

SIGNAL GENETICS, INC.
Form 10-Q
August 14, 2014

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

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Quarterly Period Ended June 30, 2014

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition Period from ___ to ___

Commission File Number 001-36483

SIGNAL GENETICS, INC.
(Exact name of Registrant as specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

47-1187261
(I.R.S. Employer
Identification Number)

667 Madison Avenue, 14th Floor
New York, New York
(Address of principal executive offices)

10065
(Zip Code)

Registrant's Telephone Number, Including Area Code: (212) 486-0040

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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company” in Rule 12b-2 of the Exchange Act. (Check one):

| | | | |
|-------------------------|-----------------------|---------------------------|----------------------------------|
| Large Accelerated Filer | <input type="radio"/> | Accelerated Filer | <input type="radio"/> |
| Non-Accelerated Filer | <input type="radio"/> | Smaller Reporting Company | <input checked="" type="radio"/> |

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes
“ No x

As of August 14, 2014, there were 3,782,629 shares of the issuer’s common stock, par value \$0.01 per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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,” “continue,” “could” 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 Quarterly Report on Form 10-Q.

You should read this quarterly report and the documents that we reference herein and therein and have filed as exhibits to this report, 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 quarterly report is accurate as of the date of this report 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 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 risk factors may 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 risk 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 Quarterly Report on Form 10-Q, and particularly our forward-looking statements, by these cautionary statements.

PART I—FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements.

Signal Genetics, Inc. and Subsidiaries
Consolidated Balance Sheets

| | June 30, 2014 (Unaudited) | December 31, 2013 |
|--|---------------------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash | \$7,696,325 | \$ 209,348 |
| Restricted cash | 50,199 | 50,180 |
| Accounts receivable | 1,359,405 | 994,010 |
| Inventory | 193,140 | 356,641 |
| Prepaid expenses and other current assets | 468,885 | 444,369 |
| Total current assets | 9,767,954 | 2,054,548 |
| Property and equipment, net | 860,006 | 928,026 |
| Deferred issuance costs | - | 655,018 |
| Security deposits | 35,034 | 35,034 |
| | \$10,662,994 | \$ 3,672,626 |
| LIABILITIES AND STOCKHOLDERS' EQUITY/MEMBERS' DEFICIENCY | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | \$1,081,704 | \$ 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 | 2,137,301 | 27,300,316 |
| Lease termination/abandonment payable | 62,527 | 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 June 30, 2014 and no shares issued and outstanding at December 31, 2013 | 37,826 | - |
| Additional paid in capital | 38,307,103 | - |
| Accumulated deficit | (29,881,763) | - |
| Members' deficiency | - | (23,887,035) |
| Total members' deficiency/stockholders' equity | 8,463,166 | (23,887,035) |
| | \$10,662,994 | \$ 3,672,626 |

See accompanying notes to unaudited consolidated financial statements.

Signal Genetics, Inc. and Subsidiaries
Unaudited Consolidated Statements of Operations

| | Three Months Ended | |
|--|--------------------|---------------|
| | June 30, 2014 | June 30, 2013 |
| Net revenue | \$1,273,571 | \$ 1,102,904 |
| Operating expenses: | | |
| Cost of revenue | 675,731 | 603,054 |
| Selling and marketing | 73,754 | 67,053 |
| General and administrative | 451,711 | 470,350 |
| Stock compensation | 2,874,740 | - |
| Research and development | 9,023 | 22,820 |
| Total operating expenses | 4,084,959 | 1,163,277 |
| Operating loss | (2,811,388) | (60,373) |
| Interest expense | (477,561) | (479,318) |
| Net loss | (3,288,949) | (539,691) |
| Dividend to member unit holder of Myeloma Health LLC | - | (90,000) |
| Net loss attributable to stockholders of Signal Genetics, Inc. | \$(3,288,949) | \$ (629,691) |
| Basic and diluted net loss per share: | | |
| Net loss attributable to stockholders of Signal Genetics, Inc. | \$(1.13) | \$ (0.24) |
| Average shares outstanding - basic and diluted | 2,903,040 | 2,591,223 |

See accompanying notes to unaudited consolidated financial statements.

Signal Genetics, Inc. and Subsidiaries
Unaudited Consolidated Statements of Operations

| | Six Months Ended | |
|--|------------------|-----------------|
| | June 30, 2014 | June 30, 2013 |
| Net revenue | \$2,364,494 | \$ 2,242,292 |
| Operating expenses: | | |
| Cost of revenue | 1,339,245 | 1,272,021 |
| Selling and marketing | 146,824 | 153,153 |
| General and administrative | 964,036 | 888,180 |
| Stock compensation | 2,874,740 | - |
| Research and development | 17,730 | 68,563 |
| Total operating expenses | 5,342,575 | 2,381,917 |
| Operating loss | (2,978,081) | (139,625) |
| Interest expense | (1,016,647) | (937,222) |
| Net loss | (3,994,728) | (1,076,847) |
| Dividend to member unit holder of Myeloma Health LLC | - | (180,000) |
| Net loss attributable to stockholders of Signal Genetics, Inc. | \$(3,994,728) | \$ (1,256,847) |
| Basic and diluted net loss per share: | | |
| Net loss attributable to stockholders of Signal Genetics, Inc. | \$(1.40) | \$ (0.49) |
| Average shares outstanding - basic and diluted | 2,847,505 | 2,545,013 |

See accompanying notes to unaudited consolidated financial statements.

Signal Genetics, Inc. and Subsidiaries
Unaudited Consolidated Statements of Cash Flows

| | Six Months Ended | |
|--|------------------|----------------|
| | June 30, | June 30, 2013 |
| | 2014 | |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | \$(3,994,728) | \$(1,076,847) |
| Adjustments to reconcile net loss from continuing operations to net cash used in operating activities: | | |
| Stock compensation | 2,874,740 | - |
| Depreciation and amortization | 72,288 | 74,943 |
| Non-cash interest on note payable – related party | 1,007,733 | 923,898 |
| Lease termination | 45,724 | - |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (365,395) | 65,658 |
| Inventory | 163,501 | 78,440 |
| Prepaid expenses and other current assets | (24,516) | (29,631) |
| Accounts payable and other accrued expenses | 77,972 | (298,669) |
| Lease termination/abandonment payable | (242,542) | (157,988) |
| Net cash used in operating activities of discontinued operations | - | (93,875) |
| Net cash used in operating activities | (385,223) | (514,071) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchases of property and equipment | (4,268) | - |
| Decrease in security deposits | - | 10,548 |
| Increase in restricted cash | (19) | (50) |
| Net cash (used in) provided by investing activities | (4,287) | 10,498 |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Distributions | - | (180,000) |
| Repayment of note payable | (31,449) | (30,445) |
| Proceeds from issuance of common stock | 8,500,000 | - |
| Payments for deferred issuance costs | (1,387,064) | - |
| Repayment of note payable - related party | - | (10,366,183) |
| Proceeds from note payable - related party | 795,000 | 11,214,727 |
| Net cash provided by financing activities | 7,876,487 | 638,099 |
| NET INCREASE IN CASH | 7,486,977 | 134,526 |
| CASH: | | |
| Beginning of period | 209,348 | 112,534 |
| End of period | \$7,696,325 | \$ 247,060 |

See accompanying notes to unaudited consolidated financial statements.

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 (“IPO”) 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 IPO, all financial support had been provided by the majority member (see Note 6). For the three months ended June 30, 2014, however, following the Debt Conversion, the Corporation Conversion and the IPO, the Company had positive working capital and stockholders’ equity. Although the Company is forecasting continued losses and negative cash flows as it funds its selling and marketing activities and research and development programs, the Company believes that it has enough cash on hand to support operations at least through August 2015. Going forward, as the Company continues its selling and marketing activities and research and development programs, 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 (“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 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 S-1/A Registration Statement filed with the SEC on June 13, 2014. The December 31, 2013 balance sheet is derived from the Company’s audited consolidated financial statements.

Signal Genetics, Inc. and Subsidiaries
Notes to Unaudited 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 noncontracted insurance companies. Accordingly, there is no allowance for doubtful accounts recorded as of June 30, 2014 and December 31, 2013.

Inventory — Inventory, which consists entirely of 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 six months ended June 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. 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 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 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 our expected revenues for current and subsequent periods accordingly.

