

NEOGENOMICS INC
Form 10-Q
August 05, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016.

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: 001-35756

NEOGENOMICS, INC.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction of
incorporation or organization)

74-2897368
(I.R.S. Employer
Identification No.)

12701 Commonwealth Drive, Suite 9, Fort Myers,
Florida
(Address of principal executive offices)

33913
(Zip Code)

(239) 768-0600

(Registrant's telephone number, including area code)

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 R 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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes R 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 company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer

Accelerated filer

R

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

As of August 3, 2016, the registrant had 77,893,305 shares of Common Stock, par value \$0.001 per share outstanding.

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FORWARD-LOOKING STATEMENTS

The information in this Quarterly Report on Form 10-Q contains “forward-looking statements” and information within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) relating to NeoGenomics, Inc., a Nevada corporation and its subsidiaries, NeoGenomics Laboratories, Inc., a Florida corporation (“NEO”, “NeoGenomics Laboratories”), NeoGenomics Bioinformatics Inc., a Florida corporation, Path Labs LLC, a Delaware limited liability company (“PathLogic”) and Clariant, Inc., a Delaware corporation and its wholly owned subsidiary, Clariant Diagnostic Services, Inc. (together “Clariant”) (collectively referred to as “we”, “us”, “our”, “NeoGenomics”, or the “Company”), which are subject to the “safe harbor” created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. These forward-looking statements involve known and unknown risks and uncertainties that could cause our actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statements, including, without limitation, the risks set forth in “Risk Factors” beginning on page 35.

Forward-looking statements include, but are not limited to, statements about:

- Our ability to implement our business strategy;
- Our ability to integrate acquired businesses, including our acquisition of Clariant, Inc. and costs related to such acquisitions;
- Our ability to expand our operations and increase our market share;
- Our ability to expand our service offerings by adding new testing capabilities;
- The impact of internalization of testing by customers;
- Our ability to compete with other diagnostic laboratories;
- Our ability to successfully scale our business, including expanding our facilities, our backup systems and infrastructure;
- Our ability to hire and retain sufficient managerial, sales, clinical and other personnel to meet our needs;
- Our ability to meet our future capital requirements;
- U.S. Food and Drug Administration proposed regulation of Laboratory Developed Tests;
- Our ability to generate sufficient cash flow from our license agreement with Health Discovery Corporation to support its fair value;
- Regulatory developments in the United States including increasing downward pressure on health care reimbursement;
- The expected reimbursement levels from governmental payers and private insurers and proposed changes to those levels, including the application of the Protecting Access to Medicare Act;
- The application, to our business and the services we provide, of existing laws, rules and regulations, including without limitation, Medicare laws, anti-kickback laws, Health Insurance Portability and Accountability Act of 1996 regulations, state medical privacy laws, federal and state false claims laws and corporate practice of medicine laws;
- Our ability to maintain our license under the Clinical Laboratory Improvement Amendments of 1988; and
- Failure to timely or accurately bill for our services.

Any forward-looking statement speaks only as of the date on which such statement is made, and the Company undertakes no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time and it is not possible for management to predict all of such factors, nor can it assess the

impact of each such factor on the 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.

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PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NEOGENOMICS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

(unaudited)

	June 30, 2016	December 31, 2015
ASSETS		
Current assets		
Cash and cash equivalents	\$21,786	\$23,420
Accounts receivable (net of allowance for doubtful accounts of \$9,197 and \$4,759, respectively)	53,513	48,943
Inventories	5,545	5,108
Other current assets	6,665	4,889
Total current assets	87,509	82,360
Property and equipment (net of accumulated depreciation of \$33,858 and \$26,534, respectively)	33,575	34,577
Intangible assets, net	84,164	87,800
Goodwill	146,179	146,421
Other assets	129	129
Total assets	\$351,556	\$351,287
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$13,435	\$12,464
Accrued compensation	8,577	6,217
Accrued expenses and other liabilities	7,604	7,374
Revolving credit facility, net	—	8,869
Short-term portion of capital leases	4,691	4,534
Short-term portion of loans	646	600
Total current liabilities	34,953	40,058
Long-term liabilities		
Long-term portion of capital leases	4,748	5,040
Long-term portion of loans, net	52,238	52,336
Deferred income tax liability, net	16,249	15,741
Total long-term liabilities	73,235	73,117

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Total liabilities	108,188	113,175
Commitments and contingencies - see Note I		
Redeemable convertible preferred stock		
Series A Redeemable Convertible Preferred Stock, \$0.001 par value, (50,000,000 shares authorized; and 14,666,667 shares issued and outstanding, respectively)	39,735	28,602
Stockholders' equity		
Common stock, \$0.001 par value, (250,000,000 shares authorized; 77,882,016 and 75,820,307 shares issued and outstanding, respectively)	78	76
Additional paid-in capital	236,183	231,375
Accumulated deficit	(32,628)	(21,941)
Total stockholders' equity	203,633	209,510
Total liabilities, redeemable convertible preferred stock and stockholders' equity	\$351,556	\$351,287

See notes to unaudited consolidated financial statements

NEOGENOMICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(unaudited)

	For the Three Months Ended		For the Six Months Ended	
	June 30, 2016	2015	June 30, 2016	2015
NET REVENUE				
Clinical testing revenue	\$56,316	\$24,055	\$110,936	\$46,894
BioPharma & research revenue	6,813	315	11,896	502
Total Revenue, net	63,129	24,370	122,832	47,396
COST OF REVENUE	34,524	13,557	67,055	27,040
GROSS MARGIN	28,605	10,813	55,777	20,356
Operating expenses:				
General and administrative	18,779	7,075	36,785	13,598
Research and development	1,306	803	2,752	1,471
Sales and marketing	6,327	2,907	12,127	5,821
Total Operating Expenses	26,412	10,785	51,664	20,890
INCOME (LOSS) FROM OPERATIONS	2,193	28	4,113	(534)
Interest expense, net	1,448	189	3,040	384
Income (loss) before taxes	745	(161)	1,073	(918)
Income tax expense	332	15	505	19
NET INCOME (LOSS)	413	(176)	568	(937)
Deemed dividends on preferred stock	1,840	—	3,680	—
Amortization of preferred stock beneficial conversion feature	3,727	—	7,453	—
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$(5,154)	\$(176)	\$(10,565)	\$(937)
NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS				
Basic	\$(0.07)	\$(0.00)	\$(0.14)	\$(0.02)
Diluted	\$(0.07)	\$(0.00)	\$(0.14)	\$(0.02)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic	77,448	60,425	76,758	60,352
Diluted	77,448	60,425	76,758	60,352

See notes to unaudited consolidated financial statements.

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NEOGENOMICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	For the Six Months Ended June 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income (loss)	\$568	\$(937)
Adjustments to reconcile net income (loss) to net cash provided by		
operating activities, net of business acquisition:		
Depreciation	7,329	3,249
Amortization of intangibles	3,636	190
Amortization of debt issue costs	358	-
Stock based compensation – options, restricted stock and warrants	2,337	1,020
Provision for bad debts	5,434	1,303
Changes in assets and liabilities, net of business acquisition:		
(Increase) in accounts receivable, net of write-offs	(10,004)	(1,958)
(Increase) in inventories	(437)	(800)
(Increase) in prepaid expenses	(602)	-
(Increase) in other current assets	—	(129)
Increase (Decrease) in accounts payable and other liabilities	3,476	(41)
Net cash provided by operating activities	12,095	1,897
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(3,425)	(1,180)
Net cash used in investing activities	(3,425)	(1,180)
CASH FLOWS FROM FINANCING ACTIVITIES		
Repayment of revolving credit facility	(10,044)	—
Repayment of capital lease obligations/loans	(2,611)	(1,833)
Proceeds from the exercise of options, warrants and		
ESPP shares, net of transaction expenses	2,351	379
Net cash used in financing activities	(10,304)	(1,454)
Net change in cash and cash equivalents	(1,634)	(737)
Cash and cash equivalent, beginning of period	23,420	33,689
Cash and cash equivalents, end of period	\$21,786	\$32,952
Supplemental disclosure of cash flow information:		
Interest paid	\$2,691	\$417
Income taxes paid	\$222	\$20
Supplemental disclosure of non-cash investing and financing information:		
Equipment acquired under capital lease/loan obligations	\$2,585	\$3,400
Deemed dividends on preferred stock	\$3,680	\$-

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Amortization of preferred stock beneficial conversion feature	\$7,453	\$-
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See notes to unaudited consolidated financial statements.

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NEOGENOMICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Unaudited

Note A – Nature of Business and Basis of Presentation

NeoGenomics, Inc., a Nevada corporation (the “Parent”), and its subsidiaries, NeoGenomics Laboratories, Inc., a Florida corporation (“NEO” or, “NeoGenomics Laboratories”), NeoGenomics Bioinformatics Inc., a Florida corporation, Path Labs LLC., a Delaware limited liability company (“PathLogic”) and Clariant Inc., a Delaware corporation, and its wholly owned subsidiary Clariant Diagnostic Services, Inc. (together, “Clariant”), (collectively referred to as “we”, “us”, “our”, “NeoGenomics”, or the “Company”), operates as a certified “high complexity” clinical laboratory in accordance with the federal government’s Clinical Laboratory Improvement Act, as amended (“CLIA”), and is dedicated to the delivery of clinical diagnostic services to pathologists, oncologists, urologists, hospitals, and other laboratories throughout the United States.

The accompanying interim consolidated financial statements are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information. These accompanying interim consolidated financial statements include the accounts of the Parent and its subsidiaries. All intercompany transactions and balances have been eliminated in the accompanying interim consolidated financial statements.

Certain information and footnote disclosures normally included in the Company’s annual audited consolidated financial statements and accompanying notes have been condensed or omitted in these accompanying interim consolidated financial statements. Accordingly, the accompanying interim consolidated financial statements included herein should be read in conjunction with the audited consolidated financial statements and accompanying notes included in the Company’s annual report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 15, 2016 and as amended and filed with the SEC on April 18, 2016. Certain amounts in previously issued financial statements were reclassified to conform to the current presentation (see Note B).

The results of operations presented in this quarterly report on Form 10-Q are not necessarily indicative of the results of operations that may be expected for any future periods. In the opinion of management, these unaudited consolidated financial statements include all adjustments and accruals, consisting only of normal recurring adjustments that are necessary for a fair statement of the results of all interim periods reported herein.

We have one reportable operating segment that delivers testing services to hospitals, pathologists, oncologists, other clinicians and researchers and represents 100% of the Company’s consolidated assets, net revenues and net loss for the three and six months ended June 30, 2016 and 2015. We have evaluated our segments based on how the Chief Operating Decision Maker (“CODM”), our Chief Executive Officer, reviews performance and makes decisions in managing the Company. At June 30, 2016, all of our services were provided within the United States and all of our assets were located in the United States.

We have two primary types of customers, clinical and biopharma. Our clinical customers include community based pathology practices, oncology groups, hospitals and academic centers. Our biopharma customers include pharmaceutical companies to whom we provide testing to support their studies and clinical trials. We continue to assess the information available to the CODM since the close of the Clariant acquisition. Currently, discrete financial information is not available to the CODM about the separate financial performance of our clinical and our biopharma customers. As we continue to integrate the two companies and focus separately on the two customer types we will

routinely assess the information available and reviewed by the CODM and determine if we meet the criteria for having separate reporting units.

Note B — Recently Adopted and Issued Accounting Guidance

Adopted

Effective January 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2015-17, Income Taxes. The standard update was issued to simplify the presentation of deferred income taxes and required deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU 2015-17 is effective for fiscal years and interim periods within those fiscal years, beginning after December 31, 2016. Earlier application is permitted as of the beginning of an interim or annual period. The Company has early adopted this ASU and applied the amendments retrospectively to all deferred tax liabilities and assets presented. The effect of the adoption on the Consolidated Balance Sheets as of June 30, 2016 and December 31, 2015, was the offset of long term deferred tax liabilities by current deferred tax assets of \$8,500,000 and \$16,668,000, respectively.

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NEOGENOMICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Unaudited

Effective September 2015, the FASB issued ASU 2015-16, Business Combinations. The standard update was issued to simplify the accounting for measurement period adjustments. The update requires that adjustments to provisional amounts identified during the measurement period be recognized in the period determined. The effect of these adjustments on current earnings that would have been related to previously reported earnings is required to be disclosed. ASU 2015-16 is effective for fiscal years and interim periods within those fiscal years, beginning after December 31, 2015. The update should be applied prospectively to adjustments that occur after the effective date of this update. The Company has adopted this ASU 2015-16 and it did not have a material effect on Company's earnings for the period ended June 30, 2016. The Company has not finalized all valuations of the assets acquired and liabilities assumed in the Clariant acquisition at June 30, 2016.

Issued

In May 2014, the FASB issued ASU 2014-09, Revenues from Contracts with Customers. This standard update calls for a number of revisions in the revenue recognition rules. In August 2015, the FASB deferred the effective date of this ASU to the first quarter of 2018, with early adoption permitted beginning in the first quarter of 2017. The ASU can be applied using a full retrospective method or a modified retrospective method of adoption. The Company is currently evaluating this update and has not yet determined the date that it will adopt this standard, the method it will use to implement the new standard or the effect this may have on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases. The update requires organizations to recognize lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous GAAP. ASU 2016-02 requires that a lessee should recognize a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term on the balance sheet. ASU 2016-02 is effective for periods beginning after December 15, 2018 and interim periods within those periods. The Company is currently evaluating the impact the adoption of this update will have on its consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Improvements to Employee Share-Based Payment Accounting. The update requires excess tax benefits and tax deficiencies to be recorded directly through earnings as a component of income tax expense. Under current GAAP, these differences are generally recorded in additional paid-in capital and thus have no impact on net income. The change will also impact the computation of diluted earnings per share, and the cash flows associated with those items will be classified as operating activities on the condensed statements of consolidated cash flows. Entities will be permitted to make an accounting policy election for the impact of forfeitures

on the recognition of expense for share-based payment awards. Forfeitures can be estimated, as required under current GAAP, or recognized when they occur. ASU 2016-09 is effective for periods beginning after December 15, 2016 and interim periods within those periods. The Company is currently evaluating the impact the adoption of this standard will have on its consolidated financial statements.

Note C — Acquisitions

Clariant

On December 30, 2015 (“the acquisition date”), the Company acquired from GE Medical Holding AB (“GE Medical”), a subsidiary of General Electric Company (“GE”), all of the issued and outstanding shares of common stock of Clariant, Inc., a wholly owned subsidiary of GE Medical, for a purchase price consisting of (i) cash consideration of approximately \$73.8 million, which includes an approximately \$6.7 million estimated working capital adjustment and adjustments for estimated cash on hand and estimated indebtedness of Clariant on the Closing Date, (ii) 15,000,000 shares of NeoGenomics’ common stock, and (iii) 14,666,667 shares of NeoGenomics’ Series A Redeemable Convertible Preferred Stock (“Series A Preferred Stock”) pursuant to the Stock Purchase Agreement.

The cash consideration paid as part of the purchase price was funded through the following:

- The Company paid approximately \$10.7 million using cash on hand
- Approximately \$9.5 million, net of transaction costs was funded using a revolving credit facility
- Approximately \$53.6 million, net of transaction costs was funded using a term loan

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NEOGENOMICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Unaudited

On December 21, 2015 shareholders approved and on December 28, 2015, NeoGenomics filed with the Secretary of State of the State of Nevada amendments to its Articles of Incorporation to increase the authorized number of shares of common stock from 100.0 million shares to 250.0 million shares and to increase the authorized number of shares of preferred stock from 10.0 million shares to 50.0 million shares in order to fund the common and preferred stock portion of the purchase price, among other things.

The Company issued 15,000,000 shares of common stock as consideration for the acquisition of Clariant. The common stock includes restrictions imposed on the holder in the Investor Board Rights, Lockup and Standstill Agreement. We estimated the fair value of the common stock consideration using inputs not observable in the market and thus represents a Level 3 measurement as defined in ASC 820. The key assumption in the fair value determination was a 15 percent discount due to lack of marketability of the common stock as a result of the restrictions imposed on the holder. The acquisition date fair value of common stock transferred is calculated below (\$ in thousands, except share and per share amounts):

Common Stock Valuation	Amount
Shares of common stock issued as consideration	15,000,000
Stock price per share on closing date	\$8.04
Value of common stock issued as consideration	\$120,600
Issue discount due to lack of marketability	\$(18,090)
Fair value of common stock at December 30, 2015	\$102,510

The Company issued 14,666,667 shares of Series A Preferred Stock as consideration for the acquisition of Clariant. The rights of the Series A Preferred Stock are described in Note F. We estimated the fair value of the Series A Preferred Stock consideration using significant inputs not observable in the market and thus represents a Level 3 measurement as defined in ASC 820. The fair value of the Series A Preferred Stock at the acquisition date was \$73.2 million or \$4.99 per share. This fair value was further reduced by the intrinsic value assigned to the beneficial conversion feature to arrive at a carrying amount of \$28.6 million.

On a fully diluted basis, assuming full conversion of the Series A Preferred Stock, GE Medical would own approximately 32% of NeoGenomics. In addition, pursuant to the Investor Board Rights, Lockup and Standstill Agreement, NeoGenomics has appointed a director designated by GE Medical to its Board of Directors.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed at the acquisition date of December 30, 2015. The Company is in the process obtaining input from third-party valuations of its tangible and intangible assets and other information necessary to measure the remaining assets acquired and liabilities assumed; thus, the provisional measurements of current assets, property and equipment, intangible assets, goodwill, current liabilities, net deferred tax liabilities and long-term liabilities are subject to change.

The preliminary acquisition fair values below are presented as of December 30, 2015 (in thousands):

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	December 30, 2015	Measurement Period	December 30, 2015
	(As Initially Reported)	Adjustments	(As Adjusted)
Current assets, including cash and cash equivalents of \$890	\$ 31,978	\$ -	\$ 31,978
Property and equipment	19,241	-	19,241
Identifiable intangible assets – customer relationships	84,000	-	84,000
Goodwill	143,493	(242)	143,251
Total assets acquired	278,712	(242)	278,470
Current liabilities	(12,631)	242	(12,389)
Deferred tax liability	(17,904)	-	(17,904)
Long-term liabilities	(103)	-	(103)
Net assets acquired	\$ 248,074	\$ -	\$ 248,074

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NEOGENOMICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Unaudited

Of the \$84.0 million of acquired intangible assets, \$81.0 million was provisionally assigned to customer relationships which are being amortized over fifteen years and \$3.0 million was provisionally assigned to trade names which are being amortized over two years. For the three and six months ending June 30, 2016, we recorded approximately \$1.5 million and \$3.5 million of amortization expense respectively.

Goodwill arising from the acquisition of Clariant includes revenue synergies as a result of our existing customers and Clariant's customers having access to each other's testing menus and capabilities and also from the new product lines which Clariant adds to the Company's product portfolio. None of the goodwill is expected to be deductible for income tax purposes.

The provisional fair value of accounts receivable acquired was approximately \$27.6 million as of the date of acquisition.

The Company recognized acquisition related transaction costs of approximately \$4.7 million during the year ended December 31, 2015. These costs include due diligence, legal, consulting and other transaction related expenses associated with the acquisition of Clariant. These expenses were included in general and administrative expenses in our consolidated statements of operations for the year ended December 31, 2015. The Company also incurred debt issuance costs of \$3.3 million which are recorded as reductions in the carrying amount of the related liabilities and are being amortized over the term of the loans.

The following unaudited pro forma information (in thousands), has been provided for illustrative purposes and is not necessarily indicative of results that would have occurred had the acquisition of Clariant been in effect since January 1, 2014, nor is it necessarily indicative of future results.

