CANCER GENETICS, INC
Form 10-K
April 02, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)
ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2017
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 001-35817

CANCER GENETICS, INC.
(Exact name of registrant as specified in its charter)

| | |
|---|---|
| Delaware | 04-3462475 |
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

201 Route 17 North 2nd Floor
Rutherford, NJ 07070
(201) 528-9200
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Name of each exchange on which registered |
|---|---|
| Common Stock, $0.0001 par value per share | NASDAQ Capital Market |

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No ý
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes: ¨ No: ý
Indicate by check mark if 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: ý No: ¨

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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. ý

Indicate by check mark if the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (check one):

| | |
|---|---|
| Large accelerated filer ¨ | Accelerated filer ¨ |
| Non-accelerated filer ¨ (do not check if a smaller reporting company) | Smaller reporting company ý |
| | Emerging growth company ý |

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. ý

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $65.8 million on June 30, 2017, the last business day of the registrant's most recently completed second fiscal quarter, based on the closing price of $3.95 on that date.

Indicate the number of shares outstanding of each of the registrant's classes of common equity, as of March 21, 2018:

| Class | Number of Shares |
|---|---|
| Common Stock, $.0001 par value | 27,748,497 |

Documents incorporated by reference

Portions of the registrant's proxy statement for the 2018 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year ended December 31, 2017, are incorporated by reference in Part III of this Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “bel “estimates,” “projects,” “predicts,” “potential,” or the negative of those terms, and similar expressions and comparable terminology intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties including those set forth below and under Part I, Item 1A, “Risk Factors” in this annual report on Form 10-K. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements represent our estimates and assumptions only as of the date of this annual report on Form 10-K and, except as required by law, we undertake no obligation to update or review publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this annual report on Form 10-K. You should read this annual report on Form 10-K and the documents referenced in this annual report on Form 10-K and filed as exhibits completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Such statements may include, but are not limited to, statements concerning the following:

- our ability to achieve profitability by increasing sales of our laboratory tests and services and to continually develop and commercialize novel and innovative laboratory tests and services focused on oncology and immuno-oncology;
- our ability to amend the financial covenants in our existing credit agreements and raise additional capital to meet our liquidity needs;
- our ability to improve efficiency of billing and collection processes;
- with respect to Clinical Services, our ability to obtain reimbursement from governmental and other third-party payors for our tests and services;
- our ability to execute on our marketing and sales strategy for our tests and services and gain acceptance of our tests and services in the market;
- our ability to keep pace with rapidly advancing market and scientific developments;
- our ability to realize anticipated benefits from the vivoPharm, Pty Ltd. acquisition;
- our ability to satisfy U.S. (including FDA) and international regulatory requirements with respect to our tests and services, many of which are new and still evolving;
- our ability to maintain our present customer base and obtain new customers;
- our ability to clinically validate our pipeline of tests currently in development;
- competition from clinical laboratory services companies, tests currently available or new tests that may emerge;
- our ability to maintain our clinical and research collaborations and enter into new collaboration agreements with highly regarded organizations in the field of oncology so that, among other things, we have access to thought leaders in the field and to a robust number of samples to validate our tests;
- potential product liability or intellectual property infringement claims;
- our dependency on third-party manufacturers to supply or manufacture our tests;
- our ability to attract and retain a sufficient number of scientists, clinicians, sales personnel and other key personnel with extensive experience in oncology and immuno-oncology, who are in short supply;
- our ability to obtain or maintain patents or other appropriate protection for the intellectual property in our proprietary tests and services;
- our dependency on the intellectual property licensed to us or possessed by third parties;
- our ability to expand internationally and launch our tests and services in emerging markets, such as China and Japan; and
- our ability to adequately support future growth.

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PART I

Item 1. Business.

Overview

We are an emerging leader in the field of precision medicine, enabling individualized therapies in the field of oncology through our tests, services and molecular markers. We develop, commercialize and provide molecular- and biomarker-based tests and services, including proprietary preclinical oncology and immuno-oncology services, that enable biotech and pharmaceutical companies engaged in oncology and immuno-oncology trials to better select candidate populations and reduce adverse drug reactions by providing information regarding genomic and molecular factors influencing subject responses to therapeutics. Through our clinical services, we enable physicians to personalize the clinical management of each individual patient by providing genomic information to better diagnose, monitor and inform cancer treatment. We have a comprehensive, disease-focused oncology testing portfolio, and an extensive set of anti-tumor referenced data based on predictive xenograft and syngeneic tumor models. Our tests and techniques target a wide range of indications, covering all ten of the top cancers in prevalence in the United States, with additional unique capabilities offered by our FDA-cleared Tissue of Origin® test for identifying difficult to diagnose tumor types or poorly differentiated metastatic disease. Following the acquisition of vivoPharm, Pty Ltd. (“vivoPharm”) we provide contract research services, focused primarily on unique specialized studies to guide drug discovery and development programs in the oncology and immuno-oncology fields.

We are currently executing a strategy of partnering with pharmaceutical and biotech companies and clinicians as oncology diagnostic specialists by supporting therapeutic discovery, development and patient care from bench to bedside. Pharmaceutical and biotech companies are increasingly attracted to work with us to provide molecular profiles on clinical trial participants. Similarly, we believe the oncology industry is undergoing a rapid evolution in its approach to diagnostic, prognostic and treatment outcomes (theranostic) testing, embracing precision testing and individualized medicine as a means to drive higher standards of patient treatment and disease management. These profiles may help identify biomarker and genomic variations that may be targetable for developing novel personalized therapeutics, or that may be responsible for differing responses to existing oncology therapies, thereby increasing the efficiency of trials while lowering costs. We believe tailored and combination therapies can revolutionize oncology care through molecular- and biomarker-based testing services, enabling physicians and researchers to target the factors that make each patient and disease unique.

We believe the next shift in cancer management will bring together testing capabilities for germline, or inherited mutations, and somatic mutations that arise in tissues over the course of a lifetime. We have created a unique position in the industry by providing both targeted somatic analysis of tumor sample cells alongside germline analysis of an individual's non-cancerous cells' molecular profile as we attempt to continue achieving milestones in precision medicine.

Cancer is genetically-driven and constitutes a diverse class of diseases with various causes, each characterized by abnormal and proliferative cell growth. Many types of cancers are becoming increasingly understood at a molecular level and it is possible to attribute specific cancers to identifiable genetic changes in these abnormal cells. Cancer cells contain modified genetic material compared to normal cells. Common genetic abnormalities correlated to cancer include gains or losses of genetic material (translocations) on specific chromosomal regions (loci) or changes in specific genes (mutations) that ultimately result in detrimental changes in molecular expression patterns and regular pathways followed by cancerous or pre-cancerous conditions. Understanding the differences in these changes supports clinicians to identify and stratify different forms of cancer in order to optimize patient treatment and patient management. Therefore, understanding and analysis of cancer at the molecular and pathway regulatory level is not only useful for diagnostic purposes, but we also believe it can play an important role in disease management and prognosis. We believe the technology we deploy can apply predictive information which has the potential to

dramatically improve treatment outcomes for patients living with cancer. Our molecular- and biomarker-based tests for cancer aim to limit subjectivity from the diagnostic phase, and add prognostic information, thus enabling personalized treatments based on cancer analysis at its most essential level.

Our business is based on demand for molecular- and biomarker-based tests and services from three main sectors, including biotechnology and pharmaceutical companies, cancer centers and hospitals, and the research community. Biotechnology and pharmaceutical companies engaged in designing and running clinical trials to determine the value and efficacy of oncology treatments and therapeutics continuously benefit from our services. We believe trial participants' likelihood of experiencing either favorable or adverse responses to the trial treatment may be influenced or dependent on genomic factors. Our testing services will increase trial efficiency, subject safety and trial success rates. Clinicians and oncologists in cancer centers and hospitals seek such testing since these methods produce higher value and more accurate cancer diagnostic information than traditional analytical methods. Our proprietary and disease-focused tests aim to provide actionable information that can guide patient management decisions, potentially resulting in decreased costs for care providers and patients while streamlining

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therapy selection. We offer preclinical test systems supporting our clinical diagnostic and prognostic offerings at early stages, valued by pharmaceutical industry, biotechnology companies and academic research centers. In particular our preclinical development of biomarker detection methods, response to immuno-oncology directed novel treatments and early prediction of clinical outcome is supported by our extended portfolio of orthotopic, xenografts and syngeneic tumor test systems as a unique service offering in the immuno-oncology space.

With the acquisition of vivoPharm on August 15, 2017, we expanded our Discovery Service capabilities. vivoPharm is a contract research organization ("CRO") that specializes in planning and conducting unique, specialized studies to guide drug discovery and development programs with a concentration in oncology and immuno-oncology. These studies range from early compound selection to developing comprehensive sets of in vitro and in vivo data, as needed for FDA Investigational New Drug ("IND") applications. vivoPharm has developed industry recognized capabilities in early phase development and discovery, especially in immuno-oncology models, tumor micro-environment studies, specialized pharmacology services, and PDx (patient derived xenograft) model studies that support basic discovery, preclinical and phase 1 clinical trials. vivoPharm's studies have been utilized to support over 200 IND submissions to date across a range of therapeutic indications, including lymphomas, leukemia, GI-cancers, liver cancer, pancreatic cancer, non-small cell lung cancer, and other non-cancer rare diseases. vivoPharm is presently serving over forty biotechnology and pharmaceutical companies across five continents in over 55 studies and trials with highly specialized development, clinical and preclinical research. Over the past 10 years, vivoPharm has also generated an extensive library of human xenograft and syngeneic tumor models, including subcutaneous, orthotopic and metastatic models.

With the acquisition, we added three international locations, enabling access to additional global market opportunities. vivoPharm's headquarters in Melbourne, VIC, Australia, specializes in safety and toxicology studies, including mammalian, genetic and in vitro, along with bioanalytical services including immune-analytical capabilities. vivoPharm's U.S.-based laboratory, located at the Hershey Center for Applied Research in Hershey, Pennsylvania, primarily focuses on screening and efficacy testing for a wide range of pharmaceutical and chemical products. The third location, in Munich, Germany, hosts project management and marketing personnel.

We execute on our market strategy by finding synergies and alignment across the three aforementioned industry groups to utilize relatively the same technologies to deliver results-oriented information and insights which we believe is or will become important to drug development and disease management. Our tests and services address the limitations of traditional approaches to cancer therapeutics, including reliance on human inspection of specimens and interpretation of clinical measurements, and inter-institutional variability. Our suite of clinical and biopharma services aim to remove subjectivity from diagnoses and additionally provide information that may influence treatment selection that cannot be obtained from anatomic pathology and staining techniques alone. Our Discovery Services aim to accelerate the development of novel treatment candidates and precision medicine in oncology. We believe the level of personalized treatment required to optimize a patient's treatment regimen and to maximize clinical trial success rates may be significantly improved through the use of molecular- and biomarker-based cancer characterization.

The following table lists our market strategy by customer category:

| Customer Category | Types of Customers | Nature of Services |
|---|---|---|
| Biopharma Services | • Pharmaceutical and Biotech companies performing clinical trials | Biopharma Services provide companies with customized solutions for patient stratification and treatment selection through an extensive suite of molecular- and biomarker-based testing services, customized assay development and trial design consultation. |
| Clinical Services | • Hospitals<br>• Cancer Centers | Clinical services provide information on diagnosis, prognosis and predicting treatment outcomes (theranosis) of cancers to guide patient |

| | | |
|---|---|---|
| | • Clinics | management. |
| Discovery Services | • Pharmaceutical and Biotech companies<br>• Academic Institutions<br>• Government-Sponsored Research Institutions | Discovery services, including preclinical anti-tumor efficacy, GLP compliant toxicity studies, small molecular and biologics analytical services, provide the tools and testing methods for companies and researchers seeking to identify and to develop new compounds and molecular-based biomarkers for diagnostics and treatment of disease. |

In 2017, we generated approximately 50% of our revenue from Biopharma Services, approximately 37% from Clinical Services and approximately 13% from Discovery Services, including the acquisition of vivoPharm in August of 2017. In

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2016, we generated approximately 57% of our revenue from Biopharma Services, approximately 39% from Clinical Services and approximately 4% from Discovery Services.

We utilize relatively the same proprietary and nonproprietary molecular diagnostic tests and technologies across all of our service offerings to deliver results-oriented information important to cancer treatment and patient management. Our portfolio primarily includes comparative genomic hybridization (CGH) microarrays, gene expression tests, next generation sequencing (NGS) panels, and DNA fluorescent in situ hybridization (FISH) probes. We provide our testing services from our Clinical Laboratory Improvement Amendments ("CLIA") - certified and College of American Pathologists ("CAP") - accredited laboratories in Rutherford, NJ, Los Angeles, CA, and Raleigh, NC, as well as our NABL and GMP-certified laboratory in Hyderabad, India. We offer preclinical services such as predictive tumor models, human orthotopic xenografts and syngeneic immuno-oncology relevant tumor models in our Hershey PA facility, and a leader in the field of immuno-oncology preclinical services in the United States. This service is supplemented with GLP toxicology and extended bioanalytical services in our Australian based facility in Bundoora VIC.

