NEOGENOMICS INC
Form 424B3
May 13, 2016
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Filed Pursuant to Rule 424(b)(3)
Registration No. 333-166526

PROSPECTUS

NEOGENOMICS, INC.

3,571,007 Shares of Common Stock

This prospectus relates to the sale of up to 3,571,007 shares of the common stock, par value $0.001 per share, of NeoGenomics, Inc. by the selling stockholders named in this prospectus. These shares were issued to the selling stockholders in a private placement or upon exercise of warrants issued in a private placement.

We are not selling any shares of common stock in this offering and therefore will not receive any proceeds from the sale of the shares under this prospectus. All costs associated with this registration will be borne by us.

The selling stockholders from time to time may offer and sell the shares held by them directly or through agents or broker-dealers on terms to be determined at the time of sale, as described in more detail in this prospectus and any accompanying prospectus supplements. The prices at which the selling stockholders may sell the shares may be determined by the prevailing market price for the shares at the time of sale, may be different than such prevailing market prices or may be determined through negotiated transactions with third parties. See Plan of Distribution.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

Our common stock is quoted on the NASDAQ Capital Market under the symbol NEO . On May 12, 2016, the last reported sale price of our common stock on the NASDAQ was $8.37 per share.

These securities are speculative and involve a high degree of risk. Please refer to Risk Factors beginning on page 5 for a discussion of these risks.

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

The date of this prospectus is May 13, 2016.

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You should rely only on the information contained or incorporated by reference in this prospectus, any prospectus supplement or in any free writing prospectus we may authorize to be delivered or made available to you. We have not and the selling stockholders have not authorized anyone to provide you with different information. The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained or incorporated by reference in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock.

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

NeoGenomics and MultiOmyx are our registered trademarks. Any other trademarks, registered marks and trade names appearing in this prospectus or the documents incorporated by reference herein are the property of their respective holders. All other trademarks, trade names and service marks appearing in this prospectus or the documents incorporated by reference herein are the property of their respective owners.

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PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere, or incorporated by reference, in this prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our common stock. You carefully should read the entire prospectus, any accompanying prospectus supplement and any related free writing prospectus, including the risks of investing in our securities discussed under the heading Risk Factors contained herein and in any accompanying prospectus supplement and any related free writing prospectus, and under a similar heading in other documents that are incorporated by reference into this prospectus. You also should carefully read the information incorporated by reference into this prospectus, including our financial statements and the exhibits to the registration statement of which this prospectus is a part. Unless the context otherwise requires, NeoGenomics, Inc. is referred to herein, collectively with all of its subsidiaries, as the Company , NeoGenomics , or we , us , or our .

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 Clarient, Inc., (Clarient) and its wholly owned subsidiary, Clarient Diagnostic Services, Inc. from GE Medical Holding AB (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 Clarient on the closing date, (ii) 15,000,000 shares of our common stock, and (iii) 14,666,667 shares of our series A convertible preferred stock (the Series A Preferred Stock) (the Acquisition).

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 Clarient.

As of December 31, 2015, the Company had 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 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.

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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 RNA analysis, bi-directional Sanger sequencing analysis, and Next-Generation Sequencing.

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 or partnering with 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 U.S. Food and Drug Administration (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 Next-Generation Sequencing on the same sample to generate multiomic phenotypes. Currently, we are only offering MultiOmyx™ 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 consultative services using our own specialized pathologists for difficult or complex cases and provide overflow interpretation services when requested by clients.

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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.

About Us

Our principal executive offices are located at 12701 Commonwealth Drive, Suite 9, Fort Myers, Florida 33913. Our telephone number is (239) 768-0600. Our principal website can be accessed at www.neogenomics.com. The information on any of our websites is deemed not to be incorporated in this prospectus or to be part of this prospectus.

