow Alpha and the other LeBow-controlled entities under the Original Promissory Note, as amended from time to time and to include certain loans that were made to the Company through December of 2013 by LeBow Alpha, LeBow Gamma and BSL Capital, Inc. Unpaid principal under the New Promissory Note bore interest at a rate of 8% per annum, compounded quarterly. In addition, interest was payable on any overdue installment of principal for the period overdue, on demand, at a rate equal to 11% per annum, compounded quarterly as of the last day of each calendar quarter.

The New Promissory Note (like the Old Promissory Note) contained customary representations and warranties and events of default, and includes a cross-default provision to any loan documents, as such term was defined in the Promissory Note, and included a Security Agreement (defined below).

At the time of our initial public offering, \$28,326,287 in principal and interest was outstanding under the New Promissory Note. In connection with our initial public offering and pursuant to the Exchange Agreement, on June 17, 2014, \$27,326,287 was converted into 2,732,629 Class C units of Signal Genetics LLC (2,032,629 of which were issued to LeBow Alpha and 700,000 of which were issued to unaffiliated trusts). We refer to this conversion as the Debt Conversion. These Class C units were then converted into an aggregate of 2,732,629 shares of common stock of Signal Genetics, Inc. in the corporate conversion which preceded our initial public offering.

From January 1, 2011 until the New Promissory Note was converted in the Debt Conversion, the largest aggregate amount of principal outstanding under the note was \$24,433,380, \$17,433,380 of which was owed to certain entities controlled by Mr. LeBow. From January 1, 2011 to our initial public offering, we repaid approximately \$9,279,000 in principal and \$1,182,000 in interest under the Original Promissory Note and the New Promissory Note.

An additional \$1,000,000 was advanced to us by Mr. LeBow prior to our initial public offering to pay for certain offering expenses. At the time of our initial public offering, our intention was that this amount would be repaid to Mr. LeBow in the form of either (1) a new secured demand promissory note or (2) preferred stock. Following the offering, this amount, along with an additional \$45,000, which was advanced to pay for certain additional offering expenses, were reclassified as amounts due to related party on our consolidated balance sheet. This aggregate amount is non-interest bearing and due on demand.

TABLE OF CONTENTS

## **Guaranty and Security Agreement**

Signal Genetics LLC and our subsidiaries (which includes Myeloma Health LLC, Respira Health LLC, CC Health LLC and any future subsidiaries of the Company), as borrowers, entered into a Guaranty and Security Agreement with LeBow Alpha, as lender and the Grantors party thereto, dated November 3, 2011, or the Guaranty and Security Agreement, pursuant to which each borrower agreed to guaranty the obligations of each of the other borrowers under the Promissory Note and to grant, in favor of the lender, a security interest in the collateral (as defined in the Guaranty and Security Agreement) and to pledge in favor of the lender, the issued and outstanding equity of all classes, or pledged collateral, of each borrower as set forth in a schedule to the Guaranty and Security Agreement. This agreement contained customary representations and warrants and covenants, and standard events of default, including that a default under such agreement would constitute a default under the Promissory Note. This agreement was terminated in connection with the Debt Conversion.

113

---

TABLE OF CONTENTS

# **MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK**

The following discussion describes the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the acquisition, ownership and disposition of our common stock issued pursuant to the public offering. This discussion is not a complete analysis of all potential U.S. federal income tax consequences and does not address any tax consequences arising under any state, local or foreign tax laws, any income tax treaties, or any other U.S. federal tax laws, including U.S. federal estate and gift tax laws (except as specifically addressed herein with respect to U.S. federal estate taxes). This discussion is based on the Internal Revenue Code of 1986, as amended ( Code ), U.S. Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the Internal Revenue Service ( IRS ), all as in effect on the date of the public offering. These authorities may change, possibly retroactively, resulting in tax consequences different from those discussed below. No rulings have been or will be sought from the IRS with respect to the matters discussed below, and there can be no assurance that the IRS will not take a different position regarding the tax consequences of a non-U.S. holder's acquisition, ownership or disposition of our common stock or that any such position would not be sustained by a court.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold our common stock as capital assets within the meaning of Code Section 1221 (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences that may be relevant to a non-U.S. holder in light of the holder's particular circumstances. It also does not consider any specific facts or circumstances that may be relevant to non-U.S. holders subject to special rules under the U.S. federal income tax laws, including, without limitation, U.S. expatriates, banks, financial institutions, insurance companies, regulated investment companies, real estate investment trusts, controlled foreign corporations, passive foreign investment companies, corporations that accumulate earnings to avoid U.S. federal income tax, brokers, dealers or traders in securities, commodities or currencies, partnerships or other pass-through entities (or investors in such entities), tax-exempt organizations, tax-qualified retirement plans, persons subject to the alternative minimum tax or the unearned income Medicare contribution tax, and persons holding our common stock as part of a straddle, hedge or other risk reduction strategy or as part of a conversion transaction or other integrated investment.

**WE RECOMMEND THAT PROSPECTIVE INVESTORS CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS, ANY APPLICABLE INCOME TAX TREATIES, OR ANY OTHER U.S. FEDERAL TAX LAWS (INCLUDING ESTATE AND GIFT TAX LAWS).**

## **Definition of Non-U.S. Holder**

As used in this discussion, a non-U.S. holder is any beneficial owner of our common stock who is not treated as a partnership for U.S. federal income tax purposes and is not:

an individual citizen or resident of the United States;

a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof or the District of Columbia;

an estate, the income of which is subject to U.S. federal income tax regardless of its source; or a trust if (1) a U.S. court is able to exercise primary supervision over its administration and one or more U.S. persons have authority to control all its substantial decisions or (2) the trust was in existence on August 20, 1996, was treated as a U.S. person prior to that date and validly elected to continue to be so treated.

If any entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and the activities of the partnership. Partnerships and their partners should consult their tax advisors as to the tax consequences to them of the acquisition, ownership and disposition of our common stock.



TABLE OF CONTENTS

## **Distributions on Our Common Stock**

As described in the section entitled, Dividend Policy, we do not anticipate paying dividends on our common stock in the foreseeable future. If we make a distribution of cash or other property with respect to our common stock, the distribution generally will constitute a dividend for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder's adjusted tax basis in its common stock, but not below zero. Any remaining excess will be treated as capital gain from the sale of property.

Dividends paid to a non-U.S. holder of our common stock that are not effectively connected to the holder's conduct of a U.S. trade or business generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends, or a lower rate specified by an applicable tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish to us or our paying agent a valid IRS Form W-8BEN (or applicable successor form) certifying the holder's qualification for the reduced rate. A non-U.S. holder may be required to obtain a U.S. taxpayer identification number to claim treaty benefits. This certification must be provided to us or our paying agent prior to the payment of dividends and may be required to be updated periodically. Non-U.S. holders that do not timely provide us or our paying agent with the required certification, but which qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on the common stock are effectively connected with the holder's U.S. trade or business and, if an income tax treaty applies, the non-U.S. holder maintains a permanent establishment in the United States to which the dividends are attributable, the non-U.S. holder will be exempt from U.S. federal withholding tax, if the appropriate certification is provided. To claim the exemption for effectively connected income, the non-U.S. holder must furnish to us or our paying agent a properly executed IRS Form W-8ECI (or applicable successor form) prior to the payment of the dividends. Any dividends paid on our common stock that are effectively connected with a non-U.S. holder's U.S. trade or business generally will be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates in the same manner as if the holder were a resident of the United States, unless the holder is entitled to the benefits of a tax treaty that provides otherwise. A non-U.S. holder that is a foreign corporation also may be subject to a branch profits tax equal to 30% (or a lower rate specified by an applicable tax treaty) of its effectively connected earnings and profits for the taxable year that are attributable to such dividends. Non-U.S. holders should consult any applicable tax treaties that may provide for different rules.

## **Gain on Disposition of Our Common Stock**

Subject to the discussions below regarding backup withholding and foreign accounts, a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States; the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or our common stock constitutes a U.S. real property interest by reason of our status as a U.S. real property holding corporation at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock and certain other requirements are met.

Unless an applicable tax treaty provides otherwise, gain described in the first bullet point above will be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates in the same manner as if the holder were a resident of the United States. Non-U.S. holders that are foreign corporations also may be subject to a branch profits tax equal to 30% (or a lower rate specified by an

## TABLE OF CONTENTS

applicable tax treaty) of its effectively connected earnings and profits for the taxable year that are attributable to such gain. Non-U.S. holders should consult any applicable tax treaties that may provide for different rules.

Gains described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or a lower rate specified by an applicable income tax treaty), but may be offset by U.S. source capital losses.

With respect to the third bullet point above, we believe we currently are not and will not become a U.S. real property holding corporation. However, because the determination of whether we are a U.S. real property holding corporation generally depends on whether the fair market value of our U.S. real property interests equals or exceeds 50% of the sum of the fair market value of our other trade or business assets and our worldwide real property interests, there can be no assurance that we will not become a U.S. real property holding corporation in the future. In the event we do become a U.S. real property holding corporation, as long as our common stock is regularly traded on an established securities market, our common stock will constitute a U.S. real property interest only with respect to a non-U.S. holder that actually or constructively holds more than five percent of our common stock at some time during the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock. Any taxable gain generally will be taxed in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax will not apply.

## **Information Reporting and Backup Withholding**

We must report annually to the IRS and to each non-U.S. holder the amount of dividends on our common stock paid to the holder and the amount of any tax withheld with respect to those dividends. These information reporting requirements apply even if no withholding was required because the dividends were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established.

Backup withholding, currently at a rate of 28%, generally will not apply to payments of dividends to a non-U.S. holder of our common stock provided the non-U.S. holder furnishes to us or our paying agent the required certification as to its non-U.S. status (typically, by providing a valid IRS Form W-8BEN or W-8ECI) or an exemption is otherwise established.

Payment of the proceeds from a non-U.S. holder's disposition of our common stock made by or through a foreign office of a broker will not be subject to information reporting or backup withholding, except that information reporting (but generally not backup withholding) may apply to those payments if the broker does not have documentary evidence that the beneficial owner is a non-U.S. holder, an exemption is not otherwise established and the broker is:

a U.S. person, as defined in the Code;

a controlled foreign corporation for U.S. federal income tax purposes;

a foreign person 50% or more of whose gross income is effectively connected with a U.S. trade or business for a specified three-year period; or

a foreign partnership if at any time during its tax year (1) one or more of its partners are U.S. persons who hold in the aggregate more than 50% of the income or capital interest in the partnership or (2) it is engaged in the conduct of a U.S. trade or business.

Payment of the proceeds from a non-U.S. holder's disposition of our common stock made by or through the U.S. office of a broker generally will be subject to information reporting and backup withholding unless the non-U.S. holder

certifies as to its non-U.S. status (such as by providing a valid IRS Form W-8BEN or W-8ECI) or otherwise establishes an exemption from information reporting and backup withholding.

Backup withholding is not an additional tax. Taxpayers may use amounts withheld as a credit against their U.S. federal income tax liability or may claim a refund if they timely provide certain information to the IRS.

TABLE OF CONTENTS

## **U.S. Federal Estate Tax**

Shares of common stock held (or deemed held) by an individual who is a non-U.S. holder at the time of his or her death will be included in such non-U.S. holder's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax treaty provides otherwise, and thus may be subject to U.S. federal estate tax.

## **Additional Withholding Tax Relating to Foreign Accounts**

Legislation enacted in 2010 will generally impose a U.S. federal withholding tax of 30% on dividends and the gross proceeds of a disposition of our common stock paid after December 31, 2012 to a foreign financial institution (whether holding stock for its own account or on behalf of its account holders/investors) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). The legislation will also generally impose a U.S. federal withholding tax of 30% on dividends and the gross proceeds of a disposition of our common stock paid after December 31, 2012 to any other foreign entity unless such entity provides the withholding agent with a certification identifying the direct and indirect U.S. owners of the entity.

Recent administrative guidance provides, however, that such withholding would generally apply only to dividends paid on or after January 1, 2014, and to other withholdable payments (including payments of gross proceeds from a sale or other disposition of our common stock) made on or after January 1, 2017. Under certain circumstances, a holder might be eligible for refunds or credits of such taxes. Prospective investors are encouraged to consult with their own tax advisors regarding the possible impact of these rules on their investment in our common stock.

**WE RECOMMEND THAT PROSPECTIVE INVESTORS CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS, ANY APPLICABLE INCOME TAX TREATIES, OR ANY OTHER U.S. FEDERAL TAX LAWS (INCLUDING ESTATE AND GIFT TAX LAWS).**

TABLE OF CONTENTS

## DESCRIPTION OF SECURITIES

*The following description of our capital stock and the provisions of our certificate of incorporation and our bylaws are summaries and are qualified by reference to the certificate of incorporation and the bylaws that will be in effect upon the closing of this offering. We have filed copies of these documents with the SEC as exhibits to our registration statement of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will occur prior to and upon the closing of this offering.*

### General

Our authorized capital stock consists of 50,000,000 shares of common stock, par value \$0.01 per share, and 5,000,000 shares of preferred stock, par value \$0.01 per share.

As of the date of this prospectus, we have 3,782,629 shares of common stock issued and outstanding, plus 25,934 shares of our common stock to be issued to an employee upon the settlement of restricted stock units that vested January 1, 2015, for an aggregate of 3,808,563 shares, which are held by four holders of record.

The following description summarizes the terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description, you should refer to our certificate of incorporation and bylaws, as in effect immediately following the closing of this offering, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

### Common Stock

*Voting rights.* The holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders, except on matters relating solely to terms of preferred stock.

*Dividend rights.* Subject to preferences that may be applicable to any outstanding preferred stock, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by the board of directors out of funds legally available therefor. See Dividend Policy.

*Rights upon liquidation.* In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of preferred stock, if any, then outstanding.

*Other rights.* The holders of our common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to our common stock.