	Three Months Ended	Six Months Ended
	June 30, 2015	June 30, 2015
Revenue	\$ 54,030	\$ 108,346
Net (loss) attributable to common stockholders	(4,032)	(49,558)
(Loss) per share:		
Basic	(0.05)	(0.66)
Diluted	(0.05)	(0.66)

The unaudited pro forma consolidated results for the three and six months ended June 30, 2015 have been prepared by adjusting our historical results to include the acquisition of Clariant as if it occurred on January 1, 2014. These unaudited pro forma consolidated historical results were then adjusted for the following:

- Remove transaction expenses from the year ended December 31, 2015 and record them in the year ended December 31, 2014.
 - Adjustments to reflect amortization and depreciation expense associated with the acquired assets, partially offset by the elimination of the amortization and depreciation expense associated with Clariant's historical assets.
 - Removal of costs associated with MultiOmyx, assets not acquired in the transaction, and to record royalty fees due to GE for continued use of the MultiOmyx product through a licensing agreement.
 - Remove general and administrative expenses related to a Lab Services Agreement with the Saudi Arabian National Guard Health Affairs, as GE Medical has retained this agreement.
 - Record interest expense under the Credit Facilities and amortization of financing costs classified as interest expense.
 - Remove royalty costs associated with the use of the GE brand as NeoGenomics will discontinue the use of the GE brand.
 - Accrue for dividends on the Series A Preferred stock and to amortize a portion of the beneficial conversion feature.
- As noted above, the unaudited pro forma results of operations do not purport to be indicative of the actual results that would have been achieved by the combined Company for the periods presented or that may be achieved by the combined Company in the future.

NEOGENOMICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Unaudited

Note D — Goodwill and Intangible Assets

The Company has recorded Goodwill of \$146.2 million as of June 30, 2016. The changes in the carrying amount of goodwill for the six month period ended June 30, 2016 and for the year ended December 31, 2015 are as follows (in thousands):

	June 30, 2016	December 31, 2015
Balance as of January 1	\$146,421	\$ 2,929
Goodwill acquired during the period	-	143,492
Adjustment to preliminary value of goodwill (Note C)	(242)	-
Balance at end of period	\$146,179	\$ 146,421

Intangible assets as of June 30, 2016 and December 31, 2015 consisted of the following (in thousands):

Trade Name	Period	June 30, 2016		
		Amortization	Cost	Accumulated Amortization Net
Trade Name	24 months	\$3,000	\$ 758	\$2,242
Customer Relationships	156 months	82,930	3,022	79,908
Support Vector Machine (SVM) technology	108 months	500	241	259
Laboratory developed test (LDT) technology	164 months	1,482	470	1,012
Flow Cytometry and Cytogenetics technology	202 months	1,000	257	743
Total		\$88,912	\$ 4,748	\$84,164

Trade Name	Period	December 31, 2015		
		Amortization	Cost	Accumulated Amortization Net
Trade Name	24 months	\$3,000	\$ 8	\$2,992
Customer Relationships	156 months	82,930	247	82,683
Support Vector Machine (SVM) technology	108 months	500	213	287
Laboratory developed test (LDT) technology	164 months	1,482	416	1,066
Flow Cytometry and Cytogenetics technology	202 months	1,000	228	772
Total		\$88,912	\$ 1,112	\$87,800

We recorded approximately \$1.6 million and \$97,000 in straight-line amortization expense of intangible assets for the three months ended June 30, 2016 and 2015, respectively. We recorded approximately \$3.6 million and \$190,000 in straight-line amortization expense of intangibles for the six months ended June 30, 2016 and 2015, respectively. The Company recorded amortization expense from customer relationships and trade names as a general and administrative expense. We will continue to record the amortization of the Support Vector Machine (SVM) technology, the LDT technology and the Flow Cytometry and Cytogenetics technology intangible assets as a research and development expense until such time that we have products, services or cost savings directly attributable to these intangible assets that would require recodation in cost of goods sold.

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NEOGENOMICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Unaudited

The estimated amortization expense related to amortizable intangible assets for each of the five succeeding fiscal years and thereafter as of June 30, 2016 is as follows (in thousands):

Year Ending December 31,	
Remainder of 2016	\$3,636
2017	7,264
2018	5,771
2019	5,771
2020	5,771
2021	5,726
Thereafter	50,225
Total	\$84,164

Note E — Debt

Term Loan

On December 30, 2015, the Company entered into a Term Loan and Guaranty Agreement (the “Term Loan Facility”) for which AB Private Credit Investors LLC acts as the administrative agent and collateral agent. The agreement provides for \$55.0 million of borrowings. On June 30, 2016, the Company had current outstanding borrowings of \$550,000 and long-term outstanding borrowings of \$52.1 million, net of unamortized debt issuance costs of \$2.1 million.

The fair value of the Term Loan Facility is estimated by discounting the future cash flow using the Company’s current borrowing rates for similar types and maturities of debt, except for floating-rate notes for which the carrying amounts were considered a reasonable estimate of fair value.

The interest rate for borrowings under the Term Loan Facility will be, at the Company’s election, (i) (A) a base rate equal to the greatest of 4%, the prime rate, the federal funds rate plus 0.5% and the one month LIBOR rate plus 1%, plus (B) an initial applicable margin of 6% , or (ii) the (A) LIBOR rate for interest periods from one to twelve months, plus (B) an initial applicable margin of 7%, with a minimum LIBOR of 1.00%. Interest on borrowings under the facility will be reduced to Base Rate plus 5.5% or LIBOR plus 6.50% upon the later of (i) NeoGenomics’ achieving maximum total leverage of less than 2.0 to 1.0 and (ii) January 1, 2017.

The Company and all of its present and future subsidiaries (other than NeoGenomics Laboratories) are guarantors under the Term Loan Facility. The Term Loan Facility contains the following financial covenants: (i) maintenance of a maximum total leverage ratio of 4.0 to 1.0 (stepping down over time to 3.25 to 1.0), and (ii) maintenance of a

minimum consolidated fixed charge coverage ratio of 1.10 to 1.0 (stepping up over time to 1.25 to 1.0). These covenants were effective beginning with the quarter ended March 31, 2016. The Company was in compliance with all such financial covenants as of June 30, 2016.

The Term Loan Facility also contains various affirmative and negative covenants, such as the delivery of financial statements, tax authority compliance, maintenance of property, limitations on additional debt, restriction of dividends and other standard clauses.

The Term Loan Facility has a maturity of five years. In addition, the Term Loan Facility provides for annual amortization payments in an amount equal to 1.0% of the original principal amount of the term loan, paid in quarterly installments, and mandatory prepayments with (i) proceeds of certain assets sales and recovery events, (ii) proceeds of certain debt issuances, (iii) proceeds of certain extraordinary receipts, as defined, (iv) a portion of certain tax refunds and insurance proceeds, and (v) a portion of excess cash flow as defined.

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NEOGENOMICS, INC.

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Auto Loans

The Company has auto loans with various financial institutions. The auto loan terms range from 36-60 months and carry interest rates from 0.0% to 5.2%.

Maturities of Long-Term Debt

Maturities of long-term debt at June 30, 2016 are summarized as follows (in thousands):

	Term Loan	Auto Loans	Total Long Term Debt
Remainder of 2016	\$275	\$ 36	\$311
2017	550	94	644
2018	550	70	620
2019	550	41	591
2020	52,799	7	52,806
	54,724	248	54,972
Less: Current portion of long-term debt	(550)	(96)	(646)
Less: Debt issuance costs, net	(2,088)	-	(2,088)
Long-term debt, net	\$52,086	\$ 152	\$52,238

Short-Term Debt - Revolving Credit Facility

On December 30, 2015, the Company entered into a Credit Agreement (the “Revolving Credit Facility”) for which Wells Fargo Bank, N.A., acts as the administrative agent. The Revolving Credit Facility provides for up to \$25.0 million of revolving loans and a letter of credit subfacility for \$1.0 million. Borrowings under the revolver and the letter of credit subfacility are limited to a borrowing base comprised of 85% of the expected net value of certain billed and unbilled accounts receivable less reserve amounts established by Wells Fargo Bank, N.A.

The carrying amount of the Revolving Credit Facility approximates fair value due to the short maturity and the variable market rates of interest that change with current prime and no change in counterparty credit risk and were classified as Level 2 of the fair value hierarchy.

The interest rate for borrowings under the Revolving Credit Facility is, at the Company’s election, (i) (A) a base rate equal to the greatest of the prime rate, the federal funds rate plus 0.5% and the three month LIBOR rate plus 1%, plus (B) an applicable margin ranging from 2.0% to 2.5%, or (ii) the (A) LIBOR rate plus (B) an applicable margin ranging from 3.0% to 3.5%. NeoGenomics will also pay 0.25% per year on any unused portion of the revolver.

NeoGenomics is a guarantor under the Revolving Credit Facility. All of NeoGenomics' present and future subsidiaries (including NeoGenomics Laboratories) are borrowers under the Revolving Credit Facility. The Revolving Credit Facility contains the following financial covenants: (i) maintenance of a maximum total leverage ratio (funded indebtedness (including the outstanding amounts under the Credit Facilities), plus capitalized lease obligations, divided by EBITDA) of not more than 4.0 to 1.0 (stepping down over time to 3.25 to 1.0), (ii) maintenance of a minimum consolidated fixed charge coverage ratio (EBITDA less capital expenditures not financed with debt or certain equity), divided by the sum of cash interest expense, scheduled payments and mandatory prepayments of principal on indebtedness, taxes and restricted payments) of at least 1.1 to 1.0 (stepping up over time to 1.25 to 1.0) and (iii) maintenance of a minimum cash velocity equal to or greater than 80%. These covenants were effective beginning with the quarter ended March 31, 2016. The Company was in compliance with all such financial covenants as of June 30, 2016.

The Revolving Credit Facility also contains various affirmative and negative covenants, such as the delivery of financial statements, tax authority compliance, maintenance of property, limitations on additional debt, restriction of dividends and other standard clauses. The Company was in compliance with all such financial covenants as of June 30, 2016.

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The Revolving Credit Facility has a maturity of five years, maturing on December 30, 2020. In addition, the Revolving Credit Facility provides for mandatory prepayment in the event that the borrowing base is less than the aggregate amount of the advances outstanding under the revolver and any letters of credit, which prepayment will be equal to the amount necessary to remedy the over-advance.

At June 30, 2016, the Company had no outstanding borrowings under the Revolving Credit Facility, nor under the letter of credit subfacility. The related debt issuance costs of approximately \$1.1 million have been reclassified into other current assets at June 30, 2016. We will continue to show debt issuance costs as a reduction in the related liability to the extent that there is an outstanding balance on the Revolving Credit Facility in the future. As of June 30, 2016, there is approximately \$25 million in available credit under the Revolving Credit Facility to be drawn upon as needed.

Note F — Class A Redeemable Convertible Preferred Stock

On December 30, 2015, NeoGenomics issued 14,666,667 shares of its Series A Preferred stock as part of the consideration for the acquisition of Clariant, see Note C. The Series A Preferred Stock has a face value of \$7.50 per share for a total liquidation value of \$110 million. During the first year, the Series A Preferred Stock has a liquidation value of \$100 million if the shares are redeemed prior to December 29, 2016. The carrying amount of the Series A Preferred Stock at June 30, 2016 was \$39.7 million as compared to the carrying amount at December 31, 2015 of \$28.6 million. The increase in the carrying amount is from the accrual of deemed dividends of approximately \$3.7 million and the accretion of the beneficial conversion feature of approximately \$7.5 million during the six months ending June 30, 2016, of which both amounts are recorded as distributions to the holders of the Series A Preferred Stock on the income statement with the corresponding entry recorded as an increase to the carrying value of the Series A Preferred Stock.

Issue Discount

The Company recorded the Series A Preferred Stock at a fair value of approximately \$73.2 million or \$4.99 per share on the date of issuance. The difference between the fair value of \$73.2 million and the liquidation value of \$110 million represents a discount of \$36.8 million from the initial face value as a result of assessing the impact the rights and features (listed below) of the instrument and their effect on the value to the Company.

Beneficial Conversion Feature

The fair value of the common stock into which the Series A Preferred Stock was convertible at the date of issuance exceeded the allocated purchase price fair value of the Series A Preferred Stock by approximately \$44.7 million on the date of issuance, resulting in a beneficial conversion feature. The Company will recognize the beneficial conversion feature as non-cash, deemed dividend to the holder of Series A Preferred Stock over the first three years the Series A Preferred Stock is outstanding, as the date the stock first becomes convertible is three years from the issue date. The amounts recognized for the three and six months ended June 30, 2016 was approximately \$3.7 million and \$7.5 million respectively.

Classification

The Company classified the Series A Preferred Stock as temporary equity on the consolidated balance sheets due to certain change in control events that are outside the Company's control, including deemed liquidation events described in the Series A Certificate of Designation.

Note G — Revenue Recognition and Contractual Adjustments

The Company recognizes revenues when (a) the price is fixed or determinable, (b) persuasive evidence of an arrangement exists, (c) the service is performed and (d) collectability of the resulting receivable is reasonably assured.

NEOGENOMICS, INC.

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The Company's specialized diagnostic services are performed based on a written test requisition form or electronic equivalent, and revenues are recognized once the diagnostic services have been performed, and the results have been delivered to the ordering physician. These diagnostic services are billed to various payers, including Medicare, commercial insurance companies, other directly billed healthcare institutions such as hospitals and clinics, and individuals. The Company reports revenues from contracted payers, including Medicare, certain insurance companies and certain healthcare institutions, based on the contractual rate, or in the case of Medicare, published fee schedules. The Company reports revenues from non-contracted payers, including certain insurance companies and individuals, based on the amount expected to be collected. The difference between the amount billed and the amount estimated to be collected from non-contracted payers is recorded as an allowance to arrive at the reported net revenues. The expected revenues from non-contracted payers are based on the historical collection experience of each payer or payer group, as appropriate. The Company records revenues from patient pay tests net of a large discount and as a result recognizes minimal revenue on those tests. The Company regularly reviews its historical collection experience for non-contracted payers and adjusts its expected revenues for current and subsequent periods accordingly.

The table below shows the adjustments made to gross service revenues to arrive at net revenues (in thousands), the amount reported on our statements of operations.

	Three Months Ended June 30,		Six Months Ending June 30,	
	2016	2015	2016	2015
Gross service revenues	\$129,235	\$56,702	\$261,955	\$110,333
Total contractual adjustments and discounts	(66,106)	(32,332)	(139,123)	(62,937)
Net revenues	\$63,129	\$24,370	\$122,832	\$47,396

Note H — Equity

A summary of the stock option activity under the Company's plans for the six months ended June 30, 2016 is as follows:

	Number of shares	Weighted average exercise price
Options outstanding at December 31, 2015	5,326,505	\$ 3.07
Options granted	2,372,527	6.77
Less:		
Options exercised	2,003,597	0.92
Options canceled or expired	258,155	4.68
Options outstanding at June 30, 2016	5,437,280	4.17

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Exercisable at June 30, 2016	1,512,503	2.32
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Of the 5,437,280 outstanding options at June 30, 2016, 1,375,000 were variable accounted stock options issued to non-employees of the Company of which 485,000 options were vested and 890,000 options were unvested as of June 30, 2016.

The fair value of each stock option award granted during the six months ended June 30, 2016 was estimated as of the grant date using a trinomial lattice model with the following weighted average assumptions:

	Six Months Ended
	June 30, 2016
Expected term (in years)	2.8 – 4.5
Risk-free interest rate (%)	1.1%
Expected volatility (%)	55%
Dividend yield (%)	0.0%
Weighted average fair value/share at grant date	\$ 2.57

As of June 30, 2016, there was approximately \$7.4 million of unrecognized share based compensation expense related to stock options that will be recognized over a weighted-average period of approximately 1.4 years. This includes \$2.4 million in unrecognized

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expense related to the 890,000 shares of unvested variable accounted for stock options subject to fair value adjustment at the end of each reporting period based on changes in the Company's stock price.

Stock based compensation expense recognized for stock options and restricted stock and included in the consolidated statements of operations was allocated as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Research and development expense	\$372	\$123	\$363	\$178
General and administrative expense	1,188	385	1,985	635
Total stock based compensation expense	\$1,560	\$508	\$2,348	\$813

Stock based compensation recorded in research and development relates to unvested options and warrants granted to a non-employee.

Common Stock Warrants

A summary of the warrant activity for the six months ended June 30, 2016 is as follows:

	Number of shares	Weighted average exercise price
Warrants outstanding at December 31, 2015	650,000	\$ 1.48
Warrants granted	—	—
Less:		
Warrants exercised	—	—
Warrants canceled or expired	—	—
Warrants outstanding at June 30, 2016	650,000	1.48
Exercisable at June 30, 2016	650,000	1.48

During the three months ended June 30, 2016 and 2015, we recorded \$74,000 and \$111,000 of warrant compensation expense, respectively. During the six months ended June 30, 2016, we recorded warrant compensation gain of \$10,000 and during the six months ended June 30, 2015, we recorded \$207,000 of warrant compensation expense, respectively. Warrant expense for the periods presented is recorded in research and development as the expense relates to unvested performance based warrants granted to a non-employee. As of June 30, 2016 all warrants are fully

vested.

Note I — Commitments

During the three and six months ended June 30, 2016, the Company entered into leases for approximately \$2.2 million and \$2.4 million respectively in laboratory and computer equipment. These leases have 36 month terms, a \$1.00 buyout option at the end of the terms and interest rates of 1.4% and 13.7%. The Company accounted for these lease agreements as capital leases.

Note J — Other Related Party Transaction

During the three months ended June 30, 2016 and 2015, Steven C. Jones, an officer, director and shareholder of the Company, earned approximately \$66,000 and \$65,000, respectively, for consulting work performed in connection with his duties as Executive Vice President of Finance. During the six months ended June 30, 2016 and 2015, Mr. Jones, earned approximately \$132,000 and \$130,000, respectively, for consulting work performed in connection with his duties as Executive Vice President of Finance. Mr. Jones also received approximately \$79,000 and \$78,000 during the six months ended June 30, 2016 and 2015, respectively as payment of his annual bonus compensation for the previous fiscal years.

On April 20, 2016, the Company granted Mr. Jones 100,000 stock options. The options were granted at a price of \$7.15 per share and had a weighted average fair market value of \$3.06 per option. The options vest ratably over the next three years.

NEOGENOMICS, INC.

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Note K —Subsequent Events

In July 2016, the Company entered into a \$1.8 million capital lease for the purchase of hardware and software components to upgrade the storage infrastructure at all locations. This capital lease has a 36 month term and an interest rate of 4.8%. Monthly payments under this lease began on August 1, 2016 in the amount of approximately \$53,000.

END OF FINANCIAL STATEMENTS

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

NeoGenomics, Inc., a Nevada corporation (referred to individually as the "Parent Company" or collectively with its subsidiaries as "NeoGenomics", "we", "us", "our" or the "Company" in this Form 10-K) is the registrant for SEC reporting purposes. Our common stock is listed on the NASDAQ Capital Market under the symbol "NEO".

Introduction

The following discussion and analysis should be read in conjunction with the unaudited consolidated financial statements, and the notes thereto included herein. The information contained below includes statements of the Company's or management's beliefs, expectations, hopes, goals and plans that, if not historical, are forward-looking statements subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. For a discussion on forward-looking statements, see the information set forth in the introductory note to this quarterly report on Form 10-Q under the caption "Forward-Looking Statements", which information is incorporated herein by reference.

Overview

We operate a network of cancer-focused genetic testing laboratories in the United States. Our mission is to improve patient care through exceptional genetic and molecular testing services. Our vision is to become the World's leading cancer testing and information company by delivering uncompromising quality, exceptional service and innovative solutions.