Signal Genetics, Inc. and Subsidiaries
Notes to Unaudited Consolidated Financial Statements

2. Summary of Significant Accounting Policies - (continued)

The table below shows the adjustments made to gross revenues to arrive at net revenues, the amount reported on our statements of operations:

| | Three Months | | Six Months | |
|------------------|------------------|------------------|------------------|------------------|
| | June 30, 2014 | June 30, 2013 | June 30, 2014 | June 30, 2013 |
| Gross revenues | \$1,525,443 | \$ 1,238,985 | \$2,864,206 | \$ 2,523,281 |
| Less: Allowances | 251,872 | 136,081 | 499,712 | 280,989 |
| Net revenues | \$1,273,571 | \$ 1,102,904 | \$2,364,494 | \$ 2,242,292 |

Contractual allowances recorded during both the three and six months ended June 30, 2014 and 2013 represented approximately 17% and 11%, respectively, of gross revenues. The increase in the percentage was primarily due to the decreased revenues to direct-billed customers, which decreased to approximately 62% of gross revenues during the three months ended June 30, 2014 from approximately 74% of gross revenues during the three months ended June 30, 2013 and decreased to approximately 60% during the six months ended June 30, 2014 from approximately 72% of gross revenues during the six months ended June 30, 2013.

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.

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 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.

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 June 30, 2014 and December 31, 2013 was approximately \$11,000 and \$42,000, respectively.

Signal Genetics LLC and Subsidiaries
Notes to Unaudited Consolidated Financial Statements

2. Summary of Significant Accounting Policies - (continued)

Supplemental Disclosures of Cash Flow Information and of Non-Cash Financing Transactions — During the six months ended June 30, 2014 and 2013, the Company paid approximately \$9,000 and \$1,197,000, respectively, in interest. Of the total paid in 2013, \$1,182,000 was paid to related parties (see Note 6). In addition, during the six months ended June 30, 2014, the Company converted \$27,326,287 of the note payable – related party into equity. Additionally, approximately \$1,124,000 of deferred issuance costs were converted into equity and at June 30, 2014, there are remaining issuance costs of approximately \$469,000 included in accounts payable and accrued expenses.

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 three and six months ended June 30, 2014 and 2013, the Company had one major customer, UAMS. Revenue sourced either from or through UAMS accounted for approximately 83% and 85% of net revenue for the three months ended June 30, 2014 and 2013, respectively, and 81% and 83% of net revenue for the six months ended June 30, 2014 and 2013, respectively. Accounts receivable sourced either from or through UAMS at June 30, 2014 and December 31, 2013 accounted for approximately 65% 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 the suppliers' 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 its business.

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 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 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.

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, 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, our

consolidated financial statements may not be comparable to companies that comply with public company effective dates.

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Signal Genetics LLC and Subsidiaries
Notes to Unaudited Consolidated Financial Statements

3. Property and Equipment

Property and equipment at June 30, 2014 and December 31, 2013, consists of the following:

| | June 30, 2014 (Unaudited) | December 31, 2013 |
|---|---------------------------------|----------------------|
| 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 | 483,342 | 411,054 |
| | \$ 860,006 | \$ 928,026 |

Depreciation and amortization expense for the three months ended June 30, 2014 and 2013 was approximately \$36,000 and \$38,000, respectively. Depreciation and amortization expense for the six months ended June 30, 2014 and 2013 was approximately \$72,000 and \$75,000, respectively.

4. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses at June 30, 2014 and December 31, 2013, consists of the following:

| | June 30, 2014 (Unaudited) | December 31, 2013 |
|--|---------------------------------|-------------------------|
| Accounts payable | \$ 167,738 | \$ — |
| Salaries and related taxes | 16,748 | 76,409 |
| Current portion of lease termination/abandonment payable | 368,141 | 319,454 |
| Legal fees | - | 48,415 |
| Deferred issuance costs | 468,611 | 154,596 |
| Other | 60,466 | 90,842 |
| | \$ 1,081,704 | \$ 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 is payable in thirty-six monthly installments of \$5,320 through August 2014. The present value of the note payable at June 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 has collateralized the notes with the related equipment, which had a net book value of approximately \$285,000 and \$305,000 at June 30, 2014 and December 31, 2013, respectively, and is included in computer and lab equipment (see Note 3).

Note Payable — Related Party — During the six months ended June 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 \$849,000, respectively, to the Company to support its operations. Prior to the Debt Conversion (described below), the note bore interest at 8% compounded quarterly and was due on demand and were collateralized by substantially all assets of the Company. Interest expense related to the note for the three months ended June 30, 2014 and 2013 was approximately \$476,000 and \$474,000, respectively. Interest expense related to the note for the six months ended June 30, 2014 and 2013 was approximately \$1,008,000 and \$924,000, respectively. Prior to the Debt Conversion, interest was accrued and included in the note payable – related party reflected on the accompanying consolidated balance sheets. During the six months ended June 30, 2013, the majority member loaned the Company approximately \$10,366,000, which was used to repay interest of approximately \$1,166,000 and principal of \$9,200,000 owed to certain entities controlled by such member who had loaned monies to the Company under the note.

Signal Genetics, Inc. and Subsidiaries
Notes to Unaudited Consolidated Financial Statements

5. Notes Payable – (continued)

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 were advanced to pay for certain offering expenses was reclassified to amounts due to a related party on the consolidated balance sheet and is non-interest bearing and due on demand.

6. Stockholders' Equity/Members' Interests

Distributions — Distributions of \$90,000 and \$180,000 during the three and six months ended June 30, 2013, respectively, were made to a member of Myeloma Health LLC, a subsidiary of the Company. The distribution was covered by a dividend made by the Company to Myeloma Health LLC.

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, 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 IPO 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).

Restricted Stock Awards — Effective with the IPO, 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.

In connection with the IPO, the Company issued restricted stock unit awards for an aggregate of 831,593 shares of its common stock to certain employees of the Company with the following terms:

- Restricted stock unit award for 745,511 shares issued to the Company's Chief Executive Officer – 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 twelve-month, eighteen-month and twenty-four-month anniversary of the date of grant.
- Restricted stock unit award for 48,442 shares issued to the Company's Vice President of Research and Operations – 29,356 vested upon the date of grant but will not be issued until January 1, 2015 with the balance of 19,086 to vest in nineteen monthly installments beginning with the month in which the date of grant occurs on the last day of each calendar month. Issuance dates for the monthly installments will be on the first day of January and July of each calendar year.

- Restricted stock unit award for 37,640 shares issued to a consultant and company founder – 25% will vest and be issued upon the first anniversary of the grant date and the remaining will vest in thirty-six monthly installments beginning with the month of the first anniversary on the last day of each calendar month. Issuance dates for the monthly installments will be on the first day of January and July of each calendar year.

The Company has recorded stock compensation expense for the above restricted stock unit awards based upon the fair value of the awards on the date of grant. Stock compensation expense for the three and six months ended June 30, 2014 was approximately \$2,875,000.

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 restricted stock unit awards.

Signal Genetics, Inc. and Subsidiaries
Notes to Unaudited Consolidated Financial Statements

6. Stockholders' Equity/Members' Interests – (continued)

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 occurred as of the beginning of the respective period. At June 30, 2014, 278,865 vested restricted stock units and 552,728 unvested restricted stock units were excluded from basic and diluted net loss per share due to the net loss incurred during the respective periods. At June 30, 2013, previously issued equity incentive units were also excluded due to the net loss incurred during the respective periods.

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.

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 as per the termination agreement, which due to changes in estimates resulted in an additional charge of approximately \$46,000 to expense during the six months ended June 30, 2014, which is included in general and administrative expenses on the accompanying unaudited consolidated statements of operations. At June 30, 2014 and December 31, 2013, the total liability was approximately \$431,000 and \$579,000, respectively.

Letters of Credit — At June 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.

8. Subsequent Events

On July 21, 2014, the Company's Chief Financial Officer submitted his resignation, effective August 4, 2014, and the Company's Board of Directors appointed a new Chief Financial Officer, effective August 4, 2014. In connection with this appointment, the Company entered into a new employment agreement which provides for an annual base salary and potential bonus and certain change of control, termination and severance clauses that require the Company to make payments if certain events occur as defined in the agreement.

During July and August 2014, the Company granted 108,500 restricted stock unit awards and 101,000 stock options to employees and members of the board of directors.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read together with our consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q.

Overview

We are 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. 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 ("MM") performed at the University of Arkansas for Medical Sciences ("UAMS") in April 2010. Our flagship service offering is the Myeloma Prognostic Risk Signature ("MyPRS®") test. The MyPRS® test is a microarray-based gene expression profile ("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 the MyPRS® test aids physicians in selecting the optimal treatment regime for each patient's unique MM condition. To our knowledge, we are the only company marketing a GEP test for assessing the status of MM in the United States.