### Preferred Stock

Our board of directors has the authority to issue preferred stock in one or more classes or series and to fix the designations, powers, preferences and rights, and the qualifications, limitations or restrictions thereof, including dividend rights, conversion right, voting rights, terms of redemption, liquidation preferences and the number of shares constituting any class or series, without further vote or action by the stockholders. We have no present plans to issue any shares of preferred stock. The issuance of shares of preferred stock, or the issuance of rights to purchase such

shares, could decrease the amount of earnings and assets available for distribution to the holders of common stock, could adversely affect the rights and powers, including voting rights, of the common stock, and could have the effect of delaying, deterring or preventing a change of control of us or an unsolicited acquisition proposal.

## **Representative s Warrants**

Please see Underwriting Representative s Warrants for a description of the warrants we have agreed to issue to the representative of the underwriters in this offering, subject to the completion of the offering. We expect to enter into a warrant agreement in respect of the Representative s Warrants prior to the closing of this offering.

## **Other Warrants**

In connection with our initial public offering, we issued warrants to purchase up to a total of 42,500 shares of our common stock to Aegis Capital Corp., as underwriter of our initial public offering, and

## TABLE OF CONTENTS

its designees at an exercise price of \$12.50 per share. These warrants are exercisable for a four year period commencing June 17, 2015, the terms of which are substantially similar to the warrants we will issue to Aegis Capital Corp. upon the closing of this offering.

### **Anti-Takeover Effects of Delaware Law**

The provisions of Delaware law, our certificate of incorporation and our bylaws described below may have the effect of delaying, deferring or discouraging another party from acquiring control of us.

#### **Section 203 of the Delaware General Corporation Law**

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (1) by persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

any merger or consolidation involving the corporation and the interested stockholder;

any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or

the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

#### **Certificate of Incorporation and Bylaws**

Our certificate of incorporation and bylaws provide that:

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;  
119

---

## TABLE OF CONTENTS

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.

### **Potential Effects of Authorized but Unissued Stock**

We have shares of common stock and preferred stock available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, to facilitate corporate acquisitions or payment as a dividend on the capital stock.

The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, the board of directors has the discretion to determine designations, rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock, all to the fullest extent permissible under the Delaware General Corporation Law and subject to any limitations set forth in our certificate of incorporation. The purpose of authorizing the board of directors to issue preferred stock and to determine the rights and preferences applicable to such preferred stock is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing desirable flexibility in connection with possible financings, acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from acquiring, a majority of our outstanding voting stock.

### **Limitations of Director Liability and Indemnification of Directors, Officers and Employees**

Our certificate of incorporation limits the liability of directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

breach of their duty of loyalty to us or our stockholders;  
act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;  
unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or  
transaction from which the directors derived an improper personal benefit.

These limitations of liability do not apply to liabilities arising under the federal or state securities laws and do not affect the availability of equitable remedies such as injunctive relief or rescission.

Our bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by law, and may indemnify employees and other agents. Our bylaws also provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding.

We have obtained a policy of directors and officers liability insurance.

We have entered into separate indemnification agreements with our directors and officers. These agreements, among other things, require us to indemnify our directors and officers for any and all expenses (including reasonable

attorneys' fees, retainers, court costs, transcript costs, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by such directors or officers or on his or her behalf in connection with any action or proceeding arising out of their services as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request provided that such person follows the procedures for determining entitlement

120

---

## TABLE OF CONTENTS

to indemnification and advancement of expenses set forth in the indemnification agreement. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might provide a benefit to us and our stockholders. Our results of operations and financial condition may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

At present, there is no pending litigation or proceeding involving any of our directors or officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

## **Requirements for Advance Notification of Stockholder Nominations and Proposals**

Our Bylaws establish advance notice procedures with respect to stockholder proposals and nomination of candidates for election as directors.

## **Limits on Special Meetings**

Special meetings of the stockholders may be called at any time only by the board of directors, the Chairman of the board of directors or our Chief Executive Officer or, in the absence of a Chief Executive Officer, our President, subject to the rights of the holders of any series of preferred stock.

## **Election and Removal of Directors**

Our stockholders may only remove directors for cause. Our board of directors may elect a director to fill a vacancy, including vacancies created by the expansion of the board of directors. This system of electing and removing directors may discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of our directors. Our certificate of incorporation and bylaws will not provide for cumulative voting in the election of directors.

## **Amendments to Our Governing Documents**

Generally, the amendment of our certificate of incorporation requires approval by our board of directors and a majority vote of stockholders. Any amendment to our bylaws requires the approval of either a majority of our board of directors or approval of at least a majority of the votes entitled to be cast by the holders of our outstanding capital stock in elections of our board of directors.

## **Listing**

Our common stock is listed on The NASDAQ Capital Market under the symbol SGNL.

## **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is VStock Transfer, LLC. Its address is 77 Spruce Street, Suite 201, Cedarhurst, New York, 11516.

121

---

TABLE OF CONTENTS**UNDERWRITING**

Aegis Capital Corp. is acting as the representative of the underwriters and Aegis Capital Corp. and Chardan Capital Markets, LLC are acting as the joint book-running managers of the offering. We have entered into an underwriting agreement dated \_\_\_\_\_, 2015 with the representative. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below and each underwriter named below has severally and not jointly agreed to purchase from us, at the public offering price per share less the underwriting discounts set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Underwriters	Number of Shares
Aegis Capital Corp.	
Chardan Capital Markets, LLC	
Total	2,884,615

The underwriters are committed to purchase all the shares of common stock offered by us other than those covered by the option to purchase additional shares described below, if they purchase any shares. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement.

Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act of 1933, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

*Over-allotment Option.* We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the underwriters to purchase a maximum of 432,692 additional shares (15% of the shares sold in this offering) from us to cover over-allotments, if any. If the underwriters exercise all or part of this option, they will purchase shares covered by the option at the public offering price per share that appears on the cover page of this prospectus, less the underwriting discount. If this option is exercised in full, the total offering price to the public will be \$ \_\_\_\_\_ and the total net proceeds, before expenses, to us will be \$ \_\_\_\_\_.

*Discount.* The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

	Per Share	Total Without Over-allotment Option	Total With Over-allotment Option
Public offering price	\$	\$	\$
Underwriting discount (7%)	\$	\$	\$

Edgar Filing: SIGNAL GENETICS, INC. - Form S-1/A

Proceeds, before expenses, to us	\$	\$	\$
Non-accountable expense allowance (1%)(1)	\$	\$	\$

(1) The expense allowance of 1% is not payable with respect to the shares sold upon exercise of the underwriters over-allotment option.

The underwriters propose to offer the shares offered by us to the public at the public offering price per share set forth on the cover of this prospectus. In addition, the underwriters may offer some of the shares to other securities dealers at such price less a concession of \$ per share. After the initial offering, the public offering price and concession to dealers may be changed.

122

---

TABLE OF CONTENTS

We have agreed to pay the underwriters' expenses relating to the offering, including (a) all filing fees and communication expenses relating to the registration of the shares of common stock to be sold in this offering (including any over-allotment shares); (b) all filing fees associated with the review of the offering by FINRA; (c) all fees and expenses relating to the listing of the shares on The NASDAQ Capital Market; (d) all fees, expenses and disbursements relating to background checks of our officers and directors in an aggregate amount not to exceed \$5,000; (e) all fees, expenses and disbursements relating to the registration or qualification of the shares of common stock under the blue sky securities laws of such states and other jurisdictions as the representative may reasonably designate (including, without limitation, all filing and registration fees, and the reasonable fees and disbursements of blue sky counsel, it being agreed that such fees and expenses will be limited as follows: (1) if the offering is commenced on The NASDAQ Capital Market, the Company will make no payment to such counsel at Closing or (2) if the offering is commenced on the Over the Counter Bulletin Board, the Company will make a payment of \$5,000 to such counsel upon the commencement of blue sky work by such counsel and an additional \$5,000 at Closing; (f) all fees, expenses and disbursements relating to the registration, qualification or exemption of the shares of common stock to be offered in this offering under the securities laws of such foreign jurisdictions as the representative may reasonably designate with the prior consent of the Company; (g) the costs of all mailing and printing of the underwriting documents (including, without limitation, the Underwriting Agreement, any blue sky surveys and, if appropriate, any agreement among underwriters, selected dealers' agreement, underwriters' questionnaire and power of attorney), registration statements, prospectuses and all amendments, supplements and exhibits thereto and as many preliminary and final prospectuses as the representative may reasonably deem necessary; (h) the costs and expenses of a public relations firm; (i) the costs of preparing, printing and delivering certificates representing the shares of common stock to be offered in this offering; (j) fees and expenses of the transfer agent for the common stock; (k) stock transfer and/or stamp taxes, if any, payable upon the transfer of securities from the Company to the representative; (l) the costs associated with the post-Closing advertising of the offering if the national editions of the Wall Street Journal and New York Times with the prior consent of the Company; (l) the costs associated with bound volumes of the public offering materials as well as commemorative mementos and lucite tombstones, each of which the Company or its designee will provide within a reasonable time after the consummation of this offering in such quantities as the representative may reasonably request but not to exceed \$2,500; (m) the fees and expenses of the Company's accountants; (n) the fees and expenses of the Company's legal counsel and other agents and representatives; (o) the \$25,000 cost associated with the use of Ipreo's book-building, prospectus tracking and compliance software for this offering; and (p) up to \$20,000 of the representative's actual accountable road show expenses for the offering. Notwithstanding the foregoing, our obligations to reimburse the representative for any out of pocket expenses actually incurred will not exceed \$50,000 in the aggregate.

We estimate that the total expenses of the offering payable by us, excluding the total underwriting discount and non-accountable expense allowance, will be approximately \$275,000.

*Lock-Up Agreements.* We, our directors and executive officers and each of our stockholders who hold 5% or more of our outstanding common stock expect to enter into lock up agreements with the representative prior to the commencement of this offering pursuant to which each of these persons or entities, for a period of 90 days from the effective date of the registration statement of which this prospectus is a part without the prior written consent of the representative, agree not to (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our securities or any securities convertible into or exercisable or exchangeable for shares of our common stock owned or acquired on or prior to the closing date of this offering (including any shares of common stock acquired after the closing date of this offering upon the conversion, exercise or exchange of such securities); (2) file or caused to be filed any registration statement relating to the offering of any shares of our capital stock; or (3) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock, whether any such transaction described in clause (1), (2)



or (3) above is to be settled by delivery of common stock or such other securities, in cash or otherwise, except for certain exceptions and limitations.

123

---

TABLE OF CONTENTS

*Representative's Warrants.* We have agreed to issue to the representative warrants to purchase up to a total of 144,230 shares of common stock (5% of the shares of common stock sold in this offering, excluding the over-allotment). The warrants will be exercisable at any time, and from time to time, in whole or in part, during the four-year period commencing one year from the effective date of the offering, which period shall not extend further than five years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(H)(i). The warrants are exercisable at a per share price equal to \$ per share, or 125% of the public offering price per share in the offering. The warrants have been deemed compensation by FINRA and are therefore subject to a 180 day lock-up pursuant to Rule 5110(g)(1) of FINRA. The representative (or permitted assignees under Rule 5110(g)(1)) will not sell, transfer, assign, pledge, or hypothecate these warrants or the securities underlying these warrants, nor will they engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the warrants or the underlying securities for a period of 180 days from the effective date of the offering. In addition, the warrants provide for registration rights upon request, in certain cases. In addition, the warrants provide for registration rights upon request, in certain cases. The demand registration right provided will not be greater than five years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(H)(iv). The piggyback registration right provided will not be greater than seven years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(H)(v). We will bear all fees and expenses attendant to registering the securities issuable on exercise of the warrants other than underwriting commissions incurred and payable by the holders. The exercise price and number of shares issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, extraordinary cash dividend or our recapitalization, reorganization, merger or consolidation. However, the warrant exercise price or underlying shares will not be adjusted for issuances of shares of common stock at a price below the warrant exercise price.

*Right of First Refusal.* For a period of either (i) twelve (12) months from the effective date of the offering if the gross proceeds from the offering are equal to or greater than \$10 million or (ii) six (6) months from the effective date of the offering if the gross proceeds from the offering are less than \$10 million, the representative has a right of first refusal to act as sole investment banker, sole-booker, running manager and/or placement agent, at the representative's sole discretion, for each and every future public and private equity and public debt offerings during such 12-month or 6-month period, as the case may be, of our company or any successor to or any subsidiary of our company.

*Electronic Offer, Sale and Distribution of Securities.* A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representative may agree to allocate a number of shares and warrants to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

*Stabilization.* In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales.

Stabilizing transactions permit bids to purchase shares so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the shares while the offering is in progress.

Over-allotment transactions involve sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase. This creates a syndicate short position that may be either a covered short

position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a

TABLE OF CONTENTS

naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing shares in the open market.

Syndicate covering transactions involve purchases of shares in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which they may purchase shares through exercise of the over-allotment option. If the underwriters sell more shares than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.

Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the shares originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our shares or common stock or preventing or retarding a decline in the market price of our shares or common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on The NASDAQ Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

*Passive market making.* In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our common stock on The NASDAQ Capital Market in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the shares and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, then that bid must then be lowered when specified purchase limits are exceeded.

*Other Relationships.* The underwriters and their affiliates have provided, or may in the future provide, various investment banking, commercial banking, financial advisory, brokerage and other services to us and our affiliates for which services they have received, and may in the future receive, customary fees and expense reimbursement. Aegis Capital Corp. acted as the underwriter in connection with our initial public offering of common stock, which was consummated on June 23, 2014.

The underwriters and their affiliates may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. In the ordinary course of their various business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own accounts and for the accounts of their customers and such investment and securities activities may involve securities and/or instruments of our company. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

## **Offer Restrictions Outside the United States**

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in

125

---

## TABLE OF CONTENTS

compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

### **Australia**

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (1) the offer of the securities under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (2) this prospectus is made available in Australia only to those persons as set forth in clause (1) above, and (3) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (1) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer for the offeree under this prospectus.

### **China**

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to qualified domestic institutional investors.

### ***European Economic Area Belgium, Germany, Luxembourg and the Netherlands***

The information in this document has been prepared on the basis that all offers of common stock will be made pursuant to an exemption under the Directive 2003/71/EC ( Prospectus Directive ), as implemented in Member States of the European Economic Area (each, a Relevant Member State ), from the requirement to produce a prospectus for offers of securities.