Market Overview

United States Clinical Oncology Market Overview

Despite many advances in the treatment of cancer, it remains one of the greatest areas of unmet medical need. In 2015, the World Health Organization attributed 8.8 million deaths (16% of all deaths) worldwide to cancer-related causes, and projects that over the next two decades the number of new cancer cases will rise to approximately 23 million by the year 2032. Within the United States, cancer is the second most common cause of death, exceeded only by heart disease, accounting for nearly one out of every four deaths. The American Cancer Society estimates that the direct medical treatment costs of cancer in the United States for 2015 were $80.2 billion. The incidence, deaths and economic loss caused by cancer are staggering. The following table published by The American Cancer Society shows estimated new cases and deaths in 2017 in the United States for selected major cancer types:

| Cancer Type | Estimated New Cases | Estimated Deaths |
|---|---|---|
| Bladder | 81,190 | 17,240 |
| Breast (Female - Male) | 266,120 - 2,550 | 40,920 - 480 |
| Colon and Rectal (Combined) | 140,250 | 50,630 |
| Endometrial | 63,230 | 11,350 |
| Kidney (Renal Cell and Renal Pelvis) Cancer | 65,340 | 14,970 |
| Leukemia (All Types) | 60,300 | 24,370 |
| Liver and Intrahepatic Bile Duct | 42,220 | 30,200 |
| Lung (Including Bronchus) | 234,030 | 154,050 |
| Melanoma | 91,270 | 9,320 |
| Non-Hodgkin's Lymphoma | 74,680 | 19,910 |
| Pancreatic | 55,440 | 44,330 |
| Prostate | 164,690 | 29,430 |
| Thyroid | 53,990 | 2,060 |

References

1. American Cancer Society: Cancer Facts and Figures 2018. Atlanta, GA: American Cancer Society, 2018. Also available online. Last accessed February 26, 2018.

United States and International Clinical Trials Market Overview

The United States is currently a world leader in biopharmaceutical research and development and manufacturing. In Fiscal Year 2017, the National Cancer Institute received a budget of $5.89 billion, an increase of $680 million over FY 2016, to issue grants to support research, , with a targeted investment in enhanced and early detection of disease through the analysis of circulating biomarkers using minimally invasive methods, as well as a focused investment in cancer prevention and treatment including research on new vaccines to prevent cancer-causing infections and investigational immuno-oncology drugs and drug combinations. The Pharmaceutical Research and Manufactures of America (PhRMA) reports that the average cost to develop a drug, including trial failures, can be as high as $2.6 billion and the approval process from development to

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market may be as long as 15 years. According to the National Cancer Institute, since the 1990s, cancer death rates in the United States have declined 23%, and approximately 83% of life expectancy increases in cancer patients are due to new treatments and oncology medications.

Outside of the United States, particularly in our targeted geographies of the Europe and Asia Pacific ("APAC") regions, growth in the pharmaceuticals and clinical trials market is continuing, and trials are increasingly becoming more complex. Growth in the European pharma market is anticipated to be driven largely by the United Kingdom, Germany, Spain, France and Italy. The size of this market is expected to grow 25% between 2017 and 2022, accounting for nearly 70% of the European pharma market by 2022. Germany is forecasted to have the highest increase in market value during this 5-year span. APAC's location provides access to large patient pools within favorable regulatory environments, and a strong intellectual property regime and available infrastructure. The pharmaceutical market in APAC is expected to grow by 8.7% CAGR from 2015 to 2021, boasting a contract research organization market that is the fastest growing in the world.

While oncology drugs have the potential to be among the most personalized therapeutics, oncology clinical trials continue to have some of the poorest approval rates. The application of pharmacogenomics to oncology clinical trials enables researchers to better predict differences in drug response, efficacy and toxicity among trial participants, as well as to optimize treatment regimens based on these differences. According to IMS Health, it is estimated that by 2020, half of all pharmaceutical sales in the United States will be from specialty drugs, a category of drugs including oncology treatments tailored to patients' genomic profiles. We believe a growing demand for faster development of personalized medicines and more effective clinical trials are growth drivers of this market, and our core expertise is pharmacogenomics, or the study of genetic analysis based on a patient's response to a particular therapy or drug.

India Clinical Oncology and Biopharma Market Overview

It is estimated by the India Brand Equity Foundation that the Indian biotech and pharmaceutical markets are expected to experience over a 30% increase in compound annual growth rate by 2025 due to favorable business conditions and increasing government expenditures in these sectors. The biopharmaceutical services segment accounted for the largest share of sector growth in 2013 and 2014, accounting for approximately 64% of total revenues, and experienced the highest growth rate in this period, with an approximately 18% compound annual growth rate. Over the next decade, growth in this industry is anticipated to come largely from India's strong position in biosimilar and molecular diagnostics, as well as from personalized medicine. The Indian government has been increasing spending on the biotech and pharmaceutical sectors through 5-year budget allocation plans aimed at research and development as well as health care.

India has a growing market for molecular diagnostics and oncology services. The Times of India reports that cancer-related claims are rising 15.5% year-on-year and an average of 1.45 million cases are detected in India. Indian Council of Medical Research estimates that by 2020, India will see more than 1.7 million new cases of cancer and almost 1 million deaths due to the disease. Data shows that breast and cervical cancer for women and lung and mouth cavity for men are most frequent. In those cancer types for which we provide diagnostic and prognostic proprietary tests and services, incidences are also predicted to rise steadily over the next decade even while the population is expected to experience a decrease in population growth rate. Gynecological cancers account for approximately 12% of the total cancer incidence among the Indian population, and 30% of the cancer incidence among women. Furthermore, 70-80% of cancers in India are first detected in advanced or terminal stages, indicating an important opportunity in this market for DNA-based oncology diagnostic tools that can provide early-stage information to guide treatment resulting in greater survival rates.

China Clinical Oncology and Biopharma Market Overview

The Chinese biopharma market is currently the third largest pharma market globally, after the United States and Japan. With more than one fifth of the world's population, China is an important market for pharmaceutical and biotech products and China's minister of health has pledged that the country will spend an additional $11.8 billion to advance biotech innovation from 2015 to 2020 in its 13th five-year plan. Cancer is one of the leading public health problems in China, representing approximately 25% of all deaths in urban areas and 21% in rural areas. Over the past 30 years, the risk factors for cancer in China have been increasing, including an aging population, decreased environmental conditions and westernization of diet and lifestyle. Our Shanghai laboratory performs clinical trials services for biotech and pharmaceutical companies in China, where governmental regulations prevent human samples from being exported from the country.

Our Strategy

We remain focused on delivering our comprehensive cancer profiling and state of the art molecular testing capabilities and services to a diverse group of market participants, including:

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- Biotechnology companies;
- Pharmaceutical companies;
- Cancer centers;
- Community hospitals; and
- Research centers

These participants require biomarker-based assessment of cancer and biomarker-based information to collect key data sets for their clinical trials, or as direct care providers, to understand and manage therapeutic development, the patient, their cancer and customized therapy choices. We believe that our integrated approach to rapidly translate research insights about the genetics and molecular mechanisms of cancer into the clinical setting, combined with our approach to diagnostic testing, will lead to improved clinical decision-making, and will become a key component in the standard of care for personalized cancer treatment. Our approach is to develop and commercialize proprietary molecular and biomarker-based tests and services to enable us to provide a full service solution to improve the diagnosis, prognosis and treatment of targeted cancers and to better predict successful therapeutic targets and drug candidates, differences in drug response, efficacy and toxicity among clinical trial participants, as well as to optimize treatment regimens based on these differences. To achieve this, and in order of our focus and priority, we intend to:

- Leverage our specialized, disease-focused genomic and molecular knowledge, insights and portfolio to secure additional collaborations or partnerships with leading biotech and pharmaceutical companies and clinical research organizations. Oncology drugs have the potential to be among the most personalized of therapeutics, and yet oncology trials have one of the worst approval success rates. In an effort to improve the outcome of these trials, and more rapidly advance targeted therapeutics, the biotechnology and pharmaceutical community is increasingly looking to companies like us that have both extensive disease insights and comprehensive testing services as they move toward biomarker-based therapeutics. We believe our comprehensive, disease-focused testing portfolio, which covers the 10 most prevalent solid and hematological cancers in the United States, positions us to help the biotech and pharmaceutical community with clinical trials and companion diagnostic development in areas of our core expertise.

- Leverage our acquisition of vivoPharm to deepen relationships with our existing clients and to expand our unique portfolio of Discovery Service offerings in the United States and internationally. Biotech and Pharmaceutical companies engaged in the identification of therapeutic targets and novel oncology and immuno-oncology treatments often require support in trial design, assay development, preclinical research and clinical research and trial management. vivoPharm's suite of oncology-focused services, including proprietary tumor models, enables us to increase our market share in drug identification, drug rescue and drug repurposing studies. We believe vivoPharm's capabilities provide us opportunities to deepen our relationships with existing customers through additional Discovery and downstream molecular work.

- Leverage our growing preclinical business to seek synergies across our biopharma sales teams in the U.S., Europe and Australia, to provide our integrated service offerings. We believe that by combining the efforts of our business development teams inside of our existing and prospective biopharma clients, we can leverage our capabilities from preclinical development of biomarker detection methods, responses to immuno-oncology directed novel treatments and early prediction of clinical outcomes, supported by our extended portfolio of orthotopic, xenografts and syngeneic tumor test systems, to help drive our access to support immuno-oncology therapies in Phase I through Phase IV trials.

- Leverage our clinical sales force and our relationships with global central laboratories to expand our customer base. We believe that our clinical sales force is among the largest oncology-focused clinical sales groups in the molecular diagnostics field. By leveraging our clinical and biopharma sales force in the United States, along with our relationships with international central laboratories and clinical research organizations, we are able to target our sales and marketing efforts to meet the needs of an expanding and diverse customer segment.

- Continue our focus on translational oncology and drive innovation and cost efficiency in diagnostics by continuing to develop next generation sequencing offerings independently and through our joint venture with Mayo Clinic and other key opinion leaders and their organizations. Translational oncology refers to our focus on bringing novel research insights that characterize cancer at the genomic level directly and rapidly into the clinical setting with the overall goal of improving value to patients and providers in the treatment and management of disease. We believe that continuing to develop our existing platforms and next generation sequencing panels will enable significant growth and efficiencies within our business. We will continue to develop next generation sequencing panels independently as well as leverage our joint venture with Mayo Clinic to advance this diagnostic technology.

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- Work with health care providers and payors to demonstrate the value of our testing in providing cost efficient and accountable care. We seek to increase market access by entering into contracts with key payors, cost management organizations and insurance providers and to secure additional coverage for FHACT®, TOO® and Focus::NGS® panels.

- Continue to aggressively manage our cost structure. We are focused on aggressively managing our operating costs while continuing to seek additional revenue growth opportunities. We are implementing measures to streamline costs across our laboratory facilities, including the consolidation of our operations, integrating administrative functions across our US operations, implementing a cloud-based laboratory management system across all of our sites, along with key financial enterprise resource planning and human resource systems that enable greater efficiency.

Our Service Offerings

Our business is based on demand for molecular- and biomarker-based characterization of cancers from three main sectors: (1) biotechnology and pharmaceutical companies, (2) cancer centers and hospitals, and (3) the research community. Our services are sought by biotechnology and pharmaceutical companies engaged in designing and running clinical trials, from pre-clinical to post market surveillance, for their value and efficacy in oncology treatments and therapeutics. We believe trial participants' likelihood of experiencing either favorable or adverse responses to the trial treatment can be determined first by our extended portfolio of orthotopic, xenografts and syngeneic tumor test systems, and in early development through biomarker testing, thereby increasing trial efficiency, participant safety and trial success rates. Biotechnology and pharmaceutical companies also seek our services in preclinical trial design and drug development, in order to effectively and efficiently select those therapeutic candidates most likely to progress to clinical treatment options. Our services are also sought by researchers and research groups seeking to identify biomarkers and panels and develop methods for diagnostic technologies and tests for disease. Clinicians and oncologists in cancer centers and hospitals seek molecular-based testing since these methods often produce higher value and more accurate cancer diagnostic information than traditional analytical methods. Our proprietary and disease-focused tests aim to provide actionable information that can guide patient management decisions, potentially resulting in decreased costs for care providers and patients while streamlining therapy selection. We continue to pursue the strategy of trying to demonstrate increased value and efficacy with payors who wish to contain costs and academic collaborators seeking to develop new insights and cures.

We utilize relatively the same proprietary tests and services, non-proprietary tests and technologies across each of these businesses to deliver results-oriented information important to drug discovery, cancer treatment and patient management.

Biopharma Services

Biopharma Services include laboratory and testing services performed for biotechnology and pharmaceutical companies engaged in clinical trials. Our Biopharma Services focus on providing these clients with oncology specific and non-oncology genetic testing services for phase I-IV trials along with critical support of ancillary services. These services include: biorepository, clinical trial logistics, clinical trial design, bioinformatics analysis, customized assay development. DNA and RNA extraction and purification, genotyping, gene expression and biomarker analyses. We also seek to apply our expertise in laboratory developed tests (“LDTs”) to assist in developing and commercializing drug-specific companion diagnostics. We have established business relationships with key instrument manufacturers to support their platforms in the market, and to drive acceptance among biopharmaceutical sponsors developing innovative immuno-oncology therapies.

Industry research has shown many promising drugs have produced disappointing results in clinical trials. For example, a 2016 article by the University of Michigan reported that 1 in 50 cancer drug candidates make it to the clinical market. Given such a high failure rate of oncology drugs, combined with constrained budgets for biotech and pharmaceutical companies, there is a significant need for drug developers to utilize molecular diagnostics to decrease these failure rates. For specific molecular-targeted therapeutics, the identification of appropriate biomarkers indicative of disease type or prognosis may help to optimize clinical trial patient selection and increase trial success rates by helping clinicians identify patients that are most likely to benefit from a therapy based on their individual genomic profile.