Our growth strategy includes the following key elements:

- Expand the U.S. market penetration of our MyPRS® test by increasing the geographic coverage of our sales force which currently consists of one employee.
 - Broaden the base of health care insurance companies that have approved reimbursements for MyPRS®.
- Expand the diagnostic indications for MyPRS® to include asymptomatic monoclonal gammopathies ("AMG"), the precursor condition to MM.
 - Establish partnerships with other reference laboratories to expand the market reach for MyPRS®.
- Pursue collaborations with pharmaceutical companies who focus on developing therapies to treat MM and its precursor disease.
 - Expand our information technology infrastructure to further improve our customer service experience.
 - Continue to leverage our relationship with UAMS via our exclusive license agreement.
 - Expand our test offering with the addition of conventional tests used by physicians who care for MM patients.
 - Pursue additional collaborations and in-licensing to expand our service offering.
- Continue to reduce the costs associated with the development, manufacture and interpretation of our proprietary genomic tests and services.

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

We believe a key challenge to achieving our growth strategy will be our ability to become contracted with additional payors beyond Medicare and Arkansas Blue Cross Blue Shield. In order to broaden our coverage policy approval to include a majority of the major health care insurance providers in the United States, we plan to hire experienced managed care professionals who can assist us with gaining contractual agreements with third-party payors.

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

Current Events

On June 17, 2014, we completed a corporate conversion and Signal Genetics LLC converted from a Delaware limited liability company to a Delaware corporation (the “Corporate Conversion”). Immediately prior to the Corporate Conversion pursuant to the terms of an Exchange Agreement, \$27,326,287 of a note payable – related party was converted into 2,732,629 Class C units (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, we completed the initial public offering (“IPO”) of shares of our common stock. We 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).

Results of Operations

Three Months Ended June 30, 2014 Compared to Three Months Ended June 30, 2013

Revenue

Revenue was \$1,273,571 for the three months ended June 30, 2014, an increase of \$170,667, or 15.5%, compared to \$1,102,904 for the same period in 2013. The increase in revenue was due to a combination of the following factors:

- A \$112,343 increase in revenue sourced either from or through our major customer, UAMS. Despite a 4% decrease in tests performed during the three months ended June 30, 2014 as compared to the same period in 2013 (899 tests performed in 2014 versus 936 tests performed in 2013), the average sales price per test increased by \$166.34, or 17%, primarily due to the mix in both the type of test being performed (research versus clinical) and the type of payor category.
- A \$58,324 increase in revenue sourced from non-UAMS customers. Despite a 27% decrease in revenue from pharmaceutical companies due to the completion of a clinical study in 2013 (\$5,512 decrease), revenue from other hospitals outside of UAMS increased by 45% (a \$63,836 increase). The increase in revenues resulted from a 39% increase in the number of tests performed during the three months ended June 30, 2014 as compared to the same period in 2013 (114 tests performed in 2014 versus 82 tests performed in 2013). The increase in volume was slightly offset by a decrease of 4 tests for pharmaceutical companies due to the completion of the clinical study in 2013. Additionally, we experienced a decrease in average selling price per test of \$42.99, or 2%. The decrease in average sales price was primarily due to the completion of the clinical study in 2013 which had a higher average selling price per test.

Cost of revenue

Cost of revenue was \$675,731 (53% of revenues) for the three months ended June 30, 2014, an increase of \$72,677, or 12.1%, compared to \$603,054 (55% of revenues) for the same period in 2013. The primary reason for the increase in dollars is due to 1) approximately \$98,000 in increased material and supply costs primarily due to increases in costs from our suppliers and increases in usage of certain materials offset by 2) approximately \$21,000 in decreased personnel cost.

Selling and marketing expenses

Selling and marketing expenses were \$73,754 for the three months ended June 30, 2014, an increase of \$6,701, or 10.0%, compared to \$67,053 for the same period in 2013. The primary reason for the increase in selling and marketing expenses was due to the increased revenues during the 2014 period resulting in increased commission expense. We plan to expand our sales force and marketing expenditures now that we have completed the IPO.

Stock Compensation

Stock compensation expense was \$2,874,740 for the three months ended June 30, 2014, compared to no expense for the same period in 2013. Stock compensation expense in 2014 relates to the restricted stock unit awards that were granted to three individuals in connection with the IPO and primarily relates to the portion of those awards that were immediately vested.

General and administrative expenses

General and administrative expenses were \$451,711 for the three months ended June 30, 2014, a decrease of \$18,639, or 4.0%, compared to \$470,350 for the same period in 2013. 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.

Research and development expenses

Research and development expenses were \$9,023 for the three months ended June 30, 2014, a decrease of \$13,797, or 60.5%, compared to \$22,820 for the same period in 2013. The primary reason for the decrease in research and development expenses was due to the abandonment of certain research projects that were deemed to no longer 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 \$477,561 for the three months ended June 30, 2014, compared to \$479,318 for the same period in 2013. The decrease was due to the Debt Conversion 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 \$(3,288,949) for the three months ended June 30, 2014 compared to a net loss attributable to stockholders of Signal Genetics, Inc. of \$(629,691) for the three months ended June 30, 2013.

Six Months Ended June 30, 2014 Compared to Six Months Ended June 30, 2013

Revenue

Revenue was \$2,364,494 for the six months ended June 30, 2014, an increase of \$122,202, or 5.4% compared to \$2,242,292 for the same period in 2013. The increase in revenue was due to a combination of the following factors:

- A \$44,122 increase in revenue sourced either from or through our major customer, UAMS. Despite an 11% decrease in tests performed during the six months ended June 30, 2014 as compared to the same period in 2013 (1,640 tests performed in 2014 versus 1,846 tests performed in 2013), the average sales price per test increased by \$154.20, or 15% primarily due to the mix in both the type of test being performed (research versus clinical) and the type of payor category.
- A \$78,080 increase in revenue sourced from non-UAMS customers. Despite a 52% decrease in revenue from pharmaceutical companies due to the completion of a clinical study in 2013 (\$37,825 decrease), revenue from other hospitals outside of UAMS increased by 39% (a \$115,905 increase). The increase in revenues resulted from a 30% increase in the number of tests performed during the six months ended June 30, 2014 as compared to the same period in 2013 (239 tests performed in 2014 versus 184 tests performed in 2013). The increase in volume was slightly offset by a decrease of 17 tests for pharmaceutical companies due to the completion of the clinical study in 2013. Additionally, we experienced a decrease in average selling price per test of \$138.00, or 7%. The decrease in average sales price was primarily due to the completion of the clinical study in 2013 which had a higher average selling price per test.

Cost of revenue

Cost of revenue was \$1,339,245 (57% of revenues) for the six months ended June 30, 2014, an increase of \$67,224, or 5.3%, compared to \$1,272,021 (57% of revenues) for the same period in 2013. The increase in dollars was primarily

due to 1) approximately \$108,000 in increased material and supply costs primarily due to increases in costs from our suppliers and increases in usage of certain materials offset by 2) approximately \$55,000 in decreased personnel cost.

Selling and marketing expenses

Selling and marketing expenses were \$146,824 for the six months ended June 30, 2014, a decrease of \$6,329, or 4.1%, compared to \$153,153 in the same period in 2013. The primary reason for the decrease in selling and marketing expenses was due to reduction of our sales staff. We plan to expand our sales force and marketing expenditures now that we have completed the IPO.

Stock Compensation

Stock compensation expense was \$2,874,740 for the six months ended June 30, 2014, compared to no expense for the same period in 2013. Stock compensation in 2014 relates to the restricted stock unit awards that were granted to three individuals in connection with the IPO and primarily relates to the portion of the awards that were immediately vested.

General and administrative expenses

General and administrative expenses were \$964,036 for the six months ended June 30, 2014, an increase of \$75,856, or 8.5%, compared to \$888,180 for the same period in 2013. The primary reason for the increase was due to an additional charge of \$46,000, which resulted from a change in estimate related to the termination agreement signed with the landlord of a previously abandoned lease, \$50,000 of additional consulting fees and \$17,000 in increased insurance expense related to our IPO, offset by \$48,000 of decreased legal costs primarily related to a tortious interference case which was initiated in 2012 and eventually settled in August 2013.

Research and development expenses

Research and development expenses were \$17,730 for the six months ended June 30, 2014, a decrease of \$50,833, or 74.1%, compared to \$68,563 in the same period in 2013. The primary reason for the decrease in research and development expenses was due to the abandonment of certain research projects that were deemed to not be viable.

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 \$1,016,647 for the six months ended June 30, 2014, compared to \$937,222 for the same period in 2013. The primary reason for the increase was due to increased borrowings on our note payable to the related party. Due to the Debt Conversion 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 \$(3,994,728) for the six months ended June 30, 2014 compared to a net loss attributable to stockholders of Signal Genetics, Inc. of \$(1,256,847) for the six months ended June 30, 2013.

