NEOGENOMICS INC Form 424B5 August 15, 2014 Table of Contents
Filed Pursuant to Rule 424(b)(5) Registration No. 333-193105
Prospectus Supplement
(to Prospectus dated January 3, 2014)
7,000,000 Shares
NeoGenomics, Inc.
Common Stock
We are offering 7,000,000 shares of our common stock pursuant to this prospectus supplement and the accompanying prospectus.
Our common stock is traded on the NASDAQ Capital Market under the symbol NEO. On August 12, 2014, the closing price of our common stock on the NASDAQ Capital Market was \$4.97 per share.
Investing in our common stock involves a high degree of risk. See <u>Risk Factors</u> beginning on page S-5 of this prospectus supplement and in the documents we incorporate by reference into this prospectus supplement and the accompanying prospectus.

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Per Share

Total

Public Offering Price	\$ 4.60	\$32,200,000
Underwriting Discounts and Commissions <sup>1</sup>	\$ 0.276	\$ 1,932,000
Proceeds to NeoGenomics, Inc. before expenses	\$ 4.324	\$30,268,000

(1) See Underwriting for additional information regarding underwriting compensation. Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional 1,050,000 shares. If the underwriters exercise the option in full, the total public offering price will be \$37,030,000, the total underwriting discounts and commissions will be \$2,221,800, and the total proceeds, before expenses, to NeoGenomics, Inc. will be \$34,808,200.

Delivery of the shares is expected to be made on or about August 20, 2014.

## William Blair

## **Craig-Hallum Capital Group**

Stephens Inc.	Roth Capital	Sidoti & Company,	Dawson James	
	Partners	LLC	Securities, Inc.	

The date of this prospectus supplement is August 15, 2014

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You should rely only on the information contained in or incorporated by reference in this prospectus supplement, the accompanying prospectus and in any free writing prospectus that we have authorized for use in connection with this offering. We have not, and the underwriters have not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus

Disclosure of Commission Position on Indemnification

supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and in any free writing prospectus that we have authorized for use in connection with this offering, is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and any free writing prospectus that we have authorized for use in connection with this offering, in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the sections of this prospectus supplement entitled Where You Can Find More Information and Incorporation of Certain Information by Reference.

## ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering of common stock and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part, the accompanying prospectus dated January 3, 2014, including the documents incorporated by reference therein, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or in any document incorporated by reference that was filed with the Securities and Exchange Commission, or SEC, before the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference in the accompanying prospectus the statement in the document having the later date modifies or supersedes the earlier statement. You should assume that the information contained in this prospectus supplement is accurate as of the date on the front cover of this prospectus supplement only and that any information we have incorporated by reference or included in the accompanying prospectus is accurate only as of the date given in the document incorporated by reference or as of the date of the prospectus, as applicable, regardless of the time of delivery of this prospectus supplement or the accompanying prospectus or any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

All references in this prospectus supplement and the accompanying prospectus to NeoGenomics, the Company, we, us, our, or similar references refer to NeoGenomics, Inc. and its subsidiaries on a consolidated basis, except where the context otherwise requires or as otherwise indicated.

This prospectus supplement, the accompanying prospectus and the information incorporated herein and therein by reference includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus supplement or the accompanying prospectus are the property of their respective owners.

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## PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information about us, this offering and selected information contained elsewhere in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common stock. For a more complete understanding of our company and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus supplement and the accompanying prospectus, including the information incorporated by reference in this prospectus supplement and the accompanying prospectus, and the information included in any free writing prospectus that we have authorized for use in connection with this offering, including the information referred to under the heading Risk Factors in this prospectus supplement beginning on page S-5.