On December 30, 2015, we acquired Clariant, and its wholly owned subsidiary Clariant Diagnostic Services, Inc. from GE Medical, a subsidiary of General Electric Company, for approximately \$249.5 million, consisting of (i) cash consideration of approximately \$74.0 million, which included an approximately \$6.7 million estimated working capital adjustment and adjustments for estimated cash on hand and estimated indebtedness of Clariant on the closing date, (ii) 15,000,000 shares of our common stock, and (iii) 14,666,667 shares of our Series A Preferred Stock (the "Acquisition"). For additional information and risks associated with the acquisition, see "Risk Factors," which appears in Item 1A of the Form 10-K which was filed with the SEC on March 15, 2016 and as amended and filed with the SEC on April 18, 2016.

We believe the acquisition will allow us to broaden our offering of innovative cancer diagnostic tests to hospitals and physicians across the United States and to accelerate growth in the worldwide market for pharmaceutical clinical trials and research. The following discussion of our business includes the effects of the acquisition of Clariant.

As of June 30, 2016, the Company has laboratory locations in Ft. Myers and Tampa, Florida; Aliso Viejo, Fresno, Irvine, and West Sacramento, California; Houston, Texas and Nashville, Tennessee, and currently offers the following types of genetic and molecular testing services:

- a) Cytogenetics - the study of normal and abnormal chromosomes and their relationship to disease. It involves looking at the chromosome structure to identify changes from patterns seen in normal chromosomes. Cytogenetic studies are often utilized to answer diagnostic, prognostic and predictive questions in the treatment of hematological malignancies.
- b) Fluorescence In-Situ Hybridization ("FISH") - a branch of cancer genetics that focuses on detecting and locating the presence or absence of specific DNA sequences and genes on chromosomes. FISH helps bridge abnormality detection between the chromosomal and DNA sequence levels. The technique uses fluorescent probes that bind to only those parts of the chromosome with which they show a high degree of sequence similarity. Fluorescence microscopy is used to visualize the fluorescent probes bound to the chromosomes. FISH can be used to help identify a number of gene alternations, such as amplification, deletions, and translocations.

- c) Flow cytometry - a rapid way to measure the characteristics of cell populations. Cells from peripheral blood, bone marrow aspirate, lymph nodes, and other areas are labeled with selective fluorescent antibodies and analyzed as they flow in a fluid stream through a beam of light. The properties measured in these antibodies include the relative size, relative granularity or internal complexity, and relative fluorescence intensity. These fluorescent antibodies bind to specific cell surface antigens and are used to identify malignant cell populations. Flow cytometry is typically performed in diagnosing a wide variety of leukemia and lymphoma neoplasms. Flow cytometry is also used to monitor patients through therapy to determine whether the disease burden is increasing or decreasing, otherwise known as minimal residual disease monitoring.
- d) Immunohistochemistry (“IHC”) and Digital Imaging – Refers to the process of localizing proteins in cells of a tissue section and relies on the principle of antibodies binding specifically to antigens in biological tissues. IHC is widely used

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

in the diagnosis of abnormal cells such as those found in cancerous tumors. Specific surface cytoplasmic or nuclear markers are characteristic of cellular events such as proliferation or cell death (apoptosis). IHC is also widely used to understand the distribution and localization of differentially expressed proteins. Digital imaging allows clients to see and utilize scanned slides and perform quantitative analysis for certain stains. Scanned slides are received online in real time and can be previewed often a full day before the glass slides can be shipped back to clients.

- e)Molecular testing - a rapidly growing cancer testing methodology that focuses on the analysis of DNA and RNA, as well as the structure and function of genes at the molecular level. Molecular testing employs multiple technologies including DNA fragment length analysis, real-time polymerase chain reaction (“RT-PCR”) RNA analysis, bi-directional Sanger sequencing analysis, and Next-Generation Sequencing (“NGS”).
 - f)Pathology consultation - services provided to clients whereby our pathologists review surgical samples on a consultative basis. NeoGenomics is one of a few laboratories in the country with an electron microscopy lab which enables us to analyze complex renal cases.
 - g)BioPharma Services and Clinical Trials – services supporting pharmaceutical firms in their drug development programs by supporting various clinical trials and other research initiatives. This growing portion of our business often involves working with the pharmaceutical firms (sponsors) on study design as well as performing the required testing. Our medical team often advises the investigators and works closely with the researchers as specimens are received from the enrolled sites. We have also worked on developing tests that will be used as part of a companion diagnostic to determine patients’ response to a particular drug. When studies are completed, our clinical trials team will report the data and often provide key analysis and insights back to the sponsors.
- Our BioPharma Services and Clinical Trials group provides comprehensive testing services in support of our pharmaceutical clients’ oncology programs from discovery to commercialization. In biomarker discovery, our aim is to help our customers discover the right content. We help our customers develop a biomarker hypothesis by recommending an optimal platform for molecular screening and backing our discovery tools with the informatics to capture meaningful data. In other pre and non-clinical work, we can use our research and testing platforms to characterize markers of interest. Moving from discovery to development, we help our customers refine their biomarker strategy and, if applicable, develop a companion diagnostic pathway using the optimal technology for large-scale clinical trial testing.

After assay design and validation, we provide laboratory services for large scale clinical trial testing. Whether serving as the single contract research organization (“CRO”) or partnering one, our BioPharma Services and Clinical Trials team provides significant technical expertise and works closely with our customers to support each stage of clinical trial development. Each trial we support comes with rapid turnaround time, dedicated project management and Quality Assurance oversight. We have experience in supporting FDA submissions for companion diagnostics and our pharma services activities are backed by our large clinical laboratory in Aliso Viejo, CA. Our BioPharma Services and Clinical Trials business is supported by full-time sales associates. Our goal remains focused on helping bring more effective oncology treatments to market through providing world class laboratory services in oncology.

Multiomyx™ - is a hyperplexed immunofluorescence assay technology that has similar staining characteristics as standard immunohistochemical stains, and has the significant advantage that up to 60 multiple proteins can be interrogated from a single FFPE section. Direct comparison of multiple biomarkers is made on the same cell, enabling routine co-expression analysis and identification of cells requiring multiple biomarkers staining. In addition to protein

analysis, MultiOmyx is able to integrate genomic data utilizing FISH and NGS on the same sample to generate multiomic phenotypes. Currently, we are only offering MultiomyxTM services to our BioPharma and research clients.

The clinical cancer testing services we offer to community-based pathologists are designed to be a natural extension of, and complementary to, the services that they perform within their own practices. We believe our relationship as a non-competitive partner to community-based pathology practices, hospital pathology labs and academic centers empowers them to expand their breadth of testing and provides a menu of services that we believe matches or exceeds the level of service found in any center of excellence around the world. Community-based pathology practices and hospital pathology labs may order certain testing services on a technical component only (“TC” or “tech-only”) basis, which allows them to participate in the diagnostic process by performing the professional component (“PC”) interpretation services without having to hire laboratory technologists or purchase the sophisticated equipment needed to perform the technical component of the tests. We also support our pathology clients with interpretation and

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consultative services using our own specialized pathologists for difficult or complex cases and provide overflow interpretation services when requested by clients.

In areas where we do not provide services to community-based pathology practices and/or hospital pathology labs, we may directly serve oncology, dermatology, urology and other clinician practices that prefer to have a direct relationship with a laboratory for cancer-related genetic and molecular testing services. We typically service these types of clients with a comprehensive service offering where we perform both the technical and professional components of the tests ordered. However, in certain instances larger clinician practices have begun to internalize pathology interpretation services, and our "tech-only" service offering allows these larger clinician practices to also participate in the diagnostic process by performing the PC interpretation services on TC testing performed by NeoGenomics.

2016 Focus Areas: Drive a "One Company Culture, Integrate, Grow and Innovate

In the past several years, NeoGenomics has experienced rapid growth, substantially all of which has been organic. In December 2015, NeoGenomics completed its acquisition of Clariant from GE Medical. As a result, we expect to more than double in revenue in 2016, and we have focused on several initiatives to continue to build our company to be the World's leading cancer testing and information company.

Create a "One Company" Culture

We believe our acquisition of Clariant in 2015 presents us with a unique opportunity to create a unified corporate culture that supports our vision, values, and strategic objectives. We believe that by engaging our people, we will be able to retain them and motivate them to meet and exceed the expectations of our clients. Excellent teamwork is required as we implement best practices across our expanded testing disciplines and consolidate operations and facilities.

To create a climate of strong teamwork, we constantly communicate company values as well as developments in our business. We invest substantially in training our employees and are working to become a "Best Place to Work" company. We conduct surveys and take action based on feedback from employees designed to make our Company a better place for people to work. We also work to develop and implement performance-based incentive plans for every employee at the company as a tool to reinforce our desired behaviors and organizational culture. Creating a single organizational culture based on values and high performance is a critical initiative and key part of our 2016 plan.

Integrate for Success

Combining the best of NeoGenomics' and Clariant's testing menus and services is one of our main objectives for 2016. There was overlap in many of our test offerings, and differences between operating processes and procedures. As a result, we are rapidly working to develop a single test menu, a single Laboratory Information System ("LIS"), a single billing process, a single brand, and a unified service offering.

Our medical and operating teams are working to develop and implement plans to ensure that we are offering the best tests for our clients. Our information technology teams are working to combine the best features from each LIS. Numerous laboratory functional teams are reviewing and revising processes and procedures to select the highest quality and lowest-cost testing platforms. Our sales teams have been combined to form one national team so that each account has one point of contact. In billing, we intend to combine our separate operations using common policies and procedures in each billing location, and will integrate all operations using a common billing information system. While we expect significant synergies from the combination of our two laboratories, we are also focused on retaining all our clients, and our goal is to ensure that we maintain the highest quality service throughout the integration process.

We believe successfully integrating Clariant's and NeoGenomics' operations will also allow us to become more efficient and to reduce our cost per test. Our best practice teams are working with our information technology teams to make improvements in efficiencies to our lab processes, including a wide-scale adoption of on-line ordering, bar coding, specimen tracking, and other tools to create a streamlined, seamless, and efficient lab.

In addition, we are working to implement plans to consolidate our Irvine Lab facility into our Aliso Viejo Lab facility, and to further streamline the design and operation of this consolidated laboratory. Historically, improvements in our processes and procedures have

NEOGENOMICS, INC.

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

had a dramatic impact on our cost structure and have allowed us to absorb reductions in average revenue per test with minimal impact to gross margin. For example, during the years ended December 31, 2015 and 2014, we reduced our average cost of goods sold per test in our legacy NeoGenomics business, which we define to exclude the PathLogic and Clariant businesses by 8.6% and 4.7%, respectively, versus the comparable periods in 2014 and 2013, and we have identified several other areas in the laboratory where we believe we can drive further automation and efficiencies.

Drive Profitable Growth

Our plans for the remainder of 2016 include initiatives to continue our strong organic growth performance. We will continue to pursue market share gains by providing high complexity, cancer-related laboratory testing services to hospitals, community-based pathology practices, and clinicians throughout the United States. We currently perform comprehensive analyses for hematopoietic cancers such as leukemia and lymphoma (blood and lymphoid tumors) as well as solid tumors such as breast, lung, colon, and bladder cancers. For hematopoietic cancers, we typically analyze bone marrow aspirate and peripheral blood specimens. For solid tumors cancers, we typically analyze tissue samples or urine.

Our growth over the past several years has been significantly influenced by our sales team performance. Our highly trained sales team has been successful in competing against other laboratories because we have one of the broadest and most comprehensive test menus in our industry. Our sales team is experienced with the scientific complexity and medical necessity of our testing services, and understands the needs of our client pathologists and oncologists. Our sales representatives often become trusted advisors to our clients who rely on them and NeoGenomics, to keep up with the latest developments in the rapidly changing field of molecular genetics. We have also been successful in expanding to new geographies where we did not previously have sales representation and this has helped us bring our service offerings to new clients. We believe the strength of our sales team, comprehensive test menu, and our reputation for high quality services, positions us to further drive growth throughout 2016.

Our growth has also been aided by strong client retention. We believe our high rates of client retention are due to strong service levels, our "tech-only" service offerings, and a culture of customer focus in which our engaged employees seek to deliver the highest customer satisfaction possible. Our "tech-only" testing option allows local pathologists to participate with us in the testing process by interpreting results and performing the professional component of certain tests. Our strong service levels are reinforced by a disciplined management process with a system of detailed measures and metrics to ensure committed turnaround times and customer service. By retaining our existing customer base and bringing in a steady stream of new customers, we have been able to organically grow our business significantly faster than the growth rate of the overall market and we plan to continue these activities throughout 2016.

We will also look to grow our business through mergers or acquisitions if the right opportunities become available. We are focused on strategic opportunities that would be complementary to our menu of services and would be accretive to our earnings and cash flow in the short to medium timeframe. In 2014 we acquired Path Labs, LLC, doing business as ("PathLogic"), a provider of specialized anatomic pathology services to hospitals and physicians

primarily in Northern California. PathLogic provides high-quality Anatomic Pathology services with significant expertise in the sub-specialties of renal pathology, dermatopathology, women's health and gastrointestinal and genitourinary pathology.

On December 30, 2015 we completed the acquisition of Clariant. Clariant specializes in advanced genetic and molecular oncology diagnostic services and will enable NeoGenomics to broaden its offering of innovative cancer diagnostic tests to hospitals and physicians across the country, and to accelerate its growth in the fast-growing worldwide market for pharmaceutical clinical trials and research. Complementary product offerings and expanded geographical reach of the combined Company are expected to provide customers with substantial benefits and create a significantly larger and more diversified provider of precision oncology diagnostics. The Clariant transaction is a good example of the type of acquisition opportunity we will consider in the future.

Continuously Innovate

We are keenly focused on innovation, and believe this has been a key factor in our growth. Over the past several years, we have developed over 125 new or improved molecular oncology tests and disease-specific panels, and believe we now have one of the most comprehensive oncology test menus of any laboratory in the world. By launching new medically significant and necessary tests at a steady rate, we are able to provide cutting-edge developments in molecular genetics for clients and their patients, and we are developing our reputation as a leader in the field of molecular oncology.

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Our broad and innovative testing menu allows us to serve community-based pathologists and clinicians as well as pharmaceutical customers and nationally recognized academic centers. In addition, our comprehensive test offering allows us to be a one-stop shop for all of the oncology testing needs of our clients. Pharmaceutical firms are also attracted to our laboratory based on our knowledgeable research and development team and our ability to offer tests at the forefront of medical developments. In many cases, customers who begin using us because of our new innovative test offerings also begin to refer portions of their other testing. Therefore, innovation helps in many ways to sustain our growth.

We are committed to being an innovative leader in oncology testing. Our goal is to develop new assays to help physician clients better manage their patients and to enable them to practice evidence-based medicine tailored specifically for each of their patients. For example, during the year ended December 31, 2015, we introduced approximately 70 new or enhanced molecular and FISH based tests and cancer profiles. In 2014, we launched our multimodality solid tumor "Discovery Profile" which analyzes 315 genes for mutation using NGS and includes 9 FISH tests to analyze translocations, amplifications and deletions that might be missed by NGS. Our multimodality testing is somewhat unique in the industry and provides the gold standard FISH testing for detecting therapy-related abnormalities, many of which are required to be confirmed by FISH prior to initiating expensive therapy.

We are also focused on opportunities to offer "liquid biopsy" testing. We recently launched twelve NeoLABTM liquid biopsy tests for hematological disease using next generation sequencing and other advanced molecular technologies. These twelve new tests use cell-free circulating DNA and RNA found in blood plasma to identify molecular abnormalities in the bone marrow without the need for a bone marrow biopsy. The technology is based on the concept that hematologic cells release their DNA, RNA, and proteins into circulation as the cells are immersed in blood. The cell-free circulating DNA, RNA and proteins are referred to as exosomes, microvesicles, apoptotic bodies or simply DNA- or RNA-protein complexes. Our new tests use proprietary methods to extract these circulating nucleic acids and analyze them using next generation sequencing and other advanced methods in order to evaluate molecular abnormalities present in hematological cancers. We estimate that more than 600,000 bone marrow biopsies are performed annually in the United States to diagnose and monitor patients with various hematologic cancers. However, bone marrow biopsies are a painful and uncomfortable procedure for patients, and can be associated with complications. These new tests are designed to help patients by reducing the need for bone marrow biopsies, and to assist clinicians in their treatment of cancer patients. Physicians can utilize the new liquid biopsy tests to: 1) screen patients to determine if a bone marrow biopsy is necessary, especially when myelodysplastic syndrome or acute leukemia is suspected; 2) monitor disease status, response to therapy and predict early relapse without having to perform repeated bone marrow biopsies at set intervals; and 3) complete testing when a bone marrow sample is inadequate or is technically difficult to obtain.

We also continue to develop new testing approaches by combining the capabilities of a variety of testing technologies. We introduced a number of NeoTYPETM profiles that combine multiple molecular tests into multi-gene tests targeting specific types of cancer to help pathologists and oncologists determine cancer subtypes on difficult cases. Managed care payers have expressed interest in the more targeted panels as a more cost effective alternative to ordering large panels that include genes that have never been tied to a particular type of cancer. We use NGS and bi-directional Sanger sequencing analysis which we believe is superior to many of the molecular tests being offered by our competitors because we are able to detect mutations that other methods would not detect. We also add other

testing modalities to NGS such as FISH, IHC and flow cytometry which allow for a more comprehensive analysis of each case.

We are working to develop a proprietary NeoLAB™ (Liquid Biopsy) Prostate cancer test that is performed on blood plasma and urine rather than on prostate tissue biopsies. There are two goals for this test: 1) to diagnose the presence of cancer in patients and 2) to distinguish high-grade from low-grade cancer in patients with prostate cancer. We completed a preliminary patient study in June 2013, and the results were published in March 2014 in the Genetic Testing and Molecular Biomarkers journal. In addition, in February 2014, we completed a follow up study with additional patient samples which confirmed the published preliminary data from the first trial. The results of this second study were presented at the American Society of Clinical Oncology (“ASCO”) meeting in 2014 and were published in the Journal of Cancer in February of 2016. We are also conducting a prospective validation study with over 2,500 patients enrolled thus far to further validate the efficacy of our NeoLAB™ Prostate Test. Recruitment for this prospective study was concluded by the end of 2015. Patients are being followed to collect outcome data and perform statistical analysis. We are planning a full commercial launch of the NeoLAB™ Prostate Test in 2016.

We also expect to continue to make investments in research and development that will allow us to commercialize a number of new and innovative genetic tests as scientific and medical technological advances are made.

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Turnaround Times

We strive to provide industry leading turnaround times for test results to our clients nationwide. By providing information to our clients in a rapid manner, physicians can begin treating their patients as soon as possible. We believe our average 4-5 day turnaround time for our cytogenetics testing services, our average 3-4 day turnaround time for FISH testing services, our 5-7 day turnaround time for molecular testing and our average 1 day turnaround time for flow cytometry and pathology testing services are industry-leading benchmarks for national laboratories. Our consistent timeliness of results is a competitive strength and a driver of additional testing requests by our referring physicians. Rapid turnaround times allow for the performance of other adjunctive tests within an acceptable diagnosis window in order to augment or confirm results and more fully inform treatment options. We believe that our fast turnaround times are a key differentiator versus other national laboratories, and our clients often cite them as a key factor in their relationship with us.

Medical and Scientific Team

Our team of medical professionals and PhDs are specialists in the field of genetics, oncology and pathology. As of June 30, 2016, NeoGenomics medical and scientific team included approximately 30 full and part time Pathologists and PhDs. The team is responsible for the quality of the Company's testing, and for the development and validation of the new assays. The addition of Clariant's pathology team has added increased depth to our medical team, and has enhanced our ability to service a wider range of specialties.

Extensive Tech-Only Service Offerings

We believe, we have the most extensive menu of "tech-only" FISH services in the country. We also offer "tech-only" flow cytometry and IHC testing services. These types of testing services allow the professional interpretation component of a test to be performed and billed separately by our physician clients. Our FISH, flow cytometry and other tech-only service offerings allow properly trained and credentialed community-based pathologists to extend their own practices by performing professional interpretations services, which allows them to better service the needs of their local clientele without a direct investment in costly lab equipment and personnel required to perform the technical component of genetic and molecular testing.

