

NEOGENOMICS INC

Form 10-K

February 26, 2019

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2018

or

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

For the transition period from _____ to _____

Commission File Number: 001-35756

NEOGENOMICS, INC.

(Exact name of registrant as specified in its charter)

Nevada

74-2897368

(State or other
jurisdiction
of incorporation
or organization)

(IRS
Employer Identification
No.)

12701 Commonwealth Drive, Suite 9, Fort Myers, FL 33913

(Address of principal executive offices, Zip code)

(239) 768-0600

(Registrant's telephone number, including area code)

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Securities registered pursuant to Section 12(b) of the Act:	Name of each exchange on which registered:
Common Stock, par value \$0.001 per share	NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act: Common Stock par value \$0.001 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes No

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer	Accelerated filer
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Non-accelerated filer	Smaller Reporting Company
	Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of June 30, 2018, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately \$790.6 million, based on the closing price of the registrant's common stock of \$13.11 per share on June 30, 2018.

The number of shares outstanding of the registrant's Common Stock, par value \$0.001 per share, as of February 22, 2019: 94,565,844.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2019 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

NEOGENOMICS, INC.

FORM 10-K ANNUAL REPORT

For the Fiscal Year Ended December 31, 2018

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The “NeoGenomics”, “Genoptix” and “Clariant” names and logos have been trademarked with the United States Patent and Trademark Office. We have also trademarked or have applications pending for the brand names NeoFISH, NeoFLOW, NeoSITE, NeoArray, NeoTYPE, NeoSCORE, NeoLAB, NeoLINK, MultiOmyx, COMPASS, and CHART. We have also trademarked the marketing slogans, “When time matters and results count” and “Time matters, results count.” Any other trademarks, registered marks and trade names appearing in this annual report on Form 10-K are the property of their respective holders.

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PART I

FORWARD-LOOKING STATEMENTS

The information in this Annual Report on Form 10-K contains “forward-looking statements” and information within the meaning of Section 27A of the Securities Act of 1933, as amended, or the “Securities Act”, and Section 21E of the Securities Exchange Act of 1934, as amended, or the “Exchange Act”, which are subject to the “safe harbor” created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, changing reimbursement levels from government payers and private insurers, projected costs, prospects and plans and objectives of management. The words “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “will,” “would” and similar expressions are intended forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. These forward-looking statements involve known and unknown risks and uncertainties that could cause our actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statements, including, without limitation, the risks set forth in Part I, Item 1A, “Risk Factors” in this Annual Report on Form 10-K and in our other filings with the Securities and Exchange Commission, or “SEC”.

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

- Our ability to respond to rapid scientific change;
- The risk of liability in conducting clinical trials and the sufficiency of our insurance to cover such claims;
- Our ability to implement our business strategy;
- The expected reimbursement levels from governmental payers and private insurers and proposed changes to those levels;
- The application, to our business and the services we provide, of existing laws, rules and regulations, including without limitation, Medicare laws, anti-kickback laws, Health Insurance Portability and Accountability Act of 1996 regulations, state medical privacy laws, federal and state false claims laws and corporate practice of medicine laws;
- Regulatory developments in the United States including downward pressure on health care reimbursement;
- Our ability to maintain our license under the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”);
- Food and Drug Administration, or FDA regulation of Laboratory Developed Tests (“LDTs”);
- Failure to timely or accurately bill for our services;
- Our ability to expand our operations and increase our market share;
- Our ability to expand our service offerings by adding new testing capabilities;
- Our ability to meet our future capital requirements;
- The impact of internalization of testing by customers;
- Our ability to manage our indebtedness;
- Our ability to protect our intellectual property from infringement;
- Our ability to successfully integrate Genoptix into NeoGenomics including consolidating systems and facilities;
- Our ability to integrate future acquisitions and costs related to such acquisitions;
- The effects of seasonality on our business;
- Our ability to maintain service levels and compete with other diagnostic laboratories;
- Our ability to hire and retain sufficient managerial, sales, clinical and other personnel to meet our needs;
- Our ability to successfully scale our business, including expanding our facilities, our backup systems and infrastructure;
- Our handling, storage and disposal of biological and hazardous materials;
- The accuracy of our estimates regarding reimbursement, expenses, future revenues and capital requirements and
- Our ability to manage expenses and risks associated with international operations, including anti-corruption and trade sanction laws and other regulations, and economic, political, legal and other operational risks associated with foreign jurisdictions.

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Contents INC.**

Any forward-looking statement speaks only as of the date on which such statement is made, and the Company undertakes no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time and it is not possible for management to predict all of such factors, nor can it assess the impact of each such factor on the business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

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ITEM 1. BUSINESS

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

Overview

We operate a network of cancer-focused genetic testing laboratories in the United States as well as a laboratories in Switzerland and Singapore. 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.

As of December 31, 2018, the Company has laboratory locations in Ft. Myers and Tampa, Florida; Aliso Viejo, Carlsbad and Fresno, California; Houston, Texas; Atlanta, Georgia; Nashville, Tennessee; Rolle, Switzerland, and Singapore 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.

e. Molecular testing - a rapidly growing 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 DNA fragment length analysis, real-time polymerase chain reaction (“RT-PCR”) RNA analysis, bi-directional Sanger sequencing analysis, and Next-Generation Sequencing (“NGS”).

f. Pathology consultation - services provided for clients in which our pathologists review surgical samples on a consultative basis. NeoGenomics expert pathologists often assist our client pathologists on their most difficult and complex cases.

Operating Segments

We have two primary types of customers, Clinical and Pharma. Our Clinical customers include community based pathology practices, oncology groups, hospitals and academic centers. Our Pharma customers include pharmaceutical companies to whom we provide testing and other services to support their studies and clinical trials.

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In 2018, our Clinical Services segment accounted for 87% of consolidated revenues and our Pharma Services segment accounted for 13% of our consolidated revenues. For further financial information about these segments, see Note R to our Consolidated Financial Statements included in this Annual Report.

Clinical Services Segment

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 provide a menu of services that 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 team of pathologists for difficult or complex cases and provide overflow interpretation services when requested by clients.

In addition, 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. 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. In these instances NeoGenomics will typically provide all of the more complex, molecular testing services.

Pharma Services Segment

Our Pharma Services segment supports pharmaceutical firms in their drug development programs by supporting various clinical trials and research. This 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 sponsor and works closely with them as specimens are received from the enrolled sites. We also work on developing tests that will be used as part of a companion diagnostic to determine patients’ response to a particular drug. As studies unfold, our clinical trials team reports the data and often provides key analysis and insights back to the sponsors.

Our Pharma Services segment 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 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.

Whether serving as the single contract research organization or partnering with one, our Pharma Services team provides significant technical expertise, working 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 submissions to the Federal Drug Administration (“FDA”) for companion diagnostics and our Pharma Services strategy is focused on helping bring more effective oncology treatments to market through providing world class laboratory services in oncology to key pharmaceutical companies in the industry.

Our Pharma Services revenue consists of three revenue streams:

- Clinical trials and research;
- Validation laboratory services; and
- Data services

Markets

The medical testing laboratory market can be broken down into three primary markets:

- Clinical Pathology testing;
- Anatomic Pathology testing; and
- Genetic and Molecular testing

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Clinical Pathology testing covers high volume, highly automated, lower complexity tests on easily procured specimens such as blood and urine. Clinical lab tests often involve testing of a less urgent nature, for example, cholesterol testing and testing associated with routine physical exams.

Anatomic Pathology testing involves evaluation of tissue, as in surgical pathology, or cells as in cytopathology. The most widely performed Anatomic Pathology procedures include the preparation and interpretation of pap smears, skin biopsies, and tissue biopsies.

Genetic and molecular testing typically involves analyzing chromosomes, genes, proteins and/or DNA/RNA sequences for abnormalities. Genetic and molecular testing requires highly specialized equipment and credentialed individuals (typically M.D. or Ph.D. level) to certify results and typically yields the highest reimbursement levels of the three market segments.

NeoGenomics operates primarily in the genetic and molecular testing market. We also act as a reference laboratory supplying anatomic pathology testing. NeoGenomics typically does not compete in the clinical pathology testing market.

The field of cancer genetics is evolving rapidly and new tests are being developed at an accelerated pace. Based on medical and scientific discoveries over the last decade, cancer testing falls into one of three categories: diagnostic testing, prognostic testing and predictive testing. Of the three, the fastest growing area is predictive testing, which is utilized by clinicians to predict a patient's response to the various treatment options in order to deliver "personalized or precision medicine" that is optimized to that patient's particular circumstances. Personalized or precision medicine allows clinicians to know if a patient will or will not respond to certain medications like Herceptin, Keytruda and Opdivo. This saves the healthcare system money by ensuring that expensive cancer drugs are only given to those who will benefit from them. This type of testing improves patient care and potentially saves lives by identifying optimized therapies much more rapidly than what was possible in previous years.

The United States market for genetic and molecular testing is divided among numerous laboratories. Many of these laboratories are attached to academic institutions and primarily provide clinical services to their affiliated university hospitals and associated physicians.

We believe several key factors are influencing the rapid growth in the market for cancer testing: (i) every year, more and more genes and genomic pathways are implicated in the development and/or clinical course of cancer; (ii) cancer is primarily a disease of the elderly - one in four senior citizens is likely to develop some form of cancer during the rest of their lifetime once they turn sixty, and now that the baby boomer generation has started to reach this age range, the incidence rates of cancer are rising; (iii) increasingly, new drugs are being targeted to certain cancer subtypes and pathways which require companion diagnostic testing; (iv) patient and payer awareness of the value of genetic and molecular testing; (v) decreases in the cost of performing genetic and molecular testing; (vi) increased coverage from third party payers and Medicare for such testing; and (vii) the health insurance coverage to uninsured Americans under the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, each enacted in March 2010. These factors have driven significant growth in the market for this type of testing.

2019 Focus Areas:

We are committed to being an innovative leader in our industry. Over the past year, we have grown our business organically as well as through the acquisition of Genoptix in December of 2018. We have continued to expand internationally with the opening of a laboratory in Singapore. Our plans for 2019 include initiatives to drive profitable growth while successfully integrating Genoptix and maintaining exceptional service levels. We expect these initiatives to continue to position our Company to be the world's leading cancer testing and information company.

Strengthen Our World-Class Culture

Our belief is that a culture of motivated and engaged employees will deliver superior service to our clients. We are focused on continuing to strengthen our culture by actively seeking feedback and ideas from employees on ways to innovate and grow our business. We will foster employee engagement through collaborative forums, frequent team dialogue and programs to reward teams for exceptional performance.

Enhancing our culture to closely align with the values of our Company is a key priority. We will focus on creating a unified culture as we bring Genoptix and NeoGenomics employees together to become one team. We will create

mentoring and training opportunities to enhance and capitalize on the talent within our Company. We believe these initiatives will foster a culture of accountability and empowerment. We also believe these initiatives are necessary to ensure the success of our Company.

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Communication is a key element in our high performance culture. Through effective communication we facilitate our employees' understanding of our Company's priorities and how they contribute to the Company's overall objectives. We believe our employee retention rate is above average for the laboratory industry and continuing to strengthen our culture will enable us to continually recruit and retain talented employees.

Provide Uncompromising Quality

Maintaining the highest quality laboratory operations and service levels has enabled us to consistently grow our business. We are continuously looking for ways to improve quality and, in integrating Genoptix and NeoGenomics, we will identify best practices and implement changes to streamline processes across the organization. We are keenly focused on increasing automation and looking for solutions that will maintain quality while improving efficiency in operations.

We plan to continue to grow a culture of quality through company-wide leadership, coaching and employee engagement initiatives. Through training, we aim to empower our employees to understand the importance of quality and how to ensure quality in their respective function. We will implement initiatives to significantly improve the Corrective and Preventative Actions ("CAPA") process to ensure FDA readiness and will challenge employees to identify quality issues and find solutions.

We have been successful in retaining clients while also gaining market share. As we integrate Genoptix, our goal is to ensure that we maintain the highest quality operation.

Pursue Exceptional Service and Growth

Our plans for 2019 include initiatives to continue to drive profitable growth. We will continue to pursue market share gains by providing high complexity, cancer-related laboratory testing services to hospitals, community-based pathology practices, academic centers, clinicians, and pharmaceutical companies.

Our laboratory teams will focus on service by improving the customer experience. This will be accomplished through the development and launch of innovative assays, informatics products and companion diagnostics as well as enhancements to our educational programs. We expect this to result in increased product and process understanding, increased ability to gain market share as well as enabling us to maintain our high levels of client retention.

We will work to maintain our broad and innovative test menu of molecular, immunohistochemistry, and other testing, which has helped make us a "one stop shop" for many clients who value that all of their testing can be sent to one laboratory. We believe successfully integrating Genoptix and NeoGenomics' operations will allow us to increase efficiency and reduce cost per test. We will continue to look for growth opportunities through mergers and/or acquisitions and are focused on strategic opportunities that would be complementary to our menu of services and would increase our earnings and cash flow in the short to medium time frame.

Competitive Strengths

In addition to the competitive strengths discussed below, the Company believes that its superior testing technologies and instrumentation, laboratory information system, client education programs and broad domestic and growing international presence also differentiate NeoGenomics from its competitors.