Our Select One® offering was created specifically to help the biopharmaceutical community with clinical trials and companion diagnostic development in areas of our core expertise. We believe that oncology drugs and immuno-oncology therapies have the potential to be among the most personalized of therapeutics, and yet oncology clinical trials continue to have some of the poorest approval rates. In an effort to improve the outcome of these trials, and more rapidly advanced targeted therapeutics, the biotechnology and pharmaceutical community is increasingly looking to companies that have both proprietary disease insights

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and comprehensive testing services as they move toward biomarker-based therapeutics, combination studies and immuno-oncology pathways.

The United States National Institutes of Health reported over 95,000 clinical trials were being conducted in the United States as of March 2017, and over 15,000 of these trials were actively recruiting participants for studies with oncology pharmaceuticals or biologics. Molecular- and biomarker-based testing services have been altering the clinical trials landscape by providing biotech and pharmaceutical companies with information about trial subjects' genetic profiles that may be able to inform researchers whether or not a subject will benefit from the trial drug or will experience adverse effects. Streamlined subject selection and stratification, and tailored therapies selected to maximally benefit each group of subjects may increase the number of trials that result in approved therapies and make conducting clinical trials more efficient and less costly for biotech and pharmaceutical companies. In 2017, 46 new drugs were approved by the FDA, and over a quarter of these drugs were oncology-focused, highlighting the potential value of incorporating genomic information into oncology clinical trial design.

In addition to the tests and services provided to biotech and pharmaceutical companies, we are developing NGS panels focused on pharmacogenomics and oncology that will inform researchers of trial subjects' drug sensitivities.

We provide the following services to biotech and pharmaceutical companies and researchers conducting clinical trials:

Genotyping and Pharmacogenomics Testing Services

- Over 400 genotyping assays including drug metabolizing enzymes, transporters and receptors.

- Over 19 validated gene expression assays.

- Testing for the FDA's Pharmacogenomic (PGx) Biomarkers in Drug Labels recommended panel.

- Loss of heterozygosity and copy number detection assays.

We also utilize our laboratories to provide clinical trial services to biotech and pharmaceutical companies and clinical research organizations to improve the efficiency and economic viability of clinical trials. Our clinical trials services leverage our knowledge of clinical oncology and molecular diagnostics and our laboratories’ fully integrated capabilities. Our Select One® program integrates clinical information into the drug discovery process in order to provide customized solutions for patient stratification and treatment. By utilizing biomarkers, we intend to optimize the clinical trial patient selection. This may result in an improved success rate of the clinical trial and may eventually help biotech and pharmaceutical companies to select patients that are most likely to benefit from a therapy based on their genetic profile. We believe we are one of only a few laboratories with the capability to combine somatic and germline mutational analyses in clinical trials.

From a laboratory infrastructure standpoint, we possess capabilities in histology, immunohistochemistry (IHC), flow cytometry, cytogenetics and fluorescent in-situ hybridization (FISH), as well as sophisticated molecular analysis techniques, including next generation sequencing. This allows for comprehensive esoteric testing within one lab enterprise, with our CAP-accredited biorepository serving as a central hub for specimen tracking. Using this approach, we are able to support demanding clinical trial protocols requiring multiple assays and techniques aimed at capturing data on multiple biomarkers. Our suite of available testing platforms allows for highly customized clinical trial design which is supported by our dedicated group of development scientists and technical personnel.

Through this combination of a variety of esoteric testing platforms powered by a team of experienced scientists, we offer a rare comprehensive approach to clinical trial support. As trial design becomes increasingly complex to cater to

more specific drug targets and patient populations, a single-source solution for esoteric testing, we believe that clinical result generation and reporting is becoming more valuable than ever.

Examples of clinical trial services offered:

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| | |
|---|---|
| Flow cytometry | Selection of individual antibodies in multiple myeloma, leukemia, lymphomas, and therapy response |
| Karyotyping | Genome-wide detection of aberrations at low resolution that have a diagnostic or prognostic significance |
| FISH | Probe library for the detection of gene abnormalities in chromosomes indicated in hematological and solid tumors |
| Anatomic pathology | Full IHC library with over 180 antibodies available |
| Exome sequencing | Sequencing of the protein-encoding genes in a genome |
| DNA and RNA sequencing | Sequencing to determine the presence and quantity of RNA or DNA in a specimen |
| Next Generation sequencing | Proprietary and custom-designed panels to deep sequence genomic material to identify substitutions, insertions and deletions, and rearrangements of genetic material |
| Cell-free DNA analysis | Multi-gene next generation sequencing panel for lung cancer to detect tumor-derived cell-free DNA obtained from a blood draw |
| DNA and RNA microarray | Measures expression levels of a large number of genes simultaneously |
| Sanger sequencing | DNA sequencing for validation of next generation sequencing results, and for smaller scale sequencing projects |
| Fragment size analysis | Analysis technique where DNA fragments are separated by size and used for mutation detection |
| DNA and RNA extraction and purification | Extraction and isolation of DNA and RNA from a wide variety of sample types for immediate testing or for storage |
| Biostatistics and Bioinformatics | Design and review of client assays and analysis of datasets |
| Biorepository and sample logistics | Collection, shipping guidance and storage of bio-specimens and related nucleic acid samples |

We also offer our clinical trial services customers our branded Select One® program, which integrates clinical information into the drug discovery process in order to provide customized solutions for patient stratification and treatment. By utilizing biomarkers, we intend to optimize the clinical trial patient selection process. This may result in an improved success rate of the clinical trial and may eventually help biotech and pharmaceutical companies to select patients that are most likely to benefit from a therapy based on their genetic profile. We believe we are one of only a few laboratories with the capability to combine somatic and germline mutational analyses in clinical trials.

Our Select One® clinical trial services are aimed at developing customizable tests and techniques utilizing our proprietary tests and laboratory services to provide enhanced genetic signature analysis and more comprehensive understanding of complex diseases at earlier stages. We leverage our knowledge of clinical oncology and molecular diagnostics and provide access to our genomic database and assay development capabilities for the development and validation of companion diagnostics. This potentially enables companies to reduce the costs associated with development by determining earlier in the development process if they should proceed with additional clinical studies. We have been chosen by leading biotech and pharmaceutical companies including Gilead Sciences Inc., GlaxoSmithKline, and H3 Bio (a division of Eisai) to provide clinical trial services and molecular profiling for patient selection and monitoring. Additionally, through our services we gain further insights into disease progression and the latest drug development that we can incorporate into our proprietary tests and services.

We also provide genetic testing for drug metabolism to aid biotech and pharmaceutical companies identify subjects' likely responses to treatment, allowing these companies to conduct more efficient and safer clinical trials. We believe pharmacogenomics drug metabolism testing helps deliver the promise of personalized medicine by enabling researchers to tailor therapies in development to differences in patients' genomic profiles.

Clinical Services

We provide our oncology and immuno-oncology tests and services to oncologists and pathologists at hospitals, cancer centers, and physician offices. Our portfolio contains proprietary tests target cancers that are difficult to prognose and predict treatment outcomes through currently available mainstream techniques. We utilize an expansive range of non-proprietary test and technologies to provide a comprehensive profile for each patient we serve. Clinical testing is available through anatomic pathology, flow cytometry, karotype, FISH, liquid biopsy and molecular diagnostics (including next generation sequencing and gene expression panels).

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Our comprehensive testing services for cancer are utilized in the diagnosis, prognosis and prediction of treatment outcomes (theranosis) of cancer patients and are growing rapidly as clinicians demand more precise and more comprehensive evaluation of their patients. We believe our ability to rapidly translate research insights about the genetics and molecular mechanisms of cancer into the clinical setting will improve patient treatment and management and that this approach can become a key component in the standard of care for personalized cancer treatment. We utilize highly skilled scientists, pathologists and hematologists in our laboratories, with 46% of individuals holding advanced degrees. These individuals assist our customers in integrating and technically assessing the testing results for their patients.

Our clinical services strategy is focused on direct sales to oncologists and pathologists at hospitals, cancer centers, and physician offices in the United States, and expanding our relationships with leading distributors and medical facilities in emerging markets. As part of our market strategy for our clinical services, we offer the branded testing programs described below.

Complete™ Program. Our Complete™ program is our branded program offering a unique suite of common and proprietary tests that assist clinicians in determining the best treatment options to improve patient outcomes. Each Complete™ program integrates the latest diagnostic and prognostic biomarkers across multiple testing methodologies. We offer Complete testing for a number of hematological cancers and solid tumors, including AML, CLL, DLBCL, MDS, myeloproliferative neoplasms (MPN), colorectal, lung and breast cancers.

Expand DX™/Technical-Only Testing. According to the American Hospital Association, there are nearly 5,000 community hospitals in the United States. Community hospitals represent a large target market for our genomic tests and services because approximately 85% of cancer patients in the United States are initially diagnosed in such hospitals as reported to the National Cancer Database. Our Expand DX™/Technical-Only Testing program is a partnership initiative offered by us to help community-based hospitals expand their clinical services. By partnering with us community-based hospitals and pathology labs have cost-effective access to advanced testing technologies and specialized testing capabilities and deep experience in hematological and solid-tumor oncology diagnostics of our clinical reference laboratories in New Jersey and California. Through this program, clinicians can send patient specimens to our laboratories, where the technical component of the testing is performed, and then access the test results through an online portal in order to perform the professional component and provide a diagnosis. We believe our Expand DX™/Technical-Only Testing program will enable community hospitals and pathology laboratories to optimize and expand their oncology services to better serve their cancer patients and reduce costs associated with cancer care.

Tissue of Origin® Test. Our FDA-cleared Tissue of Origin® test, or TOO®, is a gene expression test that is indicated when there is clinical uncertainty about a poorly differentiated or undifferentiated, or a metastatic tumor where the primary tissue of cancer development is unknown. The Tissue of Origin® test we believe is the only FDA-cleared test of its kind, and can determine the most likely tissue of origin of a patient tumor sample from the fifteen most common tumor types - including thyroid, breast, pancreas, colon, ovarian and prostate - which account for ninety percent of all incidences of solid tissue tumors, by measuring the expression levels of 2,000 individual genes. TOO® is supported by extensive analytical and clinical validation data from robust, multi-center clinical studies. We believe TOO® can reduce the need for repeated testing, examinations, imaging and biopsy procedures by providing clinicians with the primary tissue type with greater certainty than traditional diagnostic techniques. This in turn empowers physicians to select the correct type of treatment earlier in the course of the patient’s therapy.

In addition, we have developed the Summation™ Report which, we believe, provides an integrated view of a patient's test results and diagnosis in a user-friendly, visually appealing format for clinicians. Our pathologists and laboratory directors prepare these Summation™ Reports based on the clinical information and diagnosis provided by our laboratory professionals. All of our testing technologies are integrated into a Summation Report to allow oncologists

to efficiently arrive at a definitive diagnosis and drive complete and effective decisions.

Discovery Services

Through our recent acquisition of vivoPharm in 2017, we offer proprietary preclinical test systems supporting our clinical diagnostic and prognostic offerings at early stages, valued by the pharmaceutical industry, biotechnology companies and academic research centers. In particular, our preclinical development of biomarker detection methods, response to immuno-oncology directed novel treatments and early prediction of clinical outcome is supported by our extended portfolio of orthotopic, xenografts and syngeneic tumor test systems. vivoPharm specializes in conducting studies tailored to guide drug development, starting from compound libraries and ending with a comprehensive set of in vitro and in vivo data and reports, as needed for Investigational New Drug filing. vivoPharm operates in AAALAC accredited and GLP-compliant audited facilities. We provide our preclinical services, with a focus on efficacy models, from our Hershey PA facility for the U.S. and European

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markets, and supplemented with GLP toxicology and extended bioanalytical services in our Australia-based facility in Bundoora VIC.

Our Discovery Services provide the tools and testing methods for companies and researchers seeking to identify new molecular- and biomarker-based indicators for disease and to determine the pharmacogenomics, toxicity and efficacy of potential therapeutic candidate compounds. Discovery Services we offer include development of both xenograft and syngeneic animal models, toxicology and genetic toxicology services, pharmacology testing, pathology services, and validation of biomarkers for diseases including cancers. We also provide consulting, guidance and preparation of samples and clinical trial design. We believe the ability to analyze variations in biomarkers, tumor cells and compounds, and to interpret results into meaningful predictors of disease or indicators of therapeutic success is essential to discovering new molecular markers for cancer, new therapeutics, and targets for therapies.

Our Disease-Focused Testing Portfolio

Our disease-focused testing portfolio includes our portfolio of proprietary tests, along with a comprehensive range of non-proprietary oncology-focused tests and laboratory services. We have a comprehensive oncology testing portfolio, spanning nine of the ten most prevalent solid and hematological cancers, including the FDA-cleared test for tumors of unknown origin, our FDA-cleared Tissue of Origin®, or TOO® test. With the exception of the TOO® test, we offer our proprietary tests in the United States as laboratory-developed tests, or LDTs, and internationally as CE-marked in vitro diagnostic medical devices. The non-proprietary testing services we offer are focused in part on the specific oncology categories where we are developing our proprietary tests. We believe that there is significant synergy in developing and marketing a complete set of tests and services that are disease-focused and delivering those tests and services in a comprehensive manner to help guide and inform treatment decisions. The insights that we develop in delivering non-proprietary services are often leveraged in the development of our proprietary programs and in the validation of our proprietary programs.