Our tech-only services are designed to give pathologists the option to choose, on a case by case basis, whether they want to order just the technical information and images relating to a specific test so they can perform the professional interpretation, or order "global" services and receive a comprehensive test report which includes a NeoGenomics Pathologist's interpretation of the test results. Our clients appreciate the flexibility to access NeoGenomics' medical staff for difficult or complex cases or when they are otherwise unavailable to perform professional interpretations. We believe this innovative approach to serving the needs of pathology clients' results in longer term, more committed and strategic client relationships. Our extensive "tech-only" service offerings have differentiated us and allowed us to compete more effectively against larger, more entrenched competitors in our niche of the industry.

Global Service Offerings

We also offer a comprehensive suite of technical and interpretation services, to meet the needs of those clients who are not credentialed and trained in interpreting genetic tests and who are looking for specialists to interpret the testing results for them. In our global service offerings, our lab performs the technical component of the tests and our M.D.s and Ph.Ds. provide the service of interpreting the results of those tests. Our professional staff is also available for post-test consultative services. Clients using our global service offering rely on the expertise of our medical team to give them the answers they need in a timely manner to help inform their diagnoses and treatment decisions. Many of our tech-only clients also rely on our medical team for difficult or challenging cases by ordering our global testing services on a case-by-case basis or our medical team can serve as a backup to support our clients who need help to satisfy the continued and demanding requirements of their practice. Our reporting capabilities allow for all relevant case data from our global services to be captured in one summary report. When providing global services, NeoGenomics bills for both the technical and professional component of the test, which results in a higher reimbursement level.

Superior Testing Technologies and Instrumentation

We use some of the most advanced testing technologies and instrumentation in the laboratory industry. The use of next generation sequencing in our molecular testing allows us to detect multiple mutations and our proprietary techniques allow us to achieve high

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sensitivity in our next generation sequencing testing. In addition, we use high sensitivity Sanger sequencing, RNA and DNA quantification, SNP/Cytogenetic arrays, Fragment Length analysis, and other molecular testing technologies. Our automated FISH and Cytogenetics tools allow us to deliver the highest quality testing to our clients and our flow cytometry laboratory uses 10-color flow cytometry analysis technology on a technical-only basis. We are one of only a few laboratories with an electron microscopy department for diagnosis in complex renal case analysis. Our MultiOmyx platform is a unique immunofluorescence array technology that allows up to sixty immunohistochemistry stains to be analyzed on a single slide. We are continually testing new laboratory equipment in order to remain at the forefront of new developments in the testing field.

Laboratory Information System

We believe we have a state-of-the-art LIS that interconnects our locations and provides flexible reporting solutions to clients. This system allows us to standardize testing and deliver uniform test results and images throughout our network, regardless of the location that any specific portion of a test is performed within our network. This allows us to move specimens and image analysis work between locations to better balance our workload. Our LIS also allows us to offer highly specialized and customizable reporting solutions to our tech-only clients. For instance, our "tech-only" FISH and flow cytometry applications allow our community-based pathologist clients to tailor individual reports to their specifications and incorporate only the images they select and then issue and sign-out such reports using our system. Our customized reporting solution also allows our clients to incorporate test results performed on ancillary tests not performed at NeoGenomics into summary report templates. This FlexREPORT feature has been well-received by clients.

National Direct Sales Force

Our direct sales force has been trained extensively in cancer genetic testing and consultative selling skills to service the needs of clients. Our sales team for our core clinical genetic testing business is organized into five regions (Northeast, Southeast, North Central, South Central and West), and we have separate sales teams for each of our BioPharma Services and PathLogic businesses. These sales representatives all utilize our custom Customer Relationship Management System ("CRM") to manage their territories, and we have integrated all of the important customer care functionality within our LIS into the CRM so that our sales representatives can stay informed of emerging issues and opportunities within their regions. Our in-house customer care team is aligned with our field sales team to serve the needs of our clients by utilizing the same LIS and CRM. Our field teams can see in real-time when a client calls the laboratory, the reason for the call, the resolution, and if face-to-face interaction is needed for follow-up.

Geographic Locations

Many high complexity laboratories within the cancer testing niche have frequently operated a core facility on either the West Coast or the East Coast of the United States to service the needs of their customers around the country. We believe our clients and prospects desire to do business with a laboratory with national breadth and a local presence. We have eight facilities and five large laboratory locations in Fort Myers, Florida, West Sacramento, California, Aliso Viejo, California, Irvine, California and Houston Texas and three smaller laboratory locations in Fresno, California,

Nashville, Tennessee and Tampa, Florida. Our objective is to “operate one lab with multiple locations” in order to deliver standardized, high quality, test results. We intend to continue to develop and open new laboratories and/or expand our current facilities as market situations dictate and business opportunities arise.

Scientific Advances

In the past few years our field has experienced a rapid increase in tests that are tied to specific “genomic pathways”. These predictive tests are typically individualized for a small sub-set of patients with a specific subtype of cancer. The therapeutic target in the genomic pathway is typically a small molecule found at the level of the cell surface, within the cytoplasm and/or within the nucleus. These genomic pathways, known as the “Hallmarks of Cancer”, contain a target-rich environment for small-molecule “anti-therapies”. These anti-therapies target specific mutations in the major cancer pathways such as the Proliferation Pathway, the Apoptotic Pathway, the Angiogenic Pathway, the Metastasis Pathway, and the Signaling Pathways and Anti-Signaling Pathways.

Seasonality

The majority of our testing volume is dependent on patients being treated by hematology/oncology professionals and other healthcare providers. Volume of testing generally declines during the vacation seasons, year-end holiday periods and other major holidays,

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particularly when those holidays fall during the middle of the week. In addition, the volume of testing tends to decline due to adverse weather conditions, such as heavy snow, excessively hot or cold spells or hurricanes, tornados in certain regions, consequently reducing revenues and cash flows in any affected period. Therefore, comparison of the results of successive periods may not accurately reflect trends for future periods.

Please see the section captioned Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2015; as filed with the SEC on March 15, 2016, and amended on April 18, 2016, for a detailed description of our business.

Results of Operations for the Three and Six Months Ended June 30, 2016 as Compared to the Three and Six Months Ended June 30, 2015

On December 30, 2015, we completed the acquisition of Clariant and its wholly owned subsidiary Clariant Diagnostic Services, Inc., from GE Medical. Our year-over-year comparisons are significantly impacted as the results of Clariant are included in the full three and six month periods ended June 30, 2016 while the results of Clariant are not included in the three and six month periods ended June 30, 2015 as the acquisition had not yet been completed (see Note C to the consolidated financial statements for additional information).

The following table presents the consolidated statements of operations as a percentage of revenue:

	For the three months		For the six months	
	ended June 30,		ended June 30,	
	2016	2015	2016	2015
Net revenue	100.0 %	100.0 %	100.0 %	100.0 %
Cost of revenue	54.7 %	55.6 %	54.6 %	57.0 %
Gross Profit	45.3 %	44.4 %	45.4 %	43.0 %
Operating expenses:				
General and administrative	29.7 %	29.0 %	29.9 %	28.7 %
Research and development	2.1 %	3.3 %	2.2 %	3.1 %
Sales and marketing	10.0 %	12.0 %	9.9 %	12.3 %
Total operating expenses	41.8 %	44.3 %	42.0 %	44.1 %
Income (loss) from operations	3.5 %	0.1 %	3.4 %	(1.1) %
Interest expense	2.3 %	0.8 %	2.5 %	0.8 %
Net income (loss) before income taxes	1.2 %	0.9 %	0.9 %	(0.3) %
Income tax expense	0.5 %	0.1 %	0.4 %	0.1 %
Net income (loss)	0.7 %	0.8 %	0.5 %	(0.4) %

The following table presents consolidated revenue by type for the periods indicated (\$ in thousands):

	For the Three Months Ended June 30,				For the Six Months Ended June 30,			
	2016	2015	\$ Change	% Change	2016	2015	\$ Change	% Change
Net Revenue								
Clinical testing revenue	\$56,316	\$24,055	\$32,261	134%	\$110,936	\$46,894	\$64,042	137%
BioPharma & research revenue	6,813	315	6,498	2063%	11,896	502	11,394	2270%
Total Revenue	\$63,129	\$24,370	\$38,759	159%	\$122,832	\$47,396	\$75,436	159%

Revenue

The increase in our clinical testing revenue for the three and the six month periods ended June 30, 2016 as compared to the same periods in 2015 was primarily due to the acquisition of Clariant, which accounted for 77% of the dollar increase in both the three and six month periods, while the rest was from organic growth. NeoGenomics had strong growth in our clinical genetic testing business,

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where we continue to gain new clients. New tests such as PD1 and PDL1 have been well received by our client base and have also increased testing volumes from existing accounts.

The increase in our Biopharma and research revenue for the three and the six months ended June 30, 2016 as compared to the same periods in 2015 was also largely due to the acquisition of Clariant which accounted for 91% and 94% of the dollar increase for the three and six month periods, respectively. BioPharma had a strong second quarter and has seen significant growth in its MultiOmyx testing platform. MultiOmyx allows multiple assays to be run on the same cells, and is very useful to pharmaceutical firms working with limited samples or tissue.

The following table shows clinical genetic testing revenue, cost of revenue, requisitions received and tests performed for the three and six months ended June 30, 2016 and 2015. This data excludes tests performed for BioPharma customers and tests performed by PathLogic (testing revenue and cost of revenue in thousands):

	For the three months ended June 30,			For the six months ended June 30,		
	2016	2015	% Change	2016	2015	% Change
Requisitions received (cases)	90,795	34,147	165.9 %	179,619	65,244	175.3 %
Number of tests performed	140,822	54,632	157.8 %	275,726	103,748	165.8 %
Average number of tests per requisition	1.55	1.60	(3.1 %)	1.54	1.59	(3.5 %)
Total clinical genetic testing revenue	\$54,249	\$22,118	145.3 %	\$106,999	\$42,615	151.1 %
Average revenue per requisition	\$597	\$648	(7.8 %)	\$596	\$653	(8.8 %)
Average revenue per test	\$385	\$405	(4.9 %)	\$388	\$411	(5.5 %)
Total cost of revenue	\$29,153	\$11,832	146.4 %	\$56,921	\$23,415	143.1 %
Average cost per requisition	\$321	\$347	(7.3 %)	\$317	\$359	(11.7 %)
Average cost per test	\$207	\$217	(4.4 %)	\$206	\$226	(8.5 %)

Our year-over-year growth in clinical genetic testing revenue, as shown above, was primarily driven by the inclusion of Clariant, as previously mentioned. We also achieved organic (legacy NeoGenomics business) growth of approximately 32% and 35% in clinical genetic testing revenue for the three and six months ended June 30, 2016 excluding the impact of Clariant. We believe that the increase in revenues are the direct result of our efforts to innovate by developing one of the most comprehensive molecular testing menus in the industry. This broad test menu allows for existing clients to order more testing and also has also attracted many new clients and has helped us to gain market share from competitors. New tests such as PD1 and PDL1 have shown solid growth and continue to establish us at the leading edge as new tests and assays come onto the market.

The decrease in our average revenue per test of 4.9% and 5.5% for the three and six month periods ended June 30, 2016 compared to the same periods in 2015 is primarily attributable to the change in test mix, with the inclusion of Clariant's lower average reimbursement rate per test. Cost per test fell by approximately 4.4% and 8.5% for the three and six month periods ended June 30, 2016 compared to the same periods in 2015 as we continue to see the benefits of scale from the added testing volumes of the combined companies.

We have been successful at reducing cost by internalizing many tests that Clariant previously sent to outside reference laboratories. In the first quarter of 2016, we began performing these tests in house, at a lesser cost. We have also implemented numerous best practices in our laboratories and have incentivized our laboratory teams to reduce the cost of testing. We continue to make enhancements to our laboratory information system (LIS) to improve the productivity of our laboratory teams. We expect to continue to realize cost synergies and reduce our cost of testing as we consolidate our two largest testing facilities in southern California.

Cost of Revenue and Gross Profit

Cost of revenue includes payroll and payroll related costs for performing tests, maintenance and depreciation of laboratory equipment, rent for laboratory facilities, laboratory reagents, probes and supplies, and delivery and courier costs relating to the transportation of specimens to be tested.

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The consolidated cost of revenue and gross profit metrics are as follows (\$ in thousands):

	For the three months ended			For the six months ended		
	June 30,		\$ Change	June 30,		\$ Change
Consolidated	2016	2015		2016	2015	
Cost of revenue	\$ 34,524	\$ 13,557	\$20,967	\$ 67,055	\$ 27,040	\$40,015
Cost of revenue as a % of revenue	54.7	% 55.6	%	54.6	% 57.0	%
Gross Profit	\$ 28,605	\$ 10,813	\$17,792	\$ 55,777	\$ 20,356	\$35,421
Gross Profit as a % of revenue	45.3	% 44.4	%	45.4	% 43.0	%

The dollar increase in consolidated cost of revenue for the three and six months ended June 30, 2016 when compared to the same periods in 2015 were primarily a result of the Clariant acquisition, and also increases in our testing volumes. Cost of revenue as a percentage of revenue decreased year-over-year due to the cost savings initiatives, internalized tests that were previously sent out by Clariant and aforementioned synergies of the combined larger enterprise.

General and Administrative Expenses

General and administrative expenses consist of employee related costs (such as salaries, fringe benefits, and stock based compensation expense) for our billing, finance, human resources, information technology and other administrative personnel. We also allocate professional services, facilities expense, bad debt expense, depreciation, amortization and administrative-related costs to general and administrative expenses.

Consolidated general and administrative expenses for the periods presented are as follows:

	For the three months ended			For the six months ended		
	June 30,		\$ Change	June 30,		\$ Change
(\$ in thousands)	2016	2015		2016	2015	
General and administrative	\$ 18,779	\$ 7,075	\$11,704	\$ 36,785	\$ 13,598	\$23,187
As a % of revenue	29.7	% 29.0	%	29.9	% 28.7	%

The increase in our general and administrative expenses for the three and six months ended June 30, 2016 compared to the same periods in 2015 was largely due to the inclusion of Clariant and the additional resources necessary to manage the growth of the Company and the increased volume of testing. These changes were the result of increased expenses in the following areas: payroll, stock based compensation, depreciation and amortization, travel, technology and equipment, facility, bad debt, and professional fees. We also had an increase of \$1.5 million and \$3.5 million for the three and six months ended June 30, 2016 over the same periods in 2015 associated with amortization of customer lists and trade names as a result of the Clariant acquisition. Excluding these non-cash related expenses, general and administrative expenses as a percentage of revenue would have been 27.4%, versus 29.7% for the three month period and 27.1%, versus 29.9% for the six month period ending June 30, 2016 as compared to the same periods in 2015.

Bad debt expense for the three months ended June 30, 2016 increased by approximately \$2.1 million to \$2.8 million when compared to the same period in 2015. Bad debt as a percentage of revenue was 4.4%, which was higher than last year's rate of 2.9%. Bad debt expense for the six month period ended June 30, 2016 increased by approximately \$4.1 million to \$5.4 million when compared to the same period in 2015. Bad debt as a percentage of revenue was 4.4%, which was higher than last year's rate of 2.8%. These increases as a percentage of sales are primarily related to the addition of Clariant's results. Clariant has historically had a higher bad debt rate than NeoGenomics. We expect our bad debt rate as a percentage of sales to decline over time as we implement NeoGenomics' billing system and billing policies and practices into Clariant.

We expect our general and administrative expenses to increase as we add personnel and equity related compensation expenses, increase our billing and collections activities; incur additional expenses associated with the expansion of our facilities and backup systems; incur additional bad debt expense as sales increase and as we continue to expand our physical infrastructure to support our anticipated growth. A significant portion of our stock based compensation is for non-employee options which are subject to variable accounting, and our expenses will fluctuate based on the performance of our common stock. A rise in the price of our stock will increase our stock compensation expense, and a decline in our stock price will reduce this expense. However, we anticipate that general and administrative expenses as a percentage of consolidated revenue will drop over the coming years if we continue to grow.

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Research and Development Expenses

Research and development (“R&D”) expenses relate to cost of developing new proprietary and non-proprietary genetic tests, including payroll and payroll related costs, maintenance and depreciation of laboratory equipment, laboratory reagents, probes and supplies, as well as costs related to our licensing agreement with Health Discovery Corporation, including the amortization of the licensed technology.

Consolidated research and development expenses for the periods presented are as follows:

	For the three months ended			For the six months ended		
	June 30,			June 30,		
(\$ in thousands)	2016	2015	\$ Change	2016	2015	\$ Change
Research and development	\$ 1,306	\$ 803	\$ 503	\$ 2,752	\$ 1,471	\$ 1,281
As a % of revenue	2.1	% 3.3	%	2.2	% 3.1	%

Excluding stock based compensation expense of \$372,000 and \$123,000 for the three months ended June 30, 2016 and 2015, research and development expense was approximately \$934,000 and \$680,000, respectively. Excluding stock based compensation expense of \$363,000 and \$178,000 for the six months ended June 30, 2016 and 2015, research and development expense was approximately \$2.4 million and \$1.3 million respectively. The stock based compensation increases reflect the increase in the price of our common stock and the fact that the related options and warrants for a non-employee contractor is accounted for at fair value each reporting period. Excluding stock based compensation, the increase in our R&D expense was related to the development of several new tests including our NeoLAB™ Prostate test, which was made available for ordering during the first quarter of 2016. We expect our research and development expenses to fluctuate in future quarters because of increases or decreases in our stock price and the corresponding stock based compensation expense for non-employee stock options. Increases in our stock price result in additional expense and decreases in our stock price can result in recovery of previously recorded expense. We anticipate research and development expenditures will increase over time as a percentage of sales as we continue to invest in innovation and bringing new tests to market.

Sales and Marketing Expenses

Sales and marketing expenses are primarily attributable to employee related costs including sales management, sales representatives, sales and marketing consultants and marketing and customer service personnel.

Consolidated sales and marketing expenses for the periods presented are as follows:

(\$ in thousands)	For the three months ended			For the six months ended			
	June 30,			June 30,			
	2016	2015	\$ Change	2016	2015	\$ Change	
Sales and marketing	\$ 6,327	\$ 2,907	\$ 3,420	\$ 12,127	\$ 5,821	\$ 6,306	
As a % of revenue	10.0	% 11.9	%	9.9	% 12.3	%	

Sales and marketing expenses increased year-over-year, largely attributable to the inclusion of Clariant, as well as the additional sales and marketing personnel and our expansion into new territories and new geographies. We have also added representatives to our BioPharma business as we try to drive additional growth in that area. We expect our sales and marketing expenses over the long term to increase as our test volumes increase, but to remain stable as a percentage of our overall sales.

Interest Expense, net

Interest expense, net is comprised of interest incurred on our term debt, revolving credit facility and our capital lease obligations offset by the interest income we earn on cash deposits. Interest expense, net increased by \$1.3 million for the three month period ending June 30, 2016 compared to the same period in 2015. This increase is due to the debt obligations associated with financing the Clariant acquisition. Interest expense, net increased by \$2.7 million for the six month period ending June 30, 2016 compared to the same period in 2015 which was also due to the debt obligations associated with financing the Clariant acquisition.