Turnaround Times

We strive to provide industry leading turnaround times for test results to our clients nationwide, both in the Clinical Services and Pharma Services segments. By providing information to our clients in a rapid manner, physicians can begin treating their patients as soon as possible. Our consistent timeliness of results in our Clinical Services segment is a competitive strength and a driver of additional testing requests by our referring physicians. Rapid turnaround times allow for the performance of other adjunctive tests within an acceptable diagnosis window in order to augment or confirm results and more fully inform treatment options. Additionally, we believe that our rapid turnaround time on testing and our project milestones are a key differentiator in the Pharma Services segment.

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World-class Medical and Scientific Team

Our team of medical professionals and Ph.Ds. are specialists in the field of genetics, oncology and pathology. As of December 31, 2018, we employed or contracted with over 80 M.D.s and Ph.Ds. We have many nationally and world-renowned pathologists on staff, which is a key differentiator from many smaller laboratories. Our clinical customers look to our staff and their expertise and they often call our medical team on challenging cases. For our Pharma Services segment, many sponsors work with our medical team on their study design and on the interpretation of results from the studies. Again, our medical team is a key differentiator as we have a depth of medical expertise that many other laboratories cannot offer to Pharmaceutical companies.

Innovative Service Offerings

We believe we currently have the most extensive menu of tech-only FISH services in the country as well as extensive and advanced tech-only flow cytometry and IHC testing services. These types of testing services allow the professional interpretation component of a test to be performed and billed separately by our physician clients. Our tech-only services are designed to give pathologists the option to choose, on a case by case basis, whether they want to order just the technical information and images relating to a specific test so they can perform the professional interpretation, or order “global” services and receive a comprehensive test report which includes a NeoGenomics pathologist’s interpretation of the test results. Our clients appreciate the flexibility to access NeoGenomics’ medical staff for difficult or complex cases or when they are otherwise unavailable to perform professional interpretations. We offer a comprehensive suite of technical and interpretation services, to meet the needs of those clients who are not credentialed and trained in interpreting genetic tests and who require pathology specialists to interpret the testing results for them. In our global service offerings, our lab performs the technical component of the tests and our M.D.s and Ph.Ds. provide the service of interpreting the results of those tests. Our professional staff is also available for post-test consultative services. Clients using our global service offering rely on the expertise of our medical team to give them the answers they need in a timely manner to help inform their diagnoses and treatment decisions.

National Direct Sales Force

Our direct sales force has been trained extensively in cancer genetic testing and consultative selling skills to service the needs of clients. Our sales team for the clinical cancer testing services is organized into ten regions. Our Pharma Services segment has a dedicated team of business development specialists who are experienced in working with pharma sponsors and helping them with the testing needs of their research and development projects as well as Phase 1-3 studies. These sales representatives utilize our custom Customer Relationship Management System (“CRM”) to manage their territories, and we have integrated all of the important customer care functionality within our LIS into the CRM so that our sales representatives can stay informed of emerging issues and opportunities within their regions. Our in-house customer care team is aligned with our field sales team to serve the needs of our clients by utilizing the same LIS and CRM. Our field teams can see in real-time when a client calls the laboratory, the reason for the call, the resolution, and if face-to-face interaction is needed for follow-up.

Seasonality

The majority of our clinical testing volume is dependent on patients being treated by hematology/oncology professionals and other healthcare providers. The volume of our testing services generally declines modestly during the summer vacation season, year-end holiday periods and other major holidays, particularly when those holidays fall during the middle of the week. In addition, the volume of our testing tends to decline due to extreme adverse weather conditions, such as excessively hot or cold spells, heavy snow, hurricanes or tornados in certain regions, consequently reducing revenues and cash flows in any affected period. During the third quarter of 2017, Hurricane Harvey forced the closure of our Houston laboratory for three days and Hurricane Irma forced the closure of our Fort Myers facility for five days. Therefore, comparison of the results of successive periods may not accurately reflect trends for future periods.

In our Pharma Services business, we enter into both short term and long term contracts, ranging from one month to several years. While the volume of this testing is not as directly affected by seasonality as described above, the testing volume does vary based on the terms of the contract. Many of our long term contracts contain specific performance obligations whereas the testing is performed on a specific schedule. This results in revenue that is not consistent

among periods. In addition, this results in backlog that can be significant.

Competition

For our Clinical Services segment, the genetic and molecular testing niche of the laboratory testing industry is highly competitive and, given the opportunities in this industry, we expect it to become even more competitive. Competitive factors in genetic and molecular testing generally include the reputation of the laboratory, range of services offered, pricing, convenience

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of sample collection and pick-up, quality of analysis and reporting, medical staff, timeliness of delivery of completed reports (i.e. turnaround times) and post-reporting follow-up for clients.

Our competitors for our Clinical Services segment in the United States are numerous and include major national medical testing laboratories, hospital laboratories and in-house physician laboratories. Some of our competitors have greater financial resources and production capabilities than us. These companies may succeed in developing service offerings that are more effective than any that we have or may develop, and may also prove to be more successful than we are in marketing such services. In addition, technological advances or different approaches developed by one or more of our competitors may render our service offerings obsolete, less effective or uneconomical.

We intend to continue our efforts to gain market share by offering industry-leading turnaround times, a broad service menu, high-quality test reports, new tests including proprietary ones, enhanced post-test consultation services, and the personal attention from our direct sales force. In addition, we believe our flexible reporting solutions, which enable clients to report out customized results in a secure, real-time environment, will allow us to continue to gain market share.

Our Pharma Services business competes against many other clinical research organizations and central reference laboratories. Many of these competitors are much larger and have a greater international presence than we do. Over the past few years, we have expanded our Pharma Services business into Europe and Asia at the request of our clients and believe that our state of the art testing menu and our high level of service along with our international expansion will allow us to continue to gain market share in this segment. The market for oncology clinical trials continues to grow and we expect to benefit from such overall market growth.

Our Pharma Services segment competitors are numerous Contract Resource Organizations or (“CRO”). These competitors are larger than NeoGenomics and have global operations including operations in some areas where we do not yet have service capabilities. These laboratories may be more effective than us in gaining business for global clinical trials. Many clinical reference laboratories have also entered the space in support of clinical trials and the related laboratory testing. These reference laboratories can often compete with lower pricing for smaller more limited studies. We believe our service focus and our leading molecular and immunohistochemistry platforms, as well as our exclusive MultiOmyx™ platform will continue to lead to rapid growth in this segment.

Suppliers

The Company orders its laboratory and research supplies from large national laboratory supply companies. We do not believe a short term disruption from any one of these suppliers would have a material effect on our business.

Concentrations of Credit Risk

Concentrations of credit risk with respect to revenue and accounts receivable are primarily limited to certain clients and geographies to which the Company provides a significant volume of its services, and to specific payers of our services such as Medicare and individual insurance companies.

Geographic Information

In 2017, we expanded internationally and have opened locations in Rolle, Switzerland and Singapore; revenues from non U.S. locations comprise an immaterial amount of total revenue for 2017 and 2018.

Dependence on Major Clients

We market our services to pathologists, oncologists, urologists, other clinicians, hospitals, pharmaceutical companies, academic centers and other clinical laboratories throughout the United States, Europe and Asia. The Company’s client base consists of a large number of geographically dispersed clients diversified across various customer types. For the years ended December 31, 2018, 2017 and 2016, no single client accounted for more than 10% of revenue.

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Payer Mix

The following table reflects our estimate of the breakdown of net clinical revenue by type of payer for the fiscal years ended December 31, 2018, 2017 and 2016:

	2018	2017 (as adjusted)	2016 (as adjusted)
Medicare and other government	15%	14%	15%
Commercial insurance	17%	17%	25%
Client direct billing	68%	69%	60%
Total	100%	100%	100%

Our proportion of client direct billing has increased over the years shown above, as more payers, including Medicare, private commercial insurances and Medicare Advantage plans, are practicing “consolidated payment” or “bundled payment” models where they pay the hospitals a lump sum, which is intended to include laboratory testing. This reflects an increase in the amount of risk sharing that CMS and other private payers are encouraging providers such as hospital systems to undertake. We anticipate a gradual increase in the percentage of client direct billing in the coming years. All of our Pharma Services revenue is billed directly to clients, or the pharmaceutical sponsor.

Trademarks

The “NeoGenomics”, “Genoptix” and “Clariant” names and logos have been trademarked with the United States Patent and Trademark Office. We have also trademarked or have applications pending for the brand names NeoFISH, NeoFLOW, NeoSITE, NeoArray, NeoTYPE, NeoSCORE, NeoLAB, NeoLINK, MultiOmyx, COMPASS, and CHART. We have also trademarked the marketing slogans, “When time matters and results count” and “Time matters, results count.”

Insurance

We maintain professional liability and numerous other insurance policies. We believe that our present insurance is sufficient to cover currently estimated exposures, but we cannot assure that we will not incur liabilities in excess of the policy coverage limits. In addition, although we believe that we will be able to continue to obtain adequate insurance coverage, we cannot assure that we will be able to do so at acceptable cost.

Available Information

Our internet website address is www.neogenomics.com. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to section 13(a) or 15(d) of the Exchange Act are available free of charge through our website as soon as reasonably practicable after we electronically file with or furnish them to the SEC, and are available in print to any stockholder who requests a copy. Information on our website shall not be deemed incorporated into, or to be part of, this Annual Report on Form 10-K.

Additionally, the SEC maintains a website that contains reports, proxy statements, information statements and other information regarding issuers, including us, that file electronically with the SEC at www.sec.gov.

Employees

As of December 31, 2018, the Company had approximately 1,500 full-time equivalent employees and contracted pathologists. Our employees are not represented by any union and we believe our employee relations are good.

Government Regulation

The laboratory business is subject to extensive governmental regulation at the federal, state and local levels. Our laboratories are required to be licensed by the states, certified by the federal government to participate in the Medicare

and Medicaid programs, and are subject to extensive requirements as a condition of participation in various governmental health benefits programs. The failure to comply with any of the applicable federal and state laws, regulations, and reimbursement guidelines could have a material adverse effect on the Company's business. The applicable laws and regulations, and the interpretations of them, change frequently and there can be no assurance that the Company will not be subject to audit, inquiry, or investigation with respect to some aspect of its operations. Some of the federal and state laws and regulations are described below under "Clinical Laboratory Operations," "Anti-Fraud and Abuse Laws," "The False Claims Act," "Confidentiality of Health Information" and "Food and Drug Administration".

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Clinical Laboratory Operations

Licensure and Accreditation

The Company operates clinical laboratories in Florida, Georgia, Tennessee, Texas and California. The laboratories are licensed as required by the states in which they are located. In addition, the laboratories in Fort Myers, Florida, Aliso Viejo and Carlsbad, California, and Nashville, Tennessee are licensed by the State of New York as they accept clinical specimens obtained in New York. All of our domestic laboratories are certified in accordance with the Clinical Laboratory Improvement Amendments, as amended (“CLIA”). Under CLIA, the U.S. Department of Health and Human Services (“HHS”) establishes quality standards for each category of testing performed by the laboratory. The categories of testing include waived, moderate complexity and high complexity. NeoGenomics’ laboratories are categorized as high complexity. Six of the ten site locations for NeoGenomics’ laboratories are also accredited by the College of American Pathologists (“CAP”) and actively participate in CAP’s proficiency testing programs for all tests offered by the Company. Our Tampa, Florida and Fresno, California facilities are read-only laboratories and, therefore, wouldn’t qualify for CAP accreditation. Proficiency testing programs require the participating laboratories to test specimens that they receive from the testing entity and return the results. The testing entity, conducting an approved program, analyzes the results returned and provides to the Company a quality control report assessing the results. An important component of a quality assurance program is to establish whether the laboratory’s test results are accurate and valid. The federal and state certification and licensure programs establish standards for the operation of clinical laboratories, including, but not limited to, qualifications of personnel and quality control. Compliance with such standards is verified by periodic inspections by inspectors employed by federal and state regulatory agencies and accrediting organizations. The Company has a Quality Management System meeting applicable regulatory requirements and industry standards.

Quality of Care

Our mission is to improve patient care through quality cancer genetic diagnostic services. By delivering exceptional service and innovative solutions, we aspire to become the world’s leading cancer and information company. The quality of care provided to clients and their patients is of paramount importance to us. We maintain quality control processes, including standard operating procedures, controls, performance measurement and reporting mechanisms. Our employees are committed to providing accurate, reliable and consistent services at all times. Any concerns regarding the quality of testing or services provided by the Company are immediately communicated to our Medical Team, Company management and, if necessary, the Director for Quality Systems, the Compliance Department or Human Resources Department. We also continually revise and improve our tests and work with laboratory equipment vendors to ensure that our laboratory has the highest possible quality.

Compliance Program

The health care industry is highly regulated and scrutinized with respect to fraud, abusive billing practices and improper financial relationships between health care companies and their referral sources. The Office of the Inspector General of HHS (the “OIG”) has published compliance guidance, including the Compliance Program Guidance for Clinical Laboratories in August of 1998, and advisory opinions. The Company has implemented a robust Compliance Program, which is overseen by our Board of Directors. Its objective is to ensure compliance with the myriad of federal and state laws, regulations and governmental guidance applicable to our business. Our program consists of training/education of employees and monitoring and auditing Company practices. The Board of Directors has formed a Compliance Committee of the Board, which meets regularly to discuss all compliance-related issues that may affect the Company. The Company reviews its policies and procedures as new regulations and interpretations come to light to comply with applicable regulations. The Chief Compliance Officer reports directly to the Compliance Committee.