Our proprietary tests are molecular- and biomarker-based genomic tests: microarrays, probes, gene expression panels, liquid biopsy and next generation sequencing. Each is directed at identifying specific genetic aberrations in cancer cells that serve as markers for diagnosis, prognosis and theranosis. We offer microarrays, next generation sequencing, gene expression and FISH probes because each serves a unique diagnostic or prognostic function. FISH- based tests, or probes, offer great sensitivity while microarrays provide a more comprehensive analysis of the cancer genome, NGS panels offer a method of detecting mutations or chromosomal aberrations of lesser frequency while gene expression can identify which genes are affected when the cancer type is unknown, and liquid biopsy techniques provide a method of isolating and detecting rare cells, such as tumor cells, circulating in a patient's blood, enabling a less invasive approach than tissue biopsy to obtain cells for additional biomarker analysis through one or more of the aforementioned tests. The tables below list and describes our proprietary tests that target hematologic cancers, HPV-associated cancers, solid tumors, hereditary cancers and immuno-oncology biomarkers.

Hematological Cancers

As a group, hematologic cancers (cancers of the blood, bone marrow or lymph nodes) display significant clinical, pathologic and genetic complexity. Traditionally, diagnosis relies mostly on pathologic examination, flow cytometry and detection of only a few genetic markers. Importantly, the clinical course of the six main subtypes of these neoplasms ranges from indolent (follicular lymphoma) to aggressive (diffuse large B-cell lymphoma, mantle cell lymphoma and multiple myeloma), or mixed (chronic lymphocytic leukemia/small lymphocytic lymphoma, or CLL/SLL). Most risk-stratification for treatment decisions were traditionally based on clinical features of the disease. Few molecular prognostic biomarkers were utilized in a clinical setting. There remains an unmet medical need for robust biomarkers for the diagnosis, prognosis, theranosis and overall patient management in B-cell cancers. Given the higher frequency of these malignancies in the United States than in other countries due to relatively long lifespans

and an aging population, we expect significant clinical demand for our tests and services that are focused on hematological cancers.

Our Proprietary Tests for Hematological Cancers

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| Test | Targeted Cancers | Technology & Advantages |
|---|---|---|
| Focus::NGS®<br><br>Focus::AML™<br><br>Focus::CLL™<br><br>Focus::DLBCL&FL™<br><br>Focus::Lymphoma™<br><br>Focus::MCL™<br><br>Focus::MDS™<br><br>Focus::MPN™<br><br>Focus::Myeloid™<br><br>Focus: Myeloma™ | • Chronic Lymphocytic Leukemia (CLL)<br>• Myeloid Cancers<br>- Myelodysplastic Syndromes (MDS)<br>- Acute Myeloid Leukemia (AML)<br>- Myeloproliferative Neoplasms (MPN)<br>• B-Cell Lymphomas<br>• Follicular Lymphoma<br>• Mantle Cell Lymphoma (MCL) | • Focus::NGS® is our family of next generation sequencing tests developed for the analysis of genomic alterations to determine, guide and inform diagnosis, prognosis and theranosis of particular hematological cancers and solid tumors.<br>• Next generation sequencing performs massively parallel sequencing, which is able to detect biomarker mutations and aberrations that are present at very low levels in a single test, and which may be missed by other, less sensitive methodologies.<br>• Our proprietary lymphoma NGS panels provide powerful and clinically validated tools for the molecular characterization of lymphomas. These targeted panels report on clinically actionable gene mutations present in the most common types of B-cell lymphomas, and have been used to power clinical trials, clinical work-up, management and therapy selection in lymphoma patients.<br>• Our proprietary myeloid NGS panels provide actionable information for improved diagnosis, prognosis and risk stratification for myeloid malignancies. Based on the panel results, we believe patients are able to receive the most suitable treatment tailored to their unique cancer. |
| MatBA® | • Chronic Lymphocytic Leukemia (CLL)<br>• Small Lymphocytic Leukemia (SLL)<br>• Diffuse Large B-Cell Lymphoma (DLBCL)<br>• Mantle Cell Lymphoma (MCL)<br>• Follicular Lymphoma (FL) | • MatBA® the first targeted oligonucleotide-based microarray we developed for the analysis of genomic alterations to determine prognosis and theranosis in mature B-cell neoplasms.<br>• MatBA® is designed to detect genomic copy number changes in mature B-cell neoplasms either solely or in a unique combination, relying on the comparative genomic hybridization of fluorescently differentially-labeled normal DNA and DNA extracted from the cancer specimen (array-CGH).<br>• MatBA® was custom-designed to represent 80 regions of the human genome which have diagnostic and/or prognostic value in one or more of the mature B-cell neoplasm subtypes.<br>• Unlike other technologies such as FISH, array-CGH using MatBA® simultaneously permits the detection of genomic gains and losses at multiple locations on a chromosome (loci) that characterize the mature B-cell neoplasm subtypes, and can be routinely applied to the study of a range of specimen types including blood and bone marrow and FFPE biopsy specimens. |

HPV-Associated Cancers

HPV-associated cancers, including cervical, anal, and head and neck cancers, are caused by infection with high-risk variants of human papillomavirus (HPV), and are responsible for approximately 4% of all cancer diagnoses worldwide. Cervical cancer is the third most common cancer among women. According to the National Institutes of Health, while there are more than 100 types of HPV, approximately 15 types are considered to be cancer-causing, with only 2 strains being responsible for 70% of cervical cancer cases worldwide. Cervical cancer may be detected by traditional methods, including Pap smears and liquid cytology, where cervical cells obtained by Pap smear are observed by a pathologist, or by HPV typing, which identifies the strain of HPV virus presently infecting the patient. Neither of these techniques is able to identify the likelihood of the HPV-infection’s developing into cancerous or

precancerous lesions. According to the National Cancer Institute, about 50 million Pap smear tests to detect HPV are performed in the United States each year. It is estimated that approximately 2 million patients have abnormal Pap smear test results and are referred for biopsy/colposcopy as a result of such tests. However, only

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approximately 12,000 of these patients will develop cervical cancer. It is believed that early detection of HPV-associated cancers and lesions most likely to progress to cancer could eliminate unnecessary biopsies/colposcopies and thereby reduce health care costs.

Our Proprietary Tests for HPV-Associated Cancers

| Test | Targeted Cancers | Technology & Advantages |
|---|---|---|
| FHACT® | • HPV-Associated Cancers<br>- Cervical Cancer<br>- Anal Cancer<br>- Head & Neck Cancers | • FHACT® is our proprietary, 4-color FISH-based DNA probe designed to identify aberrations in four important chromosomal regions that have been implicated in cancers associated with infection by the human papilloma virus (HPV): cervical, anal and oropharyngeal.<br>• FHACT® is designed to determine copy number changes of four particular genomic regions by fluorescent in situ hybridization (FISH). These regions of DNA give specific information about the progression from HPV infection to cervical cancer, in particular the stage and subtype of disease.<br>• FHACT® is designed to enable earlier detection of abnormal cells and can identify the additional genomic biomarkers that allow for the prediction of cancer progression.<br>• FHACT® is designed to leverage the same Pap smear sample taken from the patient during routine screening, thus reducing the burden on the patient while delivering greater information to the clinician.<br>• We offer an application of FHACT® as an LDT for cervical cancer and are developing applications for additional cancer targets.<br>• We have obtained CE marking for FHACT®, which allows us to market the test in the European Economic Area. |

Solid Tissue Cancers

The term “solid tumors” encompasses abnormal masses of cells that do not include fluid areas (e.g. blood) or cysts. Solid tumors are composed of abnormal cell growths that originate in organs or soft tissue and are normally named after the types of cells that form them. Examples of solid tumors include breast cancer, lung cancer, ovarian cancer and melanoma. Solid tumors may be benign (not cancerous) or malignant (cancerous) and may spread from their primary tissue of origin to other locations in the body (metastasis). There are over 200 individual chemotherapeutic drugs available for combatting solid tumor cancers. Selection of an appropriate course of treatment for a patient may depend on identification of the gene mutation or mutations present in their particular cancer and on determining the cancer’s tissue of origin. Metastatic tumors with an uncertain primary site can be a difficult clinical problem. In tens of thousands of oncology patients every year, no confident diagnosis is ever issued, making standard-of-care treatment impossible.

Our Proprietary Tests for Solid Tissue Cancers

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| Test | Targeted Cancers | Technology & Advantages |
|---|---|---|
| Tissue of Origin® | • Solid Tissue Cancers<br>- Thyroid<br>- Breast<br>- Non-Small Cell Lung Cancer (NSCLC)<br>- Gastric<br>- Pancreas<br>- Colorectal<br>- Liver<br>- Bladder<br>- Kidney<br>- Non-Hodgkin's Lymphoma<br>- Melanoma<br>- Ovarian<br>- Sarcoma<br>- Testicular Germ Cell<br>- Prostate | • Tissue of Origin® (TOO®) is FDA-cleared, Medicare-approved, and provides extensive analytical and clinical validation for statistically significant improvement in accuracy over other methods.<br>• TOO® is a gene expression test that is used to identify the origin in cancer cases that are metastatic and/or poorly differentiated and unable to be typed by traditional testing methods.<br>• TOO® increases diagnostic accuracy and confidence in site-specific treatment decisions, and leads to a change in patient treatment based on results 65% of the time it is used.<br>• TOO® assesses 2,000 genes, covering 15 of the most common tumor types and 90% of all solid tumors.<br>• In the fourth quarter of 2015, we acquired the TOO® test through our acquisition of substantially all of the assets of Response Genetics, Inc.<br>• TOO® is FDA-cleared, Medicare-reimbursed, and provides extensive analytical and clinical validation for statistically significant improvement in accuracy over other methods. |
| Focus::Oncomine™<br><br>Oncomine Dx Target Test<br><br>Liquid::Lung cf-DNA™ | • Solid Tissue Cancers<br>- Lung<br>- Colorectal<br>- Melanoma<br>- Breast<br>- Bladder<br>- Thyroid | • Focus::Oncomine™ one test in our family of next generation sequencing tests developed for the analysis of genomic alterations to determine, guide and inform diagnosis, prognosis and theranosis of solid tumors.<br>• Focus::Oncomine™ is designed to cover hotspot mutations of 35 unique genes that have clinical utility in various different types of solid tumors, allowing for the detection of 989 hotspot variants, including single nucleotide variants (SNVs), with a very low input DNA material.<br>• We make available Thermo-Fisher's Oncomine Dx Target Test, which is an NGS-based companion diagnostic that simultaneously screens tumor samples for multiple biomarkers associated with three FDA-approved therapies for non-small cell lung cancer, including the combined therapy of dabrafenib and trametinib, crizotinib or gefitinib.<br>• The biomarkers included in Focus::Oncomine™ and the Oncomine Dx Tartet Test were selected based on information in the Oncomine Knowledgebase, which compiles genomic information from clinical trials, and were confirmed with industry-leading pharmaceutical partners. The results of the assay should be interpreted in the context of available clinical, pathologic, and laboratory information.<br>• Liquid::Lung- cfDNA™ is our multi-gene cell-free DNA next generation sequencing panel for lung cancer, which covers 11 critical genes and over 150 key hotspots related to lung cancer.<br>• Liquid::Lung- cfDNA™ is CLIA-validated and can detect lung tumor-derived cell-free DNA (cfDNA) obtained from the plasma fraction of blood. |

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| Focus::Renal™ | Kidney | • Focus::Renal™, a highly-sensitive NGS panel, detects mutations of 76 renal cancer-related genes, as well as genome-wide copy number changes, and critical single nucleotide variants (SNVs), all in a single test, that enable precision diagnosis, prognosis, and therapy selection for renal cancer patients.<br>• Focus::Renal™ is the only NGS panel to simultaneously detect genome-wide copy number changes, SNP genotypes along with mutations in 76 renal cancer-related genes, covering relevant drug pathways.<br>• Focus::Renal™ can be performed on a wide variety of patient specimen types, such as needle biopsies, fine-needle aspirates, and resected specimens using both formalin-fixed paraffin-embedded (FFPE) and fresh/fresh-frozen specimens, including the ones with minimal starting material. |
| UroGenRA® | • Kidney<br>- Clear Cell Renal Cell Carcinoma (ccRCC)<br>- Chromophobe Renal Cell Carcinoma (chrRCC)<br>- Papillary Renal Carcinoma (pRCC)<br>- Oncocytoma (OC)<br>• Prostate<br>• Bladder | • UroGenRA® has 101 regions of the human genome represented, and these regions can be used for gain/loss evaluation in urogenital neoplasms including kidney, prostate and bladder.<br>• UroGenRA®-Kidney Array-CGH provides genomic diagnostic information to assist routine histology in the subtyping of ccRCC, chrRCC and OC from either core needle biopsies or resected specimens.<br>• UroGenRA®-Kidney assesses 16 genomic regions that have diagnostic significance in the four main renal cortical neoplasm subtypes.<br>• Result from UroGenRA®-Kidney are analyzed using our proprietary algorithm KidneyPath™ to classify specimens as normal, undetermined, or into one of the four main renal cortical neoplasm subtypes. |

Hereditary Cancers

Hereditary cancer syndromes are inherited conditions in which an individual has a greater than normal lifetime risk of developing certain types of cancer, and are caused by gene mutations that are passed from parents to children. In a family with a hereditary cancer syndrome, one or more types of cancers may be present in several family members, may develop at an early age, or one person may develop more than one type of cancer. Hereditary cancer syndromes are estimated to account for up to 10% of all cancer diagnoses in the United States. Many of the gene mutations that cause hereditary cancers have been identified, and genetic testing may identify whether an individual’s cancer is due to one of these inherited genes. Genetic testing for family members who have not been diagnosed with cancer can also reveal whether they are at an increased risk for developing hereditary cancers.