An offer to the public of common stock has not been made, and may not be made, in a Relevant Member State except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State:

to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

to any legal entity that has two or more of (1) an average of at least 250 employees during its last fiscal year; (2) a total balance sheet of more than €43,000,000 (as shown on its last annual unconsolidated or consolidated financial statements) and (3) an annual net turnover of more than €50,000,000 (as shown on its last annual unconsolidated or consolidated financial statement);

to fewer than 100 natural or legal persons (other than qualified investors within the meaning of Article 2(1)I of the Prospectus Directive) subject to obtaining the prior consent of the company or any underwriter for any such offer; or in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of common stock shall result in a requirement for the publication by the company of a prospectus pursuant to Article 3 of

the Prospectus Directive.

## France

This document is not being distributed in the context of a public offering of financial securities (*offre au public de titres financiers*) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (*Code monétaire et financier*) and Articles 211-1 et seq. of the General Regulation of the

126

---

## TABLE OF CONTENTS

French *Autorité des marchés financiers* ( AMF ). The common stock has not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the common stock has not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in France.

Such offers, sales and distributions have been and shall only be made in France to (1) qualified investors (*investisseurs qualifiés*) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-1 to D.411-3, D. 744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (2) a restricted number of non-qualified investors (*cercle restreint d investisseurs non-qualifiés*) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-4, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the common stock cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

### **Ireland**

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the Prospectus Regulations ). The common stock has not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (1) qualified investors as defined in Regulation 2(1) of the Prospectus Regulations and (2) fewer than 100 natural or legal persons who are not qualified investors.

### **Israel**

The common stock offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority (the ISA), or ISA, nor have such common stock been registered for sale in Israel. The shares and warrants may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with the offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the common stock being offered. Any resale in Israel, directly or indirectly, to the public of the common stock offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

### **Italy**

The offering of the common stock in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (*Commissione Nazionale per le Società e la Borsa, CONSOB* ) pursuant to the Italian securities legislation and, accordingly, no offering material relating to the common stock may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 ( Decree No. 58 ), other than:



to Italian qualified investors, as defined in Article 100 of Decree no. 58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999 ( Regulation no. 11971 ) as amended ( Qualified Investors ); and in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

127

---

## TABLE OF CONTENTS

Any offer, sale or delivery of the common stock or distribution of any offer document relating to the common stock in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and

in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the common stock in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such common stock being declared null and void and in the liability of the entity transferring the common stock for any damages suffered by the investors.

### **Japan**

The common stock has not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the FIEL) pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder).

Accordingly, the common stock may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors. Any Qualified Institutional Investor who acquires common stock may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of common stock is conditional upon the execution of an agreement to that effect.

### **Portugal**

This document is not being distributed in the context of a public offer of financial securities (*oferta pública de valores mobiliários*) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (*Código dos Valores Mobiliários*). The common stock has not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the common stock has not been, and will not be, submitted to the Portuguese Securities Market Commission (*Comissão do Mercado de Valores Mobiliários*) for approval in Portugal and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of common stock in Portugal are limited to persons who are qualified investors (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

### **Sweden**

This document has not been, and will not be, registered with or approved by *Finansinspektionen* (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the common stock be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (*Sw. lag (1991:980) om handel med finansiella instrument*). Any offering of common stock in Sweden is limited to persons who are qualified investors (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

## Switzerland

The common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ( SIX ) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of

128

---

## TABLE OF CONTENTS

the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the common stock may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the common stock has been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of common stock will not be supervised by, the Swiss Financial Market Supervisory Authority (FINMA).

This document is personal to the recipient only and not for general circulation in Switzerland.

### **United Arab Emirates**

Neither this document nor the common stock have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor have we received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the common stock within the United Arab Emirates. This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the common stock, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by us.

No offer or invitation to subscribe for common stock is valid or permitted in the Dubai International Financial Centre.

### **United Kingdom**

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended ( FSMA )) has been published or is intended to be published in respect of the common stock. This document is issued on a confidential basis to qualified investors (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the common stock may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances that do not require the publication of a prospectus pursuant to section 86(1) FSMA. This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) received in connection with the issue or sale of the common stock has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of FSMA does not apply to us.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (1) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 ( FPO ), (2) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (3) to whom it may otherwise be lawfully communicated (together relevant persons ). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.



TABLE OF CONTENTS

## **LEGAL MATTERS**

The validity of the securities being offered by this prospectus has been passed upon for us by Reed Smith LLP, New York, New York. Certain legal matters in connection with this offering will be passed upon for the underwriters by Blank Rome LLP, New York, New York.

## **EXPERTS**

The consolidated financial statements as of December 31, 2013 and 2012 and for each of the two years in the period ended December 31, 2013 included in the Registration Statement have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, (the report on the financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern) appearing in the Registration Statement, given on the authority of said firm as experts in auditing and accounting.

## **WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock we are offering to sell. This prospectus, which constitutes part of the registration statement, does not include all of the information contained in the registration statement and the exhibits, schedules and amendments to the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits and schedules to the registration statement. Statements contained in this prospectus about the contents of any contract, agreement or other document are not necessarily complete, and, in each instance, we refer you to the copy of the contract, agreement or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You may read and copy the registration statement of which this prospectus is a part at the SEC's public reference room, which is located at 100 F Street, N.E., Room 1580, Washington, DC 20549. You can request copies of the registration statement by writing to the Securities and Exchange Commission and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's public reference room. In addition, the SEC maintains an Internet website, which is located at <http://www.sec.gov>, that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may access the registration statement of which this prospectus is a part at the SEC's Internet website. Upon completion of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934, and we will file reports, proxy statements and other information with the SEC.

TABLE OF CONTENTS

## GLOSSARY OF TERMS

ACA	Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act.
CD138+	A cell surface marker identified through flow cytometry and bead-based cell sorting.
CE MARKING	A mandatory conformity marking for certain products sold within the European Economic Area (EEA) since 1995.
CMS	Centers for Medicare & Medicaid Services; a U.S. federal agency that administers Medicare and Medicaid and the Children's Health Insurance Program.
CLIA	Clinical Laboratory Improvement Amendments of 1988; federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States.
CYTOGENETICS	The branch of biology linking the study of genetic inheritance with the study of cell structure, especially for human chromosome analysis for the detection of inheritable diseases.
FISH	Fluorescence in situ Hybridization; a molecular cytogenetic technique that is used to detect chromosomal aberrations that include deletions, amplifications and translocations; DNA FISH probes are fluorescently labeled segments of DNA that are complementary to specific sequences on a chromosome.
HITECH	Health Information Technology for Economic and Clinical Health Act.
INDUCTION THERAPY	Treatment designed to be used as a first step toward shrinking the cancer and in evaluating response to drugs and other agents. Induction therapy is followed by additional therapy to eliminate whatever cancer remains.
KARYOTYPING	A laboratory technique whereby the chromosomes from one cell are visualized under a microscope to investigate the total number and structure of the chromosomes. Cells are obtained from an individual and are viewed during metaphase, a stage in cell division when chromosomes are condensed. The chromosomes are stained with a dye (Giemsa), resulting in a banding pattern of light and dark stripes, known as G-banding. The patterns are specific, allowing the viewer to identify each chromosome.
LDTs	Laboratory Developed Tests; assays developed in the laboratory for diagnostic or prognostic purposes.
LYSIS	The disintegration of a cell by rupture of the cell wall or membrane.
MCTRJCA	Middle Class Tax Relief and Job Creation Act of 2012.
MIPPA	Medicare Improvements for Patients and Providers Act of 2008.
PMA	Pre-Market Approval; the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices.
RNA	Ribonucleic acid, a nucleic acid present in all living cells. Its principal role is to act as a messenger carrying instructions from DNA for controlling the synthesis of proteins, although in some viruses RNA rather than DNA carries the genetic information.





TABLE OF CONTENTS

**SIGNAL GENETICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED FINANCIAL STATEMENTS**

**INDEX**

Signal Genetics, Inc. Unaudited Financial Statements:

Consolidated Balance Sheets as of September 30, 2014 (unaudited) and December 31, 2013 F-2

Unaudited Consolidated Statements of Operations for the Nine Months Ended September 30, 2014 and 2013 F-3

Unaudited Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2014 and 2013 F-4

Notes to Unaudited Consolidated Financial Statements F-5

Signal Genetics LLC Audited Financial Statements:

Report of Independent Registered Public Accounting Firm F-14

Consolidated Balance Sheets as of December 31, 2013 and 2012 F-15

Consolidated Statements of Operations for the Years ended December 31, 2013 and 2012 F-16

Consolidated Statements of Members' Deficiency for the Years ended December 31, 2013 and 2012 F-17

Consolidated Statements of Cash Flows for the Years ended December 31, 2013 and 2012 F-18

Notes to the Consolidated Financial Statements F-19

F-1

---

TABLE OF CONTENTS**Signal Genetics, Inc. and Subsidiaries****Consolidated Balance Sheets**

	September 30, 2014 (Unaudited)	December 31, 2013
<b><u>ASSETS</u></b>		
Current assets:		
Cash	\$6,388,358	\$209,348
Restricted cash	50,236	50,180
Accounts receivable, net	1,549,998	994,010
Inventory	232,064	356,641
Prepaid expenses and other current assets	434,902	444,369
Total current assets	8,655,558	2,054,548
Property and equipment, net	825,882	928,026
Deferred issuance costs		655,018
Security deposits	43,326	35,034
	\$9,524,766	\$3,672,626
<b><u>LIABILITIES AND STOCKHOLDERS EQUITY/MEMBERS DEFICIENCY</u></b>		
Current liabilities:		
Accounts payable and accrued expenses	\$939,481	\$689,716
Amounts due to related party	1,045,000	
Note payable - current portion	10,597	42,046
Note payable - related party		26,568,554
Total current liabilities	1,995,078	27,300,316
Lease termination/abandonment payable		259,345
Commitments and contingencies		
Stockholders' equity/members' deficiency:		
Common stock, \$0.01 par value, 50,000,000 shares authorized, 3,782,629 shares issued and outstanding at September 30, 2014 and no shares issued and outstanding at December 31, 2013	37,826	
Additional paid in capital	39,010,827	
Accumulated deficit	(31,518,965)	
Members' deficiency		(23,887,035)
Total members' deficiency/stockholders' equity	7,529,688	(23,887,035)
	\$9,524,766	\$3,672,626

See accompanying notes to unaudited consolidated financial statements.



TABLE OF CONTENTS**Signal Genetics, Inc. and Subsidiaries****Unaudited Consolidated Statements of Operations**

	Nine Months Ended	
	September 30, 2014	September 30, 2013
Net revenue	\$ 3,665,484	\$ 3,225,881
Operating expenses:		
Cost of revenue	2,333,216	2,110,323
Selling and marketing	325,639	253,094
General and administrative	1,891,006	1,131,555
Stock compensation	3,578,465	
Research and development	148,288	182,193
Total operating expenses	8,276,614	3,677,165
Operating loss	(4,611,130 )	(451,284 )
Interest expense	(1,020,801 )	(1,505,198 )
Net loss	(5,631,931 )	(1,956,482 )
Dividend to member unit holder of Myeloma Health LLC		(240,000 )
Net loss attributable to stockholders of Signal Genetics, Inc.	\$ (5,631,931 )	\$ (2,196,482 )
Basic and diluted net loss per share:		
Net loss attributable to stockholders of Signal Genetics, Inc.	\$ (1.78 )	\$ (0.85 )
Weighted average shares outstanding basic and diluted	3,162,639	2,587,475

See accompanying notes to unaudited consolidated financial statements.

TABLE OF CONTENTS**Signal Genetics, Inc. and Subsidiaries****Unaudited Consolidated Statements of Cash Flows**

	Nine Months Ended	
	September 30, September 30,	
	2014	2013
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(5,631,931)	\$(1,956,482 )
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:		
Stock compensation	3,578,465	
Depreciation and amortization	106,412	111,886
Bad debt expense	144,492	
Non-cash interest on note payable related party	1,007,733	1,484,149
Lease termination	45,724	
Changes in operating assets and liabilities:		
Accounts receivable	(700,480 )	270,273
Inventory	124,577	(39,146 )
Prepaid expenses and other current assets	9,467	(28,409 )
Accounts payable and other accrued expenses	404,360	(270,249 )
Lease termination/abandonment payable	(305,069 )	(238,394 )
Net cash used in operating activities of discontinued operations		(143,875 )
Net cash used in operating activities	(1,216,250)	(810,247 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(4,268 )	(2,146 )
(Increase) decrease in security deposits	(8,292 )	10,548
Increase in restricted cash	(56 )	(75 )
Net cash (used in) provided by investing activities	(12,616 )	8,327
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Distributions		(240,000 )
Repayment of note payable	(31,449 )	(45,853 )
Proceeds from issuance of common stock	8,500,000	
Payments for deferred issuance costs	(1,855,675)	(154,033 )
Repayment of note payable related party		(10,460,657)
Proceeds from note payable/amounts due to related party	795,000	11,816,183
Net cash provided by financing activities	7,407,876	915,640
<b>NET INCREASE IN CASH</b>	<b>6,179,010</b>	<b>113,720</b>
<b>CASH:</b>		
Beginning of period	209,348	112,534
End of period	\$6,388,358	\$226,254

See accompanying notes to unaudited consolidated financial statements.



TABLE OF CONTENTS

# Signal Genetics, Inc. and Subsidiaries

## Notes to Unaudited Consolidated Financial Statements

### 1. Organization, Operations and Basis of Accounting

Signal Genetics, Inc. (the Company) was originally formed as Myeloma Health LLC, in January 2010. Effective January 1, 2011 with the formation of Signal Genetics LLC, substantially all the members' interests in Myeloma Health LLC were exchanged for members' interests in Signal Genetics LLC and Myeloma Health LLC became a subsidiary of the Company.