Hotline

As part of its Compliance Program, the Company provides a hotline for employees who wish to anonymously or confidentially report suspected violations of our codes of conduct, policies/procedures, or laws and regulations. Employees are strongly encouraged to report any suspected violation if they do not feel the problem can be appropriately addressed through the normal chain of command. The hotline does not replace other resources available to our employees, including supervisors, managers and human resources staff, but is an alternative channel available

24 hours a day, 365 days a year. The hotline forwards all reports to the Compliance Officer who is responsible for investigating, reporting to the Compliance Committee, and documenting the disposition of each report. The hotline forwards any calls pertaining to the financial statements or financial issues to the Chairman of the Audit Committee. The Company does not allow any retaliation against an employee who reports a compliance related issue in good faith.

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Laboratory Developed Tests (“LDTs”)

The FDA has regulatory responsibility over, among other areas, instruments, test kits, reagents and other medical devices used by clinical laboratories to perform diagnostic testing. High complexity and CLIA-certified laboratories, such as ours, frequently develop internal testing procedures to provide diagnostic results to customers. These tests are referred to as laboratory developed tests (“LDTs”). LDTs are subject to CMS oversight through its enforcement of CLIA. The FDA has also claimed regulatory authority over all LDTs, but indicates that it has exercised enforcement discretion with regard to most LDTs offered by high complexity CLIA-certified laboratories, and has not subjected these tests to FDA rules and regulations governing medical devices. However, the FDA has stated that it has been considering changes in the way it believes that laboratories ought to be allowed to offer these LDTs, and since 2010 publicly announced that it would be exercising regulatory authority over LDTs, using a risk-based approach that will direct more resources to tests with the highest risk of injury. On July 31, 2014 the FDA issued a notification to Congress of the “Anticipated Details of the Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests,” or the Draft LDT Guidance. As described in this notification, the FDA planned to provide draft guidance to clinical laboratories that develop their own LDTs regarding how the FDA intends to regulate such laboratories under the Federal Food, Drug, and Cosmetic Act. In October 2014, the FDA published Draft LDT Guidance setting forth its proposed framework and timetable for regulating LDTs. The FDA received numerous comments both in support of and opposed to the draft guidance. The FDA provided an opportunity for public comment through February 2015 and received numerous public comments in response to the Draft LDT Guidance. The FDA then announced that it would not be finalizing the draft guidance. On January 13, 2017, FDA published a non-binding Discussion Paper to “advance the public discussion by providing a possible approach to spur further dialogue.” The Discussion Paper sets forth a possible LDT regulatory approach where LDTs currently on the market would be exempt from FDA regulation except for adverse event and malfunction reporting, and regulation of new and modified LDTs would be phased in over four years, based on risk. Recently, Congress has submitted a legislative discussion draft, the Diagnostic Accuracy and Innovation Act (“DAIA”) to the FDA and requested technical assistance on the draft. FDA’s technical assistance consisted of recommendations for significant changes to the bill. In December 2018, Congress released an updated bill, the Verifying Accurate Leading-edge IVCT Development (“VALID”) Act that is largely consistent with FDA’s technical assistance on DAIA. However, it remains unknown whether Congress will enact legislation regulating LDTs and, if so, whether the legislation will be similar to the framework described in the Draft LDT Guidance, or in the VALID Act. It is possible that legislation and resulting 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, or modify existing tests and may increase our costs. We cannot be certain as to which of our tests would require FDA review and approval, and if approval was to be required, that our tests could obtain FDA approval.

The federal laws governing Medicare, Medicaid and other federal health benefits, as well as other state and federal laws, regulate certain aspects of the relationships between health care providers, including clinical laboratories, and their referral sources, including physicians, hospitals, other laboratories and other entities. We are subject to the federal Anti-Kickback Statute (“federal AKS”), as well as similar state statutes and regulations, which prohibit the offer, payment, solicitation or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing or arranging for or recommending the ordering, purchasing or leasing of items or services payable by Medicare, Medicaid or any other federally funded healthcare program. The federal AKS defines remuneration to include anything of value, in cash or in kind, and thus can implicate financial relationships including payments not commensurate with fair market value, such as in the form of space, equipment leases, professional or technical services or anything else of value.

The federal AKS is an “intent-based” statute, meaning that a violation occurs when one or both parties intend the remuneration to be in exchange for or to induce referrals. Violations of the federal AKS may result in substantial civil or criminal penalties, including criminal fines of up to \$100,000, imprisonment of up to ten years, civil penalties under the federal CMP Law of up to \$100,000 for each violation, plus three times the remuneration involved, civil penalties under the federal False Claims Act of up to a minimum of \$11,181 and a maximum of \$22,363 for each claim

submitted, plus three times the amounts paid for such claims and exclusion from participation in the Medicare and Medicaid programs.

Because of the broad proscriptions of the federal AKS, there are both statutory exceptions and regulatory safe harbors promulgated by HHS (collectively, the "Safe Harbors"). The Safe Harbors specify certain arrangements or activities that would not be considered prohibited remuneration in violation of the federal AKS. An arrangement or activity that does not meet all of the criteria of an applicable Safe Harbor is not deemed to be illegal per se, rather it may be subject to additional scrutiny by government regulators. The Company endeavors to comply with any applicable Safe Harbors, but there can be no assurance that the Company would not be subject to investigation and, if investigated, that relationships could be found not to comply with such Safe Harbors.

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

Medicare Payment Guidelines

We have various billing arrangements with our clients and with third party payers, including the Medicare program. When the Company bills the client for all, or a portion of, a laboratory test performed, these client billing arrangements are priced competitively at fair market value. These client billing arrangements may implicate the prohibition of the Medicare program against charging the Medicare or Medicaid programs fees substantially in excess of the Company's usual and customary charges. Given our participation in Medicare and Medicaid, we are subject to the federal Stark Law and the federal and state anti-kickback statutes.

Federal law authorizes the Secretary of HHS to suspend or exclude providers from participation in the Medicare and Medicaid programs if providers charge Medicare or state Medicaid programs fees "substantially in excess" of their "usual charges." In commentary the OIG has noted that "ancillary services, such as laboratory tests and drugs, would remain subject to these regulations, even when furnished by physicians." 68 Fed. Reg. 53,939, 53,940 (Sept. 15, 2003). As such, the government could scrutinize the Company's pricing and billing practices.

The Centers for Medicare and Medicaid Services promulgated, in 2009, a revision to the regulation that prohibits the mark up of purchased diagnostic services 42 C.F.R. §414.50 (the "Anti-Markup Rule"). The Anti-Markup Rule prohibits a physician or other supplier from marking up the price paid for the technical or professional component of a diagnostic test that was ordered by the billing physician or supplier and which was performed by a physician who does not share a practice with the billing physician or supplier. The billing physician is prohibited from billing the Medicare program an amount greater than the lesser of: (i) the performing supplier's net charge to the billing physician; (ii) the billing physician's actual charge; or (iii) the fee schedule amount for the test that would be allowed if the performing supplier billed directly.

In light of the various federal regulations and guidance from the OIG, the Company seeks to price its products competitively while endeavoring to meet applicable statutes and regulations.

Physician Self-Referral Laws

The federal law referred to as the "Stark Law", named after U.S. Representative Fortney "Pete" Stark, prohibits payments for certain health care services, referred to as designated health services or "DHS," which were rendered as a result of referrals by physicians to DHS entities with which the physicians (or their 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 and Medicaid for any DHS services performed as a result of such a referral, unless an arrangement is carefully structured 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, unless an exception applies. 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 \$24,748 for each violation and \$164,992 for each circumvention arrangement or scheme. The amounts may be further increased by civil monetary penalty increases imposed by the Bipartisan Budget Act of 2018. 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. The Company endeavors to structure its financial

relationships in compliance with the Stark Law and with similar state physician self-referral laws. 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 similar state self-referral laws, 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 or a similar state self-referral law, we could be subject to significant penalties, including fines as specified above, exclusion from participation in government and private payer programs and requirements to refund amounts previously received from government.

The False Claims Act

The federal False Claims Act prohibits any person or entity from knowingly presenting, or causing to be presented, to the U.S. government, or to a Medicare program contractor, a false or fraudulent claim for payment, or knowingly making or using a false record or statement to have a false claim paid by the government, or conspiring to defraud the U.S. government, or knowingly making or using a false statement to conceal an obligation to pay the government, or improperly retaining overpayments from, the government. Following enactment of the ACA, knowing retention of overpayments is also considered a false claim and could lead to liability under the False Claims Act. A violation of the federal False Claims Act is punishable by a civil penalty of a minimum of \$11,181 and a maximum of 22,363 for each separate false claim plus three times the amount of damages sustained by the government. Further, False Claims Act liability may lead to exclusion from participation in Medicare, Medicaid and other federal healthcare programs. 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. As most qui tam cases are filed by current or former employees, an effective compliance program plays a crucial role in reducing the Company's exposure to liability. It is also a criminal offense, under Title 18 U.S. Code, Section 287, for a person or entity to make a claim against the United States or any department or agency, knowing the claim to be false, fictitious or fraudulent. The penalty is a fine, and imprisonment of up to five years. The federal False Claims Act has been an effective enforcement tool for the federal government. Many states have enacted similar false claims acts as well.

The Company seeks to structure its arrangements with physicians and other clients to be in compliance with the Anti-Kickback Statute, Stark Law, state laws, and the federal False Claims Act and to stay abreast of current developments and changes in the law and regulations. However, these laws and regulations are complex and subject to interpretation. Consequently, we are unable to ascertain with certainty that any of our transactions will not be subject to scrutiny and, if scrutinized, will not result in sanctions or penalties. The Company has taken, and will continue to take, actions to endeavor to ensure compliance with the myriad federal and state laws that govern our business.

Confidentiality and Security of Personal Health Information

The Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"), contains provisions that protect individually identifiable health information from unauthorized use or disclosure by covered entities and their business associates. The Office for Civil Rights of HHS, the agency responsible for enforcing HIPAA, has published regulations to address the privacy (the "Privacy Rule") and security (the "Security Rule") of protected health information ("PHI"). The Company is a covered entity under HIPAA and has adopted policies and procedures to comply with the Privacy Rule and the Security Rule and HIPAA. The health care facilities and providers that refer specimens to the Company are also bound by HIPAA. HIPAA also requires that all providers who transmit claims for health care goods or services electronically utilize standard transaction and data sets and use standardized national provider identification codes. The Company has taken necessary steps to comply with HIPAA regulations, utilizes standard transaction data sets, and has obtained and implemented national provider identifiers, or NPIs, as the standard unique health identifier in filing and processing health care claims and other transactions.

The American Recovery and Reinvestment Act (“ARRA”) enacted the HITECH Act which extends the scope of HIPAA to permit enforcement against business associates for a violation, establishes new requirements to notify the Office for Civil Rights of a breach of PHI, and allows the Attorneys General of the states to bring actions to enforce violations of HIPAA. Rules implementing various aspects of HIPAA are continuing to be promulgated. With respect to these rules, commencing July 1, 2012, CMS required all HIPAA-covered entities such as the Company to conduct electronic claim submissions and related electronic transactions under a new HIPAA transaction standard called Version 5010. In addition to the HIPAA Privacy Rule and Security Rule described above, the Company is subject to state laws regarding the handling and disclosure of patient records and patient health information. The HIPAA Privacy Rule and Security Rule

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regulations do not supersede state laws that may be more stringent; therefore, we are required to comply with both federal privacy and security regulations and varying state privacy and security laws and regulations. These laws vary widely. Penalties for violation include sanctions against a laboratory's licensure as well as civil or criminal penalties. Additionally, private individuals may have a right of action against the Company for a violation of a state's privacy laws. We believe we are in material compliance with current state laws regarding the confidentiality of health information and will continue to monitor and comply with new or changing state laws.

The Fair and Accurate Credit Transactions Act of 2003, enacted on Dec. 4, 2003, directed the Federal Trade Commission to implement regulations to protect consumers against identity theft. The Federal Trade Commission issued what are referred to as the "Red Flag Rules", but the effective date for enforcement was delayed several times. The Red Flag Rules were subject to enforcement as of January 1, 2012. The Red Flag Program Clarification Act of 2010 ("RFPCA") gave some relief to health care providers by changing the definition of "creditor", thereby narrowing the application to health care providers who do not otherwise obtain or use consumer reports or furnish information to consumer reporting agencies in connection with a credit transaction. Health care providers who act as a "creditor" to any of its patients with respect to a "covered account" are required to implement an identity theft protection program to safeguard patient information. A creditor includes any entity that regularly in the course of business obtains or uses consumer reports in connection with credit transactions, furnishes information to a consumer reporting agency in connection with a credit transaction, or advances funds to or on behalf of a person based on the person's obligation to repay the funds or repayable from specific property pledged by or on behalf of the person. But, a creditor, as defined in the RFPCA, that advances funds on behalf of a person for expenses incidental to a services provided by the creditor to that person is not subject to the Red Flag Rules. The Company has developed a written program designed to identify and detect the relevant warning signs – or "red flags" – of identity theft and establish appropriate responses to prevent and mitigate identity theft in order to comply with the Red Flag Rules. We are also developing a plan to update the program, and the program will be managed by senior management staff under the policy direction of our Board of Directors. The Company intends to take such steps as necessary to determine the extent to which the Red Flag Rules apply to it and to take such steps as necessary to comply.

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ITEM 1A. RISK FACTORS

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

Risks Relating to Our Business

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. Additionally, certain technological changes such as advances in point-of-care testing, could reduce the need for the laboratory tests we provide. 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.

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

The market for genetic and molecular testing services is highly competitive and we expect competition to continue to increase. 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. Our competitors may develop products and services that are superior to ours or that achieve greater market acceptance than our offerings. Many of our competitors have long established relationships with their customers and third-party payers. We cannot assure you that we will be able to compete successfully with such entities in the future.