Liquidity and Capital Resources

We had cash of \$7,696,325 at June 30, 2014 compared to \$209,348 at December 31, 2013, and total current liabilities of \$2,137,301 at June 30, 2014 compared to \$27,300,316 at December 31, 2013. As of June 30, 2014, we had working capital of approximately \$7,631,000.

Prior to our IPO, our principal sources of cash were primarily borrowings on our note payable to the related party. We received net proceeds of approximately \$6,144,000 from the IPO (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.

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

At June 30, 2014, following the Debt Conversion, the Corporation Conversion and the IPO, the Company had positive working capital and stockholders' equity. Although we are forecasting continued losses and negative cash flows as we fund our selling and marketing activities and research and development programs, we believe that we have enough cash on hand to support operations at least through August 2015. Going forward, as we continue our selling and marketing activities and research and development programs, we 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 we do not 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.

Operating activities

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

| | Six Months Ended June 30, | |
|--|------------------------------|---------------|
| | 2014 | 2013 |
| Net loss | \$(3,994,728) | \$(1,076,847) |
| Non-cash adjustments | 4,000,485 | 998,841 |
| Changes in operating assets and liabilities | (390,980) | (342,190) |
| Net cash used in operating activities of discontinued operations | - | (93,875) |
| Net cash used in operations | \$(385,223) | \$(514,071) |

We used \$385,223 of net cash in operating activities in the six months ended June 30, 2014. Non-cash adjustments primarily reflect stock compensation of \$2,874,740 and non-cash accrued interest on the note to the related party of \$1,007,733. Changes in operating assets and liabilities primarily reflect a decrease in inventory of \$163,501, offset by increases in accounts receivable of \$365,395 and a decrease in lease termination/abandonment payable of \$242,542. The increase in inventory was primarily due to timing of the receipt of supplies. The increase in accounts receivable was due to increased revenues in 2014 from our non-contracted customers, who have historically taken longer to pay. Our days sales outstanding (“DSO”) for the six months ended June 30, 2014 also increased to 94 days from 89 days for the year ended December 31, 2013, due to the increased revenues from non-contracted customers. 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 \$514,071 of net cash in operating activities in the six months ended June 30, 2013. Non-cash adjustments primarily reflect non-cash accrued interest on the note to the related party of \$923,898. Changes in operating assets and liabilities primarily reflect decreases in accounts receivable and inventory of \$65,658 and \$78,440, respectively, offset by decreases in accounts payable and other accrued expenses and the lease termination/abandonment payable of \$298,669 and \$157,988, respectively. 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 DSO for the six months ended June 30, 2013 was 94 days. The decrease in inventory was primarily due to a combination of timing of purchases combined with a decrease in material costs due to re-negotiations with a key supplier. The decreases in accounts payable and other accrued expenses were primarily due to payments and reductions in fees for legal and consulting services. The decrease in the lease termination/abandonment payable was due to payments made on the now terminated lease. The net cash used in operating activities of discontinued operations was primarily due to payments made for remaining liabilities of one of our subsidiaries.

Investing activities

We had \$4,287 of net cash used in investing activities in the six months ended June 30, 2014 due primarily to purchases of property and equipment.

We had \$10,498 of net cash provided by investing activities in the six months ended June 30, 2013 due primarily to decreases in security deposits.

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

Financing activities

We generated \$7,876,487 of net cash from financing activities during the six months ended June 30, 2014, primarily due to proceeds of \$8,500,000 received from the IPO and \$795,000 received from our note payable - related party, offset by \$1,387,064 paid for deferred issuance costs.

We generated \$638,099 of net cash from financing activities during the six months ended June 30, 2013, primarily due to the net proceeds of \$848,544 from our note payable - related party, offset by distributions of \$180,000.

Description of Indebtedness

Prior to the IPO, we historically 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, which occurred prior to the Corporate Conversion. As of June 30, 2014, the aggregate amount payable 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 June 30, 2014 was approximately \$11,000. The note is payable in thirty-six monthly installments of \$5,320 through August 2014. The effective interest rate of the note is 3.4%. The related equipment is collateral for the note.

Related Party Transactions

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

Off-Balance Sheet Arrangements

As of each of June 30, 2014 and December 31, 2013, we were contingently liable for a standby letter of credit for \$50,000 issued as a security deposit on a lease. We have approximately \$50,000 of cash in a restricted account that is held as collateral for this letter of credit. Otherwise, we have no off-balance sheet arrangements.

Commitments and Contingencies

As of each of June 30, 2014 and December 31, 2013, 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 consolidated financial statements.

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 consolidated financial statements require significant judgments and estimates. For additional information relating to these and other accounting policies, see Note 2 to our audited consolidated financial statements, appearing in the final prospectus filed with the SEC on June 19, 2014.

Revenue Recognition

We recognize revenue from testing services in accordance with the Financial Accounting Standards Board Accounting Standards Codification, or FASB ASC, 605, Revenue Recognition, which requires that four basic criteria be met before revenue can be recognized: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred and title and the risks and rewards of ownership have been transferred to the client or services have been rendered; (3) the price is fixed or determinable; and (4) collectability is reasonably assured. The Company records revenues when

confirmed tests results are delivered to the ordering physicians which are evidence that the services have been performed. Revenues are recorded on an accrual basis as the contractual obligations are completed and as a set of assays is processed through our laboratory under a specified contractual protocol. Revenues are billed to various payors, including Medicare, contracted insurance companies, directly billed customers (UAMS, pharmaceutical companies, reference laboratories and hospitals) and non-contracted insurance companies. The Company reports revenues from Medicare, contracted insurance companies and directly billed customers based on the contractual rate. The contractual rate is based on established, agreed upon rates between the Company and the respective payor and is the price invoiced by the Company. The Company reports revenues from non-contracted payors based on the amount expected to be collected which is based on the historical collection experience of each payor or payor group, as appropriate. The difference between the amount billed and the amount estimated to be collected from non-contracted payors is recorded as a contractual allowance at the same time the revenue is recognized, to arrive at reported net revenue. We do not record revenue from individuals for billings, deductibles or co-pays until cash is collected as collectability is not assured at the time services are provided, therefore there are no accounts receivable from self-payors. Gross revenues from individuals have been immaterial.

Our estimates of net revenue for non-contracted insurance companies are subject to change based on the contractual status and payment policies of the third-party payors with whom we deal. We regularly refine our estimates in order to make our estimated revenue as accurate as possible based on our most recent collection experience with each third-party payor. We regularly review our historical collection experience for non-contracted payors and adjust our expected revenues for current and subsequent periods accordingly. During the year ended December 31, 2012, we did not make any adjustments to our original revenue estimates for 2011, our first year of operations. During the year ended December 31, 2013 we recorded a change in estimate related to non-contracted revenues recorded during 2012 of \$57,000 which caused a decrease in overall net revenues in 2013. This represented 6% of total non-contracted revenues during 2012 and 1% of our total net revenues for 2012. If we have a similar percentage reduction of 6% in our estimated amount to be collected from non-contracted payors on the uncollected accounts receivable from non-contracted payors at June 30, 2014 of \$691,000, this could result in a \$41,000 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. We have not had any bad debts from any of our contracted customers or noncontracted insurance companies, therefore there is no allowance for doubtful accounts recorded as of June 30, 2014 and December 31, 2013.

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 June 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:

| | June 30, 2014 | | | | |
|------------------------------------|---------------|------------|------------|-----------|-------------|
| | 0-30 Days | 31-60 Days | 61-90 Days | Over 90 | Total |
| Medicare | \$24,348 | \$ 35,586 | \$ 14,983 | \$126,523 | \$201,440 |
| Contracted insurance companies | - | 24,300 | 2,000 | 89,736 | 116,036 |
| Direct bill | 324,987 | 17,660 | 11,880 | — | 354,527 |
| Non-contracted insurance companies | 102,700 | 70,850 | 114,094 | 1,724,104 | 2,011,748 |
| | 452,035 | 148,396 | 142,957 | 1,940,363 | 2,683,751 |
| Less: Contractual allowances | 59,053 | 36,208 | 64,977 | 1,164,108 | 1,324,346 |
| Accounts receivable, net | \$392,982 | \$ 112,188 | \$ 77,980 | \$776,255 | \$1,359,405 |

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

The days sales outstanding for the six months ended June 30, 2014 and the year ended December 31, 2013 was 94 and 89 days, respectively. The increase in the number of days 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 result in our ability to fully collect on 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 18% and 13% of our total revenues during the six months ended June 30, 2014 and the year ended December 31, 2013, respectively. Since these customers are slower to pay, our accounts receivable over 90 days will increase if revenues to these customers continues to 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.