Our Proprietary Hereditary Cancer Test

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| Test | Targeted Cancers | Technology & Advantages |
|---|---|---|
| Focus::HERSite™ and Focus::BRCA™ | • Breast<br>• Ovarian | • Focus::HERSite™ and Focus::BRCA™ are in our family of next generation sequencing tests developed for the analysis of genomic alterations to determine, guide and inform diagnosis, prognosis and theranosis of some of the most prevalent hereditary cancers.<br>• Focus::HERSite™ analyzes the 16 most common genes associated with breast and ovarian cancers in a single reaction, and provides comprehensive coverage of the BRCA1 and BRCA2 genes.<br>• Focus::BRCA™ targets germline mutations, insertions and deletions in the BRCA1 and BRCA2 genes associated with Hereditary Breast and Ovarian Cancer Syndrome (HBOC), and mutations in which may impart an increased lifetime risk of breast, ovarian and prostate cancer.<br>• The mutations responsible for HBOC are inherited in an autosomal dominant manner and typically include single nucleotide variants (SNVs) and small insertions. Focus::HERSite™ and FOCUS:BRCA™ are designed to detect these mutations, as well as larger insertions and deletions in their target genes. |

Immuno-Oncology Testing

Immuno-oncology encompasses a method of cancer treatment that harnesses the power of a patient's own immune system to combat cancer growth and development. Abnormal cells are ordinarily destroyed by the body's immune system before these cells are able to proliferate and develop into a tumor. In some cancers, abnormal cells have developed mutations allowing them to avoid the body's natural defenses and these cells are not destroyed by the immune system. Immuno-oncology aims to either activate the immune system to recognize and destroy these cancer cells, or to turn off the mechanisms cancer cells develop than enable them to avoid detection by the immune system, thereby permitting the immune system to recognize and eliminate them. The Cancer Research Institute reports that although there are 6 approved immuno-oncology therapies approved for patient treatment, and there are over 150 clinical trials focused on developing immuno-oncology treatments.

We believe immuno-oncology is rapidly increasing in clinical practice and presents a unique market opportunity when combined with precision testing and traditional and combination oncology therapies. During 2016 and 2017, we launched a comprehensive immuno-oncology testing portfolio for use in clinical trials, translational research, and therapy selection for patients. This portfolio is available for clinical trials, patient care, and translational research utilizing multiple technological platforms through our New Jersey and California facilities. Our portfolio of immuno-oncology tests includes immunohistochemistry (IHC)-based tests that can detect novel biomarkers like PD-1 and PD-L1, MMR, CTLA4 and flow cytometry-based tests and panels that can assess immune response against cancers by evaluating subsets of immunomodulatory and effector cells. We also offer an NGS-based targeted RNA sequencing test that can measure expression levels of drug targets, evaluate tumor mutational burden, assess tumor neo-epitopes and total immune cell composition. Many of these assays are also available for clinical use and are CLIA- and New York State-approved.

Sales and Marketing

Our sales and marketing efforts consist of both direct and indirect efforts, with the majority of efforts focused on direct sales in the United States, Europe and Asia Pacific regions. The table below summarizes our sales approach by geography and customer segment:

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| | | |
|---|---|---|
| United States | Clinical Sales | - Collaborate with leading research universities and institutions that enable the validation of our new tests.<br>- Work with community-based cancer centers that need a reliable and collaborative partner for cancer testing.<br>- Build relationships with individual thought leaders in oncology, hematology and pathology to deliver services that provide value to their patients. |
| | Biopharma Sales | - Collaborate with scientific development teams at pharmaceutical companies on studies involving translational medicine and genotyping.<br>Build relationships in the research and development segment to identify partners with a need for preclinical efficacy and toxicity studies and biomarker discovery studies. |
| Europe and Asia Pacific | Discovery Sales | - Collaborate with preclinical development teams at pharmaceutical and biotech companies on studies involving tumor models and therapeutic candidate compound testing. |
| | Clinical Sales | - Develop relationships with oncologists and reference labs, as well as with physicians in local clinics. |
| | Biopharma Sales | - Leverage US-based and local companies conducting clinical trials with a component of those trials occurring in European or Asia Pacific populations.<br>- Collaborate with scientific development teams at biotech and pharmaceutical companies and government agencies on studies involving tests and services. |
| | Discovery Sales | - Collaborate with preclinical development teams at pharmaceutical and biotech companies on studies involving tumor models and therapeutic candidate compound testing. |

Our U.S. and European business development and sales professionals have scientific backgrounds in hematology, pathology, and laboratory services, with many years of experience in biopharmaceutical and clinical oncology sales, esoteric laboratory sales from leading biopharmaceutical, pharmaceutical or specialty reference laboratory companies. We currently have a team of 13 business development and sales professionals in the United States, 2 in Europe and 3 in India. We support our sales force with clinical specialists who bring deep domain knowledge in the design and use of our tests and services.

In addition to our direct sales force, we entered into agreements with the Laboratory Services group of ICON plc, the global CRO (Nasdaq:ICLR), and BARC Global Laboratories (a part of Cerba Healthcare) to work together to offer biotech and pharmaceutical customers a comprehensive, integrated and efficient solution for laboratory testing for global oncology trials from Phase I through Phase IV. Through our joint service offerings with ICON and BARC, we can provide biotech and pharmaceutical customers with access to combined expertise ranging from complex, oncology-focused molecular and biomarker-based testing to core central laboratory analysis, project and data management and sample logistics on a global basis.

We also promote our tests and services through marketing channels commonly used by the biopharma and pharmaceutical industries, such as internet, medical meetings and broad-based publication of our scientific and economic data. In addition, we provide easy-to-access information to our customers over the internet through dedicated websites. Our customers value easily accessible information in order to quickly review patient or study information.

Research and Development Collaborations

We formally and informally collaborate with leading oncology centers and community-based hospitals to develop our proprietary diagnostic tests, and we work closely with leading cancer researchers at these institutions to develop proprietary tests tailored to their needs and specifications. Additionally, many of these centers have obtained Specialized Programs of Research Excellence status, as designated by the National Cancer Institute. Our collaborations with these centers give us access to large datasets of information that we use to develop our proprietary tests.

Below is a summary of our active key collaborations. In certain cases we have formal written agreements with collaborators and in other cases we have no written agreement with our collaborators or only informal written arrangements.

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| Collaborating Institution | Principle Investigator(s) | Focus of Collaboration |
|---|---|---|
| North Shore-Long Island Jewish Health System, New York | Dr. Kanti Rai<br>Dr. Nicholas Chiorazzi | Clinical validation of biomarkers and signatures for CLL diagnosis and therapeutic response |
| Memorial Sloan-Kettering Cancer Center, New York | Dr. Jeremy Durack | Evaluation of FISH-based and CHG-array tests |
| National Cancer Institute, Maryland | Dr. Nicolas Wentzensen | Evaluation of FHACT® |
| Kamineni Hospital, Hyderabad, India | Dr. Annie Hassan | Evaluation of FHACT® |
| Columbia University, New York | Dr. Azra Raza<br>Dr. Siddhartha Mukherjee | Identification of genomic biomarkers for myeloid cancers |
| Apollo Hospitals, India | | Evaluation of FHACT® |
| Keck Medicine of University of Southern California, California | Dr. Imran Siddiqi | Identification and evaluation of genomic biomarkers for lymphomas and other B cell malignancies |
| | Dr. Giri Ramsingh | Transposable elements as prognostic biomarkers in acute myeloid leukemia |
| University of Southern California, California, & HTG Molecular, Arizona | Dr. Pamela Ward | MicroRNA whole transcription assay validation |
| University of Southern California, California, & HTG Molecular, Arizona | Dr. Heinz-Josef Lenz and Dr. Yu Sunakawa | Gene expression analysis using an immuno-oncology panel for measurement of response to immune therapy |
| Groupe Hospitalier Pitié Salpétriere, Paris | | Analyze the variability of genomic alterations in renal cancer |
| Huntsman Cancer Center Institute, University of Utah, Utah | Dr. Neeraj Agarwal | Evaluation of biomarkers for kidney cancer diagnosis and therapeutic response and liquid biopsy assay development |
| Huntsman Cancer Center Institute, University of Utah, Utah and Pfizer | | Validation of biomarkers to predict Stutent response and liquid biopsy assay development |
| Moffitt Cancer Center, Florida | Dr. Anna Giuliano | Evaluation of FHACT® for oral cancer |
| Mount Sinai School of Medicine, New York | Dr. Samir Parekh | Developing algorithms for precision medicine in multiple myeloma using PDx models |
| University of Virginia School of Medicine, Virginia, & HTG Molecular, Arizona | | Evaluation of genomic signatures in immune response |
| Weill Cornell Medical Center, New York | Dr. Ari Melnick | Development of PK/PD markers for epigenetic therapies |
| Yale University | Dr. Brian Shuch | Evaluation of biomarkers in NGS Focus::Renal™ to stratify and monitor patients |

Competition

With respect to our clinical services, our principal competition comes from existing mainstream diagnostic methods and laboratories that pathologists and oncologists use and have used for many years or decades. It may be difficult to change the methods or behavior of the referring pathologists and oncologists to incorporate our molecular diagnostic testing in their practices. In addition, companies offering capital equipment and kits or reagents to local pathology laboratories represent another source of potential competition. These kits are used directly by the pathologist, which can facilitate adoption.

We also face competition from companies that currently offer or are developing products to profile genes, gene expression or protein biomarkers in various cancers. Precision medicine is a new area of science, and we cannot predict what tests others will develop that may compete with or provide results superior to the results we are able to achieve with the tests we develop. Our competitors include public companies such as NeoGenomics, Inc., Quest Diagnostics, Abbott Laboratories, Inc., Johnson & Johnson, Roche Molecular Systems, Inc., bioTheranostics, Inc., Genomic Health, Inc., Myriad Genetics Inc., Foundation Medicine, Inc., Invitae Corp., and many private companies. We expect that pharmaceutical and biotech companies will

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increasingly focus attention and resources on the personalized diagnostic sector as the potential and prevalence increases for molecularly targeted oncology therapies approved by FDA along with companion diagnostics. With respect to our clinical laboratory business we face competition from companies such as Genoptix Medical Laboratory, NeoGenomics, Inc., Bio-Reference Laboratories, Inc. (a division of Opko), LabCorp, MDx Health, Quest Diagnostics and Invitae Corp. With respect to our Discovery Services, including our CRO services, we face competition from companies that offer or are developing animal models for tumors and that have capabilities in toxicology and pharmacology testing. Our competitors in our Discovery Services business include Champions Oncology, Crown BioScience (recently acquired by JSR Life Sciences), Eurofins Scientific, and Explora Biolabs.

Additionally, projects related to the molecular mechanisms driving cancer development have received increased government funding, both in the United States and internationally. The National Cancer Institutes' Cancer Moonshot is anticipated to increase both patient awareness and federal government funding for research and clinical trials. The Federal Government has committed $1.8 billion over a 7 year period to fund the 21st Century Cures Act. As more information regarding cancer genomics and biomarkers becomes available to the public, we anticipate that more products aimed at identifying targeted treatment options will be developed and that these products may compete with ours. In addition, competitors may develop their own versions of our tests in countries where we did not apply for patents or where our patents have not issued and compete with us in those countries, including encouraging the use of their test by physicians or patients in other countries.

Third-Party Suppliers

We maintain control, validation and quality assurance over our NGS panels, DNA microarrays and probes. Our microarrays and NGS panels are designed in our facility by our scientists and technicians using state of the art genomic mapping and analysis software. The specifications for our NGS panels are sent to Thermo Fisher Scientific (Ion Torrent) and Illumina for final manufacturing. Our NGS panels are manufactured under strict quality control and compliance. Upon manufacturing our custom, proprietary NGS panels, they are shipped back to our Rutherford facility for testing and acceptance.

We also currently rely on contracted manufacturers and collaborative partners to produce materials necessary for our FDA-cleared Tissue of Origin® and FHACT® tests. We plan to continue to rely on these manufacturers and collaborative partners to manufacture these materials. We order 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.

Patents and Proprietary Technology

Our business develops proprietary tests that enable oncologists and pathologists at hospitals, cancer centers, and physician offices to properly diagnose and inform cancer treatment. We rely on a combination of patents, patent applications, trademarks, trade secrets, know-how, as well as various contractual arrangements, in order to protect the proprietary aspects of our technology. We may also license our technology to others. We believe that no single patent, technology, trademark, intellectual property asset or license is material to our business as a whole.

Our patent portfolio consists of 26 issued U.S. patents, several pending U.S. applications, and 175 foreign patents. We manage our patent assets to safeguard them and to maximize their value. Our key patents include:

- Hematological cancers. We have two U.S. patents (U.S. Patent Nos. 8,580,713 and 8,557,747), directed to MatBA®, a microarray for detecting (and distinguishing) particular types of mature B cell neoplasms present in typical non-Hodgkin’s lymphoma, Hodgkin’s lymphoma and chronic lymphocytic leukemia. These patents cover our trademarked MatBA® microarray and are directed to both the microarray itself as well as associated methodologies

designed to detect the particular type of mature B cell neoplasm present in a patient. The MatBA® microarray patents issued from the first of our family of applications in the microarray space. The term of these patents runs through 2030.