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

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

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

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

results of operations and financial condition. In addition, based on the importance of the subject matter of our tests, inaccurate results could result in improper treatment of patients, and potential liability for us.

Failure to develop, or acquire licenses for, new or improved testing technologies could materially and adversely affect our revenues.

Our industry is subject to rapidly changing technology and new product introductions. Other companies or individuals, including our competitors, may obtain patents or other property rights that would prevent, limit or interfere with our ability to develop, perform or sell our solutions or operate our business or increase our costs. In addition, they could introduce new tests, technologies or services that may result in a decrease in the demand for our services or cause us to reduce the prices of our

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services. 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.

Clinical trials and research services create a risk of liability.

We conduct clinical trials, which ordinarily involve testing an investigational drug on a limited number of individuals to evaluate a product's safety, determine a safe dosage range and identify side effects. Errors or omissions could occur during a clinical trial that may result in harm to study volunteers, or if unnoticed and regulatory approval received, to consumers of the drug, or that undermine the usefulness of the clinical trial or data from the clinical trial and may delay the entry of a drug to the market.

Our contracts with the pharmaceutical firms include provisions entitling us to be indemnified or entitling us to a limitation of liability. These provisions do not uniformly protect us against liability arising from certain of our own actions, such as gross negligence or misconduct. We could be materially and adversely affected if we were required to pay damages or bear the costs of defending any claim which is not covered by or exceeds a contractual indemnification provision or in the event that a party who must indemnify us does not fulfill its indemnification obligations or which is beyond the level of our insurance coverage.

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

The development, marketing, sale and performance of healthcare services expose us to the risk of litigation, including professional negligence or product liability claims were someone to allege that our tests failed to perform as designed. We may also be subject to liability for errors in the test results we provide to pathologists and oncologists or for a misunderstanding of, or inappropriate reliance upon, the information we provide. Damages assessed in connection with, and the costs of defending, any legal action could be substantial. We may be faced with litigation claims that exceed our insurance coverage or are not covered under any of our insurance policies. In addition, litigation could have a material adverse effect on our business if it impacts our existing and potential customer relationships, creates adverse public relations, diverts management resources from the operation of the business, or hampers our ability to otherwise conduct our business.

We may not be able to implement our business strategy, 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 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 Genoptix business in December 2018, has placed, and is expected to continue to place, a significant strain on our managerial, operational and financial resources. For example, the acquisition of Genoptix is expected to result in a combined company with annual revenues in excess of \$379.0 million as compared to our annual revenues of \$276.7 million for the year ended December 31, 2018. 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. 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.

On June 25, 2018, we entered into a second amendment to our senior secured revolving credit facility, which now provides for a \$105.0 million senior secured term loan facility and a \$75.0 million revolving credit facility. At December 31, 2018, we had \$96.7 million and \$5.0 million of indebtedness outstanding under the senior secured term loan facility and revolving credit

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facility, respectively. We had \$60.9 million of available borrowing capacity under the revolving credit facility. The revolving credit facility allows for additional borrowings as long as the debt to Adjusted EBITDA ratio remains below 4.0:1.0 for the quarter ending March 31, 2019 and 3.75:1.0 for the quarters ending June 30, 2019 and September 30, 2019, and as specified in the respective agreements for future quarters. Our substantial indebtedness could have significant consequences for our business and financial condition. For example:

- We could 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. 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 may experience increased vulnerability to general adverse economic conditions, including increases in interest rates for those borrowings that bear interest at variable rates or if such indebtedness is refinanced at a time when interest are higher.
- We may 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.

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, 2018, we had cash and cash equivalents of approximately \$9.8 million and approximately \$60.9 million in 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.

Changes in the use of LIBOR could adversely affect our business.

Financial regulators are working to transition away from the London Interbank Offered Rate (“LIBOR”) as a reference rate for financial contracts by the end of 2021 and to develop benchmarks to replace LIBOR. Borrowings under our Term Loan Facility and our Revolving Credit Facility, which mature in December 2021, are derived from the LIBOR reference rate. The interest rate swap agreements we enter into to reduce our exposure to interest rate fluctuations on

our credit facilities are based on the LIBOR reference rate. Our credit agreement includes general provisions governing the use of an alternate rate of interest to the LIBOR-based rate based upon the rates used by the Federal Reserve Bank or by Regions Bank, the administrative agent under our credit agreement. At this time, the impact on the Company's borrowing costs, if any, under an alternative reference rate scenario is uncertain.

If we are unable to successfully integrate the Genoptix 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 of Genoptix, 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

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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 of Genoptix, 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 Genoptix 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.

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

Genoptix is now 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. We are in the process of migrating Genoptix operations to our system of internal controls. Therefore, we may face difficulties or experience delays in developing changes or potentially necessary improvements to Genoptix 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.

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

Genoptix is now a wholly owned subsidiary of ours and 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 Genoptix. 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 Genoptix 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, Genoptix from time to time receives payments from the U.S. government. If the U.S. government were to assert that Genoptix was 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

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the aggregate, if not covered by the indemnification obligations of the Genoptix sellers or our representation and warranty insurance, could have a material adverse effect on our business.

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 integration of Genoptix. 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.

Other manufacturers may discontinue or recall testing products used in our business.

We rely heavily on reagents, test kits and instruments manufactured by third parties in our testing services. From time to time, manufacturers discontinue or recall the reagents, test kits or instruments used by us to perform laboratory testing. Such discontinuations or recalls could adversely affect our costs, testing volume, costs and revenues.

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 laboratory testing services, a meaningful percentage of the population, returns to homes in the Northern United States to avoid the hot summer months. This combined with the usual summer vacation schedules of our clients usually results in seasonality in our business. Because of all of the foregoing factors, our operating results in future periods could be less than the expectations of investors.

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

Our business consists of clinical laboratories that provide medical testing services for doctors, hospitals, and other laboratories on patient specimens that are sent to our laboratory. In the case of some specimen referrals that are received for patients that are not in-patients or out-patients at a hospital or institution or otherwise sent by another reference laboratory, we typically bill the patient's insurance company or a government program for our services. As such, we rely on the cooperation of numerous third-party payers, including but not limited to Medicare, Medicaid, and various insurance companies, to get paid for performing services on behalf of our clients and their patients. The amount of such third-party payments is governed by contractual relationships in cases where we are a participating provider for a specified insurance company or by established government reimbursement rates in cases where we are an approved provider for a government program such as Medicare or Medicaid. However, we do not have contractual relationships with some of the insurance companies with whom we deal, nor are we necessarily able to become an approved provider for all government programs. In such cases, we are deemed to be a non-participating provider and there is no contractual assurance that we will be able to collect the amounts billed to such insurance companies or government programs. Currently, we are not a participating provider with some of the insurance companies we bill for our services. Until such time we become a participating provider with such insurance companies, there can be no

contractual assurance that we will be paid for the services we bill to such insurance companies or patients, and such third-parties may change their reimbursement policies for non-participating providers in a manner that may have a material adverse effect on our cash flow or results of operations. When new Current Procedural Terminology (“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. Medicare has also, at times, issued codes or coding guidance that conflicts with the AMA CPT coding, which can cause confusion when secondary insurance is involved. 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.

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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, Atlanta, Georgia, Rolle, Switzerland or Fresno, California laboratories locations which 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.

Additionally, our ability to retain existing clients for our specialized diagnostic services and attract new clients is dependent upon retaining existing sales representatives and hiring and training new sales representatives, which is an expensive and time-consuming process. We face intense competition for qualified sales personnel and our inability to hire or retain an adequate number of sales representatives could limit our ability to maintain or expand our business and increase sales. Even if we are able to increase our sales force, our new sales personnel may not commit the necessary resources or provide sufficient high quality service and attention to effectively market and sell our services. If we are unable to maintain and expand our marketing and sales networks or if our sales personnel do not perform to our standards, we may be unable to maintain or grow our existing business and our results of operations and financial condition will likely suffer accordingly. If a sales representative ceases employment, we risk the loss of client goodwill based on the impairment of relationships developed between the sales representative and the healthcare professionals for whom the sales representative was responsible. This is particularly a risk if the representative goes to work for a competitor, as the healthcare professionals that are our clients may choose to use a competitor's services based on their relationship with our former sales representative.

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

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. 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 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, results of operations and financial condition.

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

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Expedited, reliable shipping is essential to our operations. One of our marketing strategies entails highlighting the reliability of our point-to-point transport of patient samples. We rely heavily on a single provider of transport services, FedEx Corporation (the “Carrier”) for reliable and secure point-to-point transport of patient samples to our laboratory and enhanced tracking of these patient samples. Should the Carrier encounter delivery performance issues such as loss, damage or destruction of a sample, it may be difficult to replace our patient samples in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our services and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions by delivery services we use would adversely affect our ability to receive and process patient samples on a timely basis. If the Carrier or we were to terminate our relationship, we would be required to find another party to provide expedited, reliable point-to-point transport of our patient samples. There are only a few other providers of such nationwide transport services, and there can be no assurance that we will be able to enter into arrangements with such other providers on acceptable terms, if at all. Finding a new provider of transport services would be time-consuming and costly and result in delays in our ability to provide our specialized diagnostic services. Even if we were to enter into an arrangement with such provider, there can be no assurance that they will provide the same level of quality in transport services currently provided to us by the Carrier. If the new provider does not provide the required quality and reliable transport services, it could adversely affect our business, reputation, results of operations and financial condition.

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

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

Risks Relating to Regulation

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

In the event that, in the future, the FDA begins to regulate our tests, it may require additional pre-market clinical testing prior to submitting a regulatory notification or application for commercial sales. Such pre-market clinical testing could delay the commencement or completion of clinical testing, significantly increase our test development costs, delay commercialization of any future tests, and interrupt sales of our current tests. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial.

We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the trials. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical

protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests and/or to achieve sustained profitability.

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

We frequently develop diagnostic tests for 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 LDTs. Currently all LDTs are conducted and

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offered in accordance with the 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. Congress may enact legislation to provide a regulatory framework for the FDA's role with regard to LDTs. 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 may be time-consuming and costly, with no guarantee of ultimate approval or clearance.

On July 31, 2014 the FDA issued a notification to Congress of the "Anticipated Details of the Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests," or the Draft LDT Guidance. As described in this notification, the FDA planned to provide draft guidance to clinical laboratories that develop their own LDTs regarding how the FDA intends to regulate such laboratories under the Federal Food, Drug, and Cosmetic Act. On October 3, 2014 the FDA issued the draft guidance to clinical laboratories. The regulatory framework will use a risk-based approach to enforce the FDA's premarket review requirements, and for high-risk tests, the framework may require laboratories to use FDA-approved tests, if available, rather than LDTs. If implemented, the framework outlined in the Draft LDT Guidance may also require us to obtain premarket clearance or approval for certain of our LDTs. Implementation of this framework would include a lengthy phase-in period ranging from two to nine years depending on the risk assessment rating of each particular test. The FDA provided an opportunity for public comment through February 2015 and received numerous public comments in response to the Draft LDT Guidance. In January 2017 the FDA announced that it would not issue a final guidance on the oversight of LDTs at the request of various stakeholders to allow for further public discussion on an appropriate oversight approach, and to give congressional authorizing committees the opportunity to develop a legislative solution. At the same time, Congress, the FDA, and various industry stakeholders have worked to provide recommendations for comprehensive reform of LDTs. Recently, Congress has submitted a legislative discussion draft, the Diagnostic Accuracy and Innovation Act ("DAIA") to the FDA and requested technical assistance on the draft. FDA's technical assistance consisted of recommendations for significant changes in the bill. In December 2018, Congress released an updated bill, the Verifying Accurate Leading-edge IVCT Development ("VALID") Act that is largely consistent with the FDA's technical assistance on DAIA. However, it remains unknown whether Congress will enact legislation regulating LDTs and, if so, whether the legislation will be similar to the framework described in the Draft LDT Guidance, or in the VALID act. This legislation and resulting 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 not 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.

If the FDA and/or congressional authorizing committees begin to regulate our tests, it could require a significant volume of applications with the FDA and/or document responses to congressional authorizing committees which would be burdensome. Furthermore, FDA and/or congressional authorizing committees could take a long time to review such applications and/or document responses if every laboratory in the country files a large volume of applications and/or document responses for each of their LDTs.

In November of 2017, CMS initiated a national coverage analysis for the use of Next Generation Sequencing "NGS" diagnostic tests for patients with advanced cancer. The proposed decision memo was released and open to a public comment period. On March 16, 2018, CMS issued a final decision memorandum for NGS as a diagnostic laboratory test and determined it to be reasonable and necessary and covered nationally, when performed in a CLIA-certified laboratory, when ordered by a treating physician and when all of the following requirements are met: (a) the patient has either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer; (b) the patient has either not been previously tested using the same NGS test for the same primary diagnosis of cancer or has had repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician; and (c) the patient has decided to seek further cancer treatment (e.g., therapeutic chemotherapy). CMS also determined that the

diagnostic laboratory test using NGS must have: FDA approval or clearance as a companion in vitro diagnostic; an FDA approved or cleared indication for use in that patient's cancer; and results provided to the treating physician for management of the patient using a report template to specify treatment options. These CMS changes to reimbursement for NGS testing could directly affect our revenue for this test type.