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 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 consolidated 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable to smaller reporting companies.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

In evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were not effective, at the reasonable assurance level, as of the end of the period covered by this report to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934, as amended, (1) is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and (2) is accumulated and communicated to management, including our Chief Executive Officer and our Chief Financial Officer as appropriate to allow timely decisions regarding required disclosure because of the continued existence of the material weakness in our internal control over financial reporting described below under “—Internal Control Over Financing Reporting.”

Internal Control Over Financial Reporting

We are not required to comply with Section 404 of the Sarbanes-Oxley Act under applicable rules for newly public companies and are therefore not required to make an assessment of the effectiveness of our internal control over financial reporting. As a result, our management has not yet performed an evaluation of our internal control over financial reporting. Further, our independent registered public accounting firm is not yet required to, nor have they been engaged to express, nor have they expressed, an opinion on the effectiveness of our internal control over financial reporting. However, in connection with the audit of our consolidated financial statements as of and for the years ended December 31, 2013 and 2012, we identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis. The material weakness identified was due to a lack of accounting and finance personnel and the reliance on outside consultants. As such, our controls over financial reporting were not designed or operating effectively, and as a result there were adjustments required in connection with closing our books and records and preparing our December 31, 2013 and 2012 consolidated financial statements that were made by outside consultants.

In an effort to remediate this material weakness, effective August 4, 2014, we hired a Chief Financial Officer with public company financial reporting expertise to build our financial management and reporting infrastructure, and further develop and document our accounting policies and financial reporting procedures.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting during the period covered by this Quarterly Report on Form 10-Q.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

Not applicable.

Item 1A. 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q.

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. Since our inception, we have devoted substantial effort to develop our products and services and have incurred losses and negative cash flows from operations. We expect our losses to continue as a result of ongoing research and development expenses and increased selling and marketing costs. These losses have had, and will continue to have, an adverse effect on our working capital, total assets and members' equity. Because of the numerous risks and uncertainties associated with our research, development and commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows.

We will need to raise additional capital.

We will need to secure additional financing in order to support our operations. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all. Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative, selling and marketing and research and development activities are forward-looking statements and involve risks and uncertainties.

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

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."

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

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

Due to the early stage nature of our business and our limited selling and marketing activities to date, we have historically derived a significant portion of our revenue from a limited number of test ordering sites. In particular, the most significant portion of our revenue is generated from our MyPRS® test services provided at our clinical laboratory in Little Rock, Arkansas for UAMS. Revenue sourced either from or through UAMS accounted for approximately 81% of our revenue for the six months ended June 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 June 30, 2014, December 31, 2013 and 2012 accounted for approximately 65%, 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 laboratory located in Little Rock, Arkansas, which has been certified under the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”). MyPRS® is not assigned a specific CPT code, but our local MAC and Blue Cross Blue Shield of Arkansas have established a specific payment amount for the test, which is billed under a nonspecific code. We are in varying stages of research and development for other diagnostic tests that we may offer. We do not currently offer any other testing services. If we are unable to increase sales of MyPRS® or to successfully develop and commercialize other diagnostic tests, we will not produce sufficient revenues to become profitable. Our laboratory testing services are expensive and may be a negative factor for reimbursement.

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

Our current business strategy focuses on discovering, developing and commercializing molecular diagnostic tests and services. We believe the success of our business depends on our ability to fully commercialize our existing diagnostic tests and services and to develop and commercialize new diagnostic tests. In particular, it is essential to our business strategy that we expand the indications for use of MyPRS®. The first additional indications for which we hope MyPRS® will be used include monoclonal gammopathy of undetermined significance (MGUS) and asymptomatic or ‘smoldering’ multiple myeloma (AMM). Collectively, these precursor conditions are referred to as AMG. However, we may be unsuccessful and MyPRS® may never be used for these indications. We may not succeed because it may never be accepted by the oncologist community, third-party payors may not pay for it, and the recent peer-reviewed publication that could support these indications for MyPRS® may not be sufficient to drive adoption support coverage and reimbursement and the results may not be duplicated in additional studies.

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

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

Tests that appear promising in early development may fail to be validated in subsequent studies, and even if we achieve positive results, we may ultimately fail to obtain the necessary regulatory clearances, approvals or coverage and reimbursement. There is substantial risk that our research and development projects will not result in

commercially viable tests, and that success in early clinical trials will not be replicated in later studies. At any point, we may abandon development of a test or be required to expend considerable resources repeating clinical trials, which would adversely impact our ability to generate revenues from that test. In addition, as we develop tests, we will have to make significant investments in research, development and marketing resources. If a clinical validation study of a particular test fails to meet its endpoint, we might choose to abandon the development of that test. Further, our ability to develop and launch diagnostic tests will likely depend on our receipt of additional funding beyond that obtained by this IPO. If our discovery and development programs yield fewer commercial tests than we expect, we may be unable to execute our business plan, which may adversely affect our business, financial condition and results of operations.

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

As part of our business strategy, we may pursue acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our offerings or distribution. For example, we may seek to purchase or license proprietary tests for other cancer indications or tests that complement our current offering for MM patients. We have limited experience with acquiring other companies and limited experience with forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

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

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

We currently offer our proprietary laboratory services in our CLIA-certified laboratory. Because we currently offer these tests and services solely for use within our laboratory, we believe we may market the tests as Laboratory Developed Tests ("LDTs"). Under current U.S. Food and Drug Administration ("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 ("PMAs"), for LDTs. Please 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." We may be unable to obtain PMAs for our tests, which could make it impossible for us to legally market our services, which would mean that our business may not be viable.

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

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

journals is subject to a peer review process and peer reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our studies published in peer-reviewed journals would limit the adoption of our tests and future coverage and reimbursement decisions for our tests could be negatively affected.

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

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

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

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

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

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

Our success depends on the market's confidence that we can continue to provide reliable, high-quality diagnostic tests. We believe that our customers are likely to be particularly sensitive to test defects and errors, such as false positive or false negative results which could affect the patient's eventual diagnosis and/or 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 ("ASRs"), which serve as building blocks in the diagnostic tests we conduct in our laboratory. These suppliers are subject to regulation by the FDA, and must comply with federal regulations related to the manufacture and distribution of ASR products. Because we cannot ensure the actual production or manufacture of

such critical equipment and materials, or the ability of our suppliers to comply with applicable legal and regulatory requirements, we may be subject to significant delays caused by interruption in production or manufacturing. If any of our third-party suppliers or manufacturers were to become unwilling or unable to provide this equipment or these materials in required quantities or on our required timelines, we would need to identify and acquire acceptable replacement sources on a timely basis. While we have developed alternate sourcing strategies for the equipment and materials we use, we cannot be certain that these strategies will be effective and even if we were to identify other suppliers and manufacturers for the equipment and materials we need to perform our specialized diagnostic services, there can be no assurance that we will be able to enter into agreements with such suppliers and manufacturers or otherwise obtain such items on a timely basis or on acceptable terms, if at all. If we encounter delays or difficulties in securing necessary laboratory equipment or materials, including consumables, we would face an interruption in our ability to perform our specialized diagnostic services and experience other disruptions that would adversely affect our business, results of operations and financial condition.

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

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

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

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

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

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

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

We hold a number of insurance policies, including product liability insurance, property insurance, 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.

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 recently approved two such agents — Xalkori crizotinib from Pfizer Inc. along with its companion anaplastic lymphoma kinase fluorescence in situ hybridization (FISH) test from Abbott Laboratories, Inc. and Zelboraf vemurafenib from Genentech USA Incorporated and Daiichi-Sankyo Inc. along with its companion B-RAF kinase V600 mutation test from Roche Molecular Systems, Inc. These two recent FDA approvals are only the second and third instances of simultaneous approvals of a drug and companion diagnostic, the first being the 1998 approval of Genentech, Inc.'s Herceptin trastuzumab for HER2 positive breast cancer along with the HercepTest from partner Dako A/S.

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

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

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

In recent years, we have incurred significant costs in connection with the development of our diagnostic tests. For the six months ended June 30, 2014, our research and development expenses were \$18,000, which was 0.7% of our net revenue, and our selling and marketing expenses were \$147,000, which was 6.2% 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 biopsy samples, as well as information pertaining to their associated clinical outcomes. Other companies often compete with us for access. Additionally, the process of negotiating access to archived samples is lengthy, because it typically involves numerous parties and approvals to resolve complex issues such as usage rights, institutional review board approval, privacy rights, publication rights, intellectual property ownership and research parameters.