- Solid Tumors. We have 13 U.S. patents, including (U.S. Patent Nos. 7,049,059, 7,560,543, 7,732,144, 8,586,311, 8,026,062, 6,956,111, 6,905,821, 7,005,278, 6,686,155, 7,138,507, as well as numerous foreign patents. These patents relate to certain aspects of the gene expression technology used in our solid tumor tests. The term of these patents runs through 2023.

- We have four U.S. patents (U.S. Patent Nos. 8,977,506, 8,321,137, 7,747,547 and 8,473,217) covering our Tissue of Origin® Test. These patents are directed at systems and methods for detecting biological features in solid tumors. The term of these patents run through 2030.

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- Urogenital cancers. We have two U.S. patents (U.S. Patent Nos. 8,603,948 and 8,716,193) directed to a novel, highly sensitive and specific probe panel which detects the type of renal cortical neoplasm present in a biopsy sample. These patents cover a probe that permits diagnosis of the predominant subtypes of renal cortical neoplasms without the use of invasive methods and provides a molecular cytogenetic method for detecting and analyzing the type of renal cortical neoplasm present in a renal biopsy sample. The term of these patents runs through 2027.

- HPV-Associated Cancers. We have three U.S. patents (U.S. Patent Nos. 9,157,129, 8,865,882 and 8,883,414) that cover methods for detecting HPV-associated cancers used in our FHACT® test. The term of these patents run through 2031.

- FISH Probes. We have two patents covering our FISH probes. These patents cover probes and methodologies designed to detect and analyze particular chromosomal translocations (genetic lesions) associated with a wide range of cancers using a technique known as FISH and serve as the backbone for several of our other pending patent applications, which are more specifically geared towards other probes (and methodologies). The term of these patents run through 2022.

In addition to patents, we hold twenty-six U.S. registered trademarks, including a federal registration for the term “CGI” as well as three U.S. trademark applications and one foreign trademark registration for certain of our proprietary tests and services. Our strategic use of distinctive trademarks has garnered increased name recognition and brand awareness for our tests and services within the industry.

Through our clinical laboratories, we provide several clinical services that utilize our proprietary trade secrets. In particular, we maintain trade secrets with respect to specimen accessioning, sample preparation, and certain aspects of cytogenetic and molecular analyses. All of our trade secrets are kept under strict confidence, and we take all reasonable steps, including the use of non-disclosure agreements and confidentiality agreements, to ensure that our confidential information is not unlawfully disseminated. We also conduct training sessions on the importance of maintaining and protecting trade secrets with our scientific staff and laboratory directors and supervisors.

In addition to our proprietary intellectual property, we exclusively license from University of Southern California, or USC, the use of extraction methodologies and related technologies used in our solid tumor tests, which have been patented in the United States and a number of other jurisdictions, including Australia, Austria, Belgium, Canada, China, Denmark, France, Germany, Hong Kong, Ireland, Israel, Italy, Luxembourg, Mexico, The Netherlands, Norway, Russia, South Korea, Spain, Sweden, Switzerland and the United Kingdom. Currently, this exclusive license includes seven United States patents claiming methods related to this technology. Our USC licensed patents are scheduled to expire between December 2019 and December 2020.

We also entered into nonexclusive licenses with the National Cancer Institute for the use of its intellectual property relating to a 3q marker and with Stanford University for use and development of a diagnostic assay and predictive model that has been granted two patents for the stratification and risk prediction for DLBCL patients. Under the terms of the license, we are permitted to use the National Cancer Institute’s proprietary intellectual property for use in our patent pending FHACT® DNA probe, which is directed to the diagnosis and prognosis of certain HPV-associated cancers.

Our success in remaining an innovator in the diagnostic services industry by continuing to introduce new tests, technology and services will depend, in part, on our ability to license new and improved technologies on favorable terms. Other companies or individuals, including our competitors, may obtain patents or other property rights on tests and processes that may be performing, particularly in such emerging areas as gene-based testing that could prevent or interfere with our ability to develop, perform or sell our tests or operate our business.

Operations and Production Facilities

We are underway with the implementation of an enterprise laboratory management system licensed from a business partner to support a fully-integrated systems across all of our U.S.-based sites. We anticipate this system to be on-line by late in the third quarter of 2018. In addition to harmonizing our workflow, improving our turn-around times, and creating better operational efficiencies, it will allow us to connect with electronic medical records providers to facilitate seamless communication between our clinical laboratories and the oncologist or pathologist at the test ordering site. We do this integration through utilizing HL7 interfaces, which are standard in health care information technology systems. We currently employ HL7 for its integration with a revenue cycle management company, as well as with electronic medical records partners. The use of the HL7 interface allows systems written in different languages and running on different platforms to be able to talk to each other through the use of an abstracted data layer. This means that we do not have to spend significant extra time designing and developing common communications protocols when integrating with other electronic health records systems or billing systems providers.

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When a customer obtains a specimen from a patient for oncology testing, he or she will complete a requisition form (either by hand or electronically, or via electronic medical records technology), and package the specimen for shipment to us. Once we receive the specimen at our laboratory and we enter all pertinent information about the specimen into our clinical laboratory information system, one of our laboratory professionals prepares the specimen for diagnosis. The prepared specimen is sent to one of our pathologists or medical directors who is experienced in making the diagnosis requested by the referring oncologist or pathologist.

After diagnosis, our pathologist uses our laboratory information systems to prepare a comprehensive report, which includes any relevant images associated with the specimen. Our clinical reporting portal, cgireports.com, allows a referring oncologist or pathologist to access his/her test results in real time in a secure HIPAA compliant manner. The reports are generated in industry standard PDF formats which allows for high definition color images to be reproduced clearly. This portal has been fully operational at our facilities since 2011.

In most cases we provide both the technical analysis and professional diagnosis, although we also fulfill requests from oncologists and pathologists for only one service or the other. If an oncologist or pathologist at the hospital, cancer center, reference laboratory or physician office requires only the analysis, we prepare the data and then return it to the referring oncologist or pathologist for assessment and diagnosis.

Quality Assurance

We are committed to maintaining a standard of clinical excellence and to providing reliable and accurate laboratory services to our customers. To that goal, our independent Quality Assurance Unit (QAU) has implemented a comprehensive and integrated Quality Management System (QMS) designed to drive consistent high quality testing services while ensuring the highest ethical standards across our enterprise.

Our QMS documents quality assurance policies as well as the quality control procedures that are necessary to ensure we offer a consistently high quality of testing services. Our quality management program is designed to satisfy all the requirements necessary for local, state, and federal regulations as our laboratories are both CLIA-certified and CAP-accredited (including our biorepository), and comply with states' heightened standards (such as California and New Yok State) in order to maintain licensures applicable to our business. In addition, our QMS satisfies the Food and Drug Administration (FDA) requirements for clinical trials studies conduct, computer systems validation, electronic records and signatures, and the Good Clinical Laboratory Practices (GCLP).

The overall goal of the QMS is to ensure that all patient results meet laboratory specifications and client specifications during the pre-analytical, analytical, and post-analytical phases of sample management and reporting of results. The system is maintained and continually improved through the regular use and review of our quality policies, customers' and employees' feedback, internal and external audit or inspection results, corrective and preventive actions, key performance indicator trends, data analysis, continuous monitoring of testing methods and management review. To date, while inspected several times by FDA, we have not received any findings of violations or inspection citations on FDA's Form 483.

The management team at each of our laboratory facilities ensures that equipment and reagents are properly selected, qualified, maintained and disposed of according to established procedures and manufacturer's instructions. All clinical assays performed in our laboratories are validated per state and federal regulations prior to being processed in the laboratory as diagnostic testing services. We provide training for all personnel, which includes comprehensive training on our QMS, assigned work processes and technical procedures. We also provide continuing education programs for the ongoing professional development of all laboratory employees.

Quality indicators, which are metrics related to ensuring accurate and reliable test results, are routinely tracked at each of our facilities and are compared to previously determined benchmarks. These indicators are reviewed periodically by our clinical management team and include key performance indicators (such as test volume, turn-around-time (TAT), number of abnormal case, number of failures), non-conformance indicators (deviations, corrective and preventives actions), proficiency testing reports, and customer satisfaction surveys. We leverage third-party provided proficiency testing whenever practicable to provide objective analysis of our QMS and procedures, and we implement internal review protocols for assays for which third-party proficiency testing is not available.

Our facilities and QMS are audited internally on a periodic basis for compliance with applicable regulations, policies, analytical plans and internal standard operating procedures. Any needed revisions to the QMS that are identified through these audits are made to ensure continued compliance with applicable standards, and we believe that all pertinent regulations of the Clinical

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Laboratory Improvement Amendments (CLIA), Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), and FDA are satisfied within our QMS.

Customer satisfaction is another key to successful implementation of our QMS. We routinely monitor customer input and complaints, and actively solicit feedback from customers by way of survey. Our management team encourages employees to communicate any concerns they may have with respect to scientific misconduct, quality and safety.

In addition to maintaining a robust QMS, we have defined a plan approved by the Business Continuity Plan Team that covers a wide range of disaster recovery and business continuity issues including data recovery. Both the business continuity and disaster recovery plans are reviewed on an annual basis.

Third-Party Payor Reimbursement

Depending on the billing arrangement and applicable law, we are reimbursed for clinical services by: third-party payors that provide coverage to the patient, such as an insurance company, managed care organization or a governmental payor program; physicians or other authorized parties (such as hospitals or independent laboratories) that order testing service or otherwise refer the services to us; or the patient. For the year ended December 31, 2017, we derived approximately 20% of our total revenue from private insurance, including managed care organizations and other health care insurance providers, 12% from Medicare, and 5% from other health care facilities, including hospitals.

Where there is a coverage policy, contract or agreement in place, we bill the third-party payor, the hospital or referring laboratory as well as the patient (for deductibles and coinsurance or copayments, where applicable) in accordance with the policy or contractual terms. Where there is no coverage policy, contract or agreement in place, we pursue reimbursement on behalf of each patient on a case-by-case basis and rely on applicable billing standards to guide our claims. In addition, we have implemented a patient financial assistance program (CGI MAP Program) that complies with Federal guidelines.

We are reimbursed for three categories of tests: (1) genetic and molecular testing; (2) anatomic pathology and immunohistochemistry testing and (3) general immunology and flow cytometry. Reimbursement under the Medicare program for the diagnostic services that we offer is based on either the Medicare Physician Fee Schedule (PFS) or Medicare Clinical Laboratory Fee Schedule (CLFS). The PFS is subject to geographic adjustments and is updated annually; this was the case for the CLFS, as well, until January 1, 2018. Starting January 1, 2018, the CLFS is updated every three years, and it is not subject to geographic adjustments or multifactor productivity adjustments. Medical services provided to Medicare beneficiaries that are performed by physicians or that require a degree of physician supervision or other involvement, such as pathology tests, are generally reimbursed under the Medicare PFS, whereas clinical diagnostic laboratory tests are generally reimbursed under the CLFS. Most of the services that we provide for Medicare beneficiaries are for genetic and molecular testing, which are reimbursed as clinical diagnostic laboratory tests under the CLFS. There is currently no copayment or deductible required for tests paid under the CLFS, although Congress periodically has considered implementing such a requirement. Services paid for under the PFS are subject to copayments and deductibles.

Medicare fee schedule amounts for clinical diagnostic laboratory tests are established for each billing code, or CPT code. Until January 1, 2018, the effective date of new CLFS rates established under the Protecting Access to Medicare Act (PAMA), Medicare set a cap on the amount that it paid for any individual test. This cap, usually referred to as the National Limitation Amount, was set at a percentage of the median of all the contractor fee schedule amounts for each billing code. Through the years, Congress had lowered the percentage of the median used to calculate the National Limitation Amount in order to achieve budget savings. In 2017, the National Limitation Amount ceiling was set at 74% of the median for established tests and 100% of the median for certain new tests that were not previously

reimbursed. In billing Medicare for clinical laboratory services, we were required to accept, as payment in full, the lowest of our actual charge, the fee schedule amount for the state or local geographical area or the National Limitation Amount.

In addition, Congress routinely lowered or eliminated the update factor that would otherwise apply to the applicable CLFS payment. For example, under the health care reform legislation, passed in 2010, payments under the CLFS were reduced by 1.75% through 2015 and, in addition, a productivity adjustment, further reducing payment rates also was imposed. In addition, in February 2012, Congress passed the Middle Class Tax Relief and Job Creation Act of 2012, which required that the CLFS be “rebased” by -2%. As a result of these changes, for 2015 the CLFS was reduced by -.25%.

In 2014, Congress passed the Protecting Access to Medicare Act (PAMA) which changes the way CMS establishes Medicare reimbursement rates for clinical laboratory services under the CLFS. Under PAMA Sec. 216, certain laboratories (including our laboratories that provide clinical services) are required to report the amount that they are paid by private payors and the associated volumes for each test beginning in January 2017. CMS is to use this data to calculate a weighted median for each

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test. The first data collection period was January 1 through June 30, 2016, private payor rates and the associated volumes were reported to CMS between January 1 and May 30, 2017, and the new rates became effective on January 1, 2018. The law limits the amount by which a CLFS reimbursement rate can be reduce from year to year (10 percent in each of the first three years and 15 percent in each of the three subsequent years). This data collection and reporting process will be repeated every three years for most tests, although price and volume data for Advanced Diagnostic Laboratory Tests (ADLTs) will be reported every year ADLTs receive special payment treatment under the law, being paid initially at the test's actual list price, and afterwards having the weighted median adjusted annually to closely reflect the current private payor market. A test that meets the definition of an ADLT does not automatically become one under PAMA; rather, the laboratory offering the test voluntarily applies for ADLT designation for such a test. It is possible that some of our tests could be considered ADLTs, which will require us to report prices annually. In addition, we may also be required to obtain a code from CMS or an entity that it designates for our tests that have not previously had a code.