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," also known as the ACA, was passed into law. The ACA also makes changes that are expected to significantly impact the pharmaceutical and medical device industries and clinical laboratories. For example, the ACA provided that effective December 31, 2017, each medical device manufacturer must pay excise 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, ("LDTs"), as medical devices, none of our LDTs such as our prostate cancer test are currently listed with the FDA. In 2018, however, Congress passed an

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extension of a two-year moratorium on the Medical Device Excise Tax until December 31, 2019. The extension was retroactive, covering the time between January 1, 2018 and January 22, 2018 when the tax would have otherwise been in effect. We cannot assure you that the tax will not apply to services such as ours after the moratorium.

The ACA contains several provisions that seek to limit Medicare spending in the future. One key provision in the ACA is the establishment of “Accountable Care Organizations,” or (“ACOs”), under which hospitals and physicians are able to share savings that result from improved coordination of health care. We cannot predict how the continued establishment and implementation of these new business models will impact our business. There is the possibility that value-based payment models, such as ACOs, will drive down the utilization and/or reimbursement rates for 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.

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 subject providers to heightened government scrutiny 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, including, but not limited to the current or future Secretary of the DHHS, 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 January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. Further, in January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In December of 2017, President Trump signed into law Public Law No. 115-97, which made changes to the tax code and included, among other things, a repeal of the ACA’s penalties for the individual mandate, a provision that required individuals to buy health insurance or pay a fine. On December 14, 2018 a federal district court judge in the Northern District of Texas ruled that Public Law No. 115-97 rendered the individual mandate unconstitutional and further ruled that the rest of the ACA was inseparable from the individual mandate, rendering the ACA in its entirety invalid. As of January 2019, this ruling has been stayed pending the outcome of an appeal to the U.S. Fifth Circuit Court of Appeals. Additionally, the ACA continues to be challenged in other lawsuits. Congress also could consider subsequent legislation to replace elements of the ACA that are repealed or ruled invalid. Because of the continued uncertainty about the implementation and constitutionality of the ACA, there can be no assurance at this time that the implementation (or repeal) of these provisions, or the ACA as a whole, will not have a material adverse effect on our business.

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, prospective and/or

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 the 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; (i.e., the sustainable growth rate formula). The Medicare Access and CHIP Reauthorization Act of 2015, ("MACRA"), repealed the previous statutory formula and specified new annual conversion factors for calendar years 2015 and beyond. If the new annual 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. In June 2016, CMS published the Clinical Laboratory Fee CLFS final rule entitled "Medicare Program: Medicare Clinical Diagnostic Laboratory Tests Payment System" (CMS-1621-F). The final rule provides regulations to implement the provisions of the Protecting Access to Medicare Act of 2014, ("PAMA"), which was signed into

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law in April 2014. Under the final rule, laboratories, including physician office laboratories, are required to report private payer rate and volume data if they:

- Have \$12,500 or more in Medicare revenues from laboratory services on the CLFS and
- They receive more than 50 percent of their Medicare revenues from CLFS or PFS during a data collection period.

Tests that meet the criteria for being considered new advanced tests will be paid at actual list charge during an initial period of three calendar quarters. Once the initial period is over, payment for new, advanced tests would be based on the weighted median private payer rate reported by the single laboratory that performs the new ADLT. Advanced tests are tests furnished by only one laboratory that include a unique algorithm and, at a minimum, are an analysis of RNA, DNA or proteins or are cleared or approved by the FDA.

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” laboratory may exclude certain types of laboratories that generally receive 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 is equal to the weighted median amount for the test from the most recent data collection period. For example, applicable laboratories were required to collect private payer data from January 1, 2016 through June 30, 2016 and report it to CMS by March 31, 2017. The new Medicare CLFS rates (based on weighted median private payer rates) were released in November 2017 and were effective on January 1, 2018. 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. From January 1, 2019 through June 30, 2019, applicable laboratories are required to collect private payer data and report it to CMS by March 31, 2020. The new Medicare CLFS rates (based on weighted median private payer rates) will be released in November 2020 and will become effective January 1, 2021. For the years 2020 through 2022, any reduction in the Medicare rate 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 projected that the effect of this rule on the Medicare program will be a savings of \$360 million in program payments for CLFS tests furnished in FY 2017, and a savings of \$5.14 billion over 10 years, although estimates by the Congressional Budget Office have been significantly less. CMS also finalized its proposal that a laboratory’s failure to comply with reporting obligations, or a laboratory that makes a misrepresentation or omission in reporting required information, could lead to liability under the Civil Monetary Penalties Law.

Also under PAMA, 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, 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. 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 Alaska, Arkansas, Arizona, California, Hawaii, Indiana, Idaho, Kentucky, Missouri, Montana, Nevada, North Carolina, North Dakota, Ohio, Oregon, South Carolina, South Dakota, Utah, Virginia, Washington, West Virginia and Wyoming, Palmetto GBA administers the Molecular Diagnostic Services Program, ("MolDx"), and establishes 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

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ever be covered services by Medicare, nor can we determine when the medical literature will meet the standard for coverage that Medicare administrative contractors have set.

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

Effective January 1, 2018 CMS implemented an additional exception to the laboratory date of service rules. Prior to 2018, CMS’ 14-day rule prevented reference and independent laboratories such as ours from billing Medicare directly for clinical laboratory tests or the technical component of pathology services if, among other things, the tests were ordered less than 14 days following an outpatient's discharge from the hospital. Instead, we would seek reimbursement from the hospital and the hospital would bill Medicare. Effective January 1, 2018, certain molecular pathology tests and advanced diagnostic laboratory tests ("ADLTs") that previously had to be billed or could be billed by the hospital are now required to be billed by the performing laboratory if certain requirements are met, although CMS has indicated it will exercise enforcement discretion until July 1, 2019. Since our client-bill pricing is typically higher for Molecular testing than the Medicare fee schedule, we anticipate a reduction in revenue from this policy change. Under the MolDx program there are many policies that limit reimbursement on certain tests based on diagnosis codes, and for certain tests there is no reimbursement regardless of the patient’s condition.

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, results of operations, financial condition and prospects.

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

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

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.

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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.

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, private payers continually seek ways to reduce and control overall healthcare costs, and increasing emphasis on managed care in the United States will continue to put pressure on the pricing of healthcare services. Uncertainty exists as to the coverage and reimbursement status of new applications and 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, and 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, it could adversely affect our operating results, cash flows and/or our financial condition.

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

Billing for laboratory services is extremely complicated. 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 or contracts;
- 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.

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 is ensuring compliance with federal and state laws prohibiting fraudulent billing and the retention 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 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 \$11,181 and \$22,363 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. Following enactment of the ACA, knowing retention of overpayments is also considered a false claim and could lead to 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

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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 his or her 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. If we fail to comply with federal and state documentation, coding, and billing rules, we could be subject to criminal liability through a variety of federal and state criminal statutes.

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 a laboratory performing certain laboratory tests to directly bill Medicare instead of the ordering provider (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. While we maintain a robust compliance program that includes consistent, detailed review of our documentation, and 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.

We are subject to extensive state and federal regulatory oversight. Specifically, our laboratories must satisfy federal requirements under the CLIA to maintain the appropriate CLIA Certificate for all testing performed at the lab. Additionally, most states have adopted various laws and regulation setting standards for laboratories performing clinical laboratory testing and requiring laboratories to obtain and maintain a state laboratory license before the laboratory is authorized to perform testing. These state licensure laws address a host of requirements and often include permissible and prohibited practices involving digital health, including but not limited to telehealth and telepathology. Upon periodic inspection or survey, our laboratory locations may be found to be non-compliant with CLIA requirements or with applicable licensure or certification laws. The sanctions for failure to comply with CLIA, state licensure requirements, or other applicable laws and regulations could include the suspension, revocation, or limitation of the right to perform clinical laboratory services or receive compensation for those services, as well as the requirement to enter into a corrective action plan to monitor compliance, and the imposition of civil or criminal penalties or administrative fines. In addition, any new legislation or regulation or the application of existing laws and regulations in ways that we have not anticipated could have a material adverse effect on our business, results of operations and financial condition.

Existing federal laws governing Medicare and Medicaid, as well as some other state and federal laws, also regulate certain aspects of the relationship between healthcare providers, including clinical laboratories, and their referral sources, including physicians, hospitals and other laboratories. Certain of these laws, including the federal "anti-kickback law" and the federal physician self-referral law (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, repayment of all services tied to any impermissible referrals, 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 Work Plan by the Office of the Inspector General (“OIG”) 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

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contrary view and impose civil monetary penalties and exclude us for past or present practices related to patient incentive, coordination of care and need-based programs.

Furthermore, HIPAA, the HITECH Act, (as implemented through HIPAA's Privacy and Security Rules) and similar state laws contain provisions that require the electronic exchange of health information, such as claims submission and receipt of remittances, using standard transactions and code sets, which we refer to as "Standards," and regulate the use and disclosure of patient records and other 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 govern many healthcare providers, including physicians and clinical laboratories. Although we believe we are in material compliance with the Standards, the Privacy and Security Rules, and applicable 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 our financial condition and could subject us to liability. Additionally, while there is no private right of action under HIPAA, state Attorneys General may bring an action against a covered entity, such as us, for a violation of HIPAA, and the national Office for Civil Rights can impose fines and penalties.

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, which are referred to as designated health services ("DHS"), rendered as a result of referrals by physicians to DHS entities with which the physicians (or their 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 structured 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, unless an exception applies. 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 \$24,748 for each violation and \$164,992 for each circumvention arrangement or scheme. The amounts may be further increased by civil monetary penalty increases imposed by the Bipartisan Budget Act of 2018. Other implications of a Stark Law violation may include 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 penalties, exclusion from Medicaid, and loss of licenses.

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

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

We are subject to the federal Anti-Kickback Statute, ("AKS") and similar state statutes and regulations, which prohibit the offer, payment, solicitation or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing or arranging for or recommending the ordering, purchasing or leasing of items or services payable by

Medicare, Medicaid or any other federally funded healthcare program. The AKS defines remuneration to include anything of value, in cash or in kind, and thus can implicate financial relationships including payments not commensurate with fair market value, such as in the form of space, equipment leases, professional or technical services or anything else of value.

The AKS is an “intent-based” statute, meaning that a violation occurs when one or both parties intend the remuneration to be in exchange for or to induce referrals. In 2010, the ACA, amended the intent requirement of the AKS. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions; however, the exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny. Violations of the AKS may result in substantial civil or

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criminal penalties, including criminal fines of up to \$100,000, imprisonment of up to ten years, civil penalties under the federal CMP Law of up to \$100,000 for each violation, plus three times the remuneration involved, civil penalties under the federal False Claims Act of a minimum of \$11,181 and a maximum of \$22,363 for each claim submitted, plus three times the amounts paid for such claims and exclusion from participation in the Medicare and Medicaid programs. If we face these penalties or the participation exclusion, it could significantly reduce our revenues and could have a material adverse effect on our business.

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

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

A failure to comply with governmental payer regulations could result in our being excluded from participation in Medicare, Medicaid or other governmental payer programs.

Tests which are reimbursed by Medicare and other Government payers (for example, State Medicaid programs) accounted for approximately 15%, 14% and 15% of our revenues for the years ended December 31, 2018, 2017 and 2016, respectively. The Medicare program imposes extensive and detailed requirements on diagnostic service providers, including, but not limited to, rules that govern how we structure our relationships with physicians, how and when we submit claims for reimbursement and how we provide specialized diagnostic laboratory services. Further, we are prohibited from contracting with any individuals or entities who have been excluded from participation in Medicare or Medicaid and are listed on the OIG's List of Excluded Individuals and Entities List ("LEIE") or in the System for Award Management, which includes the previously independent Government Services Administration's Excluded Parties List System ("GSA-EPLS"). Contracting with excluded individuals or entities, such as hiring an excluded person or contracting with an excluded vendor, can result in significant penalties.

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

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

The HIPAA privacy and security regulations establish comprehensive federal standards with respect to the uses and disclosures of PHI by certain entities including health plans and health care providers, and set standards to protect the confidentiality, integrity and availability of electronic medical records. The regulations establish a complex regulatory framework governing the use and disclosure of PHI, including, for example, the circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient; a patient's right to access, amend and receive an accounting of certain disclosures of PHI; the content of notices of privacy practices describing

how PHI is used and disclosed and individuals' rights with respect to their PHI; and implementation of administrative, technical and physical safeguards to protect privacy and security of PHI. The federal privacy regulations restrict our ability to use or disclose certain individually identifiable patient health information, without patient authorization, for purposes other than payment, treatment or health care operations (as defined by HIPAA), except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy regulations. The HIPAA privacy and security regulations do not supersede state laws that may be more stringent; therefore, we are required to comply with both federal privacy and security regulations and varying state privacy and security laws and regulations.

The HIPAA privacy and security regulations also require healthcare providers like us to notify affected individuals, the Secretary of the U.S. Department of Health and Human Services, and in some cases, the media, when PHI has been "breached," as defined by HIPAA. Many states have similar breach notification laws. In the event of a breach, we could incur substantial operational and financial costs related to mitigation and remediation, including preparation and delivery of notices to affected individuals. Additionally, HIPAA, and its implementing regulations provide for significant civil fines, criminal penalties, and other sanctions for failure to comply with the privacy, security, and breach notification rules, including for wrongful or

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impermissible use or disclosure of PHI. Although the HIPAA statute and regulations do not expressly provide for a private right of action for damages, we could incur damages under state laws to private parties for the wrongful or impermissible use or disclosure of confidential health information or other private personal information. Additionally, HIPAA allows state Attorneys General to bring an action against a covered entity, such as us, for a violation of HIPAA. We insure some of our risk with respect to HIPAA security breaches, but operational costs and penalties associated with HIPAA breaches easily could exceed our insured limits.