## **Our Company**

We operate a network of cancer-focused testing laboratories whose mission is to improve patient care through exceptional genetic and molecular testing services. Our vision is to become America s premier cancer testing laboratory by delivering uncompromising quality, exceptional service and innovative products and services. We have laboratory locations in Ft. Myers and Tampa, Florida; Irvine, Fresno and West Sacramento California; and Nashville, Tennessee, and currently offer the following types of testing services:

Cytogenetics testing the study of normal and abnormal chromosomes and their relationship to disease. Cytogenetic studies are often utilized to answer diagnostic, prognostic and predictive questions in the treatment of hematological malignancies and solid tumors;

Fluorescence In-Situ Hybridization testing a branch of cancer genetics that focuses on detecting and locating the presence or absence of specific DNA sequences and genes on chromosomes. This testing service helps bridge abnormality detection between the chromosomal and DNA sequence levels;

Flow cytometry testing 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 quantified according to their surface antigens. These fluorescent antibodies bind to specific cell surface antigens and are used to identify malignant cell populations. Flow cytometry is typically performed in conjunction with morphology testing which looks at smears on glass slides for abnormal cell populations;

Immunohistochemistry testing the process of identifying cell proteins in a tissue section utilizing the principle of antibodies binding specifically to antigens. Specific surface cytoplasmic or nuclear markers are characteristic of cellular events such as proliferation or cell death (apoptosis). This testing service is also widely used to understand the distribution and localization of differentially expressed proteins; and

Molecular testing a rapidly emerging cancer diagnostic tool focusing 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 bi-directional Sanger sequencing analysis, DNA fragment length analysis, real-time

polymerase chain reaction RNA analysis and Next-Generation sequencing.

All of these testing services are widely utilized to determine the diagnosis and prognosis of various types and subtypes of cancer and to help predict a patient s potential response to specific therapies. We offer testing services on both a tech-only basis, where we perform the technical component of the testing (specimen set-up, staining, imaging, sorting and categorization of cells, chromosomes, genes or DNA) and the client physician performs the related professional interpretation component (analyzing the laboratory data, viewing the cells,

developing the diagnosis or prognosis as well as preparing and writing the final report), as well as on a full service or global basis where we perform both the technical component and our medical staff provides the professional interpretation component.

Our customer targets include pathologists, hospital pathology groups, oncologist, and clinical groups. As of June 30, 2014, approximately 73% of our revenue was attributable to pathologists and hospital pathology groups, approximately 24% of our revenue was attributable to oncologists and clinical groups, and approximately 3% of our revenue was attributable to clinical trials and other sources.

The market size for U.S. cancer testing is estimated to be between \$10 billion and \$12 billion. The total testing market for hematopoietic cancers and solid tumor cancers is estimated to be between \$3-4 billion and \$7-8 billion, respectively, with approximate new annual diagnoses of hematopoietic cancers and solid tumor cancers being 150,000 and 1.45 million, respectively. For the six months ending June 30, 2014, the Company s revenue split for hematopoietic cancer and solid tumor cancer testing was approximately 80% and approximately 20%, respectively.

# **Recent Developments**

# Acquisition of Path Logic

On July 8, 2014, we acquired through our wholly owned subsidiary, NeoGenomics Laboratories, all of the outstanding equity ownership interests of Path Labs, LLC d/b/a Path Logic for \$5.85 million, reflecting a purchase price of \$6.0 million less liabilities assumed, using cash on hand and borrowings under our revolving credit facility.

Path Logic is a provider of specialized anatomic pathology services to hospitals and physicians in Northern California. Path Logic 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. As part of the transaction, we acquired Path Logic s main laboratory in West Sacramento, California, as well as satellite facilities in Santa Ana and Fresno, California.

Path Logic reported revenue of \$9.84 million for the year ended December 31, 2013, and employed approximately 65 people. The acquisition of Path Logic enables us to provide specialized anatomic pathology services for our clinical trials and pathology clients across the country.

### **Corporate Offices**

Our principal executive offices are located at 12701 Commonwealth Drive, Suite 9, Fort Myers, Florida 33913. Our telephone number is (239) 768-0600. Our website can be accessed at www.neogenomics.com. Information found on, or accessible through, our website is not a part of, and is not incorporated into, this prospectus supplement, and you should not consider it part of this prospectus supplement or the accompanying prospectus.

# The Offering

The following is a brief summary of the terms of the offering. For a more complete description of our common stock, see Description of Our Capital Stock beginning on page 6 of the accompanying prospectus.