On June 17, 2014, the Company completed a corporate conversion and Signal Genetics LLC converted from a limited liability company to a Delaware corporation (the Corporate Conversion). Immediately prior to the Corporate Conversion, \$27,326,287 of the note payable related party was converted into 2,732,629 newly authorized Class C units (the Debt Conversion) (see Note 5 for additional information on the Debt Conversion). In connection with the Corporate Conversion, all outstanding Class A and C units of Signal Genetics LLC were converted into an aggregate of 2,932,629 shares of common stock of the Company, the members of Signal Genetics LLC became stockholders of the Company and the Company succeeded to the business of Signal Genetics LLC and its consolidated subsidiaries.

On June 23, 2014, the Company completed the initial public offering of shares of its common stock. The Company issued 850,000 shares in the offering and received net proceeds from the offering of approximately \$6,144,000 (after the payment of underwriter commissions and offering expenses).

The accompanying consolidated financial statements include the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

The Company is a 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. In 2010, the Company became the exclusive licensee to the research on multiple myeloma (MM) performed at the University of Arkansas for Medical Sciences (UAMS). Myeloma Prognostic Risk Signature (MyPRS®) is based upon more than two decades of clinical research on nearly 10,000 MM patients who received their care at UAMS. The Company currently generates revenues from the performance of MyPRS® diagnostic tests, which was launched in April 2011.

Since its inception, the Company has devoted substantial effort in developing its products and services and has incurred losses and negative cash flows from operations. Prior to the initial public offering, all financial support had been provided by the majority member (see Note 5). As of September 30, 2014, however, following the Debt Conversion, the Corporate Conversion and the initial public offering, the Company has positive working capital and stockholders' equity. Although the Company is forecasting continued losses and negative cash flows as it funds its expanding selling and marketing activities and research and development programs, the Company believes that it has enough cash on hand to support operations for at least a year. Going forward, as the Company continues its expansion, the Company may seek additional financing and/or strategic investments. 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 reduce its plans and/or certain discretionary spending, which could have a material adverse effect on the Company's ability to

achieve its intended business objectives. The accompanying consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

The accompanying unaudited consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC). Certain information and note disclosures normally included in annual financial statements prepared in accordance with generally accepted accounting principles have been omitted. The accompanying unaudited consolidated financial statements include all known adjustments necessary for a fair presentation of the results of interim periods as required by accounting principles generally accepted in the United States. These adjustments consist primarily of normal recurring accruals and estimates that impact the carrying value of assets and liabilities. Actual results may

F-5

---



TABLE OF CONTENTS

## Signal Genetics, Inc. and Subsidiaries

### Notes to Unaudited Consolidated Financial Statements

#### 1. Organization, Operations and Basis of Accounting (continued)

materially differ from these estimates. The consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements for the year ended December 31, 2013, which are included in the Company's amended Registration Statement on Form S-1 filed with the SEC on June 13, 2014. The December 31, 2013 balance sheet is derived from the Company's audited consolidated financial statements.

#### 2. Summary of Significant Accounting Policies

**Use of Estimates** The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ( GAAP ). The preparation of financial statements in conformity with GAAP requires management to make judgments, assumptions and estimates that affect the amounts reported in the Company's consolidated financial statements and accompanying notes. Significant estimates in the consolidated financial statements have been made for revenue and depreciation of property and equipment. Actual results could differ materially from those estimates.

**Accounts Receivable and Allowance for Doubtful Accounts** The Company records accounts receivable net of an allowance for doubtful accounts. The Company estimates an allowance for doubtful accounts based on the aging of the accounts receivable and the historical collection experience since the Company's inception for each type of payor. The Company has not had any bad debts from any of its contracted or non-contracted insurance companies. However during the nine months ended September 30, 2014, the Company determined that approximately \$144,000 of accounts receivable may not be collectible. Although the Company will attempt to recover these funds, an allowance for doubtful accounts of approximately \$144,000 was recorded at September 30, 2014 due to the uncertainty of these collections. There is no allowance for doubtful accounts recorded as of December 31, 2013.

**Inventory** Inventory, which consists entirely of laboratory materials and supplies, is valued at the lower of cost or market using the first-in, first-out ( FIFO ) method.

**Property and Equipment** Property and equipment is carried at cost. Expenditures for major additions and betterments are capitalized. Maintenance and repairs are charged to operations as incurred. Depreciation and amortization are calculated using the straight-line method over the estimated useful lives of the assets, which range from three to ten years. Upon sale or retirement of property and equipment, the related cost and accumulated depreciation are removed from the accounts and any gain or loss is reflected in operations.

**Long Lived Assets** The Company reviews long-lived assets, consisting of property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable based on undiscounted cash flows. If long-lived assets are impaired, an impairment loss is recognized and is measured as the amount by which the carrying value exceeds the estimated fair value of the assets. No impairment charges were recorded during the nine months ended September 30, 2014 and 2013.

**Revenue Recognition** Revenues that are derived from testing services are recognized in accordance with the Financial Accounting Standards Board Accounting Standards Codification ( 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.

Revenues are recorded on an accrual basis when the contractual obligations are completed as a set of assays is processed through our laboratory and test results are delivered to ordering physicians. 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 upon rates

F-6

---

TABLE OF CONTENTS**Signal Genetics, Inc. and Subsidiaries****Notes to Unaudited Consolidated Financial Statements****2. Summary of Significant Accounting Policies (continued)**

between the Company and the respective payor and is the price invoiced by the Company. The Company reports revenues from non-contracted insurance companies 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 insurance companies is recorded as a contractual allowance at the same time the revenue is recognized, to arrive at reported net revenue. The Company does 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. The Company's 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. The Company regularly refines its estimates in order to make its estimated revenue as accurate as possible based on its most recent collection experience with each third-party payor. The Company regularly reviews its historical collection experience for non-contracted payors and adjusts its expected revenues for current and subsequent periods accordingly.

The table below shows the adjustments made to gross revenues to arrive at net revenues, the amount reported on our statements of operations:

	Nine Months	
	September 30, 2014	September 30, 2013
Gross revenues	\$ 4,545,090	\$ 3,959,638
Less: Contractual Allowances	879,606	733,757
Net revenues	\$ 3,665,484	\$ 3,225,881

Contractual allowances recorded during both the nine months ended September 30, 2014 and 2013 represented approximately 19% of gross revenues.

**Income Taxes** Prior to the Corporate Conversion, the Company was a limited liability company, which is not a tax paying entity at the corporate level. Each member was instead individually responsible for such member's share of the Company's income or loss for income tax reporting purposes. Net operating losses incurred by the Company through the date of the Corporate Conversion have been, or will be, used by the members to offset gains on other interests and are therefore not able to be carried forward to the Company.

Effective as of the Corporate Conversion, the Company accounts for income taxes in accordance with FASB ASC 740, *Income Taxes*. Deferred tax assets and liabilities are recorded for the expected future tax consequences of events that have been included in the consolidated financial statements or income tax returns. Deferred taxes are determined on the basis of the differences between the carrying amount of assets and liabilities for financial statement and income tax purposes at enacted rates in effect for the years in which the differences are expected to reverse. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amounts expected to be realized.

Applicable accounting guidance requires that a position taken or expected to be taken in a tax return be recognized in the financial statements when it is more likely than not that the position would be sustained upon examination by tax authorities. A recognized tax position is then measured at the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. Accounting provisions also require that a change in judgment that results in subsequent recognition, derecognition, or change in a measurement of a tax position taken in a prior annual period (including any related interest and penalties) be recognized as a discrete item in the period in which the change occurs.

The Company regularly evaluates the likelihood of recognizing the benefit for income tax positions taken in various federal and state filings by considering all relevant facts, circumstances, and information available.

F-7

---

TABLE OF CONTENTS

## Signal Genetics, Inc. and Subsidiaries

### Notes to Unaudited Consolidated Financial Statements

#### 2. Summary of Significant Accounting Policies (continued)

The Company classifies any interest and penalties related to unrecognized tax benefits as a component of income tax expense.

**Equity Incentive Compensation** The Company accounts for equity incentive compensation to employees and non-employees in accordance with FASB ASC 718, Stock Compensation and FASB ASC 505-50, *Equity-Based Payments to Non-Employees*, respectively. Equity incentive compensation expense for all equity-based compensation awards granted to employees is based on the grant-date fair value estimated in accordance with the provisions of ASC 718 and for non-employees is based on the fair value of equity instruments issued as determined at the performance completion date in accordance with the provisions of ASC 505-50. The Company recognizes compensation expense in an amount equal to the estimated fair value of each stock award over the estimated period of service and vesting.

**Fair Value of Financial Instruments** The Company's management believes the carrying amounts of cash, accounts receivable and accounts payable approximate fair value due to their short-term maturity. The fair value of the note payable related party cannot be reasonably estimated as a result of the related party arrangement. The present value of the note payable at September 30, 2014 and December 31, 2013 was approximately \$11,000 and \$42,000, respectively.

**Supplemental Disclosures of Cash Flow Information and of Non-Cash Financing Transactions** During the nine months ended September 30, 2014 and 2013, the Company paid approximately \$13,000 and \$1,201,000, respectively, in interest. Of the total paid in 2013, \$1,182,000 was paid to related parties (see Note 5). In addition, during the nine months ended September 30, 2014, the Company converted \$27,326,287 of the note payable related party into equity. Additionally, approximately \$2,356,000 of deferred issuance costs were converted into equity. At September 30, 2013, there were deferred issuance costs of approximately \$63,000 included in accounts payable and accrued expenses.

**Concentration of Credit Risk, Major Customers and Suppliers** Cash is maintained at two financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to these balances.

During the nine months ended September 30, 2014 and 2013, the Company had one major customer, UAMS. Revenue sourced either from or through UAMS accounted for approximately 81% and 84% of net revenue for the nine months ended September 30, 2014 and 2013, respectively. Accounts receivable sourced either from or through UAMS at September 30, 2014 and December 31, 2013 accounted for approximately 70% and 62%, respectively.

Inventory used in the Company's testing process is procured from one supplier. Any supply interruption or an increase in demand beyond such supplier's capabilities could have an adverse impact on the Company's business. Management believes it could identify alternative suppliers, if necessary, but it is possible such suppliers may not be identified in a timely manner to avoid an adverse impact on the Company's business.

**Recent Accounting Pronouncements** Other than as disclosed below, we have reviewed all recently issued standards and have determined that they will not have a material impact on our consolidated financial statements or do not apply to our operations.

In May 2014, the FASB issued Accounting Standards Update ( ASU ) No. 2014-09, *Revenue from Contracts with Customers*, which outlines a single comprehensive model for entities to use in accounting for revenue from contracts with customers and supersedes most current revenue recognition guidance in FASB ASC 605, *Revenue Recognition*, including industry-specific guidance. The ASU is based on the principle that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and

F-8

---

TABLE OF CONTENTS

## Signal Genetics, Inc. and Subsidiaries

### Notes to Unaudited Consolidated Financial Statements

#### 2. Summary of Significant Accounting Policies (continued)

assets recognized from costs incurred to fulfill a contract. The ASU becomes effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period; early adoption is not permitted. Entities have the option of using either a full retrospective or a modified retrospective approach for the adoption of the new standard. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements – Going Concern*, which provides guidance on management’s responsibility in evaluating whether there is substantial doubt about a company’s ability to continue as a going concern and the related footnote disclosure. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company’s ability to continue as a going concern within one year from the date the financials are issued. When management identifies conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern, the ASU also outlines disclosures that are required in the company’s footnotes based on whether or not there are any plans intended to mitigate the relevant conditions or events to alleviate the substantial doubt. The ASU becomes effective for annual periods ending after December 15, 2016, and for any annual and interim periods thereafter. Early application is permitted. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

**Future Accounting Pronouncements** Section 107 of the Jumpstart Our Business Startups Act of 2012 (the JOBS Act) provides that an emerging growth company, such as the Company, may take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company may delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. Although to date, the Company has not taken advantage of this delay, the Company has elected to avail itself of the extended transition period for adopting new or revised accounting standards in the future. As a result of this election, the Company’s consolidated financial statements may not be comparable to companies that comply with public company effective dates.

**Reclassifications** Certain reclassifications in operating expenses have been made to the nine months ended September 30, 2013 amounts to conform to the 2014 presentation.

#### 3. Property and Equipment

Property and equipment at September 30, 2014 and December 31, 2013, consists of the following:

September 30,	December 31,
2014	2013
(Unaudited)	

Edgar Filing: SIGNAL GENETICS, INC. - Form S-1/A

Computer and lab equipment	\$ 1,324,359	\$ 1,320,091
Furniture and fixtures	12,550	12,550
Leasehold improvements	6,439	6,439
	1,343,348	1,339,080
Less: Accumulated depreciation and amortization	517,466	411,054
	\$ 825,882	\$ 928,026

Depreciation and amortization expense for the nine months ended September 30, 2014 and 2013 was approximately \$106,000 and \$112,000, respectively.

F-9

---



TABLE OF CONTENTS**Signal Genetics, Inc. and Subsidiaries****Notes to Unaudited Consolidated Financial Statements****4. Accounts Payable and Accrued Expenses**

Accounts payable and accrued expenses at September 30, 2014 and December 31, 2013, consists of the following:

	September 30, 2014 (Unaudited)	December 31, 2013
Accounts payable	\$ 238,516	\$
Accrued compensation and related taxes	155,563	76,409
Current portion of lease termination/abandonment payable	309,279	319,454
Legal fees	119,430	48,415
Deferred issuance costs		154,596
Other	116,693	90,842
	\$ 939,481	\$ 689,716

**5. Notes Payable**

**Note Payable** The Company has acquired certain property and equipment through the issuance of a note payable totaling approximately \$182,000. The note was payable in thirty-six monthly installments of \$5,320 and the final payment was made in October 2014. The present value of the note payable at September 30, 2014 and December 31, 2013 was approximately \$11,000 and \$42,000, respectively. The effective interest rate of the note during 2014 and 2013 was 3.4%. The Company had collateralized the note with the related equipment, which had a net book value of approximately \$275,000 and \$305,000 at September 30, 2014 and December 31, 2013, respectively.