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

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

Risks Relating to Our Common Stock

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

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

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

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of diagnostic companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because clinical laboratory service companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

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

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

The price of our common stock may fluctuate significantly.

The price of our common stock has been, and is likely to continue to be, volatile, which means that it could decline substantially within a short period of time. The price of our common stock could fluctuate significantly for many reasons including the following:

- future announcements concerning us or our competitors;
- regulatory developments and enforcement actions bearing on advertising, marketing or sales;

- reports and recommendations of analysts and whether or not we meet the milestones and metrics set forth in such reports; gaining or losing large customers or managed care plans;
- introduction of new products or services and related insurance coverage;

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- acquisition or loss of significant manufacturers, distributors or suppliers or an inability to obtain sufficient quantities of materials needed to provide our services;
- quarterly variations in operating results;
- business acquisitions or divestitures;
- changes in the regulation of Laboratory Developed Tests (“LDTs”);
- changes in governmental or third-party reimbursement practices and rates; and fluctuations in the economy, political events or general market conditions.

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None

ITEM 2. PROPERTIES

We operate an international network of laboratories. Our corporate office and most of our laboratory facilities are leased except 43,448 square feet of our Carlsbad, California facility. These leases expire at various dates through 2023. We believe that these locations are sufficient to meet our needs at existing volume levels and that, if needed, additional space will be available at a reasonable cost.

The following table summarizes our facilities by type and location:

Location	Purpose	Square Footage
Carlsbad, California	Laboratory, and administrative offices	105,066
Aliso Viejo, California	Laboratory, and administrative offices	96,917
Fort Myers, Florida	Corporate headquarters and laboratory	56,889
Houston, Texas	Laboratory	32,757
Geneva (Rolle), Switzerland	Laboratory	7,976
Nashville, Tennessee	Laboratory	7,806
Tampa, Florida	Laboratory	5,875
Singapore	Laboratory	2,861
Fresno, California	Laboratory	2,541

Atlanta, Georgia	Laboratory	1,190
Plantation, Florida	Courier office	240

Our Switzerland and Singapore laboratories support our Pharma Services segment exclusively; all other locations support both segments of our business. For further financial information about our segments, see Note R to our Consolidated Financial Statements included in this Annual Report.

ITEM 3. LEGAL PROCEEDINGS

From time to time the Company is engaged in legal proceedings that arise in the ordinary course of business. The Company believes that any resulting liability from these proceedings will not, either individually or in the aggregate have a material adverse effect on our consolidated financial position, results of operations, or cash flows.

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Legal Matters

The Company is involved in ongoing litigation with Health Discovery Corporation (“HDC”) regarding the use of certain licensed technology under a Master License Agreement (“MLA”) dated January 6, 2012 between the Company and HDC. As required under the MLA, the parties are required to submit such matters in dispute under the MLA to binding arbitration. An arbitration hearing took place in December 2018, where the Company vigorously defended its legal rights and remedies pertaining to this licensing dispute. The arbitration panel has not yet rendered a decision, and the parties are engaged in required post-hearing procedures as requested by the arbitration panel. The Company does not believe, based on currently available information, that the outcome of this matter will have a material adverse effect on the Company's financial condition.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

ITEM 5. MARKET FOR THE REGISTRANTS COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is listed on the NASDAQ Capital Market under the symbol “NEO”.

Holders of Common Stock

As of February 22, 2019, there were 504 stockholders of record of our common stock. The number of record holders does not include beneficial owners of common stock whose shares are held in the names of banks, brokers, nominees or other fiduciaries.

Dividends

We have never declared or paid cash dividends on our common stock. We intend to retain all future earnings to finance operations and future growth and, therefore, we do not anticipate paying any cash dividends in the foreseeable future. Our financing arrangements contain certain restrictions on our ability to pay dividends on our common stock.

Equity Compensation Plan Information

The following table summarizes the securities authorized for issuance under equity compensation plans as of December 31, 2018:

<u>Plan Category</u>	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders:			
Amended and Restated Equity Incentive Plan (“Equity Incentive Plan”)	6,839,417	\$ 7.63	3,298,645 (a)
Employee Stock Purchase Plan (“ESPP”)	—	N/A	505,084 (b)
Total	6,839,417	\$ 7.63	3,803,729

a. The Company’s Equity Incentive Plan was amended, restated and subsequently approved by a majority of shareholders on December 21, 2015 and amended and subsequently approved by a majority of shareholders on May 25, 2017. The most recent amendment increased the maximum aggregate number of shares of the Company’s common stock reserved and available for issuance under the Amended Plan to 18,650,000.

b. The Company’s Employee Stock Purchase Plan was amended, restated and subsequently approved by a majority of shareholders on June 6, 2013 and amended and subsequently approved by a majority of shareholders on May 25, 2017 and June 1, 2018. The most recent amendment increased the maximum aggregate number of shares reserved and available for issuance under the Plan to 1,500,000.

Currently, the Company’s Equity Incentive Plan, as amended on May 25, 2017 and the Company’s ESPP, as amended on June 1, 2018, are the only equity compensation plans in effect.

Recent Sales of Unregistered Securities

On December 10, 2018 we issued 1,000,000 shares of common stock to the shareholders of Genesis Acquisition Holding Corp. in connection with the acquisition of Genoptix. See Notes E and P to our Consolidated Financial Statements included in this Annual Report.

In August 2017, the Company acquired a customer list from Ascend Genomics in exchange for 450,000 shares of common stock. See Notes F and P to our Consolidated Financial Statements included in this Annual Report.

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Comparison of Cumulative Five Year Total Return

We have presented below the cumulative total return to our stockholders of \$100 during the period from December 31, 2013, through December 31, 2018 in comparison to the cumulative return on the S&P 500 Index and a customized peer group of six publicly traded companies during that same period. The peer group is made up of Cancer Genetics, Inc., Enzo Biochem, Inc., Genomic Health, Inc., Laboratory Corporation of America Holdings, Myriad Genetics, Inc., and Quest Diagnostics, Inc. Several of our closest competitors are part of large pharmaceutical or other multi-national firms, or are privately held and, as such, we are unable to get financial information for them.

The results assume that \$100 (with reinvestment of all dividends) was invested in our common stock, the index and in the peer group and its relative performance tracked through December 31, 2018. The comparisons are based on historical data and are not indicative of, nor intended to forecast, the future performance of our common stock. The performance graph set forth above shall not be deemed incorporated by reference into any filing by us under the Securities Act or the Exchange Act except to the extent that we specifically incorporate such information by reference therein.

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ITEM 6. SELECTED FINANCIAL DATA

The following is a summary of our historical consolidated financial data for the periods ended and at the dates indicated below. You are encouraged to read this information together with our audited consolidated financial statements and the related footnotes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this Annual Report.

The historical consolidated financial data for the years ended December 31, 2018, 2017 and 2016 (Statement of Operations Data and Other Cash Data) has been derived from our audited consolidated financial statements, which are included elsewhere in this Annual Report. The historical consolidated financial data for the years ended December 31, 2015 and 2014 has been derived from our audited consolidated financial statements, which are not included in this Annual Report.

The historical consolidated financial data as of December 31, 2018 and 2017 (Balance Sheet Data) has been derived from our audited consolidated financial statements, which are included elsewhere in this Annual Report. The historical consolidated financial data (Balance Sheet Data) as of December 31, 2016, 2015 and 2014 has been derived from our audited consolidated financial statements, which are not included in this Annual Report.

We believe that the comparability of our financial results between the periods presented in the table below is significantly impacted by factors which are more fully described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the Consolidated Financial Statements and the notes thereto included elsewhere in this Annual Report.

	Years Ended December 31,				
	2018 (4)	2017 (3) (as adjusted)	2016 (as adjusted)	2015 (1)(5)	2014 (2)(5)
	(In thousands, except per share data)				
Statement of Operations Data:					
Net revenue	\$ 276,741	\$ 240,251	\$ 231,808	\$ 99,802	\$ 87,069
Cost of revenue	149,476	138,295	133,704	56,046	46,355
Gross margin	127,265	101,956	98,104	43,756	40,714
Operating expenses	117,225	99,054	95,949	49,391	38,496
Income (loss) from operations	10,040	2,902	2,155	(5,635)	2,218
Interest and other (income) expense	6,216	5,552	9,998	(1,146)	929
Income tax expense (benefit)	1,184	(2,254)	(1,701)	(1,954)	157
Net income (loss)	2,640	(396)	(6,142)	(2,535)	1,132
	10,198	3,645	18,011	40	—

Deemed dividends on preferred stock						
Amortization of preferred stock beneficial conversion feature	(4,571)	6,902	6,663	82	—	
Gain on redemption of preferred stock	(9,075)	—	—	—	—	
Net income (loss) due to common stockholders	\$ 6,088	\$ (10,943)	\$ (30,816)	\$ (2,657)	\$ 1,132	
Net income (loss) per common share – Basic	\$ 0.07	\$ (0.14)	\$ (0.40)	\$ (0.04)	\$ 0.02	
Net income (loss) per common share – Diluted	\$ 0.07	\$ (0.14)	\$ (0.40)	\$ (0.04)	\$ 0.02	
Other Cash Data:						
Net cash – operating activities	\$ 44,786	\$ 18,037	\$ 21,477	\$ 6,393	\$ 9,450	
Net cash – investing activities	\$ (139,687)	\$ (13,690)	\$ (6,501)	\$ (75,155)	\$ (9,602)	
Net cash – financing activities	\$ 91,959	\$ (4,095)	\$ (25,871)	\$ 58,493	\$ 29,007	

1. Reflects the acquisition of Clariant in December 2015.

2. Reflects the acquisition of Path Logic in July 2014.

3. Reflects the sale of Path Logic on August 2017.

4. Reflects the acquisition of Genoptix in December 2018.

5. Does not reflect the impact of the adoption of ASU 2014-09, Revenue from Contracts with Customers (Topic 606), which was adopted in the first quarter of 2018.

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As of December 31,					
	2018 (5)	2017 (4)	2016	2015 (1)(3)(6)	2014 (2)(6)
	(as adjusted)		(as adjusted)		
	(In thousands)				
Balance Sheet Data:					
Current assets	\$ 103,668	\$ 85,875	\$ 79,398	\$ 82,360	\$ 58,742
Property and equipment	60,888	36,504	34,036	34,577	15,082
Intangible assets	140,029	74,165	77,064	87,800	4,212
Goodwill	197,892	147,019	147,019	146,421	2,929
Other assets	2,538	891	206	129	141
Total assets	\$ 505,015	\$ 344,454	\$ 337,723	\$ 351,287	\$ 81,106
Current liabilities	\$ 60,925	\$ 36,471	\$ 39,789	\$ 40,058	\$ 14,623
Long-term liabilities	123,647	103,406	112,746	73,117	6,078
Total liabilities	184,572	139,877	152,535	113,175	20,701
Series A Redeemable Convertible Preferred Stock	—	32,615	22,873	28,602	—
Stockholders' equity	320,443	171,962	162,315	209,510	60,405
Total liabilities preferred stock and stockholders' equity	\$ 505,015	\$ 344,454	\$ 337,723	\$ 351,287	\$ 81,106
Working Capital	\$ 42,743	\$ 49,404	\$ 39,609	\$ 42,302	\$ 44,119

1. Reflects the acquisition of Clariant in December 2015.

2. Reflects the acquisition of Path Logic in July 2014.

3. Reflects the adoption of ASU 2015-17, Income Taxes: Balance Sheet Classification of Deferred Taxes.

4. Reflects the sale of Path Logic on August 1, 2017.

5. Reflects the acquisition of Genoptix in December 2018.

6. Does not reflect the impact of the adoption of ASU 2014-09, Revenue from Contracts with Customers (Topic 606), which was adopted in the first quarter of 2018.

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Introduction

The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements and the Notes thereto included in this Annual Report on Form 10-K. The information contained below includes statements of management's beliefs, expectations, hopes, goals and plans that, if not historical, are forward-looking statements subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. For a discussion on forward-looking statements, see the information set forth in the Introductory Note to this Annual Report under the caption "Forward Looking Statements", which information is incorporated herein by reference.

Our Company

NeoGenomics, Inc. is a high-complexity CLIA-certified clinical laboratory that specializes in cancer genetics diagnostic testing and pharma services. The Company's testing services include cytogenetics, fluorescence in-situ hybridization (FISH), flow cytometry, immunohistochemistry, anatomic pathology and molecular genetic testing. Headquartered in Fort Myers, FL, NeoGenomics has laboratories in Aliso Viejo, Carlsbad and Fresno, CA; Tampa and Fort Myers, FL; Houston, TX; Nashville, TN; Rolle, Switzerland; and Singapore. NeoGenomics services the needs of pathologists, oncologists, pharmaceutical companies, academic centers, other clinicians, and hospitals throughout the United States, Europe, and Asia.

2018 Overview and Highlights

- We increased revenues by 15.2% compared to 2017, including an increase in Clinical revenue of 13.5% and an increase in Pharma revenue of 28.4%.
- We completed the acquisition of Genoptix in December 2018 for approximately \$125 million in cash and one million shares of NeoGenomics common stock.
- We continued our international expansion with the opening of a laboratory in Singapore and the announcement of a global strategic affiliation with Pharmaceutical Product Development, LLC ("PPD").
- We redeemed 100% of our Series A Redeemable Convertible preferred stock.
- We completed a \$135 million equity offering.