UAMS and other institutions provide us with tissue samples and other biological materials that we use in developing and validating our tests. We do not have written agreements with some of these third parties, and, in many of the cases in which the agreements are in writing, our relationships with such third parties are terminable on 30 days' notice or less. Disagreements or disputes might cause delays or termination of the research, development or commercialization of testing systems or additional test indications, might lead to additional responsibilities or costs to us or might result in litigation or arbitration, any of which could divert management attention and resources and be time-consuming and expensive. If one or more of these suppliers terminate their relationship with us, we will need to identify other third parties to provide us with tissue samples and biological materials, which could result in a delay in our research and development activities and negatively affect our business. In addition, as we grow, research and academic institutions may begin to seek financial contributions from us, which may negatively affect our results of operations. Potential suppliers may elect not to work with us based on their assessment of our financial, regulatory or intellectual property position. Even if we establish new agreements, this may not result in the successful development of future testing systems or additional test indications.

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

Our success in implementing our business strategy depends largely on the skills, experience and performance of the Chairman of our board of directors, Bennett S. LeBow, key members of our executive management team and others in key management positions, including Samuel D. Riccitelli, our President and Chief Executive Officer, and Tamara A. Seymour, our Chief Financial Officer. The collective efforts of each of these persons working as a team will be critical to us as we continue to develop our technologies, tests and research and development and sales programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies and implementing our business strategy. Our President and Chief Executive Officer, Samuel D. Riccitelli, our Chief Financial Officer, Tamara A. Seymour, our Senior Vice President of Commercial Strategy and Business Development, Michael C. Cerio, 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.

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

Our success in selling our clinical laboratory services, diagnostic tests and any other tests or products that we are able to develop will require us to expand our sales force in the United States and internationally by recruiting additional sales representatives with extensive experience in oncology and close relationships with medical oncologists, surgeons, pathologists and other hospital personnel. To achieve our marketing and sales goals, we will need to substantially expand our sales and commercial infrastructure, with which to date we have had little experience. Sales professionals with the necessary technical and business qualifications are in high demand, and there is a risk that we may be unable to attract, hire and retain the number of sales professionals with the right qualifications, scientific backgrounds and relationships with decision-makers at potential customers needed to achieve our sales goals. We may face competition from other companies in our industry, some of whom are much larger than us and who can pay greater compensation and benefits than we can, in seeking to attract and retain qualified selling and marketing employees. If we are unable to hire and retain qualified selling and marketing personnel, our business will suffer.

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

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

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

These factors could harm our business or results of operations.

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

The marketing, sale and use of our tests could lead to the filing of product liability claims were someone to allege that our tests failed to perform as designed. We may also be subject to liability for errors in the test results we provide to pathologists and oncologists or for a misunderstanding of, or inappropriate reliance upon, the information we provide. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

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

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

Our activities currently require the controlled use of potentially harmful biological materials and hazardous materials and chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject to, on an ongoing basis, federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant and could have a material adverse effect on our financial condition, results of operations and cash flows. In the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines.

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

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

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

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

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

We depend on information technology and telecommunications systems for significant aspects of our operations. In addition, our third-party billing and collections provider depends upon telecommunications and data systems provided by outside vendors and information we provide on a regular basis. These information technology and telecommunications systems support a variety of functions, including test processing, sample tracking, quality control, customer service and support, billing and reimbursement, research and development activities and our general and administrative activities. Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our systems are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from processing tests, providing test results to pathologists, oncologists, billing payors, processing reimbursement appeals, handling patient or physician inquiries, conducting research and development activities and managing the administrative aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business. Furthermore, we depend on FedEx as our courier. Any disruption in any of our mail services or transportation logistics could result in spoiled or lost samples, which could reduce revenue. Moreover, we are required to comply with laws governing the transmission, security and privacy of health information that

require significant compliance costs, and any failure to comply with these laws could result in material criminal and civil penalties and civil liabilities.

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

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

Regulatory Risks Relating to Our Business

Our business may be adversely impacted by the recent sequestration signed into law in the United States.

On March 1, 2013, most agencies of the federal government automatically reduced their budgets according to an agreement made by Congress in 2012 known as “sequestration.” Originally devised as an incentive to force Congressional agreement on budget issues, the sequestration order was approved on March 1, 2013 by the President of the United States. For claims submitted with dates of service or dates of discharge after April 1, 2013, these cuts will result in Medicare payments to health care providers, health care plans and drug plans being reduced by 2%.

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

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

- Requires each medical device manufacturer to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices, beginning in 2013. This tax may apply to some or all of the current tests that we offer and other tests which are in development.
- Mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule (the “CLFS”), of 1.75% for the years 2011 through 2015 and includes a productivity adjustment that reduces the Consumer Price Index (the “CPI”), market basket update beginning in 2011. These changes in payments apply to some or all of the clinical laboratory test services we furnish to Medicare beneficiaries.
- Establishes an Independent Payment Advisory Board to reduce the per capita rate of growth in Medicare spending. The Independent Payment Advisory Board has broad discretion to propose policies, which may have a negative impact on payment rates for services, including clinical laboratory services, beginning in 2016, and for hospital services beginning in 2020. These proposals will automatically be implemented unless Congress enacts alternative proposals that achieve the same saving targets.

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

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

Other legislative changes have been proposed and adopted since PPACA was enacted. On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions in Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions to

Medicare payments to providers and suppliers of 2%, starting in 2013. Subsequent annual reductions, currently scheduled for each year through 2021, are limited to 2% per fiscal year. The full impact on our business of PPACA and the new law is uncertain.

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

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

If any of our laboratory services are paid under the Medicare Physician Fee Schedule, under the current statutory formula, the rates for these services would be updated annually. For the past several years, the application of the statutory formula would have resulted in substantial payment reductions if Congress had failed to intervene. In the past, Congress has passed interim legislation to prevent the decreases. On November 27, 2013, CMS issued its 2014 Physician Fee Schedule Final Rule, or the 2014 Final Rule. In the 2014 Final Rule, CMS called for a reduction of approximately 20.1% in the 2014 conversion factor that is used to calculate physician reimbursement. This legislatively required reduction in physician payments was postponed until March 31, 2014, when President Obama signed into law on December 26, 2013 H.J. Res. 59, the Bipartisan Budget Act of 2013, which included the Pathway for the SGR Reform Act of 2013. This provided a short-term reprieve from the Medicare Physician Fee Schedule cut. The “Protecting Access to Medicare Act of 2014,” which was signed into law on April 1, 2014, further extended this reprieve until December 31, 2014 and provided for a zero percent update through March 31, 2015. In order to pay for the cost of eliminating or delaying the required payment reduction, Congress would have to cut spending for other programs or raise revenues. In addition, there may be unrelated legislation (e.g., resulting from budget and debt ceiling negotiations) that may require spending cuts. In either case (e.g., offsetting the cost of maintaining physician payments at their current level and/or overall Medicare payment cuts due to budget negotiations), Medicare Physician Fee Schedule payments for clinical laboratory services could be reduced. We cannot predict whether such payments cuts will occur or whether other reductions in Medicare or Medicaid spending will be enacted. If any of our tests are paid under the Medicare Physician Fee Schedule and Congress fails to act to offset legislatively required reductions in Physician Fee Schedule payments, the resulting decrease in payment could adversely impact our revenues and results of operations.

In addition, many of the CPT codes that we may use to bill our tests were recently revised by the AMA, effective January 1, 2013. The adoption of analyte specific codes will allow payors to better identify tests being performed. This could lead to limited coverage or non-coverage decisions or payment denials. In the 2014 Final Rule, CMS announced that it has decided to keep the new molecular codes on the CLFS. CMS has also announced that it will price the new codes using a “gapfilling” process by which it will refer the codes to the MACs to allow them to determine an appropriate price. In addition, it has also stated that it will not separately reimburse the algorithm portion of certain of the new codes for MAAAs, because it does not believe the algorithm qualifies as a clinical laboratory test. MACs are issuing payment and coverage decisions but the payment levels and the methodology for determining payment by Medicare and commercial health plans still remain largely unresolved. Our reimbursement could be adversely affected by any final CMS action in this area. Furthermore, CMS has given itself the authority to revise payment rates for all tests paid under the CLFS. It is anticipated that CMS will use this new authority to reduce payment for many clinical laboratory services. Even though we use an unlisted CPT code to bill for MyPRS® and reimbursement is determined by the local MAC, this authority could affect our reimbursement in the future. If CMS reduces reimbursement for new test codes or does not pay for the algorithmic portion of our MAAA tests, then our revenues will be adversely affected. There can be no guarantees that Medicare and other payors will establish positive or adequate coverage policies or reimbursement rates.