**Note Payable Related Party** During the nine months ended September 30, 2014 and 2013, the Company's then majority member, through various entities controlled by such member, loaned the net amount of approximately \$795,000 and \$1,356,000, respectively, to the Company to support its operations. Pursuant to the terms of an Exchange Agreement, and prior to the Corporate Conversion, \$27,326,287 of the note payable as of June 17, 2014 was exchanged for 2,732,629 Class C units of Signal Genetics LLC and recorded to members' equity. The remaining \$1,000,000 as of that date, along with an additional \$45,000, which was advanced to pay for certain offering expenses, were reclassified as Amounts due to related party on the consolidated balance sheet. This aggregate amount is non-interest bearing and due on demand.

Prior to the Debt Conversion, the note bore interest at 8% compounded quarterly and was due on demand and was collateralized by substantially all assets of the Company. Interest expense related to the note for the nine months ended September 30, 2014 and 2013 was approximately \$1,008,000 and \$1,484,000, respectively. Interest was accrued and included within the Note payable related party reflected on the accompanying consolidated balance sheets. During the nine months ended September 30, 2013, the majority member loaned the Company approximately \$11,816,000, which was used to repay interest of approximately \$1,182,000 and principal of \$9,279,000 owed to

certain entities controlled by such member who had loaned monies to the Company under the note.

## 6. Stockholders Equity/Members Interests

**Distributions** Distributions of \$240,000 during the nine months ended September 30, 2013 were made to a member of Myeloma Health LLC, a subsidiary of the Company. These distributions were made in the form of dividends by the Company to Myeloma Health LLC and thereafter to the member.

**Corporate Conversion** Immediately prior to the Corporate Conversion, Signal Genetics LLC had issued and outstanding 72,500 Class A units and 41,088 Class B units (23,328 of which were unvested). As described in Note 5, in connection with the Debt Conversion, the note payable related party as of June 17, 2014 was exchanged for 2,732,629 Class C units of the Company. On June 17, 2014, the outstanding Class A and Class C units of Signal Genetics LLC were converted into 200,000 shares and 2,732,629 shares,

F-10

---

TABLE OF CONTENTS

## Signal Genetics, Inc. and Subsidiaries

### Notes to Unaudited Consolidated Financial Statements

#### 6. Stockholders Equity/Members Interests (continued)

respectively, for an aggregate of 2,932,629 shares of common stock at \$10.00 per share. All outstanding Class B units, which consisted of equity incentive units, were cancelled.

On June 23, 2014, the Company completed its initial public offering of shares of its common stock and issued 850,000 shares in the offering at \$10.00 per share. The Company received net proceeds from the offering of approximately \$6,144,000 (after the payment of underwriter commissions and offering expenses).

**Warrants for Common Stock** In connection with its initial public offering in June 2014, the Company issued warrants to purchase an aggregate of 42,500 shares of its common stock at an exercise price of \$12.50 per share, or 125% of the public offering price per share. The warrants are exercisable at any time from June 2015 through June 2019. No cost or expense was recognized during the nine months ended September 30, 2014 related to the issuance of these warrants as the exercise price was in excess of the fair value of the common stock at the measurement date.

**Stock Incentive Plan** Effective with the initial public offering, the Company adopted the 2014 Stock Incentive Plan (the Plan) to promote long-term growth and profitability by (i) providing key people with incentives to improve stockholder value and to contribute to the Company's growth and financial success through their future services and (ii) enabling the Company to attract, retain and reward the best-available personnel. Under the Plan, the Company may issue awards for up to 1,245,399 shares of its common stock. Awards may be made in the form of incentive or non-statutory stock options, stock appreciation rights, restricted or unrestricted stock awards, restricted stock units, performance awards, or other stock-based awards. No awards may be granted after June 16, 2024.

**Restricted Stock Units (RSUs)** In connection with the initial public offering and through September 30, 2014, the Company issued RSU awards for an aggregate of 940,093 shares of its common stock with the following terms:

745,511 RSUs issued to the Company's Chief Executive Officer in connection with the initial public offering 33.3% vested upon the date of grant but will not be issued until January 1, 2015 and 16.67% will vest and be issued on each of January 1, 2015, and the 12-month, 18-month and 24-month anniversary of the date of grant.

48,442 RSUs issued to the Company's Vice President of Research and Operations in connection with the initial public offering 29,356 vested upon the date of grant but will not be issued until January 1, 2015 and the remaining 19,086 will vest in nineteen equal monthly installments (beginning with the month in which the first anniversary of the grant date occurs) on the last day of each such calendar month. Shares that have vested according to the foregoing schedule will be issued on the first day of January and July of each calendar year.

37,640 RSUs issued to a consultant and company founder in connection with the initial public offering 25% will vest and be issued on the first anniversary of the grant date and the remaining shares will vest in thirty-six equal monthly installments (beginning with the month in which the first anniversary of the grant date occurs) on the last day of each such calendar month. Shares that have vested according to the foregoing will be issued on the first day of January and July of each calendar year.

An aggregate of 16,500 RSUs issued to the three independent members of the board of directors (5,500 each) in July 2014 25% will vest and be issued upon each anniversary of the grant date.

92,000 RSUs issued to the Company's Chief Financial Officer in connection with her employment agreement in August 2014. 25% will vest and be issued upon each anniversary of the grant date.

Stock compensation expense related to the RSUs for the nine months ended September 30, 2014 was approximately \$3,563,000.

F-11

---

TABLE OF CONTENTS**Signal Genetics, Inc. and Subsidiaries****Notes to Unaudited Consolidated Financial Statements****6. Stockholders Equity/Members Interests (continued)**

**Stock Options** During the nine months ended September 30, 2014, the Company granted options to purchase 124,000 shares of common stock under the Plan. Of this total, options to purchase 54,000 shares vest 25% on each anniversary of their grant date; provided, however that if a recipient is terminated after the first anniversary of the grant date for a reason other than cause, such person will be entitled to receive a prorated portion of the number of shares which would have otherwise become vested on the next anniversary date. The remaining 70,000 shares subject to options vest 25% on the first anniversary of the grant date with the balance of shares vesting in thirty-six equal monthly installments thereafter.

The value of each stock option is estimated on the date of grant using the Black-Scholes option pricing model which requires the input of highly subjective assumptions. Because the option-pricing model is sensitive to change in the input assumptions, different determinations of the required inputs may result in different fair value estimates of the options. The Company has no expectation of paying cash dividends on its common stock in the foreseeable future. The Company has limited historical stock data since the initial public offering, therefore the estimated future stock price volatility is based upon the average historical volatilities of a group of peer companies. The risk-free interest rate is based on the rate currently available on U.S. Treasury issues with terms approximating the expected term of the option. The Company did not issue options prior to its initial public offering and therefore has no history of option exercises. As such, the Company has used the simplified method to calculate the expected term of its options.

The following assumptions were used in the Black-Scholes option-pricing model during the nine months ended September 30, 2014:

Expected dividend yield		0	%
Expected volatility	65.5	66.9	%
Risk-free interest rate	1.81	2.03	%
Expected term (years)		6.25	

Stock compensation expense related to stock options for nine months ended September 30, 2014 was approximately \$15,000.

**Net Loss Per Share** The Company calculates net loss per share in accordance with FASB ASC 260, Earnings Per Share. Basic net loss per share is computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock and dilutive common stock equivalents then outstanding.

Common stock equivalents consist of RSUs, stock options and warrants.

For all periods presented, the Company has adjusted the number of shares outstanding to reflect the Debt and Corporate Conversions completed on June 17, 2014 (see Notes 1 and 5) as if they had occurred as of the beginning of the respective period. During the nine months ended September 30, 2014, 658,214 unvested RSUs, 60,000 stock options and 42,500 warrants were excluded from diluted net loss per share due to the antidilutive effects of the

securities. For the nine months ended September 30, 2013, previously issued equity incentive units were also excluded due to the net loss incurred during the period.

## 7. Commitments and Contingencies

**Operating Leases** During March 2014, the Company renewed its laboratory and office facility operating lease for another annual period through March 2015. Monthly rent expense is approximately \$6,300.

In August 2014, the Company entered into a new lease for approximately 5,560 square feet of office space that will be used as the corporate headquarters in California. The Company began occupying the space on October 1, 2014. The lease term begins in November 2014 and will continue for 36-months with monthly rent of approximately \$14,000, which will increase at a rate of 3% annually. The lease terms include

F-12

---

TABLE OF CONTENTS

## Signal Genetics, Inc. and Subsidiaries

### Notes to Unaudited Consolidated Financial Statements

#### 7. Commitments and Contingencies (continued)

three months of rent abatement during the first year and an option to renew the lease for one additional 36-month period. The newly leased space in Carlsbad, California, replaces the Company's headquarters which were in New York, New York.

**Lease Termination/Abandonment** During the year ended December 31, 2012, the Company recorded approximately \$932,000 in costs associated with an operating lease (resulting from its abandonment of the related property and its unsuccessful attempts to sublease the lease), which amount represented the then present value of the remaining payments due under the lease. In calculating such liability, the Company took into account a termination clause in the lease pursuant to which it could terminate the lease after August 2015 and the lack of any sublease income, due to the Company's inability as of such date to sublet such space.

During March 2014, the Company entered into a termination agreement with the landlord related to the operating lease. As an inducement for the landlord to agree to the termination of the lease, the Company agreed to pay a termination fee of approximately \$565,000 in monthly installments of \$31,400 until the fee is paid in full (August 2015). The Company has recorded the present value of the remaining payments under the termination agreement, which due to changes in estimates resulted in an additional charge of approximately \$46,000 to expense during the nine months ended September 30, 2014, which is included in general and administrative expenses on the accompanying unaudited consolidated statements of operations. At September 30, 2014 and December 31, 2013, the total liability was approximately \$309,000 and \$579,000, respectively.

**Letters of Credit** At September 30, 2014, the Company was contingently liable for a standby letter of credit issued by a commercial bank for \$50,000, for security on a lease. The Company has approximately \$50,000 in a restricted cash account that is held as cash collateral for the letter of credit.

**Litigation** The Company is, from time to time, involved in legal proceedings, regulatory actions, claims and litigation arising in the ordinary course of business. Currently, the Company is not a defendant in any lawsuits.

TABLE OF CONTENTS

# Report of Independent Registered Public Accounting Firm

Board of Directors and Members  
Signal Genetics LLC  
New York, New York

We have audited the accompanying consolidated balance sheets of Signal Genetics LLC and Subsidiaries (the Company ) as of December 31, 2013 and 2012 and the related consolidated statements of operations, members deficiency, and cash flows for each of the two years in the period ended December 31, 2013. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Signal Genetics LLC and Subsidiaries at December 31, 2013 and 2012, and the results of their operations and their cash flows for each of two years in the period ended December 31, 2013, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO USA, LLP  
New York, New York  
March 18, 2014



TABLE OF CONTENTS**Signal Genetics LLC and Subsidiaries****Consolidated Balance Sheets**

	December 31, 2013	December 31, 2012	Pro forma December 31, 2013 (Unaudited see Note 2)
<b><u>ASSETS</u></b>			
Current assets:			
Cash	\$209,348	\$112,534	\$209,348
Restricted cash	50,180	50,086	50,180
Accounts receivable	994,010	1,195,599	994,010
Inventory	356,641	169,539	356,641
Prepaid expenses and other current assets	444,369	129,625	444,369
Current assets of discontinued operations		6,125	
Total current assets	2,054,548	1,663,508	2,054,548
Property and equipment, net	928,026	1,071,572	928,026
Deferred issuance costs	655,018		655,018
Security deposits	35,034	45,582	35,034
	\$3,672,626	\$2,780,662	\$3,672,626
<b><u>LIABILITIES AND MEMBERS DEFICIENCY</u></b>			
Current liabilities:			
Accounts payable and accrued expenses	\$689,716	\$814,854	\$689,716
Note payable current portion	42,046	61,387	42,046
Note payable related party	26,568,554	22,525,942	655,018
Current liabilities of discontinued operations		200,000	
Total current liabilities	27,300,316	23,602,183	1,386,780
Note payable		42,046	
Lease abandonment payable	259,345	578,799	259,345
Commitments and contingencies			
Members deficiency/stockholders equity:			
Common stock, \$0.01 par value, 50,000,000 shares authorized, no shares issued and outstanding, actual, 2,791,354 shares issued and outstanding, pro forma			27,914
Additional paid-in capital			27,885,622
Members deficiency/accumulated deficit	(23,887,035)	(21,442,366)	(25,887,035)
Total members deficiency/stockholders equity	(23,887,035)	(21,442,366)	2,026,501
	\$3,672,626	\$2,780,662	\$3,672,626

See accompanying notes to consolidated financial statements.



TABLE OF CONTENTS

# Signal Genetics LLC and Subsidiaries

## Consolidated Statements of Operations

	Year Ended	
	December 31, 2013	December 31, 2012
Net revenue	\$4,316,484	\$4,406,042
Operating expenses:		
Cost of revenue	2,498,940	3,042,184
Selling and marketing	378,769	1,325,245
General and administrative	1,788,141	2,907,947
Research and development	96,847	225,378
Lease abandonment		932,287
Gain on legal settlement	(250,000 )	
Total operating expenses	4,512,697	8,433,041
Operating loss	(196,213 )	(4,026,999 )
Interest expense	(1,963,456)	(1,591,341 )
Loss from continuing operations	(2,159,669)	(5,618,340 )
Net loss from discontinued operations, net of tax benefit of \$0		(1,592,945 )
Net loss	(2,159,669)	(7,211,285 )
Dividend to member unit holder of Myeloma Health LLC	(285,000 )	(390,000 )
Net loss attributable to member of Signal Genetics LLC	\$(2,444,669)	\$(7,601,285 )
Basic and diluted net loss per unit:		
Net loss from continuing operations attributable to member of Signal Genetics LLC	\$(27.20 )	\$(68.40 )
Net loss from discontinued operations attributable to member of Signal Genetics LLC		(18.13 )
Net loss attributable to member of Signal Genetics LLC	\$(27.20 )	\$(86.53 )
Average units outstanding basic and diluted	89,891	87,847
Pro forma basic and diluted net loss per common stock	\$(0.88 )	
Average shares outstanding basic and diluted	2,791,354	

See accompanying notes to consolidated financial statements.