Issuer	NeoGenomics, Inc.
Shares of common stock offered by us	7,000,000 shares (or 8,050,000 shares if the underwriters exercise their option to purchase additional shares in full).
Common stock to be outstanding immediately after this offering	57,003,799 shares (or 58,053,799 shares if the underwriters exercise their option to purchase additional shares in full).
Option to purchase additional shares	We have granted an option to the underwriters to purchase up to an additional 1,050,000 shares of common stock within 30 days of the date of this prospectus supplement.
Use of proceeds	We intend to use the net proceeds for working capital, capital expenditures and other corporate purposes, including potential acquisitions. The Company may also use proceeds to repay debt, although at this time no decision has been made to the amount or timing of repayment. See Use of Proceeds.
Risk factors	Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page S-5 of this prospectus supplement for a discussion of factors that you should carefully consider before deciding to invest in shares of our common stock.
Listing and trading symbol	Our common stock is listed and traded on the NASDAQ Capital Market under the symbol NEO.

The number of shares of our common stock to be outstanding after this offering is based upon 50,003,799 shares outstanding as of June 30, 2014. This number does not include, as of such date:

5,814,794 shares of common stock issuable upon the exercise of outstanding stock options, at a weighted average exercise price of \$1.38 per share;

650,000 shares of common stock issuable upon the exercise of outstanding warrants, at a weighted average exercise price of \$1.48 per share; and

1,187,056 shares of common stock available for future issuance under our equity compensation plans.

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## **Summary Historical Financial Data**

The following table sets forth a summary of our historical financial data as of the dates and for each of the periods indicated. The historical financial data as of and for the years ended December 31, 2011, December 31, 2012 and December 31, 2013 is derived from our audited consolidated financial statements, which are incorporated by reference into this prospectus supplement. The historical financial data for the six months ended June 30, 2013 and June 30, 2014 and as of June 30, 2014 is derived from our unaudited consolidated financial statements, which are incorporated by reference into this prospectus supplement. The historical financial data as of June 30, 2013 is derived from our unaudited consolidated financial statements that are not incorporated by reference into this prospectus supplement. We have prepared the unaudited consolidated financial statements on the same basis as the audited consolidated financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that should be expected in the future, and our interim results are not necessarily indicative of the results that should be expected for the full year or any other period.

The following summary historical financial data should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our audited consolidated financial statements and the related notes appearing in our Annual Report on Form 10-K for the year ended December 31, 2013, and our unaudited consolidated financial statements and related notes appearing in our Form 10-Q for the six-month period ended June 30, 2014. See Where You Can Find More Information.

	Fiscal Year Ended December 31,			Six Months Ended June 30, (unaudited)			
	2011	2012	2013	2013	2014		
O (* D)			(in thou	(in thousands)			
Operating Data:	¢ 42 404	Φ.50.0 <i>6</i> 7	ф. СС 4 <b>С</b> 7	¢ 21 260	ф 20.0 <b>52</b>		
Net revenue	\$ 43,484	\$ 59,867	\$ 66,467	\$31,260	\$ 38,852		
Cost of revenue	24,056	33,031	34,730	16,857	19,904		
Gross profit	19,428	26,836	31,737	14,403	18,948		
Operating expenses							
General and administrative	12,331	15,843	17,397	8,239	10,924		
Research and development	543	2,281	2,440	1,451	1,261		
Sales and marketing	6,963	7,501	8,726	3,903	5,791		
Total operating expenses	19,837	25,625	28,563	13,593	17,976		
Income (loss) from operations	(409)	1,211	3,174	810	972		
Interest and other income (expense)	(768)	(1,146)	(989)	(517)	(518)		
-							
Income (loss) before taxes	(1,177)	65	2,185	293	454		
Income taxes	, ,		152	17	78		
Net income (loss)	(1,177)	\$ 65	\$ 2,033	\$ 276	\$ 376		

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Balance Sheet Data (at period end):					
Cash and cash equivalents	\$ 2,628	\$ 1,868	\$ 4,834	\$ 4,636	\$ 5,023
Working capital	1,734	823	13,168	11,107	12,856
Total assets	19,949	30,071	39,916	34,459	43,638
Revolving credit line	3,898	8,458	4,282	3,193	1,989
Long-term debt, including current portion	4,715	5,309	6,080	5,517	7,785
Total stockholders equity	5,897	9,216	21,711	19,440	23,133

