SIGNAL GENETICS LLC Form S-1/A June 13, 2014

As filed with the Securities and Exchange Commission on June 13, 2014

Registration No. 333-194668

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

AMENDMENT NO. 6
TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

SIGNAL GENETICS LLC

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

SIGNAL GENETICS, INC.

(Exact name of registrant as specified in its charter)

(State or other jurisdiction of incorporation or organization)

(Primary Standard Industrial Classification Code Number)

(I.R.S. Employer Identification No.)

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

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

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

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

Copies to:

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

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

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

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

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

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

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

Accelerated filer o Smaller reporting company x

CALCULATION OF REGISTRATION FEE

	Proposed		
	Maximum	Amount of	
Title of Each Class of Securities to be Registered	Aggregate	Registration	
	Offering	$Fee^{(2)}$	
	Price ⁽¹⁾		
Common Stock, par value \$0.01 per share ⁽²⁾⁽³⁾	\$31,353,600	\$ 4,039	
Representative s Warrants			
Shares of Common Stock underlying Representative s Warrants ⁽⁵⁾	\$1,704,000	\$ 220	
Total	\$33,057,600	\$ 4,259 (6)	

- (1) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(o) of the Securities Act of 1933, as amended.
- (2) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional securities as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.
- (3) Includes shares of common stock the underwriters have the option to purchase to cover over-allotments, if any.

 (4) No fee pursuant to Rule 457(g) under the Securities Act of 1933, as amended.
- Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act (5) of 1933, as amended. The proposed maximum aggregate offering price of the representative s warrants is \$1,704,000, which is equal to 125% of \$1,363,200 (5% of \$27,264,000).
- (6) The Registrant previously paid this amount in connection with the filing of this Registration Statement on March 19, 2014.

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

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 JUNE 13, 2014

1,150,000 Shares Common Stock

This is a firm commitment initial public offering of 1,150,000 shares of common stock by Signal Genetics, Inc. No public market currently exists for our shares. We anticipate that the initial public offering price of our shares of common stock will be between \$10.00 and \$12.00 per share.

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

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

Our business and an investment in our securities involves a high degree of risk. See Risk Factors beginning on page 13 of this prospectus for a discussion of information that you should consider before investing in our securities.

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

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

The underwriters will receive compensation in addition to the underwriting discount. The registration statement, of which this prospectus is a part, also registers for sale warrants to purchase—shares of our common stock to be issued to the representative of the underwriters. We have agreed to issue the warrants to the representative of the underwriters as a portion of the underwriting compensation payable to the underwriters in connection with this offering. See—Underwriting—beginning on page 114 of this prospectus for a description of compensation payable to the underwriters, including a description of the warrants.

We have granted a 45-day option to the underwriters to purchase up to 172,500 additional shares of common stock solely to cover over-allotments, if any.

The underwriters expect to deliver the shares against payment therefor on or about , 2014.

Aegis Capital Corp

, 2014

Aegis Capital Corp 6

Aegis Capital Corp 7

TABLE OF CONTENTS

	Page
PROSPECTUS SUMMARY	1
THE OFFERING	<u>9</u>
SUMMARY HISTORICAL CONSOLIDATED FINANCIAL DATA	<u>11</u>
RISK FACTORS	<u>13</u>
CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS	<u>45</u>
<u>USE OF PROCEEDS</u>	<u>46</u>
DIVIDEND POLICY	<u>47</u>
<u>CORPORATE CONVERSION</u>	<u>47</u>
<u>CAPITALIZATION</u>	<u>48</u>
<u>DILUTION</u>	<u>50</u>
MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND	52
RESULTS OF OPERATIONS	<u>52</u>
<u>BUSINESS</u>	<u>63</u>
<u>MANAGEMENT</u>	<u>89</u>
EXECUTIVE COMPENSATION	<u>94</u>
SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT	<u>101</u>
CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS	<u>102</u>
SHARES ELIGIBLE FOR FUTURE SALE	<u>104</u>
MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF	<u>106</u>
<u>OUR COMMON STOCK</u>	100
DESCRIPTION OF SECURITIES	<u>110</u>
<u>UNDERWRITING</u>	<u>114</u>
<u>LEGAL MATTERS</u>	<u>122</u>
<u>EXPERTS</u>	<u>122</u>
WHERE YOU CAN FIND ADDITIONAL INFORMATION	<u>122</u>
GLOSSARY OF TERMS	<u>123</u>
INDEX TO FINANCIAL STATEMENTS	<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

i

TABLE OF CONTENTS 8

the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of securities and the distribution of this prospectus outside the United States.