TABLE OF CONTENTS**Signal Genetics LLC and Subsidiaries****Consolidated Statements of Members Deficiency  
For the Years Ended December 31, 2013 and 2012**

	Class A Units	Class B Units	Amount
Balance January 1, 2012	72,500	31,030	\$ (13,519,036 )
Net loss			(7,211,285 )
Equity incentive compensation		22,725	7,955
Cancellation of unvested equity incentive units		(12,667 )	
Distributions			(720,000 )
Balance December 31, 2012	72,500	41,088	(21,442,366 )
Net loss			(2,159,669 )
Distributions			(285,000 )
Balance December 31, 2013	72,500	41,088	\$ (23,887,035 )

See accompanying notes to consolidated financial statements.

TABLE OF CONTENTS

# Signal Genetics LLC and Subsidiaries

## Consolidated Statements of Cash Flows

	Year Ended	
	December 31, 2013	December 31, 2012
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(2,159,669 )	\$(7,211,285 )
Net loss from discontinued operations		(1,592,945 )
Net loss from continuing operations	(2,159,669 )	(5,618,340 )
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	148,315	144,289
Equity incentive compensation expense		7,955
Loss on disposal of property and equipment		11,871
Non-cash interest on note payable related party	1,936,881	1,560,270
Lease abandonment		932,287
Gain on legal settlement	(250,000 )	
Changes in operating assets and liabilities:		
Accounts receivable	201,589	(369,579 )
Inventory	(187,102 )	166,392
Prepaid expenses and other current assets	(64,744 )	(33,470 )
Accounts payable and other accrued expenses	(279,734 )	(1,294,809 )
Lease abandonment payable	(319,454 )	(76,856 )
Net cash used in operating activities of discontinued operations	(193,875 )	(1,654,812 )
Net cash used in operating activities	(1,167,793 )	(6,224,802 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(4,769 )	(106,913 )
Proceeds from sale of property and equipment		19,300
Increase in restricted cash	(94 )	(86 )
Decrease (Increase) in security deposits	10,548	(31,734 )
Net cash provided by (used in) investing activities	5,685	(119,433 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Cash transferred into a restricted account		(50,000 )
Distributions	(285,000 )	(720,000 )
Repayment of note payable	(61,387 )	(59,427 )
Payments for deferred issuance costs	(500,422 )	
Proceeds from note payable related party	12,566,183	6,635,000
Repayment of note payable related party	(10,460,452)	
Net cash provided by financing activities	1,258,922	5,805,573
<b>NET INCREASE (DECREASE) IN CASH</b>	<b>96,814</b>	<b>(538,662 )</b>
<b>CASH:</b>		
Beginning of period	112,534	651,196

End of period	\$209,348	\$112,534
---------------	-----------	-----------

See accompanying notes to consolidated financial statements.

F-18

---

TABLE OF CONTENTS

## Signal Genetics LLC and Subsidiaries

### Notes to Consolidated Financial Statements

#### 1. Organization, Operations and Basis of Accounting

Signal Genetics LLC (the Company) was originally formed as Myeloma Health LLC, in January 2010. Effective January 1, 2011 with the formation of Signal Genetics LLC, substantially all the members' interests in Myeloma Health LLC were exchanged for members' interests in Signal Genetics LLC and Myeloma Health LLC became a wholly-owned subsidiary. The accompanying consolidated financial statements include the Company and its wholly-owned subsidiaries, all intercompany accounts and transactions have been eliminated in consolidation.

The Company is a 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. In 2010 the Company became the exclusive licensee to the research on multiple myeloma (MM) performed at the University of Arkansas for Medical Sciences (UAMS). Myeloma Prognostic Risk Signature (MyPRS®) is based upon more than two decades of clinical research on nearly 10,000 MM patients who received their care at UAMS. The Company currently generates revenues from the performance of MyPRS® diagnostic tests, which was launched in April 2011.

Since its inception, the Company has devoted substantial effort in developing its product and has incurred losses and negative cash flows from operations, and at December 31, 2013 has a members' deficiency of approximately \$23,887,000. All financial support to-date has been provided by the majority member (see Note 7). The Company is forecasting continued losses and negative cash flows as it funds its selling and marketing activities and research and development programs.

These factors raise substantial doubt about the Company's ability to continue as a going concern. The Company's ability to successfully continue is primarily dependent upon continued support from the majority member. In addition, the Company expects to seek additional financing and/or strategic investments. 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 reduce certain discretionary spending, which could have a material adverse effect on the Company's ability to achieve its intended business objectives. The accompanying consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

#### 2. Summary of Significant Accounting Policies

**Use of Estimates** The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of financial statements in conformity with GAAP requires management to make judgments, assumptions and estimates that affect the amounts reported in the Company's consolidated financial statements and accompanying notes. Significant estimates in these financial statements have been made for revenue, depreciation of property and equipment and equity incentive compensation. Actual results could differ materially from those estimates.

**Cash** The Company considers all highly liquid investments with a maturity at date of purchase of three months or less to be cash equivalents. The Company's cash is currently comprised only of cash on hand and deposits in banks. As of December 31, 2013 and 2012, the Company had approximately \$50,000 in a restricted cash account that was held as cash collateral against an outstanding letter of credit for security on a lease.

**Accounts Receivable and Allowance for Doubtful Accounts** The Company records accounts receivable net of an allowance for doubtful accounts. The Company estimates an allowance for doubtful accounts based on the aging of the accounts receivable and the historical collection experience since the Company's inception for each type of payor. The Company has not had any bad debts from any of its contracted or noncontracted insurance companies, therefore there is no allowance for doubtful accounts recorded as of December 31, 2013 and 2012.

F-19

---



TABLE OF CONTENTS

## Signal Genetics LLC and Subsidiaries

### Notes to Consolidated Financial Statements

#### 2. Summary of Significant Accounting Policies (continued)

**Inventory** Inventory, which consists entirely of finished goods, is valued at the lower of cost or market using the first-in, first-out ( FIFO ) method.

**Property and Equipment** Property and equipment is carried at cost. Expenditures for major additions and betterments are capitalized. Maintenance and repairs are charged to operations as incurred. Depreciation and amortization are calculated using the straight-line method over the estimated useful lives of the assets, which range from three to ten years. Upon sale or retirement of property and equipment, the related cost and accumulated depreciation are removed from the accounts and any gain or loss is reflected in operations.

**Long Lived Assets** The Company reviews long-lived assets, consisting of property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable based on undiscounted cash flows. If long-lived assets are impaired, an impairment loss is recognized and is measured as the amount by which the carrying value exceeds the estimated fair value of the assets. No impairment charges were recorded during the years ended December 31, 2013 and 2012.

**Revenue Recognition** Revenues that are derived from testing services are recognized in accordance with the Financial Accounting Standards Board Accounting Standards Codification ( 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, and test results are delivered to ordering physicians. 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 upon rates between the Company and the respective payor and is the price invoiced by the Company. The Company reports revenues from non-contracted insurance companies 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 insurance companies is recorded as a contractual allowance at the same time the revenue is recognized, to arrive at reported net revenue. The Company does 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. The Company's 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. The Company regularly refines 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. The Company regularly reviews our historical collection experience for non-contracted payors and adjusts our expected revenues for current and subsequent periods accordingly.

The table below shows the adjustments made to gross revenues to arrive at net revenue, the amount reported on our statements of operations:

	Year Ended	
	December 31,	December 31,
	2013	2012
Gross revenues	\$ 5,090,739	\$ 6,378,242
Less: Contractual allowances	774,255	1,972,200
Net revenue	\$ 4,316,484	\$ 4,406,042

F-20

---

TABLE OF CONTENTS

## Signal Genetics LLC and Subsidiaries

### Notes to Consolidated Financial Statements

#### 2. Summary of Significant Accounting Policies (continued)

Contractual allowances recorded during the years ended December 31, 2013 and 2012 represented approximately 15% and 31%, respectively, of gross revenues. The decrease in the percentage was primarily due to the increased revenues to direct-billed customers which increased to approximately 67% of gross revenues during the year ended December 31, 2013 from approximately 52% of gross revenues during the year ended December 31, 2012.

**Cost of Revenue** Cost of revenue represents the cost of materials, direct labor, costs associated with processing specimens including pathological review, quality control analyses, and delivery charges necessary to render an individualized test result. Costs associated with performing tests are recorded as the tests are processed.

**License Fees** The Company has licensed technology for patents for uses of a gene expression profiling ( GEP ) assay called MyPRS® and its related technology. Under the terms of the license agreement, the Company is required to pay a fee and royalties to UAMS. The license fees are calculated as a fixed percentage of the net revenue received from third parties that the Company generates by using this technology. The Company accrues for such license fees when incurred which is based on when revenue is collected. Such license fees are included in selling and marketing expenses in the accompanying consolidated statements of operations.

**Selling and Marketing Expenses** The Company's selling and marketing consist primarily of sales commissions and support costs, salaries and related employee benefits, travel, license fees and marketing costs.

**General and Administrative Expenses** The Company's general and administrative expenses consist primarily of salaries and related employee benefits, professional service fees, associated travel costs and depreciation and amortization expense.

**Advertising costs** The Company markets its services through its advertising activities in trade publications and on the internet. Advertising costs are included in selling and marketing expenses on the statements of operations and are expensed as incurred. Advertising costs for the years ended December 31, 2013 and 2012 were approximately \$1,000 and \$67,000, respectively.

**Research and Development** The Company expenses costs associated with research and development activities as incurred. Research and development costs primarily include laboratory supplies, reagents and consulting costs. To date, the Company has not included an allocation of any indirect costs in research and development.

**Income Taxes** The Company is a limited liability company which is not a tax paying entity at the corporate level. Each member is instead individually responsible for their share of the Company's income or loss for income tax reporting purposes. 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.

Applicable accounting guidance requires that a position taken or expected to be taken in a tax return be recognized in the financial statements when it is more likely than not that the position would be sustained upon examination by tax

authorities. A recognized tax position is then measured at the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. Accounting provisions also require that a change in judgment that results in subsequent recognition, derecognition, or change in a measurement of a tax position taken in a prior annual period (including any related interest and penalties) be recognized as a discrete item in the period in which the change occurs. The Company regularly evaluates the likelihood of recognizing the benefit for income tax positions taken in various federal and state filings by considering all relevant facts, circumstances, and information available.

F-21

---

TABLE OF CONTENTS

## Signal Genetics LLC and Subsidiaries

### Notes to Consolidated Financial Statements

#### 2. Summary of Significant Accounting Policies (continued)

The Company classifies any interest and penalties related to unrecognized tax benefits as a component of income tax expense.

**Equity Incentive Compensation** The Company accounts for equity incentive compensation in accordance with FASB ASC 718, *Stock Compensation*. Equity incentive compensation expense for all equity-based compensation awards granted is based on the grant-date fair value estimated in accordance with the provisions of ASC 718. The Company recognizes these compensation costs on a straight-line basis over the requisite service period of the award, which is generally the vesting period.

**Fair Value of Financial Instruments** The Company's management believes the carrying amounts of cash, accounts receivable and accounts payable approximate fair value due to their short-term maturity. The fair value of the note payable related party cannot be reasonably estimated as a result of the related party arrangement. The present value of the note payable at December 31, 2013 and 2012 was approximately \$42,000 and \$103,000, respectively.

**Supplemental Disclosures of Cash Flow Information and of Non-Cash Financing Transactions** During the years ended December 31, 2013 and 2012, the Company paid approximately \$1,209,000 and \$20,000, respectively, in interest. Of the total paid in 2013 \$1,182,000 was paid to related parties (see Note 7). In addition, at December 31, 2013, there are deferred issuance costs of approximately \$155,000 included in accounts payable and accrued expenses.

**Segment Reporting** The Company operates as one segment.

**Reclassification** Certain reclassifications have been made to the 2012 financial statements to conform to the 2013 presentation.

**Concentration of Credit Risk, Major Customers and Suppliers** Cash is maintained at one financial institution and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to these balances.

During 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 83% and 86%, respectively, of net revenue.

Accounts receivable sourced either from or through UAMS at December 31, 2013 and 2012 accounted for approximately 62% and 85%, respectively.

Inventory used in the Company's testing process is procured from one supplier. Any supply interruption or an increase in demand beyond the suppliers' capabilities could have an adverse impact on the Company's business. Management believes it can identify alternative sources, if necessary, but it is possible such sources may not be identified in sufficient time to avoid an adverse impact on its business.

**Unaudited Pro Forma Data** The pro forma balance sheet data as of December 31, 2013 and calculation of pro forma net loss per share for the year ended December 31, 2013 give effect to the conversion of the Company from a limited liability company into a corporation by the following transactions included in the anticipated public offering of the Company's common stock:

The conversion of the note payable related party (\$26,568,554) less the amount of deferred offering costs recorded as of December 31, 2013 (\$655,018) into an aggregate of 2,591,354 Class C units, and

The consummation of the corporate conversion, pursuant to which all of the outstanding Class A and Class C units of the Company will be automatically converted into an aggregate of 2,791,354 shares of Signal Genetics, Inc. common stock.

F-22

---

TABLE OF CONTENTS

## Signal Genetics LLC and Subsidiaries

### Notes to Consolidated Financial Statements

#### 2. Summary of Significant Accounting Policies (continued)

The pro forma net loss per share excludes the vesting of 264,474 restricted stock unit awards issued to certain employees of the Company simultaneously with the public offering which will be immediately vested upon grant, but the common stock will not be issued until January 1, 2015.

**Recent Accounting Pronouncements** Other than as disclosed below, we have reviewed all recently issued standards and have determined they will not have a material impact on our consolidated financial statements or do not apply to our operations.

In July 2011, the FASB issued Accounting Standards Update ( ASU ) No. 2011-07, *Health Care Entities (Topic 954): Presentation and Disclosure of Patient Service Revenue, Provision for Bad Debts, and the Allowance for Doubtful Accounts for Certain Health Care Entities* which requires certain health care entities to record the provision for bad debts associated with patient service revenue as a deduction from patient service revenue (net of contractual allowances and discounts). Additionally, those entities are required to provide enhanced disclosures about their policies for recognizing revenue and assessing bad debts. For nonpublic entities, the amendments were effective for the first annual period ending after December 15, 2012 with early adoption permitted and the presentation should be applied retrospectively to all prior periods presented. The Company has adopted this guidance retrospectively in the accompanying consolidated financial statements.