Company Outlook

We have developed a company-wide focus for 2019, which includes the following three critical success factors:

- To strengthen our world-class culture by seeking feedback from employees on ways to innovate and grow our business. We will focus on employee engagement and inclusion through collaboration forums, team dialogue and programs to reward teams.
- To provide uncompromising quality and service through company-wide leadership, coaching and employee engagement initiatives. Our laboratory teams will focus on quality by improving the Corrective and Preventative Actions ("CAPA") process and streamlining and simplifying processes.
- To pursue exceptional service and growth through renewed focus on improving the customer experience through the launch of innovative assays, informatics products and companion diagnostics as well as enhanced educational programs. We will continue to pursue market share gains in both our Clinical and Pharma Services businesses. These critical success factors have been communicated throughout our Company. We have structured departmental goals around these factors and have created employee incentive plans in which every employee will have a meaningful incentive for our success.

As we focus on profitable growth, we will continue to pursue large purchasing group contracts. In 2018, we were successful in gaining market share by entering into contracts with managed care organizations and large hospital groups, which will be part of our strategy as we continue to gain scale. In addition, our molecular testing menu remains a strong selling point as it enables us to offer clients a "one stop shop" where they can send all of their oncology testing rather than using multiple labs.

Innovation and changes in science and technology will lead to new therapeutic and diagnostic tests. Our Company strives to lead in innovation with the launch of new assays, informatics products, research projects, educational programs and companion

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diagnostics. We will continue to work with pharmaceutical clients on their clinical trials and will work to be on the leading edge of developments in the field of oncology.

We believe lower cost and increased value of testing is extremely important to the healthcare industry and creates a competitive advantage for our company. We will invest in information technology, automation and best practices to continually improve our processes and drive down the cost of testing. We will continue to expand our test menu and remain at the forefront of the ongoing revolution in cancer related genetic and molecular testing to achieve our vision of becoming the world's leading cancer testing and information company.

We have significantly expanded our capacity, especially in the Pharma Services area of our business. The opening of a laboratory in Switzerland in 2017 and in Singapore in 2018 as well as the recent expansion of our Houston laboratory will allow us to better serve our existing Pharma Services clients and obtain new business in the U.S. and across Europe and Asia. We expect our strong growth momentum as well as our added capacity to create opportunities for improved quality and revenue growth.

Regulatory Environment

The FDA has been considering changes which may include increased regulation of Laboratory Developed Tests ("LDTs"). These changes could impact the laboratory testing industry and our business, as further described the discussion of Government Regulations in Item 1. In October 2014, the FDA announced its proposed framework and timetable. However, at this point the FDA has not released a proposed rule, and it is anticipated that there would be a comment period related to such a significant change. The FDA has indicated that there will be a "phase in" period that in some instances will take as long as nine years. On January 13, 2017 the FDA released a discussion paper in which the FDA said that they "hope that it advances public discussion on future LDT oversight". The paper does not represent formal FDA policy, nor is it enforceable. Recently, Congress has submitted a legislative discussion draft, the Diagnostic Accuracy and Innovation Act ("DAIA"), to the FDA and requested technical assistance on the draft. In December 2018, Congress released an updated bill, the Verifying Accurate Leading-edge IVCT Development ("VALID") Act that is largely consistent with FDA's technical assistance on DAIA. However, it remains unknown whether Congress will enact legislation regulating LDTs and, if so, whether the legislation will be similar to the framework described in the Draft LDT Guidance, or in the VALID Act. NeoGenomics is a member of the American Clinical Laboratory Association ("ACLA"), which has been in active discussions with the FDA and Congress regarding FDA oversight of LDT's. At this point we cannot predict the outcome of this issue, or if there will be any changes to current rules and regulations.

We closely monitor changes in legislation and take specific actions to identify and estimate the impact of changes in legislation whenever possible as regulatory changes can affect reimbursement for clinical laboratory services. We do not anticipate significant changes to our clinical revenue in 2018 based on known changes in legislation.

Operating Segments

The Company reports its activities in two operating segments the Clinical Services Segment and the Pharma Services Segment. We have presented the financial information reviewed by the Chief Operating Decision Maker ("CODM") including revenues, cost of revenue and gross margin for each of our operating segments. The segment information presented in these financial statements has been conformed to present segments on this revised basis for all prior periods. Assets are not presented at the segment level as that information is not used by the CODM.

Clinical Services

Our Clinical Services segment includes the cancer testing services we offer to community-based pathologists, hospitals, academic centers, and oncology groups and is 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 provide a menu of services that matches or exceeds the level of service found in any center of

excellence around the world.

Pharma Services

Our Pharma Services segment supports pharmaceutical firms in their drug development programs by supporting various clinical trials. This portion of our business often involves working with the pharmaceutical firms (sponsors) on study design as well as performing the testing required to validate assays in development and support of Phase I - III clinical trials. Our medical team often advises the sponsor and works closely with them as specimens are received from enrolled sites. We also work on

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developing tests that will be used as part of a companion diagnostic to determine patients' response to a particular drug. As studies unfold, our clinical trials team reports the data and often provide key analysis and insights back to the sponsors.

Our Pharma Services segment 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 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.

Whether serving as the single contract research organization or partnering with one, our Pharma Services group provides significant technical expertise working 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 submissions to the Federal Drug Administration for companion diagnostics and our Pharma Services strategy is focused on helping bring more effective oncology treatments to market through providing world class laboratory services in oncology to key pharmaceutical companies in the industry.

Critical Accounting Policies

The preparation of financial statements in conformity with United States generally accepted accounting principles ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Our management routinely makes judgments and estimates about the effects of matters that are inherently uncertain. For a complete description of our significant accounting policies, see Note B to our Consolidated Financial Statements. Our critical accounting policies are those where we have made difficult, subjective or complex judgments in making estimates, and/or where these estimates can significantly impact our financial results under different assumptions and conditions. Our critical accounting policies are:

- Revenue Recognition
- Accounts Receivable
- Intangible Assets
- Stock Based Compensation
- Deferred taxes

Revenue Recognition

We adopted Accounting Standards Codification ("ASC") 606, *Revenues from Contracts with Customers*, on January 1, 2018 using a full retrospective method of adoption. Under this method, the Company has restated its results for each prior reporting period presented as if ASC 606 had been effective for those periods. The adoption of this standard required us to implement new revenue policies, procedures and internal controls related to revenue recognition. In addition, the adoption resulted in enhanced financial statement disclosures surrounding the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

The new standard impacted each of our two reportable segments differently due to the transactional nature of the Clinical Services segment versus the generally long-term nature of our Pharma Services segment contracts. The specific effect on our reportable segments is explained further in Note B to our Consolidated Financial Statements.

Clinical Services Revenue

The Company's specialized diagnostic services are performed based on a written test requisition form or electronic equivalent. The performance obligation is satisfied and revenues are recognized once the diagnostic services have been performed and the results have been delivered to the ordering physician. These diagnostic services are billed to various payers, including Medicare, commercial insurance companies, other directly billed healthcare institutions such

as hospitals and clinics, and individuals. Revenue is recorded for all payers based on the amount expected to be collected, which considers implicit price

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concessions. Implicit price concessions represent differences between amounts billed and the estimated consideration the Company expects to receive based on negotiated discounts, historical collection experience and other anticipated adjustments, including anticipated payer denials. Collection of consideration the Company expects to receive typically occurs within 30 to 60 days of billing for commercial insurance, Medicare and other governmental and self-pay payers and within 60 to 90 days of billing for client payers.

The following table reflects our estimate of the breakdown of net revenue by type of payer for the fiscal years ended December 31, 2018, 2017, and 2016:

	2018	2017 (as adjusted)	2016 (as adjusted)
Medicare and other government	15%	14%	15%
Commercial insurance	17%	17%	25%
Client direct billing	68%	69%	60%
Total	100%	100%	100%

Our proportion of client direct billing has increased over the years shown above, as more payers, including private commercial insurances and Medicare Advantage plans are practicing “consolidated payment” or “bundled payment” models where they pay the hospitals a lump sum, which is intended to include laboratory testing. This reflects an increase in the amount of risk sharing that CMS and other private payers are encouraging providers such as hospital systems to undertake. We had previously anticipated a gradual increase in the percentage of client direct billing over the coming years; however, on January 1, 2018 Medicare made a significant change to what is known as the “14-day rule”. The net result of this rule change is that certain molecular tests that were previously billed to clients, are now once again eligible to be billed directly to the Medicare program. As a result, our Medicare direct bill revenue increased slightly in 2018 and our client direct bill revenue decreased slightly.

Pharma Services Revenue

The Company’s Pharma Services segment generally enters into contracts with pharmaceutical and biotech customers as well as other Contract Research Organizations (“CROs”) to provide research and clinical trial services ranging in duration from one month to several years. The Company records revenue on a unit-of-service basis based on number of units completed and the total expected contract value. The total expected contract value is estimated based on historical experience of total contracted units compared to realized units as well as known factors on a specific contract-by-contract basis. Certain contracts include upfront fees, final settlement amounts or billing milestones that may not align with the completion of performance obligations. The value of these upfront fees or final settlement amounts is usually recognized over time based on the number of units completed, which aligns with the progress of the Company towards fulfilling its obligations under the contract. The Company also enters into other contracts, such as validation studies, for which the sole deliverable is a final report that is sent to sponsors at the completion of contracted activities. For these contracts, revenue is recognized at a point in time upon delivery of the final report to the sponsor. Any contracts that contain multiple performance obligations and include both units-of-service and point in time deliverables are accounted for as separate performance obligations and revenue is recognized as previously disclosed. The Company negotiates billing schedules and payment terms on a contract-by-contract basis. While the contract terms generally provide for payments based on a unit-of-service arrangement, the billing schedules, payment

terms and related cash payments may not align with the performance of services and, as such, may not correspond to revenue recognized in any given period.

Amounts collected in advance of services being provided are deferred as contract liabilities on the balance sheet. The associated revenue is recognized and the contract liability is reduced as the contracted services are subsequently performed. Contract assets are established for revenue that has been recognized but not yet billed. These contract assets are reduced once the customer is invoiced and a corresponding account receivable is recorded. Additionally, certain costs to obtain contracts, primarily for sales commissions, are capitalized when incurred and are amortized over the term of the contract. Amounts capitalized for contracts with an initial contract term of twelve months or less are classified as current assets and all others are classified as non-current assets.

Most contracts are terminable by the customer, either immediately or according to advance notice terms specified within the contracts. All contracts require payment of fees to the Company for services rendered through the date of termination and may require payment for subsequent services necessary to conclude the study or close out the contract.

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Trade Accounts Receivable

Accounts receivable are reported for all clinical services payers based on the amount expected to be collected, which considers implicit price concessions. Implicit price concessions represent differences between amounts billed and the estimated consideration the Company expects to receive based on negotiated discounts, historical collection experience and other anticipated adjustments, including anticipated payer denials.

For Pharma Services, the Company negotiates billing schedules and payment terms on a contract-by-contract basis which often includes payments based on certain milestones being achieved. Receivables are generally reported over time based on the number of units completed, which aligns with the progress of the Company towards fulfilling its obligations under the contract.

Days Sales Outstanding (“DSO”) decreased from 91 days at December 31, 2017 to 77 days at December 31, 2018. These consolidated results include a decrease in Clinical Services DSO’s from 87 days to 76 days as well as a decrease in Pharma Services DSO’s from 115 days to 82. The decreases are the result of improved billing practices in both segments as well as the resolution of aged receivables in Pharma.

Intangible Assets

We review our long-lived assets for recoverability if events or changes in circumstances indicate the assets may be impaired. Impairment exists when the carrying amount of the asset exceeds fair value.

Genoptix

As a result of the acquisition of Genoptix in December 2018, we recorded an estimated \$71.8 million in intangible assets comprised of \$56.6 million in customer relationships which will be amortized over a fifteen-year period, \$0.7 million related to the Genoptix trade name which we will amortize over a one-year period, and \$14.6 million in trademarks which are indefinite-lived assets. The amortization expense for these assets is included in general and administrative expense.

Clariant

As a result of the acquisition of Clariant in December 2015, we recorded \$84.0 million in intangible assets comprised of \$81.0 million in customer relationships which is being amortized over a fifteen-year period and \$3.0 million related to the Clariant trade name which was amortized over a two-year period. The amortization expense for these assets is included in general and administrative expense.

Purchase of Third-Party Customer List

In August 2017, we acquired a customer list and recorded \$4.1 million in intangible assets comprised of customer relationships which is being amortized over a fifteen-year period. The amortization expense for this asset is included in general and administrative expense.

Stock Based Compensation

We recognize compensation costs for all share-based payment awards made to employees, non-employee contracted physicians and directors based upon the awards’ initial grant-date fair value. For stock options, we use a trinomial lattice option-pricing model to estimate the fair value of stock option awards, and recognize compensation cost on a straight-line basis over the awards’ requisite service periods. The Company’s periodic expense is adjusted for actual forfeitures.

See Note B and Note L in the Consolidated Financial Statements included in this Annual Report for more information regarding the assumptions used in our valuation of stock-based compensation.

Deferred Taxes

Our accounting for deferred tax consequences represents our best estimate of future events that can be appropriately reflected in accounting estimates. The factors included in the analysis are historical and projected future taxable income including expectations of pending contracts and evolving business practices of our industry. Changes in existing tax laws, regulations, rates and future operating results may impact the amount of deferred tax liabilities and deferred tax assets over time.

Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets.