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THE OFFERING

Common Stock Offered by the Selling Stockholders	3,571,007 shares
Common Stock Outstanding	77,117,678 shares
Use of Proceeds	We will not receive any proceeds of the shares offered by the selling stockholders. See Use of Proceeds on page 26.
Risk Factors	The securities offered hereby involve a high degree of risk. See Risk Factors beginning on page 5 for a discussion of these risks.
NASDAQ Symbol	NEO

The number of shares of our common stock outstanding is based on 77,117,678 shares of our common stock outstanding as of April 20, 2016 and excludes the following:

- 4,734,087 shares of common stock issuable upon exercise of stock options outstanding as of March 31, 2016, at a weighted average exercise price of $4.17 per share;
- 650,000 shares of our common stock issuable upon exercise of warrants outstanding as of March 31, 2016, at a weighted average exercise price of $1.48 per share;
- 3,456,066 shares of common stock reserved for future grants under our Equity Incentive Plan as of March 31, 2016;
- 14,666,667 shares of common stock issuable upon conversion of our Series A Preferred Stock outstanding as of March 31, 2016, subject to anti-dilution adjustments; and
- up to an additional 10,775,454 shares of common stock issuable upon conversion of any Series A Preferred Stock that we are required to issue as payment-in-kind dividends on the Series A Preferred Stock if all such stock is not redeemed prior the December 30, 2025, subject to anti-dilution adjustments.

Unless otherwise indicated, all information in this prospectus assumes no exercise of the outstanding options or warrants or conversion of the outstanding Series A Preferred Stock, each as described above.

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RISK FACTORS

We are subject to various risks that may materially harm our business, financial condition and results of operations. An investor should carefully consider the risks and uncertainties described below, together with all of the other information contained or incorporated by reference in this prospectus, including our consolidated financial statements and related notes, before deciding whether to purchase shares of 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 Clarient business in December 2015, has placed, and is expected to continue to place, a significant strain on our managerial, operational and financial resources. For example, the Acquisition is expected to result in a combined company with annual revenues in excess of $215 million as compared to our annual revenues of $99.8 million for the year ended December 31, 2015. 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 Clarient 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 December 31, 2015, we had $10 million of indebtedness outstanding, and $15.0 million of available borrowing capacity under our senior secured revolving credit facility. In December 2015, we entered into the senior secured revolving credit facility, providing for up to $25.0 million of borrowings, and a senior secured term loan facility, providing for $55.0 million of borrowings. The full amount of borrowings under the term loan facility and $10.0 million of borrowings under the revolving credit facility were used to pay the cash consideration and related fees and expenses in connection with our Acquisition. 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.

- 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.

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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 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 conversion price of $7.50 per share, subject to adjustments. 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 the Stock Purchase 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 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.

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, Clarient 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. Clarient s internal control structure was previously assessed with regard to the

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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 Clarient s operations to our system of internal controls. Therefore, we may face difficulties or experience delays in developing changes or potentially necessary improvements to Clarient 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 Clarient 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.

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 Clarient 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.

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

As a result of the Acquisition, Clarient 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 Clarient. 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 Clarient 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, Clarient from time to time receives payments from the U.S. government. If the U.S. government were to assert that Clarient 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 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 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.

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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.

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

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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.

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.

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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 December 31, 2015, we had cash and cash equivalents of approximately $23.4 million and $15.0 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 FDA. The FDA has been considering changes to the way that it regulates these Laboratory Developed Tests (LDTs). Currently all LDTs are conducted and offered in accordance with the Clinical Laboratory Improvements Amendments (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 (LDTs) (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 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

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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 Clarient, 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 (HIPAA), the Health Information Technology for Economic and Clinical Health Act (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 was passed into law (the ACA). 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 (ACO) under which hospitals and physicians are able to share savings that 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 (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

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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 (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.

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 (MPFS) or Clinical Laboratory Fee Schedule (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 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 (PAMA), which was signed to law on

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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 (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 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

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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 U.S. 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

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.

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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 Clarient 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.

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

As discussed in the Government Regulation section of our business description contained in this report, 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

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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 (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 (Standards) and regulate the use and disclosure of patient records and other Protected Health Information (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 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.

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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 paye