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

ii

TABLE OF CONTENTS 10

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, Signal Genetics and Company refer to Signal Genetics LLC a us, our, consolidated subsidiaries for the periods prior to the consummation of the corporate conversion (as described below), and such terms refer to Signal Genetics, Inc. and its consolidated subsidiaries for the periods after the consummation of the corporate conversion. Except as disclosed in the prospectus, the consolidated financial statements and selected historical consolidated financial data and other financial information included in this registration statement are those of Signal Genetics LLC and its subsidiaries and do not give effect to the corporate conversion. We have provided definitions for some of the terms we use to describe our business and industry and other terms used in this prospectus in the Glossary of Terms beginning on page 123 of this prospectus.

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

Signal Genetics, Inc.

Business Overview

We are an emerging commercial stage, molecular diagnostic company focused on providing innovative diagnostic services that help physicians make better-informed decisions concerning the care of their patients suffering from cancer. Our mission is to develop, validate and deliver innovative diagnostic services that enable better patient-care decisions. We were founded in January 2010 and became the exclusive licensee in our licensed field to the renowned research on multiple myeloma performed at the University of Arkansas for Medical Sciences, or UAMS, in April 2010.

Multiple myeloma, or MM, is a hematologic, or blood, cancer that develops in the bone marrow and specifically affects the plasma cells of the bone marrow. Normal plasma cells produce immunoglobins, otherwise known as antibodies, which help the body fight infection and disease. In MM, the normal plasma cells become malignant and inhibit the production of normal blood cells and antibodies, including red blood cells, white blood cells and blood platelets, and crowd the bone marrow with malignant plasma cells, which produce an abnormal antibody called a monoclonal protein, or M protein. The hallmark characteristic of myeloma is a high level of M protein in the blood. MM can also cause soft spots in the bone known as osteolytic lesions. MM is the second most common blood cancer after leukemia and represents approximately 15% of all hematomalignancies. According to the American Cancer Society, or ACS, approximately 22,350 new cases of MM are expected to be diagnosed in the United States in 2013 and approximately 10,710 deaths from MM are expected to occur in the United States in 2013. More Americans will die from MM this year than from any other blood cancer. Although a relatively rare disease, MM is responsible for 2% of all cancer deaths in the United States each year and will kill more Americans than melanoma, the deadliest

Signal Genetics, Inc.

form of skin cancer. There are an estimated 77,617 people currently living with MM in the United States. The five-year survival rate for people with MM is about 43%. The ACS estimates that the lifetime risk in the United States of getting MM is 1 in 149.

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

1

Business Overview 12

staging. Staging is the process of determining how widespread or advanced the cancer is. Under the International Staging System, or ISS, MM is classified into three stages based upon the presence of serum beta-2 microglobulin and serum albumin, which are blood proteins that are measured through a blood test. Staging is the key factor in a physician s determination of the course of treatment for a patient and that patient s outlook or prognosis for recovery. Prognosis is typically based on the existence of different signs, symptoms and circumstances. Certain laboratory and clinical findings, or prognostic indicators, provide important information for myeloma, including when treatment should begin and what treatments to use, based upon a patient s individual risk for relapse. However, those experts caring for MM patients have been faced with a staging system that predates the current era and a large amount of new genomic information that could assist in the staging process. The traditional approach which utilizes cytogenetic techniques, such as karyotyping and fluorescent in-situ hybridization, or FISH, for staging has not been able to accurately stage MM patients or fully assess the risk of relapse and classify MM. A more comprehensive and systematic approach is necessary to meet this unmet medical need.

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

Specifically, the test helps allow:

risk stratification to help distinguish patients with indolent myeloma that may not need treatment from those patients with aggressive MM that requires more aggressive treatment; and identification of important genomic alterations that allow for myeloma sub classification that may affect the specific choice of therapies.