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" lab may exclude certain types of laboratories that generally received more favorable pricing than other laboratories, and thus the make-up of laboratories reporting pricing data to CMS under the proposed rule may result in lower overall pricing data. Beginning in 2017, the Medicare payment rate for each clinical diagnostic lab test is equal to the weighted median amount for the test from the most recent data collection period. For example, 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) was released in November 2017 and were effective on January 1, 2018. Also for the years 2017 through 2019, the amount of reduction in the Medicare rate (if any) shall not exceed 10 percent from the prior year's rate and for the years 2020 through 2022, any reduction shall not exceed 15 percent from the prior year's rate. It is too early to predict the impact on reimbursement for our tests reimbursed under the CLFS, though we believe the government's goal is to reduce Medicare program payments for CLFS tests. Specifically, CMS states that it anticipates the effect of the proposed rule on the Medicare program to save $360 million in program payments for CLFS tests furnished in FY 2017, and to save $5.14 billion over 10 years. CMS has also proposed that a laboratory's failure to comply with reporting obligations, or a laboratory that makes a misrepresentation or omission in reporting required information, would be a violation of the Civil Monetary Penalties Law. Also under PAMA, 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," or 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.

Certain of our tests are paid under the Medicare PFS, rather than the CLFS. Tests paid for under the PFS are based on "relative value units" (RVUs) established for each service. These RVUs are then multiplied by a conversion factor to arrive at a monetary amount. Until recently, each year, CMS calculated an update to this conversion factor based on a formula included in the Medicare law, referred to as the Sustainable Growth Rate (SGR) Formula. When it applied, this SGR formula often would require a decrease in reimbursement unless Congress acted to overturn this result. As a result, Congress consistently passed legislation to prevent implementation of significant cuts that would otherwise be effective. For 2014, CMS had projected the reimbursement cut resulting from the SGR formula would be approximately 20 percent, unless Congress acted to prevent the reduction. On December 18, 2013, Congress passed legislation that enacted a 0.5 percent increase in the conversion factor,

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which was effective until March 31, 2014. On April 1, 2014, President Obama signed the Protecting Access to Medicare Act of 2014, or PAMA. PAMA extended the 0.5 percent increase through March 31, 2015 and made other changes to laboratory reimbursement discussed above.

On April 16, 2015, President Obama signed the Medicare and CHIP Reauthorization Act (MACRA. MACRA repealed the provisions related to the Medicare SGR formula and implements a new physician payment system that is designed to reward the quality of care. In addition, it extended the current Medicare Physician Fee Schedule rates through June 2015, and then increases them by 0.5 percent for the remainder of 2015. Beginning on January 1, 2016, the rates will be increased annually by 0.5 percent, through 2019. For 2020 through 2025 payments will be frozen, although payment will be adjusted to account for performance on certain quality metrics under the Merit-Based Incentive Payment Systems (MIPS) or to reflect physician participation in alternative payment models (APMs). For 2026 and subsequent years, qualified APM participants receive an annual 0.75% update on Medicare physician payment rates, while those not participating receive a 0.25% annual payment update, plus any applicable MIPS-based payment adjustments. It is too early to determine how these changes may impact our business.

On October 30, 2015, CMS issued the Medicare Physician Fee Schedule Final Rule for 2016, which set out policies that were effective January 2016. Among those policy changes are reductions in the payments for flow cytometry and immunohistochemistry, two types of tests that we frequently perform. CMS has also stated that certain of these same tests may be considered "misvalued" which means they could be subject to additional scrutiny in the future. The CY 2017 Physician Fee Schedule final rule reduced reimbursement rates for flow cytometry by approximately 19%. However, CMS did not finalize its proposal to combine flow cytometry codes 88184 and 88185 into one code. In the CY 2018 Physician Fee Schedule final rule, reimbursement for flow cytometry (additional markers) and immunohistochemistry was reduced further. At this time, we are still assessing the potential impact of these changes.

Medicare also has policies that may limit when we can bill directly for our services and when we must instead bill another provider, such as a hospital. When the testing that we perform is done on a specimen that was collected while the patient was in the hospital, as either an inpatient or outpatient, we may be required to bill the hospital for some of our services, rather than the Medicare program, depending on whether or not the service was ordered more than 14 days after the patient’s discharge from the hospital and depending on the nature of the test. In the CY 2018 Outpatient Prospective Payment System final rule, CMS finalized a policy that permits a laboratory to bill the Medicare program directly for molecular pathology tests and ADLTs under certain conditions: (1) the test is performed following the hospital outpatient’s discharge; (2) the specimen was collected during a hospital encounter; (3) it was medically appropriate to have collected the specimen during the hospital encounter; (4) the results of the test do not guide treatment during the hospital encounter; and (5) the test was reasonable and medically necessary for treatment of an illness. These requirements are complex and time-consuming and, depending on what they require, may affect our ability to collect for our services.

In addition, as part of the Middle Class Tax Relief and Job Creation Act of 2012, signed into law by President Obama on February 22, 2012, Congress eliminated the special billing rule that had allowed laboratories to bill Medicare for the technical component of certain pathology services furnished to patients of qualifying hospitals. Effective July 1, 2012, independent laboratories, like our laboratories, are required to bill the hospital, rather than the Medicare Program, for the technical component of these services in most instances.

Our reimbursement rates from private third-party payors can vary based on whether we are considered to be an “in-network” provider, a participating provider, a covered provider or an “out-of-network” provider. These definitions can vary from insurance company to insurance company, but we are generally considered an “out of network” or non-participating provider in the vast majority of our cases. It is not unusual for a company that offers highly specialized or unique testing to be an “out of network” provider. An “in-network” provider usually has a contracted arrangement with the insurance company or benefits provider. This contract governs, among other things, service-level agreements and

reimbursement rates. In certain instances an insurance company may negotiate an “in-network” rate for our testing rather than pay the typical “out-of-network” rate. An “in-network” provider usually has rates that are lower per test than those that are “out-of-network”, and that rate is based on the laboratory fee schedule. The discount rate varies based on the insurance company, the testing type and the often times the specifics of the patient’s insurance plan.

We have contracts with commercial insurance carriers that provide access to certain of our tests. When a test is covered as part of these contracts it is paid at the rate stated in the contract. The Company also has preferred provider agreements and when a claim is processed through one of these organizations, reimbursement is based on usual and customary fees in the specific geography with a discount applied.

Billing Codes for Third-Party Payor Reimbursement

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CPT codes are the main data code set used by physicians, hospitals, laboratories and other health care professionals to report separately-payable clinical laboratory tests for reimbursement purposes. The CPT coding system is maintained and updated on an annual basis by the American Medical Association. Although there is no specific code to report microarrays for oncology, such as our MatBA®-CLL, there are existing codes that describe all of the steps in our MatBA®-CLL testing process. We currently use a combination of different codes to describe the various steps in our testing process. Many of the CPT codes used to bill for molecular pathology tests such as ours have been significantly revised by the CPT Code Editorial Panel. These new codes replace the more general “stacking” codes that were previously used to bill for these services with more test-specific codes, which became effective January 2013. In the CY 2013 Physician Fee Schedule Final Rule, which was issued in November 2012, CMS stated that it had determined it would pay for molecular pathology tests as clinical laboratory tests, which are payable on the Clinical Laboratory Fee Schedule (CLFS), rather than as physician services payable under the Physician Fee Schedule (PFS). CMS also stated that it would “gapfill” the new codes; that is, ask the contractors to determine a reasonable price for the new codes. This process was completed in 2013. Starting January 1, 2018, these codes have been priced based on the weighted median of private payor rates reported to CMS by certain laboratories, in the same way that all other tests on the CLFS are.

Among the codes that have been created by the American Medical Association’s CPT Editorial Panel is a specific subset of codes called Multi-analyte Assays with Algorithmic Analysis (MAAAs). These tests typically use an algorithm applied to certain specific components to arrive at a score that is used to predict a particular clinical outcome. CMS stated that it will not issue a categorical determination for all MAAA tests, but will consider on its own merits each individual test that is classified by the CPT as a MAAA. On September 25, 2015, CMS released its Preliminary Determinations for new CPT codes effective in 2016, including several new MAAA CPT codes. CMS had proposed "crosswalking" these codes to an unrelated test, resulting in a significant cut in their reimbursement. However, on November 17, 2015, CMS reversed its policy and directed that the tests be gapfilled by the local contractors. It is expected that many of these MAAA codes may be considered and reimbursed as ADLTs. For 2017, none of our revenue is derived from tests that may be considered MAAAs.

As of January 1, 2014 we are utilizing the “Not Otherwise Classified” (NOC) codes when billing for some of our MAAA tests. The reimbursement policies for the NOC codes vary from payor to payor with regard to specific tests, although some payors adopt other payors’ policies as their own. This extends our revenue cycle for these particular tests, where the normal timeframe for reimbursement of a claim is approximately 90 to 180 days. These tests can take upwards of a year or more to be reimbursed. There can be no guarantees that Medicare and other payors will establish positive or adequate coverage policies or reimbursement rates in the future. We continue to work with Medicare and managed care plans to obtain billing codes for our tests, however it is uncertain to determine the results of these efforts. A specific code for our tests does not assure an adequate coverage policy or reimbursement rate. Please see the section entitled “Legislative and Regulatory Changes Impacting Clinical Laboratory Tests” for further discussion of certain legislative and regulatory changes to these billing codes and the impact on our business.

On October 30, 2015, CMS issued the Medicare Physician Fee Schedule Final Rule for 2016, which set out policies that were effective January 2016. Among those policy changes are reductions in the payments for flow cytometry and immunohistochemistry, two types of tests that we frequently perform. CMS has also stated that certain of these same tests may be considered "misvalued" which means they could be subject to additional scrutiny in the future. The 2017 Physician Fee Schedule Final rule reduced reimbursement rates for flow cytometry by approximately 19%. However, CMS did not finalize its proposal to combine flow cytometry codes 88184 and 88185 into one code. At this time, we are still assessing the potential impact of these changes.

Coverage and Reimbursement for Our Proprietary Tests

We have been able to receive reimbursement for our tests from some payors based on their established policies, including major commercial third-party payors.

The current landscape with payors is generally as follows:

Commercial Third-party Payors and Patient Pay. Where there is a coverage policy in place, we bill the payor and the patient in accordance with the established policy. Where there is no coverage policy in place, we pursue reimbursement on behalf of each patient on a case-by-case basis. Our efforts in obtaining reimbursement based on individual claims, including pursuing appeals or reconsiderations of claims denials, take a substantial amount of time, and bills may not be paid for many months, if at all. Furthermore, if a third-party payor denies coverage after final appeal, payment may not be received at all. We are working to decrease risks of nonpayment by implementing a revenue cycle management system. Third party payors are still establishing payment policies for panel-based tests.

Medicare and Medicaid. We believe that as much as 30% to 40% of our future market for our tests may be derived from patients covered by Medicare and Medicaid.

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We cannot predict whether, or under what circumstances, payors will reimburse our proprietary tests. Payment amounts can also vary across individual policies. Denial of coverage by payors, or reimbursement at inadequate levels, would have a material adverse impact on market acceptance of our tests.

Legislative and Regulatory Changes Impacting Clinical Laboratory Tests

From time to time, Congress has revised the Medicare statute and the formulas it establishes for both the Medicare Clinical Laboratory Fee Schedule (CLFS) and the Physician Fee Schedule (PFS). The payment amounts under the Medicare fee schedules are important not only for our reimbursement under Medicare, but also because the schedules often are used as a basis for establishing the payment amounts set by other third party payors. For example, state Medicaid programs are prohibited from paying more than the Medicare fee schedule limit for clinical laboratory services furnished to Medicaid recipients.

Until December 31, 2017, under the statutory formula for clinical laboratory fee schedule amounts, increases were made annually based on the Consumer Price Index for All Urban Consumers (CPI-U) as of June 30 for the previous twelve-month period. From 2004 through 2008, Congress eliminated the CPI-U update in the Medicare Prescription Drug, Improvement and Modernization Act of 2003. In addition, for years 2009 through 2013, the Medicare Improvements for Patients and Providers Act of 2008 (“MIPPA”) mandated a 0.5% cut to the CPI-U. Accordingly, the update for 2009 was reduced to 4.5% and negative 1.9% for 2010. In March 2010, President Obama signed into law the Affordable Care Act (ACA), which, among other things, imposed additional cuts to the Medicare reimbursement for clinical laboratories. The ACA replaced the 0.5% cut enacted by MIPPA with a “productivity adjustment” that reduced the CPI-U update in payments for clinical laboratory tests. In 2011, the productivity adjustment was -1.2%. In addition, the ACA included a separate 1.75% reduction in the CPI-U update for clinical laboratories for the years 2011 through 2015. On February 22, 2012, President Obama signed the MCTRJCA, which mandated an additional change in reimbursement for clinical laboratory services payments. This legislation required CMS to reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which in turn served as a base for 2014 and subsequent years. Based on the changes required by ACA and MCTRJCA, payment for clinical laboratory services were reduced by approximately 0.25% for 2015.