**Future Accounting Pronouncements** Section 107 of the Jumpstart Our Business Startups Act of 2012 (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 otherwise apply to private companies. Although to date, the Company has not yet taken advantage of this delay, the Company has elected to avail ourselves of this extended transition period for adopting new or revised accounting standards in the future. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

#### 3. Discontinued Operations

In May 2011, the Company formed a new wholly-owned subsidiary, CC Health LLC, that on June 28, 2011 entered into and consummated the transactions contemplated by an Asset Purchase Agreement (the Purchase Agreement ) with Diagnostics US, GP and Diagnostics Inc. (collectively, the Sellers ), pursuant to which the Company purchased various assets relating to a clinical research study. During 2011, the Company further assessed the developmental stage of the studies and determined that the technology was not as far developed as originally believed. Management weighed the expected costs that would need to be incurred and the time period that would be involved to complete development and in early 2012, determined to discontinue the studies and instead concentrate on the Company's core business.

Therefore at December 31, 2011, the Company impaired the remaining assets and began unwinding outstanding contracts pertaining to the CC Health LLC business. Operations were completely closed in the second quarter of 2012.

All operations related to CC Health LLC have been classified as discontinued operations in the accompanying statements of operations. Revenue included in discontinued operations was approximately \$99,000 for the year ended December 31, 2012. For the year ended December 31, 2012 the net loss from discontinued operations was approximately \$1,593,000.

The remaining assets of discontinued operations consisted of accounts receivable as of December 31, 2012 and the remaining liabilities of discontinued operations consisted of accounts payable and accrued expenses as of December 31, 2012.

F-23

---



TABLE OF CONTENTS

# Signal Genetics LLC and Subsidiaries

## Notes to Consolidated Financial Statements

### 4. Property and Equipment

Property and equipment at December 31, 2013 and 2012, consists of the following:

	2013	2012
Computer and lab equipment	\$ 1,320,091	\$ 1,315,622
Furniture and fixtures	12,550	12,250
Leasehold improvements	6,439	6,439
	1,339,080	1,334,311
Less: Accumulated depreciation and amortization	411,054	262,739
	\$ 928,026	\$ 1,071,572

Depreciation and amortization expense for the years ended December 31, 2013 and 2012 was approximately \$148,000 and \$144,000, respectively.

### 5. Deferred Issuance Costs

During the year ended December 31, 2013, the Company has incurred approximately \$655,000 of direct costs related to the anticipated public offering of the Company's common stock. These costs have been recorded as a long-term asset until the related transactions are complete, at which time they will be treated as a reduction of the proceeds.

### 6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses at December 31, 2013 and 2012, consists of the following:

	2013	2012
Accounts payable	\$	\$ 26,665
Salaries and related taxes	76,409	
Current portion of lease abandonment payable	319,454	303,716
Legal fees	48,415	249,167
Consulting		155,833
Deferred issuance costs	154,596	
Other	90,842	79,473
	\$ 689,716	\$ 814,854

### 7. Notes Payable

**Note Payable** The Company has acquired certain property and equipment through the issuance of a note payable totaling approximately \$182,000. The note is payable in thirty-six monthly installments of \$5,320 through August

2014. The present value of the note payable at December 31, 2013 and 2012 was approximately \$42,000 and \$103,000, respectively. The effective interest rate of the notes during 2013 and 2012 was 3.4%. The Company has collateralized the notes with the related equipment, which had a net book value of approximately \$305,000 and \$345,000 at December 31, 2013 and 2012, respectively, and is included in computer and lab equipment (see Note 4).

**Note Payable Related Party** During the years ended December 31, 2013 and 2012, the Company has been loaned the net amount of approximately \$2,106,000 and \$6,635,000, respectively, to support operations by its majority member through various entities owned by him. The notes bear interest at 8% compounded quarterly and are due on demand. Interest expense for the years ended December 31, 2013 and 2012 was approximately \$1,937,000 and \$1,560,000, respectively, and has been accrued and included in the balance reflected on the accompanying consolidated balance sheets. During the year ended December 31, 2013, the member loaned the Company approximately \$10,461,000 which was used to repay interest of approximately \$1,182,000 and principal of \$9,279,000 to the other entities. These notes have the same terms

F-24

---

TABLE OF CONTENTS

# Signal Genetics LLC and Subsidiaries

## Notes to Consolidated Financial Statements

### 7. Notes Payable (continued)

as described above. All the notes are collateralized by substantially all assets of the Company. As of March 18, 2014, the total amount of indebtedness (including principal and interest) under the notes is \$27,023,171.

### 8. Equity Incentive Compensation

In January 2011, the Company issued 29,500 units to three employees in connection with equity incentive agreements, 20,000 of the units vested in six month increments beginning with 33% in July 2011 and then 16% through July 2013, 7,500 of the units vested in six month increments beginning with 33% in April 2011 and then 16% through April 2013 and 2,000 of the units vested 25% on the first anniversary and then in thirty-six monthly increments through March 2016. All of these individuals were terminated during 2012 and their vested units (totaling 16,833) were repurchased by the majority member. The remaining unvested units (12,667) were cancelled. In December 2011, the Company issued 1,530 units to another employee in connection with an equity incentive agreement. The units vest 25% on the first anniversary and then in thirty-six monthly increments through December 2014.

In October 2012, the Company issued 22,725 units to the Chief Executive Officer which were subject to a performance condition, the Company closing a funding of at least \$25 million. Once achieved, the units vest 33% upon the closing and then 16% every six months thereafter. Since the likelihood of achieving the performance condition on the grant date was not deemed probable, no equity incentive compensation had been recorded related to these units. On October 9, 2013, this equity incentive agreement was modified to reduce the funding target to \$15 million which is deemed probable however the grant was determined to have a diminimus grant-date fair value.

All of the above units were recorded based upon their fair value on the date of grant and the weighted-average grant-date fair value of the units issued. The Company expensed approximately \$8,000 during the year ended December 31, 2012 related to the 2011 grants. The unrecognized expense as of December 31, 2013 is diminimus.

### 9. Members Interests

**LLC Agreement** The Company's operating agreement defines the rights and obligations of its members. The members of the Company are not obligated personally for any debt, obligation or liability of the Company solely by reason of being a member. Upon liquidation of the Company, the assets of the Company will be distributed first to creditors, including notes payable to members, and then to the members as described below. The Company has authorized 100,000 Class A units and 50,000 Class B units. The Class B units consist entirely of equity incentive units (see Note 8) and are considered a profits interest. Upon liquidation, distributions will first be returned to Class A unit holders to the extent of their unreturned contribution account (\$2,000,000) and then pro rata to all members. All units are entitled to one vote. Dissolution of the LLC will occur upon the earlier of a date approved by the members or December 31, 2060.

**Distributions** Distributions of \$285,000 and \$390,000 during the years ended December 31, 2013 and 2012, respectively, were made to a member interest unit holder in Myeloma Health LLC, a subsidiary of the Company. The distribution was covered by a dividend made by the Company to Myeloma Health LLC.

**Net Loss Per Unit** The Company calculates net loss per unit in accordance with FASB ASC 260, Earnings Per Share. Basic net loss per unit is computed by dividing the net loss for the period by the weighted average number of units of members' interests outstanding for the period. Diluted net loss per unit is computed by dividing the net loss by the weighted average number of units of members' interests and dilutive unit equivalents then outstanding. Unit equivalents consist of equity incentive units.

F-25

---

TABLE OF CONTENTS

# Signal Genetics LLC and Subsidiaries

## Notes to Consolidated Financial Statements

### 9. Members Interests (continued)

At December 31, 2013 and 2012, 23,520 and 24,255 equity incentive units were excluded from basic and diluted net loss per unit since they had not yet vested and due to the net loss incurred during the respective years.

### 10. Commitments and Contingencies

**Operating Leases** The Company leases a laboratory and office facility under non-cancellable operating lease agreements, which expires in March 2014. The Company is currently in discussions with the landlord and intends to renew this lease for another annual period on the same terms. At December 31, 2013, the future minimum rental commitment under the operating lease excluding the abandoned lease described below is approximately as follows:

2014

\$ 19,000

Rent expense for the years ended December 31, 2013 and 2012 was approximately \$76,000 and \$256,000, respectively. Of these totals for the year ended December 31, 2012, approximately \$182,000 was included in discontinued operations. In addition, certain administrative functions are performed at an office location leased by the majority member at no charge to the Company. No amount has been charged for these functions as it is not deemed reasonable to estimate.

**Lease Abandonment** During the year ended December 31, 2012, the Company recorded costs associated with an operating lease for which it had abandoned the use of the related property and has been unsuccessful in subleasing of approximately \$932,000 which represented the present value of the remaining payments due under the lease. In the determination of such liability, the Company has taken into account a termination clause in the lease whereby they can terminate the lease after August 2015 as well as no estimated sublease income due to the Company's inability to date to sublet such space. At December 31, 2013 and 2012, the total liability is approximately \$579,000 and \$883,000, respectively. At December 31, 2013, the remaining payments under the lease agreement consist of monthly installments ranging from approximately \$27,000 - \$28,000 through August 2015.

**Services Agreement** The Company has entered into a systems and services agreement with a third party to assist with billing and collections from customers which originally expired in February 2013 and was renewed until February 2015. The agreement contains automatic one year renewals, unless termination notice is given by either party. The Company pays \$10,000 per month under the agreement.

**Licensing Agreement** The Company has entered into a licensing agreement with UAMS for the exclusive use of patents used in the GEP assay, MyPRS® and its related technology through April 2020. The agreement is effective through the earlier of the expiration of the related patents or termination of the agreement pursuant to its terms. The Company may terminate the agreement for any reason upon ninety days written notice. UAMS may terminate the agreement with ninety days written notice upon a material breach of the agreement by the Company or if the Company challenges the validity of any licensed patent in a court of competent jurisdiction. Under the terms of the

license agreement, the Company is required to pay \$30,000 in annual minimum royalty fees on sales to customers other than UAMS unless sales, as defined in the agreement, exceed certain thresholds in which case the additional royalty fee would range from 2% - 4%. Total royalty fee expense, including that to UAMS and one-time charges, for the years ended December 31, 2013 and 2012 were approximately \$30,000 and \$85,000, respectively.

***Employment Agreements*** The Company has employment contracts with two individuals, which provide for annual base salaries and potential bonuses. These contracts contain certain change of control, termination and severance clauses that require the Company to make payments to certain of these employees if certain events occur as defined in their respective contracts.

F-26

---

TABLE OF CONTENTS

## Signal Genetics LLC and Subsidiaries

### Notes to Consolidated Financial Statements

#### 10. Commitments and Contingencies (continued)

**Letters of Credit** At December 31, 2013, the Company was contingently liable for a standby letter of credit issued by a commercial bank for \$50,000, for security on a lease. The Company has approximately \$50,000 in a restricted cash account that is held as cash collateral for the letter of credit.

**Cost-Containment Measures** Both government and private pay sources have instituted cost-containment measures designed to limit payments made to providers of health care services, which include diagnostic test providers such as the Company, and there can be no assurance that future measures designed to limit payments made to providers will not adversely affect the Company.

**Litigation** The Company is, from time to time, involved in legal proceedings, regulatory actions, claims and litigation arising in the ordinary course of business. As of December 31, 2013, the Company is not a defendant in any lawsuits.

**Litigation Settlement** In August 2013, the Company settled a suit in which they were the plaintiff for a tortious interference claim regarding a potential acquisition and agreed to settle for a payment of at least \$350,000. Of the total, \$250,000 is to be paid no later than January 2014 and \$100,000 is to be paid no later than January 2015. In addition if the defendants have made sales of their technology by the end of 2015, the Company will also be paid the lesser of 10% of the total sales as of the end of 2015 or \$100,000. This payment is due to be received in January 2016. As of December 31, 2013, the Company recorded a receivable in prepaid expenses and other current assets and the related gain for the \$250,000 which was received in January 2014. The Company has not recorded the remaining future payments as either a receivable or 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.

#### 11. Subsequent Events

The Company has evaluated subsequent events through the date the financial statements were issued.

TABLE OF CONTENTS

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

**PROSPECTUS**

*Joint Book-Running Managers*

**Aegis Capital Corp**

**Chardan Capital Markets, LLC**



, 2015



TABLE OF CONTENTS**PART II INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth all expenses to be paid by the registrant, other than estimated underwriting discounts and commissions, in connection with our public offering. All amounts shown are estimates except for the SEC registration fee, the FINRA filing fee and the NASDAQ listing fee:

SEC registration fee	\$ 1,056.70
FINRA filing fee	1,864.06
Legal fees and expenses	100,000
Accounting fees and expenses	40,000
Transfer agent and registrar's fees and expenses	1,000
Printing and engraving expenses	37,500
Miscellaneous expenses	93,579.24
Total	\$ 275,000

**Item 14. Indemnification of Directors and Officers.**

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities, including reimbursement for expenses incurred, arising under the Securities Act of 1933, as amended, or the Securities Act.

Our certificate of incorporation provides for indemnification of our directors and executive officers to the maximum extent permitted by the Delaware General Corporation Law, and our bylaws provide for indemnification of our directors and executive officers to the maximum extent permitted by the Delaware General Corporation Law.

We have entered into indemnification agreements with each of our current directors and executive officers. These agreements will require us to indemnify these individuals to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to us and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified. We also intend to enter into indemnification agreements with our future directors and executive officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us, within the meaning of the Securities Act, against certain liabilities.

**Item 15. Recent Sales of Unregistered Securities.**

During the last three years, we have issued unregistered securities to the persons described below. None of these transactions involved any underwriters, underwriting discounts or commissions, or any public offering. We believe that each transaction was exempt from the registration requirements of the Securities Act by virtue of Section 4(a)(2)

thereof as a transaction not involving a public offering. The recipients both had access, through their relationship with us, to information about us.

In December 2011, we issued 1,530 Class B units of Signal Genetics LLC, which were subject to time vesting conditions, to Dr. Van Laar, pursuant to the terms of his employment agreement with the Company. These Class B units were cancelled and forfeited in connection with the corporate conversion.