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Net Income

The following table provides consolidated net loss available to common stockholders for each period along with the computation of basic and diluted net loss per share for the three and six months ended June 30, 2016 and 2015:

(in thousands, except per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net loss available to common stockholders	\$(5,154)	\$(176)	\$(10,565)	\$(937)
Basic weighted average shares outstanding	77,448	60,425	76,758	60,352
Effect of potentially dilutive securities	—	—	—	—
Diluted weighted average shares outstanding	77,448	60,425	76,758	60,352
Basic net loss per share	\$(0.07)	\$(0.00)	\$(0.14)	\$(0.02)
Diluted net loss per share	\$(0.07)	\$(0.00)	\$(0.14)	\$(0.02)

Non-GAAP Measures

Use of non-GAAP Financial Measures

The Company's financial results are provided in accordance with accounting principles generally accepted in the United States of America (GAAP) and using certain non-GAAP financial measures. Management believes that presentation of operating results using non-GAAP financial measures provides useful supplemental information to investors and facilitates the analysis of the Company's operating results and comparison of operating results across reporting periods and between entities. Management also uses non-GAAP financial measures for financial and operational decision making, planning and forecasting purposes and to manage the Company's business. Management believes that Adjusted EBITDA is a key metric for our business because it is used by our lenders in the calculation of our debt covenants. Management also believes that these non-GAAP financial measures enable investors to evaluate our operating results and future prospects in the same manner as management. The non-GAAP financial measures do not replace the presentation of GAAP financial results and should only be used as a supplement to and not as a substitute for the Company's financial results presented in accordance with GAAP. There are limitations inherent in non-GAAP financial measures because they exclude charges and credits that are required to be included in a GAAP presentation, and do not therefore present the full measure of the Company's recorded costs against its net revenue. In addition, the Company's definition of the non-GAAP financial measures below may differ from non-GAAP measures used by other companies.

Definitions of non-GAAP measures

Non – GAAP EBITDA

We define “EBITDA” as net income from continuing operations before: (i) interest expense, (ii) tax expense, (iii) depreciation and amortization expense.

Non – GAAP Adjusted EBITDA

We define “Adjusted EBITDA” as net income from continuing operations before: (i) interest expense, (ii) tax expense, (iii) depreciation and amortization expense, (iv) non-cash, stock-based compensation expense, and if applicable in a reporting period (v) acquisition related transaction expenses and other significant non-recurring or non-operating (income) or expenses.

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Basis for Non-GAAP Adjustments

Our basis for excluding certain expenses from GAAP financial measures, are outlined below:

- Interest expense – The capital structure of companies significantly affects the amount of interest expense incurred. This expense can vary significantly between periods and between companies. In order to compare performance between periods and companies that have different capital structures and thus different levels of interest obligations, NeoGenomics excludes this expense.
- Income tax expense – The tax positions of companies can vary because of their differing abilities to take advantage of tax benefits and because of the tax policies of the jurisdictions in which they operate. As a result, effective tax rates and the provision for income taxes can vary considerably among companies. In order to compare performance between companies, NeoGenomics excludes this expense.
- Depreciation expense – Companies utilize assets with different useful lives and use different methods of both acquiring and depreciating these assets. These differences can result in considerable variability in the costs of productive assets and the depreciation and amortization expense among companies. In order to compare performance between companies, NeoGenomics excludes this expense.
- Amortization expense – The intangible assets that give rise to this amortization expense relate to acquisitions, and the amounts allocated to such intangible assets and the terms of amortization vary by acquisition and type of asset. NeoGenomics excludes these items to provide a consistent basis for comparing operating results across reporting periods, pre and post-acquisition.
- Stock-based compensation expenses – Although stock-based compensation is an important aspect of the compensation paid to NeoGenomics employees, the related expense is substantially driven by changes in the Company's stock price in any given quarter, which can fluctuate significantly from quarter to quarter and result in large positive or negative impacts to total operating expenses. The variable accounting treatment causing expense to be driven by changes in quarterly stock price is required because many of the Company's full-time Physicians reside in California and are classified as consultants rather than employees due to State regulations. GAAP provides that variable stock based compensation treatment be applied for consultants but not for employees. Without adjusting for these non-cash expenses, the Company believes it would be difficult to compare financial results from operations across reporting periods on a consistent basis.

We believe that EBITDA and Adjusted EBITDA provide more consistent measures of operating performance between entities and across reporting periods by excluding cash and non-cash items of expense that can vary significantly between companies. In addition, adjusted EBITDA is a metric that is used by our lenders in the calculation of our debt covenants. Adjusted EBITDA also assists investors in performing analyses that are consistent with financial models developed by independent research analysts.

EBITDA and Adjusted EBITDA (as defined by us) are not measurements under GAAP and may differ from non-GAAP measures used by other companies. We believe there are limitations inherent in non-GAAP financial measures such as EBITDA and Adjusted EBITDA because they exclude a variety of charges and credits that are

required to be included in a GAAP presentation, and do not therefore present the full measure of NeoGenomics recorded costs against its net revenue. Accordingly, we encourage investors to consider both non-GAAP results together with GAAP results in analyzing our financial performance.

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

The following is a reconciliation of GAAP net income (loss) to Non-GAAP EBITDA and Adjusted EBITDA for the three and six months ended June 30, 2016 and 2015:

	For the three months ended		For the six months ended	
(in thousands)	June 30, 2016	2015	June 30, 2016	2015
Net income (loss) (Per GAAP)	\$413	\$(176)	\$568	\$(937)
Adjustments to Net Income:				
Interest expense (income), net	1,448	189	3,040	384
Income taxes	332	15	505	19
Amortization of intangibles	1,610	97	3,636	190
Depreciation	3,744	1,663	7,329	3,249
EBITDA	7,547	1,788	15,078	2,905
Further Adjustments to EBITDA:				
Non-cash stock based compensation	1,634	619	2,337	1,020
Adjusted EBITDA (non-GAAP)	\$9,181	\$2,407	\$17,415	\$3,925

Trade Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are reported, net of an allowance for doubtful accounts, which is estimated based on the aging of accounts receivable with each payer category and the historical data on bad debts in these aging categories. In addition, the allowance is adjusted periodically for other relevant factors, including regularly assessing the state of our billing operations in order to identify issues which may impact the collectability of receivables or allowance estimates. Revisions to the allowance are recorded as an adjustment to bad debt expense within general and administrative expenses. After appropriate collection efforts have been exhausted, specific receivables deemed to be uncollectible are charged against the allowance in the period they are deemed uncollectible. Recoveries of receivables previously written-off are recorded as credits to the allowance.

The following tables present the Company's gross outstanding accounts receivable (\$ in thousands) by payer group at June 30, 2016 and December 31, 2015:

NEOGENOMICS AGING OF RECEIVABLES BY PAYER GROUP

June 30, 2016

Payer Group	0-30	%	31-60	%	61-90	%	91-120	%	>120	%	Total	%
Client	\$14,924	24%	\$7,941	13%	\$3,976	6%	\$1,352	2%	\$5,215	8%	\$33,408	53%
Commercial Insurance	2,448	4%	2,705	4%	2,000	3%	1,983	3%	6,786	11%	15,922	25%

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Medicaid	111	0 %	88	0 %	56	0 %	54	0%	131	0 %	440	0 %
Medicare	1,478	2 %	1,071	2 %	654	2 %	500	1%	2,316	4 %	6,019	11 %
Private Pay	16	0 %	11	0 %	9	0 %	5	0%	(4)	0 %	37	0 %
Unbilled Revenue	6,185	11%	195	0 %	178	0 %	138	0%	188	0 %	6,884	11 %
Total	\$25,162	41 %	\$12,011	19%	\$6,873	11%	\$4,032	6%	\$14,632	23 %	\$62,710	100%

NEOGENOMICS AGING OF RECEIVABLES BY PAYER GROUP

December 31, 2015

Payer Group	0-30	%	31-60	%	61-90	%	91-120	%	>120	%	Total	%
Client	\$12,444	22%	\$6,383	11%	\$3,271	6%	\$2,138	4%	\$4,287	8%	\$28,523	51%
Commercial												
Insurance	2,572	4%	2,734	5%	2,185	4%	1,825	3%	5,268	9%	14,584	25%
Medicaid	93	0%	77	0%	94	0%	58	0%	82	0%	404	1%
Medicare	1,617	3%	1,306	2%	792	1%	660	1%	2,056	4%	6,431	10%
Private Pay	16	0%	11	0%	9	0%	5	0%	5	0%	46	0%
Unbilled												
Revenue	6,346	11%	279	0%	154	0%	96	0%	568	1%	7,443	13%
Total	\$23,088	40%	\$10,790	19%	\$6,505	11%	\$4,782	8%	\$12,266	22%	\$57,431	100%

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

The following table represents the balance in allowance for doubtful accounts (in thousands) and that allowance as a percentage of gross accounts receivable at June 30, 2016 and December 31, 2015:

	June 30, 2016	December 31, 2015	\$ Change
Allowance for doubtful accounts	\$9,197	\$ 4,759	\$ 4,438
Allowance as a % of gross accounts receivable	14.7 %	8.9 %	

The increase in the allowance for doubtful accounts for the period ended June 30, 2016 as compared to the period ended December 31, 2015 is attributed to the acquisition of Clariant and the historically higher rate of bad debt expense that Clariant has experienced.

Liquidity and Capital Resources

To date, we have financed our operations primarily through public and private sales of equity securities, borrowings against our accounts receivables balances, private debt used for the Clariant acquisition, and cash generated from operations. The following table presents a summary of our consolidated cash flows for operating, investing and financing activities (in thousands) for the six months ended June 30, 2016 and 2015 as well as the period ended cash and cash equivalents and working capital.

	For the six months ended	
	June 30, 2016	2015
Net cash provided by (used in):		
Operating activities	\$ 12,095	\$ 1,897
Investing activities	(3,425)	(1,180)
Financing activities	(10,304)	(1,454)
Net change in cash and cash equivalents	(1,634)	(737)
Cash and cash equivalents, beginning of period	\$ 23,420	\$ 33,689
Cash and cash equivalents, end of period	\$ 21,786	\$ 32,952
Working Capital (1), end of period	\$ 52,556	\$ 44,476

(1) Defined as current assets minus current liabilities.

Cash Provided by Operating Activities

During the six months ended June 30, 2016, cash provided by operating activities increased by approximately \$10.2 million compared with the same period in 2015. The increase was primarily related to the acquisition of Clariant and the related increases in our cash receipts, in addition to our net income for the period ending June 30, 2016 compared to our net loss for the period ended June 30, 2015.

Cash Used in Investing Activities

During the six months ended June 30, 2016, cash used by investing activities increased by approximately \$2.2 million compared with the same period in 2015. This increase was primarily due to equipment purchases which were necessary to support our continued growth and efficiency. In addition, we have begun to incur costs related to the remodel of our laboratory facility in Aliso Viejo as well as the expansion of our billing department in Fort Myers, FL. As we continue to make investments in these areas, we expect to continue to incur expenditures through the remainder of 2016.

Cash Used in Financing Activities

During the six months ended June 30, 2016, cash used by financing activities increased by approximately \$8.9 million compared with the same period in 2015. This increase was primarily due to the \$10 million repayment made on our revolving credit facility in the first quarter of 2016 which was originally used to finance the acquisition of Clariant. Cash used for financing activities was also comprised of repayments on our term loan and our capital lease obligations. These repayments were partially offset by cash received for the issuance of our common stock for the exercise of stock options and Employee Stock Purchase Plan shares.

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

Liquidity Outlook

We had approximately \$21.8 million in cash and cash equivalents as of June 30, 2016. In addition, we have a revolving credit facility which provides for up to \$25.0 million in borrowing capacity. As of June 30, 2016, the entire \$25 million line was undrawn and was available. We believe that the cash on hand, available credit lines and positive cash flows generated from operations will provide adequate resources to meet our operating commitments and interest payments for at least the next 12 months. Our Series A Preferred Stock has certain restrictions that will result in the Company having to dedicate fifty percent of the net proceeds from any future equity raise, to redeeming shares of the Series A Preferred Stock until such time as all of the shares of Series A Preferred Stock have been redeemed.

Capital Expenditures

We currently forecast capital expenditures in order to execute on our business plan and keep up with the growth in our testing volumes, although the actual amount and timing of such capital expenditures will ultimately be determined by the volume of our business. We currently anticipate that our capital expenditures for the year ended December 31, 2016 will be in the range of \$12 million to \$14 million. During the three and six months ended June 30, 2016, we purchased approximately \$4.8 million and \$6.0 million respectively of capital equipment, software and leasehold improvements of which \$2.2 million and \$2.4 million respectively was acquired through capital lease obligations. We have in the past and plan to continue funding these capital expenditures with capital lease financing arrangements, cash, and through bank loan facilities if necessary.

Critical Accounting Policies

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions and select accounting policies that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

While many operational aspects of our business are subject to complex federal, state and local regulations, the accounting for our business is generally straightforward with net revenues primarily recognized upon completion of the testing process. Our revenues are primarily comprised of laboratory tests, and approximately one-half of total operating costs and expenses consist of employee compensation and benefits. Due to the nature of our business, several of our accounting policies involve significant estimates and judgments. These accounting policies have been described in our Annual Report on Form 10-K for the year ended December 31, 2015 as amended

Related Party Transactions

Consulting Agreements

During the three month period ended June 30, 2016 and 2015, Steven C. Jones, an officer, director and shareholder of the Company, earned approximately \$66,000 and \$65,000, respectively, for consulting work performed in connection

with his duties as Executive Vice President of Finance. During the six month period ended June 30, 2016 and 2015, Mr. Jones, earned approximately \$132,000 and \$130,000, respectively, for consulting work performed in connection with his duties as Executive Vice President of Finance. Mr. Jones also received approximately \$79,000 and \$78,000 during the six months ended June 30, 2016 and 2015, respectively as payment of his annual bonus compensation for the previous fiscal years.

On April 20, 2016, the Company granted Mr. Jones 100,000 stock options. The options were granted at a price of \$7.15 per share and had a weighted average fair market value of \$3.06 per option. The options vest ratably over the next three years.

Off-balance Sheet Arrangements

We do not use special purpose entities or other off-balance sheet financing techniques that we believe have, or are reasonably likely to have, a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity or capital resources.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We do not invest in or trade instruments which are sensitive to market risk. We also do not have any material foreign operations or foreign sales so we have no exposure to foreign currency exchange rate risk.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized, and reported within the time periods specified in the SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

As required by SEC Rule 15d-15, our management carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of 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 principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of the end of the period covered by this report.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended June 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time the Company is engaged in legal proceedings in the ordinary course of business. We do not believe any current legal proceedings are material to our business. No material proceedings were terminated during the quarter ended June 30, 2016.

ITEM 1A. RISK FACTORS

We are subject to various risks that may materially harm our business, financial condition and results of operations. They are not, however, the only risks we face. Additional risks and uncertainties not presently known to us or that we currently believe not to be material may also adversely affect our business, financial condition or results of operations. An investor should carefully consider the risks and uncertainties described below and the other information in this filing before deciding to purchase our common stock. If any of these risks or uncertainties actually occurs, our business, financial condition or operating results could be materially harmed. In that case, the trading price of our common stock could decline or we may be forced to cease operations.

Risks Relating to Our Business

We may not be able to implement our business strategies which could impair our ability to continue operations.

Implementation of our business strategies will depend in large part on our ability to (i) attract and maintain a significant number of clients; (ii) effectively provide acceptable products and services to our clients; (iii) develop and license new products and technologies; (iv) obtain adequate financing on favorable terms to fund our business strategies; (v) maintain appropriate internal procedures, policies, and systems; (vi) hire, train, and retain skilled employees and management; (vii) continue to operate despite increasing competition in the medical laboratory industry; (viii) be paid reasonable fees by government payer's that will adequately cover our costs; (ix) establish, develop and maintain our name recognition; and (x) establish and maintain beneficial relationships with third-party insurance providers and other third-party payers. Our inability to obtain or maintain any or all these factors could impair our ability to implement our business strategies successfully, which could have material adverse effects on our results of operations and financial condition.

We may be unsuccessful in managing our growth which could prevent us from operating profitably.

Our growth, including through our acquisition of the business of Clariant, Inc., or Clariant, in December 2015, which we refer to as the Acquisition, has placed, and is expected to continue to place, a significant strain on our managerial, operational and financial resources. On a pro-forma basis the Acquisition would have resulted in combined company revenue for the year ended December 31, 2015 of \$216 million as compared to our annual revenues of \$99.8 million without Clariant. To manage our expanded business and our potential growth, we must continue to implement and improve our operational, financial and billing systems and to expand, train and manage our employee base. We may not be able to effectively manage the expansion of our operations and our systems and our procedures or controls may not be adequate to support our operations. Our management may not be able to achieve the rapid execution necessary to fully exploit the market opportunity for our products and services. Any inability to manage growth could have a material adverse effect on our business, results of operations, potential profitability and financial condition.

We have a substantial amount of indebtedness, much of which was incurred in connection with our acquisition of the Clariant business. This level of indebtedness could adversely affect our flexibility in operating our business and our ability to react to changes in the economy or our industry.

At June 30, 2016, we had \$62.3 million of indebtedness outstanding, and \$25.0 million of available borrowing capacity under our senior secured revolving credit facility. Our substantial indebtedness could have significant consequences for our business and financial condition. For example:

- We will be required to dedicate a greater percentage of our cash flows to payments on our debt, thereby reducing the availability of cash flow to fund capital expenditures, pursue other acquisitions or investments in new technologies, make stock repurchases and fund other general corporate purposes.

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- If we fail to meet our payment obligations or otherwise fail to comply with the covenants in our debt, including failure as a result of events beyond our control, it could result in an event of default on our debt. Upon an event of default, the lenders of that debt could elect to cause all amounts outstanding with respect to that debt to become immediately due and payable and we would be unable to access our revolving credit facility.
- Our debt imposes operating and financial covenants and restrictions on us, and compliance with such covenants and restrictions may adversely affect our ability to adequately finance our operations or capital needs, pursue attractive business opportunities that may arise, redeem or repurchase capital stock, pay dividends, sell assets, and make capital expenditures.
- We will experience increased vulnerability to general adverse economic conditions, including increases in interest rates as the borrowings bear interest at variable rates or if such indebtedness is refinanced at a time when interest rates are higher.
- We will experience limited flexibility in planning for, or reacting to, changes in or challenges relating to our businesses and industry, creating competitive disadvantages compared to other competitors with lower debt levels and borrowing costs.

We cannot assure you that cash flows, combined with additional borrowings under the revolving credit facility or any future credit facility, will be available in an amount sufficient to enable us to repay our indebtedness, or to fund other liquidity needs.

In addition, we may incur substantial additional indebtedness in the future, which could cause the related risks to intensify. We may need to refinance all or a portion of our indebtedness on or before their respective maturities. We cannot assure you that we will be able to refinance any of our indebtedness on commercially reasonable terms or at all. If we are unable to refinance our debt, we may default under the terms of our indebtedness, which could lead to an acceleration of the debt. We do not expect that we could repay all of our outstanding indebtedness if the repayment of such indebtedness was accelerated.

In addition, for so long as any shares of our series A convertible preferred stock, remain outstanding, in the event that we issue any other shares of capital stock or any unsecured debt securities for cash, we are required to apply at least 50% of the net cash proceeds to redeem shares of Series A Preferred Stock at the then-effective liquidation preference, which is \$7.50 per share as of the date of this prospectus, less any applicable redemption discounts. See “Description of Capital Stock—Preferred Stock—Series A Preferred Stock.” As a result, our ability to repay our outstanding indebtedness will be constrained by the fact that we will only receive half of the net cash proceeds from certain capital raising activities for as long as any shares of our Series A Preferred Stock remains outstanding.

Our right to recover for certain breaches of the covenants, agreements, representations and warranties made by GE Medical in connection with the Acquisition are limited.

Pursuant to the stock purchase agreement we entered into in connection with the Acquisition, all covenants, agreements, representations and warranties made by the parties in such agreement survive until March 30, 2017, subject to certain exceptions for the “fundamental representations.” Subject to the terms, conditions and limitations set forth in the stock purchase agreement, GE Medical Holding AB, or GE Medical, will indemnify us against any losses that are suffered or incurred by us resulting from or arising out of a breach of GE Medical’s representations or warranties or covenants contained in the stock purchase agreement. However, other than instances of fraud and breaches of certain “fundamental” representations, GE Medical will not be liable for any losses unless and until the aggregate amount of losses that are suffered or incurred by us exceed \$2.0 million, and then only for losses incurred by us that are in excess of this amount, subject to a limit on GE Medical’s maximum aggregate liability for breaches of representations other than certain “fundamental” representations of \$50.0 million. If we incur any material losses for which GE Medical will not provide indemnification, or if our losses are in excess of GE Medical’s maximum

aggregate liability, our financial condition could be materially and adversely affected.