Our Services

We offer our MyPRS® test in our approximately 2,800 square foot state-of-the-art laboratory located in Little Rock, Arkansas, which has been certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, to perform high complexity testing. We are either licensed, or not subject to licensure, and can thus perform our test using specimens collected in 49 of the 50 states. We are currently seeking a license in New York for the MyPRS® test, which would enable us to perform MyPRS® testing for patients located in New York. We are dedicated to making our extensively validated diagnostic services available to all patients who need them.

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

Over the next 12 to 18 months, we intend to expand our test menu by adding tests that are used to help manage MM patients. There is a broad array of molecular and cytogenetic testing modalities that are utilized in the management of patients with MM, such as conventional cytogenetics, FISH, molecular tests, M protein serum test and flow cytometry (especially in the context of minimum residual disease testing for MM therapy response). We also plan to launch a

Our Services 13

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

Market Opportunity

Over the past several decades, improved awareness and diagnostic testing technologies have led to an increase in the early diagnosis of cancer. Although the goals of these efforts were to decrease cancer mortality,

2

Market Opportunity 14

TABLE OF CONTENTS

national data demonstrate significant increases in early-stage disease, without a proportional decline in later-stage disease. What has emerged amongst clinicians and researchers has been an appreciation of the complexity of cancer. Cancers are heterogeneous and do not follow a uniform course. In some cases, cancer can lead to severe disease and death, and in other cases can be indolent. Unfortunately, identifying those patients who will likely die of something other than their particular cancer diagnosis is difficult.

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

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

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

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

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

Market Opportunity 15

newly diagnosed and relapsed patients. We believe we currently service just over 2% of this market. We estimate that the addition of an AMG progression indication feature for the MyPRS® test could expand the MyPRS® addressable market to more than 130,000 patients per year. As a specialty focused diagnostic laboratory company, we hope for such opportunities to expand our service offerings for the benefit and convenience of physicians and patients.

3

Market Opportunity 16

Our Competitive Strengths

Differentiated value proposition of the MyPRS® test

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

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

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

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

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

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

Because of our exclusive relationship with UAMS, we are uniquely positioned to benefit from the breadth of clinical

research and expertise developed at UAMS. We intend to continue to use this relationship to improve our MyPRS® test and develop additional indications for the MyPRS® test, as well as additional tests. Our relationship with UAMS also provides us with credibility within the oncology community beyond that related to the MyPRS® validation we have received in published articles, and we benefit from this association in our pursuit of additional collaborations with leading universities and research institutions.

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

We currently license, or own outright, ten (10) issued patents and twenty-six (26) pending patent applications, many of which protect and defend our exclusive ability to market the MyPRS® test as well as additional proprietary tests and treatments. We also have six registered U.S. trademarks to further differentiate our products and services in the marketplace.

There are four issued U.S. patents related to the MyPRS® test, which form the basis of our right to exclude others from practicing the MyPRS® test. The patents claim methods of gene expression-based

4

classification for multiple myeloma using RNA from plasma cells, methods of identifying groups of genes that can distinguish normal and multiple myeloma plasma cells by isolating RNA from CD138 positive plasma cells and identifying differentially expressed genes, methods of diagnosing multiple myeloma by examining mRNA levels or chromosomal translocations of particular genes from plasma cells, and methods of determining the prognosis of a multiple myeloma patient by determining the copy number of the CKS1B gene in plasma cells. CKS1B is one of the genes in the 70 gene signature.

In addition to the issued U.S. patents, we have several pending patent applications in the U.S. and abroad directed to other aspects of the MyPRS® test. For example, one U.S. application, along with Canadian and European counterpart applications, describes the full 70 gene signature used in the MyPRS® test. Another pending U.S. application provides methods of prognosing subjects with MGUS using the 70 gene signature. We fully expect that additional advances will come out of our ongoing work and form the basis of additional intellectual property to protect and refine the MyPRS® test, through new patent filings, trademarks, trade secrets, and copyrights.

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

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

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

Early success in establishing positive reimbursement coverage for MyPRS®

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

Experienced oncology-centered laboratory and clinical trial services

Our specimens are tested and interpreted by highly qualified oncology-focused laboratory professionals with more than 56 years of cumulative experience with gene expression-based diagnostic testing technology. Because our

clinical staff is highly specialized in oncology, we are better positioned to consult with our oncologist customers to help them derive maximum value from the diagnostic and prognostic data generated by our tests.

Our Growth Strategy