The “Protecting Access to Medicare Act of 2014,” which was signed into law on April 1, 2014, contains provisions that significantly affect Medicare payment for tests that are reimbursed under the CLFS. Starting in 2017, Medicare payment for each test will be based on the amount of payment being made by private payors for that test. Private payor payment amounts, adjusted for discounts and other price concessions, will be collected by laboratories, starting in 2016, and submitted to CMS so that market-based payment rates can be calculated. New tests will generally be paid using the crosswalk or gapfilling methodology described elsewhere in this Quarterly Report on Form 10-Q. However, some new tests, termed Advanced Diagnostic Laboratory Tests, will be paid based on the laboratory’s actual list charge for a brief period of time until private payor payment data is available. Furthermore, in order to facilitate implementation of the new payment methodology, starting in 2016, CMS is required to assign specific billing codes to many CLFS tests existing at the time of enactment and to all new CLFS tests. The Secretary of Health and Human Services (“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. Moreover, Congress has proposed on several occasions to impose a 20% coinsurance on patients for clinical laboratory tests reimbursed under the CLFS, which would require us to bill patients for these amounts.

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

Pathologists and oncologists may not order our molecular diagnostic tests unless third-party payors, such as managed care organizations and government payors such as Medicare and Medicaid, pay a substantial portion of the test price. Coverage and reimbursement by a third-party payor may depend on a number of factors, including a payor's determination that tests using our technologies are:

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

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

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

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

For the six months ended June 30, 2014, we derived approximately 18% of our total revenue from private insurance, including managed care organizations and other health care insurance providers, 16% from government payor programs, most of which was derived from Medicare, and 66% from direct-bill customers, including hospitals and other laboratories. In addition, for the year ended December 31, 2013, we derived approximately 13% of our total revenue from private insurance, including managed care organizations and other health care insurance providers, 14% from government payor programs, most of which was derived from Medicare, and 73% from direct-bill customers,

including hospitals and other laboratories. Medicare and other third-party payors may withdraw their coverage policies or cancel their contracts with us at any time, review and adjust the rate of reimbursement or stop paying for our tests altogether, which would reduce our total revenues.

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

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

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

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

Under current Medicare billing rules, claims for our tests performed on Medicare beneficiaries who were hospital patients when the tumor tissue samples were obtained and whose tests were ordered less than 14 days from discharge must be included in the payment that the hospital receives for the patient services provided. Accordingly, we must bill individual hospitals for tests performed on Medicare beneficiaries during these timeframes in order to receive payment for our tests. Because we generally do not have a written agreement in place with these hospitals that purchase these tests, we may not be paid for our tests or may have to pursue payment from the hospital on a case-by-case basis. This could be especially problematic for us if the hospital does not receive separate payment from Medicare for our test.

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

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

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

We are subject to CLIA, a federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. Our clinical laboratory must be certified under CLIA in order for us to perform testing on human specimens. In addition, our proprietary tests must also be categorized as part of our CLIA certification so that we can offer them in our laboratory. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We have a current certificate under CLIA to perform high complexity testing. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make periodic inspections of our clinical reference laboratory outside of the renewal process.

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

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

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

Although 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 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. 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.

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 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 additional 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 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 the 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 the 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 the FDA or foreign authorities will agree with our conclusions regarding our test results. Success in early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and studies. If we are required to conduct pre-market clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our test development costs and delay commercialization. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial. Moreover, the clinical trial process may fail to demonstrate that our tests are effective for the proposed indicated uses, which could cause us to abandon a test candidate and may delay development of other tests.

We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform 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 (“HIPAA”), which establishes federal crimes for knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the federal Physician Payment Sunshine Act requirements under PPACA, which require manufacturers of drugs, devices, biologics and medical supplies to report to HHS information related to payments and other transfers of value made to or at the request of covered recipients, such as physicians and teaching hospitals, and physician ownership and investment interests in such manufacturers. Payments made to physicians and research institutions for clinical trials are included within the ambit of this law; and
- state law equivalents of each of the above federal laws, such as anti-kickback, physician self-referral and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

We seek to comply with these laws. However, it is possible that we could be the subject of a government investigation regarding our compliance with these laws and that the government could take the position that we are not in compliance with one or more of them. In such case, we may be judged to be in violation of those laws and subject to civil and criminal penalties. In addition, many of these laws and regulations are vague or indefinite and have not been interpreted by the courts or regulatory agencies. These laws and regulations may be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that could subject us to liability and/or require us to make changes in our operations.

We believe that federal and state governments continue to strengthen their enforcement efforts against health care fraud. In addition, PPACA increases the funding, power, penalties and remedies to pursue suspected cases of fraud and abuse and provides the government with expanded opportunities to pursue actions under the federal Anti-Kickback Statute, the False Claims Act, and the Stark Law. For example, PPACA narrowed the public disclosure bar under the False Claims Act, allowing increased opportunities for whistleblower litigation. In addition, the legislation modified the intent standard under the federal Anti-Kickback Statute, making it easier for prosecutors to prove that alleged violators had met the requisite knowledge requirement. PPACA also requires providers and suppliers to report any Medicare or Medicaid overpayment and return the

overpayment on the later of 60 days of identification of the overpayment or the date the cost report is due (if applicable), or all claims associated with the overpayment will become false claims. PPACA also provides that any claim submitted from an arrangement that violates the Anti-Kickback Statute is a false claim. Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, and/or exclusion from participation in Medicare, Medicaid or other state or federal health care programs, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business, our financial condition and results of operations.

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 ("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 (the “HITECH Act”), enacted pursuant to the American Recovery and Reinvestment Act of 2009 (the “ARRA”), made sweeping changes to the health information privacy and security regulations of HIPAA by expanding the scope and application of the statute. These changes include, among other things, (i) establishing an affirmative obligation to provide patient data breach notification in the event of the unauthorized acquisition, access, use or disclosure of unsecured PHI; (ii) elaborating upon the standard for “minimum necessary” uses and disclosures of PHI by a covered entity (iii) restricting certain uses of PHI for marketing purposes (by expanding the definition of marketing activities requiring authorization); (iv) prohibiting certain sales of PHI; (v) establishing an affirmative obligation to provide an accounting of disclosures made for payment, treatment and health care operations (up to 3 years made through an electronic health record); (vi) requiring covered entities to agree to individuals’ requests to restrict disclosure of PHI in certain circumstances; (vii) applying the security regulations and certain provisions of the privacy regulations to business associates; and (viii) modifying an individuals’ right to access PHI in an electronic format. HHS issued modifications to the HIPAA Regulations, effective March 26, 2013, implementing some of these changes including the obligation to provide patient data breach notifications, which subject the Company to additional administrative requirements in the U.S. With regard to the accounting of disclosures, the HITECH Act provides for removing the exception in the existing HIPAA privacy regulations’ accounting of disclosures of PHI requirement for disclosures of PHI for payment, treatment, and health care operations purposes made through an electronic health record (within the past 3 years). HHS issued proposed regulations to implement this provision of the HITECH Act in May 2011, but those regulations have not been finalized.

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

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

HIPAA, the HITECH Act and state privacy restrictions, which could result in the incurrence of significant monetary penalties.

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

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

Intellectual Property Risks Related to Our Business

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

Our ability to protect our proprietary discoveries and technologies affects our ability to compete and to achieve sustained profitability. Currently, we rely on a combination of issued U.S. patents, U.S. and foreign patent applications, copyrights, trademarks and trademark applications, confidentiality or non-disclosure agreements, material transfer agreements, licenses, work-for-hire agreements and invention assignment agreements to protect our intellectual property rights. We also maintain certain company know-how, trade secrets and technological innovations designed to provide us with a competitive advantage in the market place as trade secrets.

Currently, we are the worldwide exclusive licensee, in our licensed field, of 11 issued U.S. patents, 1 Japanese patent and 22 pending patent applications, which include both U.S. (1 of which has recently been allowed) and foreign patent applications, relating to various aspects of our technology. Of the 22 pending patent applications, four are owned outright by Signal Genetics, Inc. Our exclusive field of use covers, inter alia, therapeutic, diagnostic, prognostic, and personalized medicine applications worldwide, excluding applications using fluorescence in situ hybridization (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 (the "USPTO"), as well as counterpart agencies and bodies in corresponding foreign jurisdictions, may change the standards of patentability and any such changes could have a negative impact on our business.

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

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

In addition, on February 5, 2010, the Secretary's Advisory Committee on Genetics, Health and Society voted to approve a report entitled "Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests." That report defines "patent claims on genes" broadly to include claims to isolated nucleic acid molecules as well as methods of detecting particular sequences or mutations. The report also contains six recommendations, including the creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale or selling a test developed under the patent for patient care purposes, or for anyone using the patent-protected genes in the pursuit of research. The report also recommended that the Secretary should explore, identify and implement mechanisms that will encourage more voluntary adherence to current guidelines that promote nonexclusive in-licensing of diagnostic genetic and genomic technologies. It is unclear whether HHS will act upon these recommendations, or if the recommendations would result in a change in law or process that could negatively impact our patent portfolio or future research and development efforts.