In October 2012, we issued 22,725 Class B units of Signal Genetics LLC, as incentive units, to Mr. Riccitelli, pursuant to the terms of his employment agreement with the Company. These Class B units were cancelled and forfeited in connection with the corporate conversion.

We converted \$27,326,287 of principal debt into an aggregate of 2,732,629 Class C units, immediately prior to our initial public offering. The issuance of Class C units in the Debt Conversion was exempt from registration under the Securities Act by virtue of the exemption provided under Section 3(a)(9) as the exchange was made by us with our existing security holders exclusively and no commission or other remuneration was paid or given directly or indirectly for soliciting such exchange. The issuance of common

II-1

---

TABLE OF CONTENTS

stock was also exempt from registration under the Securities Act by virtue of Section 4(a)(2) thereof as a transaction not involving a public offering. The 2,732,629 Class C units were converted into 2,732,629 shares of our common stock in the corporate conversion, which took place immediately prior to our initial public offering. The issuance of common stock in the corporate conversion was exempt from registration under the Securities Act by virtue of the exemption provided under Section 3(a)(9) thereof as the common stock was exchanged by us with our existing security holders exclusively and no commission or other remuneration was paid or given directly or indirectly for soliciting such exchange. The issuance of common stock was also exempt from registration under the Securities Act by virtue of Section 4(a)(2) thereof as a transaction not involving a public offering.

We issued 831,593 restricted stock units to certain employees immediately prior to our initial public offering. The issuance of these securities was also exempt from registration under the Securities Act by virtue of Section 4(a)(2) thereof as a transaction not involving a public offering or Rule 701 promulgated under Section 3(b) of the Securities Act as a transaction pursuant to a compensatory benefit plan or contract relating to compensation.

## **Item 16. Exhibits and Financial Statement Schedules.**

The exhibits listed in the accompanying Exhibit Index are filed or incorporated by reference as part of this registration statement.

## **Item 17. Undertakings.**

(a) The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
  - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933; To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement.
  - (ii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
  - (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

II-2

---

TABLE OF CONTENTS

(6) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424 (§230.424 of this chapter);
- (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(i) The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

II-3

---

TABLE OF CONTENTS

# SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Amendment No. 2 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Carlsbad, State of California, on February 13, 2015.

**SIGNAL GENETICS, INC.**

/s/ Samuel D. Riccitelli

By:

Name: Samuel D. Riccitelli

Title: President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this Amendment No. 2 to the Registration Statement has been signed by the following persons in the capacities and on the date indicated.

Signature	Title	Date
/s/ Samuel D. Riccitelli	President, Chief Executive Officer and Director (Principal Executive Officer)	February 13, 2015
Samuel D. Riccitelli		
/s/ Tamara A. Seymour	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 13, 2015
Tamara A. Seymour		
*	Chairman of the Board of Directors	February 13, 2015
Bennett S. LeBow		
*	Director	February 13, 2015
David A. Gonyer, R. Ph.		
*	Director	February 13, 2015
Douglas A. Schuling		
*	Director	February 13, 2015
Robin L. Smith, M.D.		

\* By:

/s/ Samuel D. Riccitelli

Samuel D. Riccitelli

Attorney-in-Fact

TABLE OF CONTENTS

**EXHIBIT INDEX**

Exhibit Number	Description of Exhibit
1.1*	Form of Underwriting Agreement.
3.1	Certificate of Incorporation of Signal Genetics, Inc. (incorporated by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q (No. 001-36483) filed with the Securities and Exchange Commission on August 14, 2014).
3.2	Bylaws of Signal Genetics, Inc. (incorporated by reference to Exhibit 3.2 to the Quarterly Report on Form 10-Q (No. 001-36483) filed with the Securities and Exchange Commission on August 14, 2014).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1 (No. 333-194668) filed with the Securities and Exchange Commission on March 19, 2014).
4.2*	Form of Representative's Warrant.
4.3	Form of Representative's Warrant (incorporated by reference to Exhibit 10.24 to the Registration Statement on Form S-1/A (No. 333-194668) filed with the Securities and Exchange Commission on June 6, 2014).
5.1*	Opinion of Reed Smith LLP.
10.1	Assignment of Membership Interests between LeBow Alpha LLLP and Signal Genetics LLC, dated January 1, 2011 (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-1 (No. 333-194668) filed with the Securities and Exchange Commission on March 19, 2014).
10.2	License Agreement, dated April 1, 2010, by and between The Board of Trustees of the University of Arkansas on behalf of the University of Arkansas for Medical Sciences and Myeloma Health LLC (the "UAMS License Agreement") (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1 (No. 333-194668) filed with the Securities and Exchange Commission on April 9, 2014).
10.2.1	Letter Agreement, dated April 1, 2010, of Signal Genetics LLC (f/k/a Myeloma Health, LLC) (as referenced in the UAMS License Agreement) (incorporated by reference to Exhibit 10.2.1 to the Registration Statement on Form S-1 (No. 333-194668) filed with the Securities and Exchange Commission on March 19, 2014).
10.3	First Amendment to License Agreement, dated September 1, 2010, by and between The Board of Trustees of the University of Arkansas on behalf of the University of Arkansas for Medical Sciences and Myeloma Health LLC (the "First Amendment to UAMS License Agreement") (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-1 (No. 333-194668) filed with the Securities and Exchange Commission on March 19, 2014).
10.3.1	Letter Agreement, dated February 25, 2014, of Signal Genetics LLC (f/k/a Myeloma Health, LLC) (as referenced in the First Amendment to UAMS License Agreement) (incorporated by reference to Exhibit 10.3.1 to the Registration Statement on Form S-1 (No. 333-194668) filed with the Securities and Exchange Commission on March 19, 2014).
10.4	Second Amendment to License Agreement, dated September 14, 2010, by and between The Board of Trustees of the University of Arkansas on behalf of the University of Arkansas for Medical Sciences and Myeloma Health LLC (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form S-1 (No. 333-194668) filed with the Securities and Exchange Commission on March 19, 2014).

- 10.5 Third Amendment to License Agreement, dated October 2011, by and between The Board of Trustees of the University of Arkansas on behalf of the University of Arkansas for Medical Sciences and Myeloma Health LLC (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1 (No. 333-194668) filed with the Securities and Exchange Commission on March 19, 2014).

II-5

---



TABLE OF CONTENTS

Exhibit Number	Description of Exhibit
10.6	Fourth Amendment to License Agreement, dated December 1, 2011, by and between The Board of Trustees of the University of Arkansas on behalf of the University of Arkansas for Medical Sciences and Myeloma Health LLC (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1 (No. 333-194668) filed with the Securities and Exchange Commission on March 19, 2014).
10.7	Reference Laboratory Services Agreement, dated March 21, 2011, by and between The Board of Trustees of the University of Arkansas on behalf of the University of Arkansas for Medical Sciences Clinical Laboratory and Signal Genetics LLC (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1 (No. 333-194668) filed with the Securities and Exchange Commission on March 19, 2014).
10.8	Reference Laboratory Services Agreement, dated September 20, 2014, by and between The Board of Trustees of the University of Arkansas on behalf of the University of Arkansas for Medical Sciences and Signal Genetics, Inc. (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q (No. 001-36483) filed with the Securities and Exchange Commission on November 11, 2014).
10.9	Reference Laboratory Services Agreement for Research Specimens, dated March 21, 2011, by and between The Board of Trustees of the University of Arkansas on behalf of the University of Arkansas for Medical Sciences Myeloma Institute for Research Therapy and Signal Genetics LLC (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1 (No. 333-194668) filed with the Securities and Exchange Commission on March 19, 2014).
10.10	Reference Laboratory Services Agreement for Research Specimens, dated September 20, 2014, by and between The Board of Trustees of the University of Arkansas on behalf of the University of Arkansas for Medical Sciences and Signal Genetics, Inc. (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q (No. 001-36483) filed with the Securities and Exchange Commission on November 11, 2014).
10.11	Amended and Restated Secured Demand Promissory Note, dated December 11, 2013, by and between Signal Genetics LLC, Myeloma Health LLC, Respira Health LLC and CC Health LLC and LeBow Alpha LLLP (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1 (No. 333-194668) filed with the Securities and Exchange Commission on March 19, 2014).
10.12	Guaranty and Security Agreement, dated November 3, 2011, by and between Signal Genetics LLC, Myeloma Health LLC, Respira Health LLC and CC Health LLC and LeBow Alpha LLLP (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form S-1 (No. 333-194668) filed with the Securities and Exchange Commission on March 19, 2014).
10.13	Form of Indemnification Agreement between Signal Genetics, Inc. and each of its directors and executive officers (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1 (No. 333-194668) filed with the Securities and Exchange Commission on March 19, 2014).
10.14	2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (No. 001-36483) filed with the Securities and Exchange Commission on August 14, 2014).
10.15	Exchange Agreement, dated June 17, 2014, by and between Signal Genetics LLC, LeBow Alpha LLLP, LeBow Gamma Limited Partnership, BSL Capital, Inc., Bennett S. LeBow, the LeBow 2012 Nevada Trust and the LFIT-A Trust (incorporated by reference to Exhibit 10.8 to

the Quarterly Report on Form 10-Q (No. 001-36483) filed with the Securities and Exchange Commission on August 14, 2014).

II-6

---

TABLE OF CONTENTS

Exhibit Number	Description of Exhibit
10.16	Amended and Restated Employment Agreement, dated June 17, 2014, by and between Signal Genetics, Inc. and Samuel D. Riccitelli (incorporated by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q (No. 001-36483) filed with the Securities and Exchange Commission on August 14, 2014).
10.17	Form of Restricted Stock Unit Agreement by and between Signal Genetics, Inc. and Samuel D. Riccitelli (incorporated by reference to Exhibit 10.18 to the Registration Statement on Form S-1/A (No. 333-194668) filed with the Securities and Exchange Commission on April 9, 2014).
10.18	Letter Agreement, dated March 18, 2014, by and between The Board of Trustees of the University of Arkansas on behalf of the University of Arkansas for Medical Sciences and Signal Genetics, Inc. (incorporated by reference to Exhibit 10.19 to the Registration Statement on Form S-1/A (No. 333-194668) filed with the Securities and Exchange Commission on April 9, 2014).
10.19	UAMS Bioventures Lease Agreement, dated March 31, 2014, by and between The Board of Trustees of the University of Arkansas for Medical Sciences and Myeloma Health LLC (incorporated by reference to Exhibit 10.20 to the Registration Statement on Form S-1/A (No. 333-194668) filed with the Securities and Exchange Commission on April 9, 2014).
10.20	Employment Agreement, dated May 12, 2014, by and between Signal Genetics, Inc. and Robert Johnson (incorporated by reference to Exhibit 10.21 to the Registration Statement on Form S-1/A (No. 333-194668) filed with the Securities and Exchange Commission on May 15, 2014).
10.21	Agreement for Termination of Lease and Voluntary Surrender of Premises, dated March 14, 2014, by and between ARE-Acquisitions, LLC and Signal Genetics LLC (incorporated by reference to Exhibit 10.22 to the Registration Statement on Form S-1/A (No. 333-194668) filed with the Securities and Exchange Commission on May 15, 2014).
10.22	Letter Agreement, dated May 16, 2014, by and between The Board of Trustees of the University of Arkansas on behalf of the University of Arkansas for Medical Sciences and Signal Genetics, Inc. (incorporated by reference to Exhibit 10.23 to the Registration Statement on Form S-1/A (No. 333-194668) filed with the Securities and Exchange Commission on May 27, 2014).
10.23	Employment Agreement, dated August 4, 2014, by and between Signal Genetics, Inc. and Tamara A. Seymour (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K (No. 001-36483) filed with the Securities and Exchange Commission on July 23, 2014).
10.24	Amendment to Amended and Restated Employment Agreement, dated July 23, 2014, by and between Signal Genetics, Inc. and Samuel D. Riccitelli (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K (No. 001-36483) filed with the Securities and Exchange Commission on July 23, 2014).
10.25	Office Building Lease Agreement, dated August 18, 2014, by and between OT9 Owner, LLC and Signal Genetics, Inc. (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (No. 001-36483) filed with the Securities and Exchange Commission on November 11, 2014).
10.26	Form of Stock Option Grant Agreement under the 2014 Stock Incentive Plan (incorporated by reference to Exhibit 4.5 to the Registration Statement on Form S-8 (No. 333-197316) filed with the Securities and Exchange Commission on July 9, 2014).
10.27	

Edgar Filing: SIGNAL GENETICS, INC. - Form S-1/A

Form of Restricted Stock Unit Grant Agreement under the 2014 Stock Incentive Plan  
(incorporated by reference to Exhibit 4.6 to the Registration Statement on Form S-8 (No.  
333-197316) filed with the Securities and Exchange Commission on July 9, 2014).

- 21.1\* Subsidiaries of Signal Genetics, Inc.
- 23.1 Consent of BDO USA, LLP.
- 23.2\* Consent of Reed Smith LLP (See Exhibit 5.1 above).

II-7

---

TABLE OF CONTENTS

Exhibit Number	Description of Exhibit
24.1*	Power of Attorney (included in the signature page of the initial filing of this Registration Statement).
101**	The following materials formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of September 30, 2014 (unaudited) and December 31, 2013, (ii) unaudited consolidated statements of operations for the nine months ended September 30, 2014 and 2013, (iii) unaudited consolidated statements of cash flows for the nine months ended September 30, 2014 and 2013, (iv) Notes to Unaudited Consolidated Financial Statements, (v) Consolidated Balance Sheets as of December 31, 2013 and 2012, (vi) Consolidated Statements of Operations for the Years ended December 31, 2013 and 2012, (vii) Consolidated Statements of Members Deficiency for the Years ended December 31, 2013 and 2012, (viii) Consolidated Statements of Cash Flows for the Years ended December 31, 2013 and 2012, and (ix) Notes to the Consolidated Financial Statements.

Confidential treatment granted as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

\*

Previously filed.

In accordance with Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 to this Registration Statement on Form S-1 are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

II-8

---