We also have agreed to indemnify GE Medical for any breaches of our representations, warranties or covenants contained in the stock purchase agreement, subject to similar deductibles and limitations, including the maximum aggregate liability for breaches of representations other than certain “fundamental” representations of \$50.0 million. If we are required to indemnify GE Medical for a material amount pursuant to the stock purchase agreement, our financial condition could be materially and adversely affected.

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We may be unable to make, on a timely basis, necessary changes to our internal control structure resulting from the Acquisition.

As a result of the completion of the Acquisition, Clariant is included in our reporting under the Securities Exchange Act of 1934. Under the Sarbanes-Oxley Act of 2002, we must maintain effective disclosure controls and procedures and internal control over financial reporting. Clariant's internal control structure was previously assessed with regard to the broader environment of General Electric Company and was not subject to a stand-alone review for compliance within the requirements of the Sarbanes-Oxley Act. We are in the process of migrating Clariant's operations to our system of internal controls. Therefore, we may face difficulties or experience delays in developing changes or potentially necessary improvements to Clariant's internal controls and accounting systems in order to ensure compliance with the requirements of the Sarbanes-Oxley Act. We may need to commit substantial resources, including substantial time from existing accounting personnel and from external consultants, to implement additional procedures and improved controls. This in turn could have an adverse effect on our business, results of operations, or financial condition, harm our reputation, or otherwise cause a decline in investor confidence and our stock price.

If we are unable to successfully integrate the Clariant business, or any future business we may acquire, with our legacy business, the anticipated benefits of such transaction may not be realized.

Acquisitions, including the Acquisition, involve the combination of two companies that formerly operated as independent companies. Acquisitions require us to devote significant management attention and resources to integrating the acquired company's business practices and operations with our own. Potential difficulties we may encounter as part of the integration process, all of which could materially and adversely affect our business, financial condition, results of operations, and cash flows, include the following:

- the potential inability to successfully combine the acquired company's business with our legacy business in a manner that permits us to achieve the cost synergies expected to be achieved when expected, or at all, and other benefits anticipated to result from such transaction;
- challenges optimizing the customer information and technology of the two companies, including the goal of consolidating to one laboratory information system and one billing system;
- challenges effectuating any diversification strategy, including challenges achieving revenue growth from sales of each company's products and services to the customers of the other company;
- difficulties offering products and services across our expanded portfolio;
- the need to revisit assumptions about reserves, revenues, capital expenditures, and operating costs, including expected synergies;
- challenges faced by a potential diversion of the attention of our management as a result of the integration, which in turn could adversely affect our ability to maintain relationships with customers, employees and other constituencies or our ability to achieve the anticipated benefits of such transaction;
- the potential loss of key employees, customers, managed care contracts or strategic partners, or the ability to attract or retain key management and other key personnel, which could have an adverse effect on our ability to integrate and operate the acquired business;
- complexities associated with managing the combined businesses, including difficulty addressing possible differences in corporate cultures and management philosophies and the challenge of integrating complex systems, technology, networks and other assets of each of the companies in a seamless manner that minimizes any adverse impact on customers, suppliers, employees and other constituencies;
- costs and challenges related to the integration of the acquired company's internal controls over financial reporting with ours; and
- potential unknown liabilities and unforeseen increased expenses.

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We cannot be assured that all of the goals and anticipated benefits of an acquisition, including the Acquisition, will be achievable, particularly as the achievement of the benefits are in many important respects subject to factors that we do not control. These factors would include such things as the reactions of third parties with whom we enter into contracts and to business and the reactions of investors and analysts.

If we cannot integrate our legacy business and the Clariant business, or any future business we may acquire, successfully, we may fail to realize the expected benefits of such transaction, including the anticipated cost synergies. We could also encounter additional transaction and integration costs or be subject to other factors that affect preliminary estimates.

Clariant may have liabilities that are not known, probable or estimable at this time.

As a result of the Acquisition, Clariant is now an indirect wholly owned subsidiary of ours, and we have effectively assumed all of its past liabilities, whether or not asserted. There could be unasserted claims or assessments that we failed or were unable to discover or identify in the course of performing due diligence investigations of Clariant. In addition, there may be liabilities that are neither probable nor estimable at this time which may become probable and estimable in the future. We may learn additional information about Clariant that adversely affects us, such as unknown, unasserted or contingent liabilities and issues relating to compliance with applicable laws, including federal healthcare laws. For example, Clariant from time to time receives payments from the U.S. government. If the U.S. government were to assert that Clariant were not entitled to receive such payments in the amount provided, or at all, in light of applicable billing guidance, the government could impose fines and penalties, in addition to recovery of the overpayments, under federal healthcare laws. Any of the foregoing, individually or in the aggregate, could have a material adverse effect on our business.

We may experience discontinuation or recalls of existing testing products or failures to develop, or acquire, licenses for new or improved testing technologies which could materially and adversely affect our revenues.

From time to time, manufacturers discontinue or recall reagents, test kits or instruments used by us to perform laboratory testing. Such discontinuations or recalls could adversely affect our costs, testing volume and revenue.

Our industry is subject to changing technology and new product introductions. Our success will depend, in part, on its ability to develop, acquire or license new and improved technologies on favorable terms and to obtain appropriate coverage and reimbursement for these technologies. We may not be able to negotiate acceptable licensing arrangements and we cannot be certain that such arrangements will yield commercially successful diagnostic tests. If we are unable to license these testing methods at competitive rates, our research and development costs may increase as a result. In addition, if we are unable to license new or improved technologies to expand our testing operations, our testing methods may become outdated when compared with our competition and testing volume and revenue may be materially and adversely affected.

We may incur greater costs than anticipated, which could result in sustained losses.

We use reasonable efforts to assess and predict the expenses necessary to pursue our business strategies. However, implementing our business strategies may require more employees, capital equipment, supplies or other expenditure items than management has predicted, particularly as we continue to assess any further needs resulting from the Acquisition. Similarly, the cost of compensating additional management, employees and consultants or other operating costs may be more than we estimate, which could result in ongoing and sustained losses.

We may face fluctuations in our results of operations and we are subject to seasonality in our business which could negatively affect our business operations.

Management expects that our results of operations may fluctuate significantly in the future as a result of a variety of factors, including, but not limited to: (i) the continued rate of growth, usage and acceptance of our products and services; (ii) demand for our products and services; (iii) the introduction and acceptance of new or enhanced products or services by us or by competitors; (iv) our ability to anticipate and effectively adapt to developing markets and to rapidly changing technologies; (v) our ability to attract, retain and motivate qualified personnel; (vi) the initiation, renewal or expiration of significant contracts with any major clients; (vii) pricing changes by us, our suppliers or our competitors; (viii) seasonality; and (ix) general economic conditions and other factors. Accordingly, future sales and operating results are difficult to forecast. Our expenses are based in part on our expectations as to future revenues and to a significant extent are relatively fixed, at least in the short-term. We may not be able to adjust spending in a timely

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manner to compensate for any unexpected revenue shortfall. Accordingly, any significant shortfall in relation to our expectations would likely have an immediate adverse impact on our business, results of operations and financial condition. In addition, we may determine from time to time to make certain pricing or marketing decisions or acquisitions that could have a short-term material adverse effect on our business, results of operations and financial condition and may not result in the long-term benefits intended. Furthermore, in Florida, historically our largest referral market for lab testing services, a meaningful percentage of the population, returns to homes in the Northern United States to avoid the hot summer months. This combined with the usual summer vacation schedules of our clients usually results in seasonality in our business. Because of all of the foregoing factors, our operating results in future periods could be less than the expectations of investors.

We depend substantially upon third parties for payment of services, which could have a material adverse effect on our cash flows and results of operations.

Our business consists of clinical laboratories that provide medical testing services for doctors, hospitals, and other laboratories on patient specimens that are sent to our laboratory. In the case of some specimen referrals that are received for patients that are not in-patients or out-patients at a hospital or institution or otherwise sent by another reference laboratory, we typically bill the patient's insurance company or a government program for our services. As such, we rely on the cooperation of numerous third-party payers, including but not limited to Medicare, Medicaid, and various insurance companies, to get paid for performing services on behalf of our clients and their patients. The amount of such third-party payments is governed by contractual relationships in cases where we are a participating provider for a specified insurance company or by established government reimbursement rates in cases where we are an approved provider for a government program such as Medicare or Medicaid. However, we do not have contractual relationships with some of the insurance companies with whom we deal, nor are we necessarily able to become an approved provider for all government programs. In such cases, we are deemed to be a non-participating provider and there is no contractual assurance that we will be able to collect the amounts billed to such insurance companies or government programs. Currently, we are not a participating provider with some of the insurance companies we bill for our services. Until such time we become a participating provider with such insurance companies, there can be no contractual assurance that we will be paid for the services we bill to such insurance companies or patients, and such third-parties may change their reimbursement policies for non-participating providers in a manner that may have a material adverse effect on our cash flow or results of operations. When new CPT codes are introduced by the American Medical Association it often takes time for commercial insurance providers to recognize the new codes, which can significantly impact the timing of payments, if any, and can increase our days-sales-outstanding. Insurance companies may also try to steer business away from us towards in-network providers by sending letters to physicians and even imposing financial penalties, if they continue to send us business.

Our business is subject to rapid scientific change, which could have a material adverse effect on our business, results of operations and financial condition.

The market for genetic and molecular testing services is characterized by rapid scientific developments, evolving industry standards and customer demands, and frequent new product introductions and enhancements. For example, new tests developed by our competitors may prove superior and replace our existing tests. Our future success will depend in significant part on our ability to continually improve our offerings in response to both evolving demands of the marketplace and competitive service offerings, and we may be unsuccessful in doing so which could have a material adverse effect on our business, results of operations and financial condition. Certain technological changes such as advances in point-of-care testing, could reduce the need for the laboratory tests we provide.

The market for our services is highly competitive, which could have a material adverse effect on our business, results of operations and financial condition.

The market for genetic and molecular testing services is highly competitive and we expect competition to continue to increase. We compete with other commercial clinical laboratories in addition to the in-house laboratories of many major hospitals and physician practices. Many of our existing competitors have significantly greater financial, human, technical and marketing resources than we do. Some physician groups and hospitals have made the decision to internalize testing rather than using an outsourced laboratory such as us and therefore control the referral of their own specimens. Our competitors may develop products and services that are superior to ours or that achieve greater market acceptance than our offerings. We may not be able to compete successfully against current and future sources of competition and in such cases, this may have a material adverse effect on our business, results of operations and financial condition.

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Increased competition, including price competition, could have a material adverse impact on our net revenues and profitability.

Our industry is characterized by intense competition. Our major competitors including Quest Diagnostics and Laboratory Corporation of America are large national laboratories that possess greater name recognition, larger customer bases, and significantly greater financial resources and employ substantially more personnel than we do. Many of our competitors have long established relationships with their customers and third-party payers. We cannot assure you that we will be able to compete successfully with such entities in the future.

The laboratory business is intensely competitive both in terms of price and service. Pricing of laboratory testing services is often one of the most significant factors used by health care providers and third-party payers in selecting a laboratory. As a result of the laboratory industry undergoing consolidation, larger laboratory providers are able to increase cost efficiencies afforded by large-scale automated testing. This consolidation results in greater price competition. We may be unable to increase cost efficiencies sufficiently, if at all, and as a result, our net earnings and cash flows could be negatively impacted by such price competition. Additionally, we may also face changes in fee schedules, competitive bidding for laboratory services or other actions or pressures reducing payment schedules as a result of increased or additional competition.

Additional competition, including price competition, could have a material adverse impact on our net revenues and profitability.

We face the risk of capacity constraints, which could have a material adverse effect on our business, results of operations and financial condition.

We compete in the market place primarily on three factors: (i) the quality and accuracy of our test results; (ii) the speed or turn-around times of our testing services; and (iii) our ability to provide after-test support to those physicians requesting consultation. Any unforeseen increase in the volume of clients could strain the capacity of our personnel and systems, leading to unacceptable turn-around times, or customer service failures. In addition, as the number of our clients and specimens increases, our products, services, and infrastructure may not be able to scale accordingly. We may also not be able to hire additional licensed medical technologists that we need to handle increased volumes. Any failure to handle higher volume of requests for our products and services could lead to the loss of established clients and have a material adverse effect on our business, results of operations and financial condition. If we produce inaccurate test results, our clients may choose not to use us in the future. This could severely harm our business, results of operations and financial condition. In addition, based on the importance of the subject matter of our tests, inaccurate results could result in improper treatment of patients, and potential liability for us.

We may fail to protect our facilities, which could have a material adverse effect on our business, results of operations and financial condition.

Our operations are dependent in part upon our ability to protect our laboratory operations against physical damage from explosions, fire, floods, hurricanes, earthquakes, power loss, telecommunications failures, break-ins and similar events. We do not presently have an emergency back-up generator in place at our Tampa, Florida, Nashville, Tennessee, or Fresno, West Sacramento, or Irvine, California laboratory locations that would otherwise mitigate to some extent the effects of a prolonged power outage. The occurrence of any of these events could result in interruptions, delays or cessations in service to clients, which could have a material adverse effect on our business, results of operations and financial condition.

The steps we have taken to protect our proprietary rights may not be adequate, which could result in infringement or misappropriation by third-parties.

We regard our copyrights, trademarks, trade secrets and similar intellectual property as critical to our success, and we rely upon trademark and copyright law, trade secret protection and confidentiality and/or license agreements with our employees, clients, partners and others to protect our proprietary rights. The steps taken by us to protect our proprietary rights may not be adequate or third parties may infringe or misappropriate our copyrights, trademarks, trade secrets and similar proprietary rights. In addition, other parties may assert infringement claims against us.

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We are dependent on key personnel and need to hire additional qualified personnel in order for our business to succeed.

Our performance is substantially dependent on the performance of our senior management and key technical personnel. In particular, our success depends substantially on the continued efforts of our senior management team, which currently is composed of a small number of individuals. The loss of the services of any of our executive officers, our medical staff, our laboratory directors or other key employees could have a material adverse effect on our business, results of operations and our financial condition. Our future success also depends on our continuing ability to attract and retain highly qualified managerial and technical personnel as we grow. Competition for such personnel is intense and we may not be able to retain our key managerial and technical employees or may not be able to attract and retain additional highly qualified managerial and technical personnel in the future. The inability to attract and retain the necessary managerial and technical personnel could have a material adverse effect upon our business, results of operations and financial condition.

The failure to obtain necessary additional capital to finance growth and capital requirements, could adversely affect our business, financial condition and results of operations.

We may seek to exploit business opportunities that require more capital than we have currently available. We may not be able to raise such capital on favorable terms or at all, and may be restricted in amount and type of such capital by the agreements governing our existing indebtedness. If we are unable to obtain such additional capital, we may be required to reduce the scope of our anticipated expansion, which could adversely affect our business, financial condition and results of operations.

As of June 30, 2016, we had cash and cash equivalents of \$21.8 million and \$25.0 million of available borrowing capacity under our senior secured revolving credit facility. We may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, there could be a material adverse effect on our long-term business, rate of growth, operating results, financial condition and prospects.

Proposed government regulation of Laboratory Developed Tests may result in delays to launching certain laboratory tests and increase our costs to implement new tests.

We frequently develop testing procedures to provide diagnostic results to clients that cannot currently be provided using test kits approved or cleared by the U.S. Food and Drug Administration, or FDA. The FDA has been considering changes to the way that it regulates these Laboratory Developed Tests, or LDTs. Currently all LDTs are conducted and offered in accordance with the Clinical Laboratory Improvements Amendments, or CLIA, and individual state licensing procedures. The FDA has published a draft guidance document that would require FDA clearance or approval of a subset of LDTs, as well as a modified approach for some lower risk LDTs that may require FDA oversight short of the full premarket approval or clearance process. FDA is taking the position that it can implement these new LDT regulatory requirements without promulgating formal regulations. As a result, there is a risk that the FDA's proposed regulatory process could delay the offering of certain tests and result in additional validation costs and fees. There is also an associated risk for us that some tests currently offered might become subject to FDA premarket approval or clearance. This FDA approval or clearance process would be time-consuming and costly, with no guarantee of ultimate approval or clearance.

On July 31, 2014 the FDA issued a notification to Congress of the "Anticipated Details of the Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of

Laboratory Developed Tests,” or the Draft LDT Guidance. As described in this notification, the FDA planned to provide draft guidance to clinical laboratories that develop their own LDTs regarding how the FDA intends to regulate such laboratories under the Federal Food, Drug, and Cosmetic Act. On October 3, 2014 the FDA issued the draft guidance to clinical laboratories. The regulatory framework will use a risk-based approach to enforce the FDA’s premarket review requirements, and for high-risk tests, the framework may require laboratories to use FDA-approved tests, if available, rather than LDTs. If implemented, the framework outlined in the Draft LDT Guidance may also require us to obtain premarket clearance or approval for certain of our LDTs. Implementation of this framework would include a lengthy phase-in period ranging from two to nine years depending on the risk assessment rating of each particular test. The FDA provided an opportunity for public comment through February 2015, but the Draft LDT Guidance has not been finalized to date. Through the ACLA, the industry has announced its opposition to the Draft LDT Guidance and submitted comments to the FDA in response to the draft guidance. In addition to the ACLA public comment, the FDA received 169 public comments in response to the Draft LDT Guidance, however it remains unknown whether the regulatory framework ultimately implemented by the FDA will differ substantially from the framework described in the Draft LDT Guidance. This FDA regulation may result in increased regulatory burdens for us to register and continue to offer our tests or to develop and introduce new tests and may increase our costs. We do yet

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know which of our tests would be classified as high-risk and would require a full FDA approval. If such approval was required, we cannot be certain that our tests would obtain FDA approval or clearance.

The FDA's current proposal could require a significant volume of applications with the FDA which would be burdensome and the FDA could take a long time to review them if every lab in the country files a large volume of registrations and applications for each of their LDT's.

If we were required to conduct additional clinical trials prior to continuing to sell our current tests or launching any other tests we may develop, those trials could result in delays or failure to obtain necessary regulatory approvals, which could harm our business.

In the event that, in the future, the FDA begins to regulate our tests, it may require additional pre-market clinical testing prior to submitting a regulatory notification or application for commercial sales. Such pre-market clinical testing could delay the commencement or completion of clinical testing, significantly increase our test development costs, delay commercialization of any future tests, and interrupt sales of our current tests. 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.

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. 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.

Failure in our information technology systems could significantly increase testing turn-around time or billing processes and otherwise disrupt our operations.

Our laboratory operations depend, in part, on the continued performance of our information technology systems. Our information technology systems are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptions. In addition, we are in the process of integrating the information technology systems of Clariant, and we may experience system failures or interruptions as a result of this process. Sustained system failures or interruption of our systems in one or more of our laboratory operations could disrupt our ability to process laboratory requisitions, perform testing, provide test results in a timely manner and/or bill the appropriate party. Breaches with respect to protected health information could result in violations of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, and analogous state laws, and risk the imposition of significant fines and penalties. Failure of our information technology systems could adversely affect our business, profitability and financial condition.

Healthcare reform programs may impact our business and the pricing we receive for our services.

In March of 2010, health care reform legislation known as the “Patient Protection and Affordable Care Act,” which we refer to as the ACA, was passed into law. The ACA also makes changes that are expected to significantly impact the pharmaceutical and medical device industries and clinical laboratories. For example, effective December 31, 2017, each medical device manufacturer must pay sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices that are listed with the FDA. Although the FDA issued Draft LDT Guidance that, if finalized, would regulate certain clinical laboratory tests that are developed and validated by a laboratory for its own use, or LDTs, as medical devices, none of our LDT’s such as our prostate cancer test are currently listed with the FDA. We cannot assure you that the tax will not apply to services such as ours in the future.