## **RISK FACTORS**

An investment in our common stock is subject to numerous risks. You should carefully consider these risk factors, along with the information provided elsewhere in this prospectus supplement, the accompanying prospectus, the documents we incorporate by reference herein and therein, and in any free writing prospectus that we have authorized for use in connection with this offering, before investing in our common stock. If any of these risks actually occur, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

#### Risks Related 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 has placed, and is expected to continue to place, a significant strain on our managerial, operational and financial resources. To manage 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. Part of our business strategy may be to acquire assets or other companies that will complement our existing business, such as our recent acquisition of Path Labs, LLC. At this time, we are unable to predict whether or when any material transaction will be completed should negotiations commence. We may not be able to effectively integrate the operations of Path Labs, LLC, or the acquired operations from any other transaction we may complete, with our own operations. We may also seek to finance any future acquisition by debt financings or issuances of equity securities and such financing may not be available on acceptable terms or at all.

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

We rely on third parties for the manufacture and supply of some of our critical laboratory instruments, equipment and materials that we need to perform our specialized diagnostic services, and rely on a limited number of suppliers for certain laboratory materials and some of the laboratory equipment with which we perform our diagnostic services. Generally, we do not have long-term contracts with our suppliers and manufacturers that commit them to supply equipment and materials to us. Because we cannot ensure the actual production or manufacture of such critical equipment and materials, or the ability of our suppliers to comply with applicable legal and regulatory requirements, we may be subject to significant delays caused by interruption in production or manufacturing. If any of our third party suppliers or manufacturers were to become unwilling or unable to provide this equipment or these materials in required quantities or on our required timelines, we would need to identify and acquire acceptable replacement sources on a timely basis. While we have developed alternate sourcing strategies for most of the equipment and materials we use, we cannot be certain that these strategies will be effective and even if we were to identify other suppliers and manufacturers for the equipment and materials we need to perform our specialized diagnostic services, there can be no assurance that we will be able to enter into agreements with such suppliers and manufacturers or otherwise obtain such items on a timely basis or on acceptable terms, if at all. In addition, some of the reagents are covered by patents and thus are only available from one supplier. If we encounter delays or difficulties in securing necessary laboratory equipment or materials, including consumables, we would face an interruption in our ability to perform our specialized diagnostic services and experience other disruptions that would adversely affect our business, results of operations and financial condition.

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 our 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 manner to compensate for any unexpected revenue

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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 affect on our business, results of operations and financial condition and may not result in the long-term benefits intended. Furthermore, in Florida, currently our largest referral market for lab testing services, a meaningful percentage of the population, returns to homes in the Northern U.S. 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 affect on our cash flows and results of operations.

Our business consists of a clinical laboratory that provides 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 as 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. 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.

The market for our services is highly competitive, which could have a material adverse affect 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

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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.

# We face the risk of capacity constraints, which could have a material adverse affect 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, which could lead to inaccurate test results, 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 affect 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 Nashville, Tennessee 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 taken by us 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.

# 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. Competition for such personnel is intense and we may not be able to retain our key managerial and technical employees or

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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. 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, 2014, we had cash and cash equivalents of \$5.0 million and had \$8.0 million of availability under our credit facility with CapitalSource. We used approximately \$3.0 million in cash and borrowed approximately \$3.0 million on our credit facility, to finance the purchase of PathLogic on July 8, 2014.

Even if we are able to access the full amount available under our credit facility with CapitalSource, 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 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 Clinical Laboratory Improvements Amendments, or CLIAs, and individual state licensing procedures. The FDA is considering requiring FDA clearance or approval of a subset of LDTs, as well as a modified approach that may require FDA oversight short of the full approval process. There are currently no formal definitions or regulations on how such approvals would be requested and granted, but there is a risk that such a 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 the prior approval of the FDA. This FDA approval process would be time-consuming and costly, with no guarantee of ultimate approval success.

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 (LDTs). As described in this notification, FDA plans to provide draft guidance to clinical laboratories that develop their own LDTs regarding how FDA intends to regulate such laboratories under the Federal Food, Drug, and Cosmetic Act. The anticipated regulatory framework would 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 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. Once the draft guidance is issued, the FDA will provide an opportunity for public comment before the guidance is finalized. We anticipate the Agency will receive numerous comments on this issue, and the regulatory framework ultimately implemented by the FDA may differ substantially from the framework described in the notification to Congress.