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

Our 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. patents and pending U.S. and foreign applications as the worldwide exclusive licensee in our licensed field from UAMS.

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

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

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

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

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

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

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

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

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

We 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

We are a “controlled company,” and qualify for exemptions from certain corporate governance requirements. Despite the availability of these exemptions, we have agreed with the underwriters of our IPO that we will not rely on these exemptions for a period of two years following the offering. However, to the extent we still qualify, we may in the future elect to rely on these exemptions, and to the extent we do, our stockholders will not have the same protections afforded to stockholders of companies that are subject to such requirements.

Because Bennett S. LeBow, our Chairman, through his control of LeBow Alpha LLP (“LeBow Alpha”), controls more than 50% of the outstanding voting power of our common stock, we are deemed a “controlled company” within the meaning of NASDAQ corporate governance standards. Under the rules of NASDAQ, a “controlled company” 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 have agreed with the underwriters from our IPO that we will not rely on these exemptions for a period of two years following the offering. However, to the extent we still qualify, we may in the future elect to rely on these exemptions, and to the extent we do, our stockholders will not have the same protections afforded to stockholders of companies that are subject to such requirements.

Our majority stockholder has the ability to control significant corporate activities and our majority stockholder’s interests may not coincide with yours.

For so long as LeBow Alpha retains its ability to control over 50% of the voting power of our outstanding common stock, 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 include:

- the election of our board of directors and the appointment and removal of our officers;
- mergers and other business combination transactions, including proposed transactions that would result in our stockholders receiving a premium price for their shares;
 - other acquisitions or dispositions of businesses or assets;
 - incurrence of indebtedness and the issuance of equity securities;
 - repurchase of stock and payment of dividends; and
- the issuance of shares to management under our equity incentive plans.

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

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

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- the authorized number of directors can be changed only by resolution of our board of directors;
- our bylaws may be amended or repealed by our board of directors or our stockholders;
- stockholders may not call special meetings of the stockholders or fill vacancies on the board of directors;
- our board of directors is 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.

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

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

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than \$5.00 (other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). The OTCBB does not meet such requirements and if the price of our common stock drops to less than \$5.00, our common stock will be deemed penny stocks. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that prior to effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser’s written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stock holders may have difficulty selling their

shares.

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

Prior to our IPO, there was no public market for our common stock. Although our common stock is listed on The NASDAQ Capital Market, 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.

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. The market price for our common stock may be influenced by many factors, including:

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- 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.

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 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, 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 our IPO are freely tradable, without restriction, in the public market, except for any shares sold to our affiliates.

In connection with our IPO, we, our officers and directors and holders of our outstanding common stock agreed, subject to limited exceptions, not to issue, sell or transfer any shares of common stock for 180 days after June 17, 2014 without the consent of Aegis Capital Corp. However, Aegis Capital Corp. may release these shares from any restrictions at any time. We cannot predict what effect, if any, market sales of shares held by any stockholder or the availability of shares for future sale will have on the market price of our common stock.

All of the shares of our common stock outstanding immediately prior to the IPO may be sold in the public market by our stockholders on or about 181 days after June 17, 2014, although the shares held by LeBow Alpha will be subject to volume and other limitations imposed under the federal securities laws. Sales of substantial amounts of our

common stock in the public market, or the perception that such sales could occur, could adversely affect the market price of our common stock and could materially impair our ability to raise capital through offerings of our common stock.

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

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

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
 - reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

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

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

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

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The NASDAQ Capital Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it

more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

We do not anticipate paying future dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We currently do not have any net operating loss carryforwards.

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

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

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

In an effort to remediate this material weakness, effective August 4, 2014, we hired a Chief Financial Officer with public company financial reporting expertise to build our financial management and reporting infrastructure, and further develop and document our accounting policies and financial reporting procedures. However, we cannot assure you that the remediation measures that we have taken thus far and plan to take in the future will be sufficient to address our existing material weakness or to identify or prevent additional material weaknesses.

Neither we nor our independent registered public accounting firm has performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. It is possible

that, had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, material weaknesses or significant control deficiencies may have been identified. However, for as long as we remain an “emerging growth company” as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Unregistered Sales of Equity Securities

On June 23, 2014, we completed our IPO, pursuant to which we offered and sold 850,000 shares of common stock, par value \$0.01 per share, at a public offering price of \$10.00 per share. Also on June 17, 2014, in connection with our IPO, we converted from a Delaware limited liability company to a Delaware corporation.

Immediately prior to our IPO, we converted \$27,326,287 aggregate principal amount of debt into an aggregate of 2,732,629 Class C units of Signal Genetics LLC, which Class C units were subsequently converted into 2,732,629 shares of common stock in connection with the Corporate Conversion. The issuance of Class C units in the Debt Conversion was exempt from registration under the Securities Act of 1933, as amended (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.

At the time of the Corporate Conversion, all of the outstanding Class A and Class C units of the Signal Genetics LLC were automatically converted into an aggregate of 2,932,629 shares of our common stock. The issuance of common stock to our members 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.

Immediately prior to our IPO, we also issued 831,593 restricted stock units to certain employees of the Company. 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.

Use of Proceeds

As noted above, on June 23, 2014, we completed our IPO pursuant to which we offered and sold 850,000 shares of our common stock at a public offering price of \$10.00 per share (for an aggregate offering price of \$8,500,000), pursuant to the Company's Registration Statement on Form S-1 (File No. 333-194668) which was declared effective by the SEC on June 17, 2014. After deducting underwriting discounts and commissions of approximately \$595,000, and other offering expenses payable by us of approximately \$1,761,000, the Company received approximately \$6,144,000 in net proceeds. Aegis Capital Corp. acted as the sole book-running manager for the offering

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on June 19, 2014 pursuant to Rule 424(b). No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries. Pending the uses described, we have invested the net proceeds in our operating cash account.

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Item 6. Exhibits.

| Exh. No. | Exhibit Name |
|-------------------|---|
| 3.1 | Certificate of Incorporation of Signal Genetics, Inc., effective as of June 17, 2014. |
| 3.2 | Bylaws of Signal Genetics, Inc., effective as of June 17, 2014. |
| 10.1 [^] | 2014 Stock Incentive Plan. |
| 10.2 | 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). |
| 10.3 | 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). |
| 10.4 | Amended and Restated Employment Agreement between Signal Genetics, Inc. and Samuel D. Riccitelli, dated June 17, 2014. |
| 10.5 | Amendment to Amended and Restated Employment Agreement between Signal Genetics, Inc. and Samuel D. Riccitelli, dated July 23, 2014 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K (File No. 001-36483) filed on July 23, 2014). |
| 10.6 | Employment Agreement between Signal Genetics, Inc. and Tamara A. Seymour, dated July 21, 2014 (effective as of August 4, 2014) (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K (File No. 001-36483) filed on July 23, 2014). |
| 10.7 | Employment Agreement between Signal Genetics, Inc. and Robert Johnson, dated May 12, 2014 (incorporated by reference to Exhibit 10.21 to Amendment No. 2 to the Form S-1 (No. 333-194668) filed on May 15, 2014). |
| 10.8 | Exchange Agreement, dated June 17, 2014, by and among 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. |
| 10.9 | Letter Agreement between The Board of Trustees of the University of Arkansas on behalf of the University of Arkansas for Medical Sciences and Signal Genetics, Inc., dated May 16, 2014 (incorporated by reference to Exhibit 10.23 to Amendment No. 3 to the Form S-1 (No. 333-194668) filed on May 27, 2014). |
| 31.1 | Rule 13a-14(a) Certification of Principal Executive Officer of Registrant |
| 31.2 | Rule 13a-14(a) Certification of Principal Financial Officer of Registrant |
| 32+ | Section 1350 Certification |
| 101.INS* | XBRL Instance Document |
| 101.SCH* | XBRL Taxonomy Extension Schema |
| 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase |
| 101.DEF* | XBRL Taxonomy Extension Definition Linkbase |
| 101.LAB* | XBRL Taxonomy Extension Label Linkbase |
| 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase |

[^] Corrected version of previously filed exhibit.

+ This certification is being furnished solely to accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

* Pursuant to Rule 406T of Regulation S-T, the XBRL (Extensible Business Reporting Language) information included in Exhibit 101 hereto is deemed furnished and 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, or deemed not filed for purposes of Section

18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

August 14, 2014

SIGNAL GENETICS, INC.

By: /s/ Samuel D. Riccitelli
Samuel D. Riccitelli
President and Chief Executive Officer