The ACA contains several provisions that seek to limit Medicare spending in the future. One key provision in the ACA is the establishment of “Accountable Care Organizations,” or ACOs, under which hospitals and physicians are able to share savings that

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result from cost control efforts. We cannot predict how the continued establishment and implementation of these new business models will impact on our business. There is the possibility that these organizations will seek to lower reimbursement for the services we provide and some may potentially restrict access to our services. We may not be able to gain access into certain ACOs. These changes could have an adverse and material impact on our operations. In furtherance of health care reform and the reduction in health care expenditures, the ACA contains numerous provisions to be implemented through 2018. There can be no assurance at this time that the implementation of these provisions will not have a material adverse effect on our business.

The ACA provided for states to create health insurance “Marketplaces” where individuals can compare and enroll in Qualified Health Plans, or QHPs. Individuals with an income less than 400% of the federal poverty level that purchase insurance on a Marketplace may be eligible for federal subsidies to cover a portion of their health insurance premium costs and cost sharing of co insurance or co pay obligations. Our patients may be enrolled in QHPs, and we may begin to submit bills to QHPs for services we provide. The presence of federal funds in QHPs in the form of subsidies and cost-sharing may subject providers to heightened government attention and enforcement, which could significantly increase the cost of compliance and could materially impact our operations. For example, it is not clear whether the availability of these federal subsidies classifies a QHP as a federal healthcare program, particularly for purposes of federal fraud and abuse laws. In letters published on October 30, 2013 and February 6, 2014, the former Secretary of the Department of Health & Human Services, or DHHS, Kathleen Sebelius, indicated that DHHS does not consider QHPs to be federal healthcare programs. However, a judge may not agree with this statement by Secretary Sebelius, and other government regulators may take a different position. For example, subsequent letters from U.S. Senator Charles Grassley to Secretary Sebelius and Attorney General Eric Holder on November 7, 2013 and February 12, 2014 indicate that this issue remains an outstanding question. If QHPs are classified as federal healthcare programs it could significantly increase our costs of compliance.

In furtherance of health care reform and the reduction in health care expenditures, the ACA contains numerous provisions to be implemented through 2018. Additionally, future legislative or judicial actions could materially affect the implementation of the ACA, including its potential repeal. Members of Congress continue to introduce legislation that would repeal, restrict funding for, or significantly amend the ACA, and presidential candidates in the 2016 election have also called for significant overhaul of the ACA. Additionally, the ACA continues to be challenged in a variety of lawsuits. Because of the continued uncertainty about the implementation of the ACA, there can be no assurance at this time that the implementation (or repeal) of these provisions will not have a material adverse effect on our business.

Failure to comply with environmental, health and safety laws and regulations, including the federal Occupational Safety and Health Administration Act, and the Needlestick Safety and Prevention Act could result in fines and penalties and loss of licensure, and have a material adverse effect upon our business.

We are subject to licensing and regulation under federal, state and local laws and regulations relating to the protection of the environment and human health and safety, including laws and regulations relating to the handling, transportation and disposal of medical specimens, infectious and hazardous waste and radioactive materials, as well as regulations relating to the safety and health of laboratory employees. The federal Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for health care employers, including clinical laboratories, whose workers may be exposed to blood-borne pathogens such as HIV and the hepatitis B virus. These requirements, among other things, require work practice controls, protective clothing and equipment, training, medical follow-up, vaccinations and other measures designed to minimize exposure to, and transmission of, blood-borne pathogens. In addition, the Needlestick Safety and Prevention Act requires, among other things, that we include in our safety programs the evaluation and use of engineering controls such as safety needles if

found to be effective at reducing the risk of needlestick injuries in the workplace.

Failure to comply with such federal, state and local laws and regulations could subject us to denial of the right to conduct business, fines, criminal penalties and/or other enforcement actions, any of which could have a material adverse effect on our business. In addition, compliance with future legislation could impose additional requirements for us, which may be costly.

Steps taken by government payers, such as Medicare and Medicaid to control the utilization and reimbursement of healthcare services, including esoteric testing may diminish our net revenue.

We face efforts by government payers to reduce utilization as well as reimbursement for laboratory testing services. Changes in governmental reimbursement may result from statutory and regulatory changes, retroactive rate adjustments, administrative rulings and other policy changes.

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From time to time, legislative freezes and updates affect some of our tests that are reimbursed by the Medicare program under the Medicare Physician Fee Schedule, or MPFS, or Clinical Laboratory Fee Schedule, or CLFS. The MPFS is updated on an annual basis. In the past, the MPFS was updated using a prescribed statutory formula; when application of the statutory formula resulted in lower payments, Congress has passed interim legislation to prevent the reductions. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, repealed the previous statutory update formula and specified the update adjustment factors for calendar years 2015 and beyond. If the updated conversion factor results in negative reimbursement in future years, the resulting decrease in payment may adversely affect our revenue, business, operating results, financial condition and prospects.

In addition, recent laws have made changes to Medicare reimbursement for our tests that are reimbursed under the CLFS, many of which have already gone into effect. On October 1, 2015, CMS published a proposed rule to significantly revise the Medicare payment system for clinical diagnostic laboratory tests. The proposed rule provides proposed regulations to implement the provisions of the Protecting Access to Medicare Act of 2014, or PAMA, which was signed to law on April 1, 2014. Under PAMA, applicable laboratories will be required to report to CMS certain information about the payment rates paid by private payers for each clinical diagnostic lab test and the corresponding volumes of such tests furnished during a period of time specified by the Department of Health and Human Services. Under the October 2015 proposed rule, an “applicable laboratory” for purposes of reporting requirements is defined as a laboratory that receives more than 50 percent of its Medicare revenues from the CLFS and MPFS, but only to the extent that a lab receives at least \$50,000 in Medicare revenues from the CLFS in a data collection period. Applicable laboratories must report data that includes the payment rate (reflecting all discounts, rebates, coupons and other price concessions) and the volume of each test that was paid by each private payer (including health insurance issuers, group health plans, Medicare Advantage plans and Medicaid managed care organizations). The definition of “applicable” lab may exclude certain types of laboratories that generally received more favorable pricing than other laboratories, and thus the make-up of laboratories reporting pricing data to CMS under the proposed rule may result in lower overall pricing data. Beginning in 2017, the Medicare payment rate for each clinical diagnostic lab test will be equal to the weighted median amount for the test from the most recent data collection period. Also for the years 2017 through 2019, the amount of reduction in the Medicare rate (if any) shall not exceed 10 percent from the prior year’s rate and for the years 2020 through 2022, any reduction shall not exceed 15 percent from the prior year’s rate. It is too early to predict the impact on reimbursement for our tests reimbursed under the CLFS, though we believe the government’s goal is to reduce Medicare program payments for CLFS tests. Specifically, CMS states that it anticipates the effect of the proposed rule on the Medicare program to save \$360 million in program payments for CLFS tests furnished in FY 2017, and to save \$5.14 billion over 10 years. CMS has also proposed that a laboratory’s failure to comply with reporting obligations, or a laboratory that makes a misrepresentation or omission in reporting required information, would be a violation of the Civil Monetary Penalties Law.

Also under PAMA, the CMS, is required to adopt temporary billing codes to identify new tests and new advanced diagnostic laboratory tests that have been cleared or approved by the FDA. For an existing test that is cleared or approved by the FDA and for which Medicare payment is made as of April 1, 2014, CMS is required to assign a unique billing code if one has not already been assigned by the agency. Further, PAMA provides special payment status to “advanced diagnostic laboratory tests,” or ADLTs, to allow such ADLTs to be paid using their actual list charge amount during a certain time frame. However, the October 2015 proposed rule would limit the application of such favorable payment status, for example by narrowing the scope of the status to laboratories that provide the ADLT under a single CLIA certificate. We cannot determine at this time the full impact of the new law on our business, financial condition and results of operations.

CMS also adopts regulations and policies, from time to time, revising, limiting or excluding coverage or reimbursement for certain of the tests that we perform. Likewise, many state governments are under budget pressures and are also considering reductions to their Medicaid fees. Further, Medicare, Medicaid and other third party payers audit for overutilization of billed services. Even though all tests performed by us are ordered by our clients, who are responsible for establishing the medical necessity for the tests ordered, we may be subject to recoupment of payments, as the recipient of the payments for such tests, in the event that a third party payer such as CMS determines that the tests failed to meet all applicable criteria for payment. When third party payers like CMS revise their coverage regulations or policies, our costs generally increase due to the complexity of complying with additional administrative requirements. Furthermore, Medicaid reimbursement and regulations vary by state. Accordingly, we are subject to varying administrative and billing regulations, which also increase the complexity of servicing such programs and our administrative costs. Finally, state budget pressures have encouraged states to consider several courses that may impact our business, such as delaying payments, restricting coverage eligibility, service coverage restrictions and imposing taxes on our services.

In certain jurisdictions including California, North Carolina, Washington, and Tennessee, Medicare administrative contractors CGS Administrators, Noridian Healthcare Solutions and Palmetto GBA, administer the Molecular Diagnostic Services Program, or MolDX, and establish coverage and reimbursement for certain molecular diagnostic tests, including many of our tests. To obtain Medicare

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coverage for a molecular diagnostic test (FDA approved or LDT), laboratories must apply for and obtain a unique test identifier or what is known as a “Z” code. For newly developed tests or for established tests that have not been validated for clinical and analytical validity and clinical utility, laboratories must submit a detailed dossier of clinical data to substantiate that the test meets Medicare’s requirements for coverage. We have received favorable coverage for many of our molecular tests, however we have also received non-coverage determinations for many newer tests. The field of molecular diagnostics is evolving very rapidly, and clinical studies on many new tests are still underway. We cannot be assured that some of our molecular tests will ever be covered services by Medicare, nor can we determine when the medical literature will meet the standard for coverage that Medicare administrative contractors have set.

In recent years, Medicare has encouraged beneficiaries to participate in managed care programs, known as “Medicare Advantage” programs, and has encouraged beneficiaries from the traditional fee-for- service Medicare program to switch to Medicare Advantage programs. This has resulted in rapid growth of health insurance and managed care plans offering Medicare Advantage programs and growth in Medicare beneficiary enrollment in these programs. Also in recent years, many states have increasingly mandated that Medicaid beneficiaries enroll in managed care arrangements. If these efforts continue to be successful, we may experience a further shift of traditional Medicare and Medicaid fee-for-service beneficiaries to managed care programs. As a result, we would be required to contract with those private managed care programs in order to be reimbursed for services provided to their Medicare and Medicaid members. There can be no assurance that we will be successful in entering into agreements with these managed care programs at rates of payment similar to those we realize from our non-managed care lines of business.

We expect the initiatives described above to continue and, if they do, to reduce reimbursements for clinical laboratory services, to impose more stringent cost controls on clinical laboratory services and to reduce utilization of clinical laboratory services. These efforts, including changes in law or regulations that may occur in the future, may each individually or collectively have a material adverse impact on our business, operating results, financial condition and prospects.

Our net revenue will be diminished if payers do not adequately cover or reimburse our services.

There has been and will continue to be significant efforts by both federal and state agencies to reduce costs in government healthcare programs and otherwise implement government control of healthcare costs. In addition, increasing emphasis on managed care in the United States may continue to put pressure on the pricing of healthcare services. Uncertainty exists as to the coverage and reimbursement status of new applications or services. Third party payers, including governmental payers such as Medicare and private payers, are scrutinizing new medical products and services and may not cover or may limit coverage and the level of reimbursement for our services. Third party insurance coverage may not be available to patients for any of our existing tests or for tests we discover and develop. In addition, a substantial portion of the testing for which we bill our hospital and laboratory clients is ultimately paid by third party payers. Any pricing pressure exerted by these third party payers on our clients may, in turn, be exerted by our clients on us. If government and other third party payers do not provide adequate coverage and reimbursement for our tests, our operating results, cash flows or financial condition may decline.

Third party billing is extremely complicated and results in significant additional costs to us.

Billing for laboratory services is extremely complicated. The customer refers the tests; the payer pays for the tests, and the two may not be the same. Depending on the billing arrangement and applicable laws, we must bill various payers, such as patients, insurance companies, Medicare, Medicaid, doctors and employer groups, hospitals and other laboratories, all of which have different billing requirements. Additionally, we undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Insurance

companies and government payers such as Medicare and Medicaid also impose routine external audits to evaluate payments, which adds further complexity to the billing process.

Among others, the primary factors which complicate our billing practices are:

- pricing differences between our fee schedules and the reimbursement rates of the payers;
- changes in payer rules;
- disputes with payers as to the party who is responsible for payment;

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- disparity in coverage and information requirements among various carriers; and
- differing pre-authorization requirements across insurance carriers

We incur significant additional costs as a result of our participation in the Medicare and Medicaid programs, as billing and reimbursement for clinical laboratory services are subject to considerable and complex federal and state regulations. The additional costs we expect to incur include those related to: (i) complexity added to our billing processes and systems; (ii) training and education of our employees and clients; (iii) implementing compliance procedures and oversight; (iv) collections and legal costs; and (v) costs associated with, among other factors, challenging coverage and payment denials and providing patients with information regarding claims processing and services, such as advance beneficiary notices.

Our operations are subject to strict laws prohibiting fraudulent billing and other abuse, and our failure to comply with such laws could result in substantial penalties.

Of particular importance to our operations are federal and state laws prohibiting fraudulent billing and providing for the recovery of overpayments. In particular, if we fail to comply with federal and state documentation, coding and billing rules, we could be subject to liability under the federal False Claims Act, including criminal and/or civil penalties, loss of licenses and exclusion from the Medicare and Medicaid programs. The False Claims Act prohibits individuals and companies from knowingly submitting false claims for payments to, or improperly retaining overpayments from, the government.

If an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between \$5,500 and \$11,000 for each separate false claim. Further, False Claims Act liability may lead to exclusion from participation in Medicare, Medicaid and other federal healthcare programs. There are a number of potential bases for liability under the federal False Claims Act. For example, liability arises when an entity knowingly submits, or causes another to submit, a claim for reimbursement to the federal government for a service which was not provided or which did not qualify for reimbursement. Submitting a claim with reckless disregard or deliberate ignorance of its truth or falsity could also result in liability under the False Claims Act. The False Claims Act's "whistleblower" or "qui tam" provisions are being used with more frequency to challenge the reimbursement practices of providers and suppliers. Those provisions allow a private individual to bring an action on behalf of the government alleging that the defendant has submitted false claims for payment to the federal government. The government must decide whether to intervene in the lawsuit and whether to prosecute the case. If it declines to do so, the individual may pursue the case alone, although the government must be kept apprised of the progress of the lawsuit. Whether or not the federal government intervenes in the case, it will receive the majority of any recovery. The successful qui tam relator who brought the case is entitled to a portion of the proceeds and its attorneys' fees and costs. In addition, various states have enacted laws modeled after the federal False Claims Act, which prohibit submitting false claims for payment to the state or, in some states, to other commercial payers.

Government investigations of clinical laboratories have been ongoing for a number of years and are expected to continue in the future. When we submit bills for our services to third party payers, we must follow complex documentation, coding and billing rules which are based on federal and state laws, rules and regulations, various government publications, and on industry practice. A large number of laboratories have entered into substantial settlements with the federal and state governments for alleged noncompliance under these laws and rules. Private payers have also brought civil actions against laboratories which have resulted in substantial judgments. Failure to follow these rules could result in potential civil liability under the False Claims Act, under which extensive financial penalties can be imposed. It could further result in criminal liability under various federal and state criminal statutes. For example, there are various state and federal laws and rules regulating laboratory billing practices, such as

prohibiting a clinical laboratory from charging a higher price for tests ordered by a physician and provided by a third party (anti-markup rules) as well as requiring direct billing of certain laboratory services by the laboratory performing the tests instead of allowing the laboratory to bill the ordering clinician for the test (direct billing rules).

We submit thousands of claims for Medicare and other payments and we cannot guarantee that there have not been errors in our claims, or in Clariant's claims. While we maintain a robust compliance program that includes consistent, detailed review of our documentation, coding and billing practices, the rules are frequently vague, complex, and continually changing and we cannot assure that governmental investigators, private insurers or private whistleblowers will not challenge our practices. Such a challenge could result in a material adverse effect on our business.

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The failure to comply with significant government regulation and laboratory operations may subject us to liability, penalties or limitation of operations.

We are subject to extensive state and federal regulatory oversight. Specifically, our laboratories must satisfy federal requirements under the Clinical Laboratory Improvements Amendments to maintain the appropriate CLIA Certificate for all testing performed at the lab. Additionally, most states have adopted various laws and regulations setting standards for laboratories performing clinical laboratory testing and requiring laboratories to obtain and maintain a state laboratory license prior before the laboratory is authorized to perform testing. These state licensure laws often address permissible and prohibited practices involving telehealth and telepathology.

Upon periodic inspection or survey, our laboratory locations may be found to be non-compliant with CLIA requirements or with applicable licensure or certification laws. The sanctions for failure to comply with CLIA, state licensure requirements, or other applicable laws and regulations could include the suspension, revocation, or limitation of the right to perform clinical laboratory services or receive compensation for those services, as well as the requirement to enter into a corrective action plan to monitor compliance, and the imposition of civil or criminal penalties or administrative fines. In addition, any new legislation or regulation or the application of existing laws and regulations in ways that we have not anticipated could have a material adverse effect on our business, results of operations and financial condition.

Existing federal laws governing Medicare and Medicaid, as well as some other state and federal laws, also regulate certain aspects of the relationship between healthcare providers, including clinical laboratories, and their referral sources, including physicians, hospitals and other laboratories. Certain of these laws, known as the “anti-kickback laws” and the “Stark Law,” contain extremely broad proscriptions. Violation of these laws may result in criminal penalties, exclusion from participation in the Medicare, Medicaid, and other federal healthcare programs, and significant civil monetary penalties, as well as False Claims Act liability. We seek to structure our arrangements with physicians and other clients to be in compliance with the anti-kickback laws, Stark Law and similar state laws, and to keep up-to-date on developments concerning their application by various means, including consultation with legal counsel and review of the annual OIG Work Plan identifying targeted issues. We cannot guarantee, however, that government authorities will not take a contrary view and impose civil monetary penalties and exclude us based on our arrangements with physicians and other clients.

The federal Civil Monetary Penalties Law, or the federal CMP Law, imposes civil monetary penalties and exclusion from Medicare and Medicaid programs on any person who offers or transfers remuneration to any patient who is a Medicare or Medicaid beneficiary, when the person knows or should know that the remuneration is likely to induce the patient to receive medical services from a particular provider. The federal CMP Law applies, among other things, to many kinds of inducements or benefits provided to patients, including complimentary items, services or transportation that are of more than a nominal value. We have structured our operations and provision of services to patients in a manner that we believe complies with the law and its interpretation by government authorities. We cannot guarantee, however, that government authorities will not take a contrary view and impose civil monetary penalties and exclude us for past or present practices.

Furthermore, HIPAA, the HITECH Act, and associated regulations and similar state laws contain provisions that require the electronic exchange of health information, such as claims submission and receipt of remittances, using standard transactions and code sets, which we refer to as the Standards, and regulate the use and disclosure of patient records and other Protected Health Information, or PHI. These provisions, which address security and confidentiality of patient information as well as the administrative aspects of claims handling, have very broad applicability and they specifically apply to many healthcare providers, including physicians and clinical laboratories. Although we believe

we are in material compliance with the Standards, Security and Privacy rules under HIPAA and the HITECH Act and state privacy and security laws, a failure to comply with these laws could have a material adverse effect on our business, results of operations and financial condition and subject us to liability. Additionally, the amendments to HIPAA in the HITECH Act provide that the state Attorneys General may bring an action against a covered entity, such as us, for a violation of HIPAA.