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, as amended by the Health Care and Education Reconciliation Act of 2010, or commonly referred to collectively

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as the Affordable Care Act, was passed into law. The Affordable Care Act contains several provisions that seek to limit Medicare spending in the future. One key provision is the establishment of Accountable Care Organizations under which hospitals and physicians will be able to share savings that result from cost control efforts. We cannot predict what the final business models will be, nor can we predict with certainty the future 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 Accountable Care Organizations. 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 Affordable Care Act contains numerous provisions to be implemented through 2018. Other significant measures contained in the Affordable Care Act include, for example, coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. There can be no assurance at this time that the implementation of these provisions will not have a material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, increased the period for the government to recover overpayments from providers from three to five years.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our services or additional pricing pressures.

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.

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 Clinical Laboratory Fee Schedule. The Medicare Physician Fee Schedule, which is updated on an annual basis using a prescribed statutory formula, is subject to significant reductions in reimbursement unless Congress intervenes. In the past, when the application of the statutory formula resulted in lower payments, Congress has passed interim legislation to prevent the reductions. The most recent legislative intervention passed was Protecting Access to Medicare Act of 2014, or PAMA, which provided for a 0.5% update from 2013 MPFS payment rates through 2014 and a 0% update from January 1 until April 1, 2015. If Congress fails to intervene to prevent the negative update factor in future years, the resulting decrease in payment may adversely affect our revenue, business, operating results, financial condition and prospects.

In addition, recent laws make changes to Medicare reimbursement for our tests that are reimbursed under the Clinical Laboratory Fee Schedule, or CLFS, many of which have already gone into effect. The Affordable Care Act includes a

reduction in the annual update factor used to adjust payments under the CLFS for inflation. This update factor reflects the consumer price index for all urban consumers, or CPI-U, and the ACA reduces the

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CPI-U by 1.75% for the years 2011 through 2015. The Affordable Care Act also imposes a multifactor productivity adjustment in addition to the CPI-U, which may further reduce payment rates. Further, in February 2012, the Middle Class Tax Relief and Job Creation Act of 2012 was passed, which, among other things, reduced the update to the CLFS by an additional 2% for CY 2013, and rebased payments at the reduced rate for subsequent years. Overall, when adding this 2% reduction to the Affordable Care Act s adjustments, the payment rates under the CLFS declined by 2.95% and 0.75% for 2013 and 2014, respectively. This reduction does not include the additional sequestration adjustment.

Most recently, on April 1, 2014, PAMA was signed to law, which, among other things, is expected to significantly alter the current payment methodology under the CLFS. Under the new law, starting January 1, 2016 and every three years thereafter (or annually in the case of advanced diagnostic lab tests), clinical laboratories must report laboratory test payment data for each Medicare-covered clinical diagnostic lab test that it furnishes during a time period to be defined by future regulations. The reported data must include 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). 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. The payment rate will apply to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. It is too early to predict the impact on reimbursement for our tests reimbursed under the CLFS.

Also under PAMA, the Centers for Medicare & Medicaid Services, or 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. In addition to assigning the code, CMS must publicly report payment for the tests no later than January 1, 2016. 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 policies, from time to time, limiting or excluding coverage 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 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, Palmetto GBA, a Medicare administrative contractor, administers the Molecular Diagnostic Services Program, or MolDX, and establishes coverage and reimbursement for certain molecular diagnostic tests, including many of our tests. To obtain coverage for an established molecular diagnostic test or LDT, laboratories must apply for and obtain a unique test identifier. 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 determination 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 Palmetto GBA has set.

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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 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.

CMS has, as part of its regulatory structure, developed the National Correct Coding Initiative, or NCCI to promote national correct coding methodologies and to control improper coding leading to inappropriate payment in Medicare Part B claims. The most recent NCCI Coding Policy Manual resulted in changes in how we bill both FISH and immunohistochemistry testing. The language relates to what NCCI considers bundled services, and will impact the quantity of certain tests that are billed. NCCI limits the number of units we may bill for certain test codes which lowers the overall reimbursement we receive for that test. While many in the laboratory industry are not in agreement with the determination, there can be no assurance that CMS will make any modifications to the existing language.

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 pricin