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As of December 31, 2018, the Company determined that sufficient positive evidence did not exist to conclude that it is more likely than not that the net operating losses being generated by the Company's Switzerland and Singapore operations would be able to be utilized in future periods and has therefore established a full valuation allowance against the deferred tax assets generated by these jurisdictions. As of December 31, 2017, the Company did not record a valuation allowance as management determined that sufficient positive evidence existed to conclude that it was more likely than not that deferred tax assets were realizable.

Results of Operations for the year ended December 31, 2018 as compared with the year ended December 31, 2017

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

	For the years ended December 31,	
	2018	2017 (as adjusted)
NET REVENUE	100.0	100.0
Cost of revenue	54.0	57.6
GROSS PROFIT	46.0	42.4
OPERATING EXPENSES:		
General and administrative	30.7	29.3
Research and development	1.7	1.7
Sales and marketing	10.6	10.0
Loss on sale of Path Logic	—	0.0
Total operating expenses	42.4	41.2
INCOME FROM OPERATIONS	3.7	1.2
Interest expense, net	2.7	2.7
Net income (loss) before income taxes	1.0	(1.5)
Income tax expense (benefit)	0.0	(0.9)
NET INCOME (LOSS)	0.0	(0.2)

Revenue

Clinical and Pharma Services revenue for the periods presented are as follows (\$ in thousands):

	For the Years Ended December 31,	
	2018	2017 (as adjusted)

			% Change
Net revenues:			
Clinical Services	\$ 241,873	\$ 213,097	13% 5
Pharma Services	34,868	27,154	28% 4
Total Revenue	\$ 276,741	\$ 240,251	15% 2

Consolidated revenues increased \$36.5 million, or 15.2%, year-over-year. Growth in our clinical segment year-over-year, was \$28.8 million, or 13.5%. Testing volumes also increased in our clinical segment by approximately 11.4% year-over-year. The increases in revenue and volume were due to strong, balanced growth with continued growth in all modalities. We continue to negotiate managed care and group purchasing contracts to increase our in-network coverage, which should improve reimbursement rates and facilitate the addition of new accounts.

Pharma Services revenue increased \$7.7 million, or 28.4%, year-over-year. In addition, our backlog of signed contracts has continued to grow from \$68.7 million as of December 31, 2017 to \$98.9 million as of December 31, 2018. We define backlog as the stated amount of signed contracts less dormant contracts with no activity for twelve months, contingencies and cancellations. The recently completed expansion of our Pharma facility in Houston, Texas, provides additional capacity to manage this backlog. We expect this backlog to result in higher revenues in future years.

We also expect to achieve accelerating revenue growth in our Pharma Services segment due to our growing international presence. In addition to our laboratory in Rolle, Switzerland, we announced a global strategic partnership with PPD in 2018, and continued our international expansion including the opening of a laboratory in Singapore.

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The following table shows clinical revenue, cost of revenue, requisitions received and tests performed for the years ended December 31, 2018 and 2017. This data excludes tests performed for Pharma customers and tests performed by Path Logic, which was sold on August 1, 2017. Testing revenue and cost of revenue are presented in thousands below:

	December 31,		
	2018	2017 (as adjusted)	% Change
Requisitions received (cases)	439,597	394,520	11%
Number of tests performed	749,902	657,394	14%
Average number of tests/requisition	1.71	1.67	2%
Total clinical genetic testing revenue	\$ 241,873	\$ 209,584	15%
Average revenue/requisition	\$ 550	\$ 531	3%
Average revenue/test	\$ 323	\$ 319	1%
Cost of revenue	\$ 128,296	\$ 117,838	8%
Average cost/requisition	\$ 292	\$ 299	(2)%
Average cost/test	\$ 171	\$ 179	(4)%

We continue to realize growth in our clinical testing revenue which we believe is the direct result of our efforts to innovate by developing and maintaining one of the most comprehensive cancer testing menus in the industry. Our broad test menu enables our sales teams to identify opportunities for increasing revenues from existing clients and allows us to gain market share from competitors as well as attract new clients looking for a one-stop shop.

Average revenue per test increased 1.2%, year-over-year, reflecting the positive impact of our internal reimbursement initiatives, partially offset by changes in Medicare reimbursement and regulation.

Cost of Revenue and Gross Margin

Average cost per test decreased 4.5%, year over year, primarily due to increased automation in our laboratories as well as the benefit of increased economies of scale. In addition, our laboratory teams have been extremely focused on reducing their cost per test across all departments.

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

Clinical and Pharma Services cost of revenue and gross profit metrics for the periods presented are as follows (\$ in thousands):

	For the Years Ended December 31,		
	2018	2017 (as adjusted)	% Change

Cost of revenue:

Clinical Services	\$ 128,297	\$ 121,785	5%
Pharma Services	21,179	16,510	28%
Total Cost of Revenue	\$ 149,476	\$ 138,295	8%
Cost of revenue as a % of revenue	54.0%	57.6%	
Gross Profit:			
Clinical Services	\$ 113,576	\$ 91,313	24%
Pharma Services	13,689	10,643	28%
Total Gross Profit	\$ 127,265	\$ 101,956	24%
Gross Profit Margin	46.0%	42.4%	

For 2018, consolidated cost of revenue as a percentage of revenue was 54.0% compared to 57.6%, in 2017, and 2018 gross profit margin was 46.0% compared to 42.4% in 2017. This improvement was partially due to an increase in our revenue per test in 2018 as well as a decrease in our cost per test. This increase was also driven by the divestiture of Path Logic in the third quarter of 2017.

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General and Administrative Expenses

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

Consolidated general and administrative expenses for the periods presented are as follows (\$ in thousands):

	For the years ended December 31.			
	2018	2017 (as adjusted)	\$ Change	% Change
General and administrative	\$ 84,822	\$ 70,359	\$ 14,463	20%
General and administrative as a % of revenue	30.7%	29.3%		

For fiscal 2018, general and administrative expenses increased \$14.5 million, compared to 2017, primarily reflecting increases in payroll and payroll related expenses due to increases in headcounts, depreciation and amortization expense as well as approximately \$2.5 million in moving expenses associated with the relocation of our expanded Houston, Texas laboratory, and \$2.3 million in transaction fees and integration expenses associated with the acquisition of Genoptix.

Payroll expense for the year ended December 31, 2018 increased by approximately \$8.3 million when compared to the same period in 2017, primarily reflecting additional staff hired for support functions related to additional growth. Depreciation expense for the year ended December 31, 2018 increased by approximately \$1.5 million, when compared to the same period in 2017, primarily reflecting increases in capital expenditures over the last three years including capital expenditures associated with the relocation of our expanded Houston, Texas laboratory and continued investment in our laboratory information system.

We expect our general and administrative expenses to increase in order to support our anticipated growth through the addition of personnel and related payroll and stock compensation, increased expenses associated with the expansion and maintenance of our facilities, and continued investment in the maintenance and development of our information systems. However, we anticipate that general and administrative expenses as a percentage of consolidated revenue will decrease over the coming years as we continue to grow.

Research and Development Expenses

Research and development expenses relate to cost of developing new proprietary and non-proprietary genetic tests, including payroll and payroll-related costs, maintenance of laboratory equipment, laboratory supplies, outside consultants and experts assisting our research and development team.

Consolidated research and development expense for the periods presented are as follows (\$ in thousands):

	For the years ended December 31.			
	2018	2017 (as adjusted)	\$ Change	% Change
Research and development	\$ 3,001	\$ 3,636	\$ (635)	(17.5)
Research and development as a % of revenue	1.1%	1.5 %		

Research and development expenses for the year ended December 31, 2018 decreased \$0.6 million, when compared to the same period in 2017. This decrease was largely attributable to reductions in stock based compensation expense, including the impact of our adoption of ASU 2018-07 in the second quarter of 2018.

We anticipate research and development expenditures will increase over time as we continue to invest in innovative projects and bringing new tests to market.

Sales and Marketing Expenses

Sales and marketing expenses are primarily attributable to employee-related costs including sales management, sales representatives, sales and marketing consultants, marketing, and customer service personnel. Costs also include various marketing-related costs such as attending trade shows, advertising and maintaining our website.

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Consolidated sales and marketing expenses for the periods presented are as follows (\$ in thousands):

	For the years ended December 31.			
	2018	2017 (as adjusted)	\$ Change	% Change
Sales and marketing	\$ 29,402	\$ 24,001	\$ 5,401	22.5
Sales and marketing as a % of revenue	10.6	10.0%		

Sales and marketing expenses for the year ended December 31, 2018, increased \$5.4 million, when compared to the same period in 2017. This increase is primarily attributable to higher commissions due to our increase in revenues as well as the expansion of our sales team and continued investment in marketing. We expect commissions expense will increase over time as the sales representatives continue to generate new business. We expect our sales and marketing expenses over the long term will increase as our test volumes increase.

Net Interest Expense and Other Income

Net interest expense is comprised of interest incurred on our term debt, revolving credit facility and our capital lease obligations, offset by the interest income earned on cash deposits. Net interest expense for the year ended December 31, 2018, increased \$0.7 million compared to the same period in 2017, reflecting changes in interest rates as well as the additional \$30 million term loan entered into in the second quarter of 2018. We expect our interest expense to fluctuate based on timing of advances and payments on our revolving credit facility.

Net Income (Loss)

The following table provides the net loss for each period along with the computation of basic and diluted net income per share (in thousands, except per share amounts):

	Years Ended December 31,	
	2018	2017 (as adjusted)
NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS		
Basic weighted average common shares outstanding	85,618	79,426
Effect of potentially dilutive securities	5,950	—
Diluted weighted average shares outstanding	91,568	79,426
Basic net income (loss) per common share	\$ 0.07	\$ (0.14)

Diluted net income (loss) per share	\$	0.07	\$	(0.14)
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Non-GAAP Measures

Use of non-GAAP Financial Measures

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

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Definitions of non-GAAP measures

Non – GAAP EBITDA

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

Non – GAAP Adjusted EBITDA

We define Non-GAAP “Adjusted EBITDA” as net income from continuing operations before: (i) interest expense, (ii) tax expense, (iii) depreciation and amortization expense, (iv) non-cash, stock-based compensation and warrant amortization expense, and if applicable in a reporting period (v) transaction expenses related to acquisitions and potential acquisitions, (vi) non-cash impairments of intangible assets (vii) debt financing costs and (viii) other significant non-recurring or non-operating (income) or expenses.

Basis for Non-GAAP Adjustments

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

- Amortization of intangible assets** - The intangible assets that give rise to this amortization expense relate to acquisitions, and the amounts allocated to such intangible assets and the terms of amortization vary by acquisition and type of asset. NeoGenomics excludes these items to provide a consistent basis for comparing operating results across reporting periods, pre- and post-acquisition.
- Deemed dividends on preferred stock** - GAAP accounting for the unique structure of the Series A Redeemable Convertible Preferred Stock requires the Company to assume that such preferred stock would be outstanding for its entire ten-year term. In addition, GAAP requires that the escalating preferred dividend rate over time be accelerated for accounting purposes and amortized on a straight-line basis over the ten-year life of the instrument, irrespective of the minimal contractual requirements for "paid in kind" stock dividends in the early years. Since such implied dividends were not paid in cash, and since the Company believed that such preferred stock would have been redeemed within the first three years it was outstanding, before any significant dividends accrued under the contractual terms, the Company believed these non-cash expenses were not meaningful in evaluating the operating performance of the Company and it would have been misleading to not adjust for such expenses across reporting periods.
- Amortization of preferred stock beneficial conversion feature** - This non-cash expense is also a direct result of the complex GAAP accounting requirements for our Series A Redeemable Convertible Preferred Stock. The Company believes this expense is not meaningful in evaluating the operating performance of the Company, distorts comparisons across reporting periods, and that it would be misleading to not adjust for such expenses across reporting periods.
- Loss on sale of business** – The impact of disposals of assets or businesses have been excluded as these losses represent infrequent transactions that impact the comparability between operating periods. We believe the adjustment of these losses supplements the GAAP information by providing a measure that may be used to assess the sustainability of our operating performance.
- Non-cash, stock-based compensation expenses** - Because many of the company's full-time physicians reside in California, state regulations against the corporate practice of medicine require us to retain their professional service corporations rather than hire them as employees. Prior to ASU 2018-07, which we adopted in the second quarter of 2018, GAAP provided that variable stock- based compensation treatment be applied for non-employee service providers. This variable accounting treatment can cause significant fluctuations in quarterly expense based on changes in the Company's stock price from one quarter to the next and result in large positive or negative impacts to total operating expenses. Without adjusting for these non-cash expenses, the Company believed it would have been difficult to compare financial results from core operations across reporting periods on a consistent basis.

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•**Moving expenses** - These expenses include costs associated with the move of our Houston, Texas facility in 2018 and the move of our Irvine, California facility in 2017 as well as restoring these facilities back to their original condition at the end of the lease terms. We are adjusting for these costs in Adjusted EBITDA as the moves were related to the Clariant acquisition and will not be annually recurring. Without adjusting for these expenses, the Company believes it would be difficult to compare financial results from operations across reporting periods on a consistent basis.

•**Acquisition and integration expenses** - We incurred significant expenses in connection with our recent acquisition of Genoptix related to transaction costs and integration expenses. These expenses include acquisition-related transaction costs, consultants, severance, systems integration and conversion expenses, and other costs related to integration activities. In order to compare across periods on a consistent basis we believe it is appropriate to exclude these expenses.

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

EBITDA and Adjusted EBITDA (as defined by us) ar