The failure to comply with physician self-referral laws may subject us to liability, penalties or limitation of operations

We are subject to the federal Stark Law, as well as similar state statutes and regulations, which prohibit payments for certain health care services (“designated health services” or “DHS”) rendered as a result of referrals by physicians to DHS entities with which the physicians (or immediate family members) have a financial relationship. A “financial relationship” includes both an ownership interest and/or a compensation arrangement with a physician, both direct and indirect, and DHS includes, but is not limited to, laboratory services. The Stark Law prohibits an entity that receives a prohibited DHS referral from seeking payment from Medicare

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for any DHS services performed as a result of such a referral, unless an arrangement is carefully structure to satisfy every requirement of a regulatory exception. The Stark Law is a strict liability statute, and thus any technical violation requires repayment of all “tainted” referrals, regardless of the intent. Penalties for violating the Stark Law may include the denial of payment to an entity for the impermissible provision of DHS, the requirement to refund any amounts collected in violation of the Stark Law, and civil monetary penalties of up to \$15,000 for each violation and \$100,000 for each circumvention arrangement or scheme. Other implications of a Stark Law violation may include criminal penalties, exclusion from Medicare and Medicaid programs, and potential False Claims Act liability, including via “qui tam” action.

Further, many states have promulgated self referral laws and regulations similar to the federal Stark Law, but these vary significantly based on the state. In addition to services reimbursed by Medicaid or government payers, often these state laws and regulations can encompass services reimbursed by private payers as well. Penalties for violating state self-referral laws and regulations vary based on the state, but often include civil and criminal penalties, exclusion from Medicaid, and loss of licenses.

Our financial arrangements with physicians are governed by the federal Stark Law, and we rely on certain exceptions to the Stark Law with respect to such relationships. While we believe that our financial relationships with physicians and referral practices are in compliance with applicable laws and regulations, we cannot guarantee that government authorities would agree. If we are found by the government to be in violation of the Stark Law, we could be subject to significant penalties, including fines as specified above, exclusion from participation in government and private payer programs and requirements to refund amounts previously received from government. Further, as our operations expand into new states and jurisdictions, we must continually evaluate whether our relationships with physicians comply with that jurisdiction’s laws. This may require structural and organizational modifications to our relationships with physicians which could adversely affect our results of operations and financial condition.

The failure to comply with Anti-Kickback laws may subject us to liability, penalties or limitation of operations

We are subject to the federal Anti-Kickback Statute, or the AKS, as well as similar state statutes and regulations, which prohibit the offer, payment, solicitation or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing or arranging for or recommending the ordering, purchasing or leasing of items or services payable by Medicare, Medicaid or any other federally funded healthcare program. The AKS defines remuneration to include anything of value, in cash or in kind, and thus can implicate financial relationships including payments not commensurate with fair market value, such as in the form of space, equipment leases, professional or technical services or anything else of value.

The AKS is an “intent based” statute, meaning that a violation occurs when one or both parties intend the remuneration to be in exchange for or to induce referrals; however, the ACA, among other things, amended the intent requirement of the AKS. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the false claims statutes. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions; however, the exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny. Violations of the AKS may result in substantial civil or criminal penalties, including criminal fines of up to \$25,000, imprisonment of up to five years, civil penalties under the federal CMP Law of up to \$50,000 for each violation, plus three times the remuneration involved, civil penalties under the federal False Claims Act of up to \$11,000 for each claim submitted, plus three times the amounts paid for such claims and exclusion from participation in the Medicare and Medicaid programs. If

we face these penalties or the participation exclusion, it could significantly reduce our revenues and could have a material adverse effect on our business.

Further, most states have adopted similar anti-kickback laws prohibiting the offer, payment, solicitation or receipt of remuneration in exchange for referrals, and typically impose criminal and civil penalties as well as loss of licenses. Some of these state laws apply to items and services paid for by private payers as well as to government payers. In addition, many states have adopted laws prohibiting the splitting or sharing of fees between physicians and non-physicians, as well as between treating physicians and referral sources. We believe our arrangements with physicians comply with the AKS, and state anti-kickback and fee-splitting laws of the states in which we operate, however, if government regulatory authorities were to disagree, we could be subject to civil and criminal penalties, and be required to restructure or terminate our contractual and other arrangements with physicians. This could result in a loss of revenue and have a material adverse effect on our business.

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Some states have also adopted laws prohibiting the corporate practice of medicine, or prohibiting business corporations from employing physicians or engaging in activities considered to be the “practice of medicine.” In these states, we rely on service agreements with physicians and/or professional associations owned by physicians, to perform needed professional pathology services. We cannot assure you that a physician or physician’s professional organization will not seek to terminate an agreement with us on any basis, nor can we assure you that governmental authorities in those states will not seek termination of these arrangements on the basis of state laws prohibiting the corporate practice of medicine.

A failure to comply with governmental payer regulations could result in our being excluded from participation in Medicare, Medicaid or other governmental payer programs, which would decrease our revenues and adversely affect our results of operations and financial condition.

Tests which are reimbursed by Medicare and other government payers (for example, state Medicaid programs) accounted for approximately 21%, 20% and 25% of our revenues for the years ended December 31, 2015, 2014 and 2013, respectively, and approximately 14% of our revenues for the six-months ended June 30, 2016. We anticipate that the acquisition of Clariant will lower our Medicare mix slightly moving forward. The Medicare program imposes extensive and detailed requirements on diagnostic service providers, including, but not limited to, rules that govern how we structure our relationships with physicians, how and when we submit claims for reimbursement and how we provide specialized diagnostic laboratory services. Further, we are prohibited from contracting with any individuals or entities who have been excluded from participation in Medicare or Medicaid and are listed on the OIG’s List of Excluded Individuals and Entities List. Contracting with excluded individuals or entities, such as hiring an excluded person or contracting with an excluded vendor, can result in significant penalties.

Our failure to comply with applicable Medicare, Medicaid and other governmental payer rules could result in our inability to participate in a governmental payer program, an obligation to repay funds already paid to us for services performed, civil monetary penalties, criminal penalties, False Claims Act liability and/or limitations on the operational function of our laboratory. If we were unable to receive reimbursement under a governmental payer program, a substantial portion of our revenues would be lost, which would adversely affect our results of operations and financial condition.

Failure to comply with the HIPAA Privacy, Security and Breach Notification Regulations may increase our operational costs.

The HIPAA privacy and security regulations establish comprehensive federal standards with respect to the uses and disclosures of PHI by certain entities including health plans and health care providers, and set standards to protect the confidentiality, integrity and availability of electronic PHI. The regulations establish a complex regulatory framework on a variety of subjects, including, for example, the circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient; a patient’s right to access, amend and receive an accounting of certain disclosures of PHI; the content of notices of privacy practices describing how PHI is used and disclosed and individuals’ rights with respect to their PHI; and implementation of administrative, technical and physical safeguards to protect privacy and security of PHI. Recent revisions to HIPAA allow patients the option to obtain certain of their test reports directly from the laboratory, instead of learning the results from the ordering physician. We have implemented policies and procedures to comply with the HIPAA privacy and security laws and regulations. The privacy regulations establish a uniform federal standard but do not supersede state laws that may be more stringent. Therefore, we are required to comply with both federal privacy and security regulations and varying state privacy and security laws and regulations. The federal privacy regulations restrict our ability to use or disclose certain individually identifiable patient health information, without patient authorization, for purposes other than

payment, treatment or health care operations (as defined by HIPAA), except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy regulations.

The HITECH Act and its implementing regulations also require healthcare providers like us to notify affected individuals, the Secretary of the U.S. Department of Health and Human Services, and in some cases, the media, when PHI has been breached as defined under and following the requirements of HIPAA. Many states have similar breach notification laws. In the event of a breach, we could incur operational and financial costs related to remediation as well as preparation and delivery of the notices, which costs could be substantial. Additionally, HIPAA, the HITECH Act, and their implementing regulations provide for significant civil fines, criminal penalties, and other sanctions for failure to comply with the privacy, security, and breach notification rules, including for wrongful or impermissible use or disclosure of PHI. Although the HIPAA statute and regulations do not expressly provide for a private right of action for damages, we could incur damages under state laws to private parties for the wrongful or impermissible use or disclosure of confidential health information or other private personal information. Additionally, amendments to HIPAA provide that the state Attorneys General may bring an action against a covered entity, such as us, for a violation of HIPAA. We insure some of

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our risk with respect to HIPAA security breaches although there could be operational costs associated with HIPAA breaches above our insured limits.

Changes in regulations, payer policies or contracting arrangements with payers or changes in other laws, regulations or policies may adversely affect coverage or reimbursement for our specialized diagnostic services, which may decrease our revenues and adversely affect our results of operations and financial condition.

Governmental payers, as well as private insurers and private payers, have implemented and will continue to implement measures to control the cost, utilization and delivery of healthcare services, including clinical laboratory and pathology services. Congress and federal agencies, such as CMS, have, from time to time, implemented changes to laws and regulations governing healthcare service providers, including specialized diagnostic service providers. These changes have adversely affected and may in the future adversely affect coverage for our services. We also believe that healthcare professionals may not use our services if third-party payers do not provide adequate coverage and reimbursement for them. These changes in federal, state, local and third-party payer regulations or policies may decrease our revenues and adversely affect our results of operations and financial condition. We will continue to be a non-contracting provider until such time as we enter into contracts with third-party payers with whom we are not currently contracted. Because a portion of our revenues is from third-party payers with whom we are not currently contracted, it is likely that we will be required to make positive or negative adjustments to accounting estimates with respect to contractual allowances in the future, which may adversely affect our results of operations, our credibility with financial analysts and investors, and our stock price.

We are subject to security risks which could harm our operations.

HIPAA and the HITECH Act imposed additional requirements, restrictions and penalties on covered entities and their business associates to, among other things, deter breaches of security. As a result, the remedial actions required, the reporting requirements, and sanctions for a breach are stringent. Our electronic health records system is periodically modified to meet applicable security standards. Despite the implementation of various security measures by us, our infrastructure may be vulnerable to computer viruses, break-ins and similar disruptive problems caused by our clients or others, which could lead to interruption, delays or cessation in service to our clients. Further, such incidents, whether electronic or physical could also potentially jeopardize the security of confidential information, including PHI stored in our computer systems as it relates to clients, patients, and other parties connected through us, which may deter potential clients and give rise to uncertain liability to parties whose security or privacy has been infringed. A significant security breach could result in fines, loss of clients, damage to our reputation, direct damages, costs of repair and detection, costs to remedy the breach, and other expenses. We insure some of our risk with respect to security breaches but the occurrence of any of the foregoing events could have a material adverse effect on our business, results of operations and financial condition.

Clinicians or patients using our services may sue us, and our insurance may not sufficiently cover all claims brought against us, which will increase our expenses.

The development, marketing, sale and performance of healthcare services expose us to the risk of litigation, including professional negligence. Damages assessed in connection with, and the costs of defending, any legal action could be substantial. We may be faced with litigation claims that exceed our insurance coverage or are not covered under any of our insurance policies. In addition, litigation could have a material adverse effect on our business if it impacts our existing and potential customer relationships, creates adverse public relations, diverts management resources from the operation of the business, or hampers our ability to otherwise conduct our business.

We must hire and retain qualified sales representatives to grow our sales, if not, our existing business and our results of operations and financial condition will likely suffer

Our ability to retain existing clients for our specialized diagnostic services and attract new clients is dependent upon retaining existing sales representatives and hiring and training new sales representatives, which is an expensive and time-consuming process. We face intense competition for qualified sales personnel and our inability to hire or retain an adequate number of sales representatives could limit our ability to maintain or expand our business and increase sales. Even if we are able to increase our sales force, our new sales personnel may not commit the necessary resources or provide sufficient high quality service and attention to effectively market and sell our services. If we are unable to maintain and expand our marketing and sales networks or if our sales personnel do not perform to our standards, we may be unable to maintain or grow our existing business and our results of operations and financial condition will likely suffer accordingly. If a sales representative ceases employment, we risk the loss of client goodwill based on the impairment of

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relationships developed between the sales representative and the healthcare professionals for whom the sales representative was responsible. This is particularly a risk if the representative goes to work for a competitor, as the healthcare professionals that are our clients may choose to use a competitor's services based on their relationship with our former sales representative.

Further, non-compliant activities and unlawful conduct by sales and marketing personnel could give rise to significant risks under the AKS. We require extensive, comprehensive training of all sales and marketing personnel, but cannot guarantee that every staff member will comply with the training. Thus, in addition to the cost of training sales and marketing personnel, we could face liability under the Anti-Kickback Statute for non-compliance by individuals engaged in prohibited sales and marketing activities.

Performance issues, service interruptions or price increases by our shipping carrier could adversely affect our business, results of operations and financial condition, and harm our reputation and ability to provide our specialized diagnostic services on a timely basis

Expedited, reliable shipping is essential to our operations. One of our marketing strategies entails highlighting the reliability of our point-to-point transport of patient samples. We rely heavily on a single provider of transport services, FedEx Corporation, or the Carrier, for reliable and secure point-to-point transport of patient samples to our laboratory and enhanced tracking of these patient samples. Should the Carrier encounter delivery performance issues such as loss, damage or destruction of a sample, it may be difficult to replace our patient samples in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our services and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions by delivery services we use would adversely affect our ability to receive and process patient samples on a timely basis.

If the Carrier or we were to terminate our relationship, we would be required to find another party to provide expedited, reliable point-to-point transport of our patient samples. There are only a few other providers of such nationwide transport services, and there can be no assurance that we will be able to enter into arrangements with such other providers on acceptable terms, if at all. Finding a new provider of transport services would be time-consuming and costly and result in delays in our ability to provide our specialized diagnostic services. Even if we were to enter into an arrangement with such provider, there can be no assurance that they will provide the same level of quality in transport services currently provided to us by the Carrier. If the new provider does not provide the required quality and reliable transport services, it could adversely affect our business, reputation, results of operations and financial condition.

We use biological and hazardous materials that require considerable expertise and expense for handling, storage or disposal and may result in claims against us

We work with hazardous materials, including chemicals, biological agents and compounds, blood samples and other human tissue that could be dangerous to human health and safety or the environment. Our operations also produce hazardous and bio hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair business efforts. If we do not comply with applicable regulations, we may be subject to fines and penalties. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Our general liability insurance and/or workers' compensation insurance policy may not cover damages and fines arising from

biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our operations could be suspended or otherwise adversely affected.

Risks Relating to Our Common Stock

As a result of the Clariant acquisition, GE Medical has a significant influence over us and actions requiring general stockholder approval.

As a result of the Acquisition, GE Medical owns approximately 32% of our total voting power based on the number of shares of common stock outstanding as of August 3, 2016. This percentage may increase upon the conversion of shares of Series A Preferred Stock (including any additional shares of Series A Preferred Stock issued as payment-in-kind dividends into common stock) if such preferred stock is not first redeemed. In connection with the Acquisition, we increased the size of our Board of Directors from eight to ten with one of the vacancies created by such increase filled by a director selected for appointment to the Board of Directors by GE

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Medical. The Investor Board Rights, Lockup And Standstill Agreement with GE Medical contains certain rights in favor of GE Medical, including the right to appoint one director to our Board of Directors, requiring GE Medical's approval before we can further increase the size of our Board of Directors and providing GE Medical with the right to participate in future rights offerings to our current stockholders as if the Series A Preferred Stock issued to GE Medical had been converted into shares of common stock. We are not party to any other agreement with any of our stockholders with respect to the nomination or election of our directors. The terms of the Series A Preferred Stock issued to GE Medical provide that, without GE Medical's consent, we may not, among other things, repurchase outstanding shares of our common stock, or engage in certain other transactions.

As a result, GE Medical will have significant influence over matters requiring stockholder approval, including future amendments to our Amended and Restated Articles of Incorporation or other significant or extraordinary transactions. GE Medical's interests may differ from the interests of our other shareholders with respect to certain matters.

In addition, having GE Medical as a significant stockholder may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from seeking to acquire, a majority of our outstanding shares of common stock or control of the Board of Directors through a proxy solicitation.

Future sales of our common stock by GE Medical, or the perception that such sales may occur, could cause our stock price to decline.

The shares of common stock we issued to GE Medical as consideration in the Acquisition are restricted, but GE Medical may sell such shares under certain circumstances. Under the Investor Board Rights, Lockup and Standstill Agreement, GE Medical's ability to sell its shares of our common stock is limited for the specified lockup period, subject to volume limitations under Rule 144 under the Securities Act of 1933 and other exceptions. Furthermore, under the Registration Rights Agreement with GE Medical we are required to file, upon expiration of a lockup period, a registration statement for the resale of common stock by GE Medical, which registration statement when declared effective will allow GE Medical to sell a significant number of shares of our common stock in a short period of time. The sale of a substantial number of shares of our common stock by GE Medical or our other stockholders or the perception that such sales may occur could cause our stock price to decline, make it more difficult for us to raise funds through future offerings of our common stock or acquire other businesses using our common stock as consideration.

We currently do not expect to pay any cash dividends and the price of our stock may not appreciate.

We do not anticipate paying dividends on our common stock in the foreseeable future. Rather, we plan to retain earnings, if any, for the operation and expansion of our business. If we do not pay dividends, the price of our common stock must appreciate for you to recognize a gain on your investment upon sale. This appreciation may not occur.

We may become involved in securities class action litigation that could divert management's attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of diagnostic companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because

clinical laboratory service companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

If any securities analyst downgrades our common stock or our sector, the price of our common stock could be negatively affected.

Securities analysts may publish reports about us or our industry containing information about us that may affect the trading price of our common stock. If a securities or industry analyst downgrades the outlook for our common stock or one of our competitors' stocks or chooses to terminate coverage of our common stock, the trading price of our common stock may be negatively affected.

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The price of our common stock may fluctuate significantly.

The price of our common stock has been, and is likely to continue to be, volatile, which means that it could decline substantially within a short period of time. For example, the per share price of our common stock traded on the NASDAQ Capital Market ranged from \$2.95 to \$9.17 for the period from January 1, 2014 to June 30, 2016. The price of our common stock could fluctuate significantly for many reasons, including the following:

- future announcements concerning us or our competitors;
- regulatory developments and enforcement actions bearing on advertising, marketing or sales;
- reports and recommendations of analysts and whether or not we meet the milestones and metrics set forth in such reports;
- gaining or losing large customers or managed care plans;
- introduction of new products or services;
- acquisition or loss of significant manufacturers, distributors or suppliers or an inability to obtain sufficient quantities of materials needed to provide our services;
- quarterly variations in operating results;
- business acquisitions or divestitures;
- changes in governmental or third-party reimbursement practices and rates; and fluctuations in the economy, political events or general market conditions.

In addition, stock markets in general and the market for shares of health care stocks in particular, have experienced extreme price and volume fluctuations in recent years, fluctuations that frequently have been unrelated to the operating performance of the affected companies. These broad market fluctuations may adversely affect the market price of our common stock. The market price of our common stock could decline below its current price and the market price of our shares may fluctuate significantly in the future. These fluctuations may be unrelated to our performance.

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ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable

ITEM 5. OTHER INFORMATION

None

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ITEM 6. EXHIBITS

EXHIBIT

NO.	DESCRIPTION
31.1	Certification by Principal Executive Officer pursuant to Rule 13a-14(a)/ 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification by Principal Financial Officer pursuant to Rule 13a-14(a)/ 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification by Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Cash Flows and (iv) related notes.

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SIGNATURES

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

Date: August 5, 2016 NEOGENOMICS, INC.

By: /s/ Douglas M. VanOort
Name: Douglas M. VanOort
Title: Chairman and Chief Executive Officer

By: /s/ George Cardoza
Name: George Cardoza
Title: Chief Financial Officer