With respect to our diagnostic services for which we are reimbursed under the Medicare Physician Fee Schedule, because of the statutory formula, the “Sustainable Growth Rate” (SGR), the rates would have decreased for the past several years if Congress failed to intervene. In the past, when the application of the statutory formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions. On November 1, 2012, the Centers for Medicare & Medicaid Services (CMS) issued its CY 2013 Medicare PFS Final Rule. In that rule, CMS called for a reduction of approximately 26.5% in the 2013 conversion factor that is used to calculate physician reimbursement. However, the American Taxpayer Relief Act of 2012, which was signed into law on January 2, 2013, prevented this proposed reduction and kept the existing reimbursement rate in effect until December 31, 2013.

For 2014, CMS projected the cut to reimbursement for services furnished under the PFS would be about 24%, unless Congress acted. However, on December 18, 2013, Congress passed legislation that enacted a 0.5% update in the conversion factor, which will be effective until March 31, 2014. On April 1, 2014, President Obama signed the Protecting Access to Medicare Act of 2014, or PAMA. PAMA extended the 0.5 percent increase through March 31, 2015 and made other changes to laboratory reimbursement discussed below. As discussed above, on April 16, 2015, President Obama signed MACRA, which replaces the SGR process with an alternative payment system.

In addition to the reductions described above, our Medicare payments under both the CLFS and the PFS are also subject to an additional 2% reduction, as a result of “sequestration.” Payments are reduced automatically because the Joint Select Committee on Deficit Reduction, which was created by congress in 2011, was unable to agree on a set of

deficit reduction recommendations for Congress to vote on. The reduction is scheduled to continue until 2025.

For the years ended December 31, 2017 and December 31, 2016, approximately 12% and 14%, respectively, of our total revenues are derived from Medicare generally and any changes to the physician fee schedule that result in a decrease in payment could adversely impact our revenues and results of operations.

In addition, periodically CMS also changes its payment policies related to laboratory reimbursement in ways that could have an impact on the revenues of the Company. For example, in CY 2013 PFS Final Rule, CMS included a reduction of certain relative value units and geographic adjustment factors used to determine reimbursement for a number of commonly used pathology codes, including CPT codes 88300, 88302, 88304, and 88305. In particular, the CY 2013 PFS Final Rule implemented a cut of approximately 33% in the global billing code for 88305 and a 52% cut in the Technical Component of that code. These codes describe services that we must perform in connection with our tests and we bill for these codes in connection with the services that we provide. In the CY 2013 PFS Final Rule, CMS also announced how it intended to set prices for the new molecular diagnostic

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tests, for which the American Medical Association had adopted over 100 new codes. In that rule, CMS announced it intended to continue to pay for the new molecular codes on the CLFS rather than move them to the Physician Fee Schedule, as some stakeholders had urged. It would then request that the Medicare Administrative Contractors "gapfill" the new codes and set an appropriate price for them. That "gapfilling" process took place over 2013 and CMS announced the new prices for these codes in September, 2013. The median of the prices set by the contractors became the new prices for these codes, effective January 1, 2014.

In the CY 2014 PFS Proposed Rule, issued on July 8, 2013, CMS made two proposals that could affect laboratory reimbursement. First, CMS made a proposal to change how it establishes the RVUs used to calculate payments under the PFS. Under this proposal, where a service was paid at a lower rate in the hospital based on the hospital Outpatient Prospective Payment System (OPPS) than it is under the PFS, CMS proposed to reduce the RVUs for that service in order to equalize the payment between the two systems. This change, if implemented, would have resulted in approximately a 25% cut in aggregate payments to independent laboratories. In the CY 2014 PFS Final Rule, however, CMS chose not to implement this proposal, although it stated that it would develop a revised proposal in the future. At this point, it is impossible to know what the impact of such a proposal might be on the Company, were it to be proposed again and finalized.

In addition, in the CY 2014 PFS Proposed Rule, CMS also noted that payments for many codes paid under the Clinical Laboratory Fee Schedule have not been revised to reflect technological advances that have occurred since the CLFS was first developed in 1984. The Social Security Act gave the Secretary of Health and Human Services, acting through CMS, the authority to adjust prices on the CLFS that the Secretary believed were "justified by technological changes." CMS therefore proposed that it would begin to review all codes on the CLFS and adjust them to reflect technological changes, a process that it expected would take about five years. However, in April of 2014, Congress passed the Protecting Access to Medicare Act (PAMA), which eliminated that provision of the Social Security Act and, consequently, the Secretary's authority to implement its plan to adjust payments based on technological advances.

In PAMA, Congress also changed the way CMS establishes Medicare reimbursement rates for clinical laboratory services on the CLFS. Under PAMA Sec. 216, certain laboratories are required to report the amount that they are paid by third party payors and the associated volume for each test on the CLFS beginning in January 2016. CMS will use this data to calculate a weighted median for each test. The first data collection period was January 1 through June 30, 2016, private payor rates and associated volumes were reported between January 1 and May 30, 2017, and the new rates became effective on January 1, 2018. The law limits the amount by which a CLFS reimbursement rate can be reduced from year to year (10 percent in each of the first three years and 15 percent in each of the three subsequent years). This data collection and reporting process will be repeated every three years for most tests, although laboratories that offer Advanced Diagnostic Laboratory Tests ("ADLTs") will report private payor rates for those tests every year. A test that meets the definition of an ADLT does not automatically become one under PAMA; rather, the laboratory offering the test voluntarily applies for ADLT designation for such a test. It is possible that some of our tests could be considered ADLTs, and if we applied for ADLT designation for such tests, we would be required to report prices for those tests annually. In addition, we may also be required to obtain a code from CMS or an entity that it designates for our tests that have not previously had a unique code.

CMS made several other changes in recent Medicare PFS rules that impact our business. In the CY 2015 PFS Final Rule, CMS implemented a policy that bundles payment for the examination of 10 or more prostate biopsies for an individual patient, rather than paying separately for each individual procedure as had been done previously. This will result in a significant reduction in reimbursement on each of these procedures. That year it also developed new prices for Immunohistochemistry procedures, based on new CPT codes that were developed to describe the procedures. In the CY 2016 final rule, CMS finalized standard times for certain pathology clinical labor tasks, and in the CY 2017 final rule, it said it may adopt standard times for other pathology labor tasks in the future. In 2014, CMS also implemented an edit under its National Correct Coding Initiative, under which it will pay only for a single unit of

service when we perform a FISH (Fluorescent In Situ Hybridization) test. As many FISH tests require two or more probes, this change will also reduce the reimbursement received by the Company.

Further, with respect to the Medicare Program, Congress has proposed on several occasions to impose a 20% coinsurance on patients for clinical laboratory tests reimbursed under CLFS, which would require us to bill patients for these amounts. Because of the relatively low reimbursement for many clinical laboratory tests, in the event that Congress ever were to enact such legislation, the cost of billing and collecting for these services would often exceed the amount actually received from the patient and effectively increase our costs of billing and collecting.

Finally, some of our Medicare claims may be subject to policies issued by Palmetto GBA, the current Medicare Administrative Contractor for Alabama, Georgia, North Carolina, South Carolina, Tennessee, Virginia and West Virginia. In 2013, Palmetto issued a Local Coverage Determination that affects coverage, coding and billing of many molecular diagnostic tests. Under this Local Coverage Determination, Palmetto will not cover any molecular diagnostic tests, including our tests, unless the test is expressly included in a National Coverage Determination issued by CMS or a Local Coverage Determination or coverage article issued by

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Palmetto. Currently, laboratory providers may submit coverage determination requests to Palmetto for consideration and apply for a unique billing code for each test (which is a separate process from the coverage determination). In the event that a non-coverage determination is issued, the laboratory must wait six months following the determination to submit a new request. In addition, effective May 1, 2012, Palmetto implemented the Molecular Diagnostic Services Program ("MolDx"), under which, among other things, a laboratory must use a newly-assigned unique test identifier when submitting a claim for a molecular test. These unique test identifiers enable Palmetto to measure utilization and apply coverage determinations. Denial of coverage by Palmetto, or reimbursement at inadequate levels, would have a material adverse impact on market acceptance of our tests. Certain other Medicare contractors are also following the policies adopted by Palmetto for molecular diagnostic tests.

Governmental Regulations

Clinical Laboratory Improvement Amendments of 1988 and State Regulation

As a diagnostic service provider, we are required to hold certain federal, state and local licenses, certifications and permits to conduct our business. As to federal certifications, in 1988, Congress passed the Clinical Laboratory Improvement Amendments ("CLIA") establishing quality standards for all laboratories testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. Our U.S.-based laboratories are CLIA accredited. Under CLIA, a laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of, or assessment of health. CLIA also requires that we hold a certificate applicable to the type of work we perform and comply with certain standards. CLIA further regulates virtually all clinical laboratories by requiring they be accredited by the federal government and comply with various operational, personnel, facilities administration, quality and proficiency requirements intended to ensure that their clinical laboratory testing services are accurate, reliable and timely. CLIA compliance and accreditation is also a prerequisite to be eligible to receive payment for services provided to governmental payor program beneficiaries. CLIA is user-fee funded. Therefore, all costs of administering the program must be covered by the regulated facilities, including certification and survey costs.

We are subject to survey and inspection every two years to assess compliance with program standards, and may be subject to additional unannounced inspections. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. In addition, a laboratory like ours that is certified as "high complexity" under CLIA may obtain analyte specific reagents, which are used as the basis for diagnostic tests that are developed and validated for use in examinations the laboratory performs itself known as laboratory-developed tests ("LDTs").

We participate in the oversight program of the College of American Pathologists ("CAP"). Under CMS requirements, accreditation by CAP is sufficient to satisfy the requirements of CLIA. Therefore, because we are accredited by CAP, we are deemed to also comply with CLIA.

CLIA also provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states have implemented their own more stringent laboratory regulatory schemes. State laws may require that laboratory personnel meet certain qualifications, specify certain quality controls, or prescribe record maintenance requirements. Our clinical operations at our Rutherford and Los Angeles laboratories are required to meet certain state laboratory licensing and other requirements, which in some areas are more stringent than CLIA requirements. Our laboratories are required hold the required licenses and accreditations obtained from the applicable state agencies in which we operate. State clinical laboratory laws generally require that laboratories and/or laboratory personnel meet certain qualifications. State clinical laboratory laws also generally require laboratories to specify certain quality assurance metrics and to maintain certain records. Several states, including Rhode Island, Florida,

Maryland, New York and Pennsylvania, require that clinical laboratories hold licenses to test specimens from patients residing in those states, even though the laboratory is not located in such state. From time to time, other states may require out of state laboratories to obtain licensure in order to accept specimens from the state. If we identify any other state with such requirements or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements. In addition, the New York Department of Health separately approves certain LDTs offered to New York State patients. The Company has obtained the requisite approvals for its LDTs.

Our Rutherford laboratory is licensed and in good standing under the State Departments of Health standards for New Jersey, New York, Pennsylvania, California, Florida and Maryland. Our Los Angeles laboratory is licensed and in good standing in California, New York, Pennsylvania, Rhode Island, Florida and Maryland. If we are found to be out of compliance with applicable federal and state statutory or regulatory standards we may be subject to suspension, restriction or revocation of our laboratory license, civil money penalties, and temporary revocation of Medicare billing privileges. A noncompliant laboratory may also be found guilty of a misdemeanor under applicable state laws. A finding of noncompliance, therefore, may result in harm to our business.

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Our Hershey, Pennsylvania and Melbourne, Australia facilities comply with Good Laboratory Practices ("GLP") to the extent required by the FDA, Environmental Protection Agency, USDA, Organization for Economic Co-operation and Development (OECD), as well as other international regulatory agencies. Furthermore, our early-stage discovery work, which is not subject to GLP standards, is typically carried out under a quality management system or internally developed quality systems. Our facilities are regularly inspected by U.S. and other regulatory compliance monitoring authorities, our clients' quality assurance departments, and our own internal quality assessment program. We are also accredited by AAALAC International, a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. We volunteer to participate in the AAALAC's program to demonstrate our commitment to responsible animal care and use, in addition to our compliance with local, state and federal laws that regulate animal research.

FDA

The U.S. Food and Drug Administration ("FDA") regulates the sale or distribution, in interstate commerce, of medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA"), including in vitro diagnostic test kits, reagents and instruments used to perform diagnostic testing. Such devices must undergo pre-market review by FDA prior to commercialization unless the device is of a type exempted from such review by statute or pursuant to FDA's exercise of enforcement discretion. FDA, to date, has not exercised its authority to actively regulate the development and use of LDTs such as ours as medical devices and therefore we do not believe that our LDTs currently require pre-market clearance or approval.

Section 1143 of the Food and Drug Administration Safety and Innovation Act, signed by the President on July 9, 2012, requires FDA to notify Congress at least 60 days prior to issuing a draft or final guidance regulating LDTS and provide details of the anticipated action. On July 31, 2014, FDA notified Congress pursuant to the FDASIA that it intended to issue draft Guidances that would regulate LDTs. On October 3, 2014, the FDA issued two separate draft guidances: "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" ("The Framework Draft Guidance") and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests" (the "Notification Draft Guidance."). In the Framework Draft Guidance, FDA states that after the Guidances are finalized, it no longer would exercise enforcement discretion with respect to most LDTs and instead would, regulate them in a risk-based manner consistent with the existing classification of medical devices.

The Framework Draft Guidance states that within six months after the Guidances were finalized, all laboratories would be required to give notice to the FDA and provide basic information concerning the nature of the LDTs offered. The FDA then would begin a phased-in review of the LDTs available, based on the risk associated with the tests. For the highest risk LDTs, which the FDA classifies as Class III devices, the Framework Draft Guidance stated that the FDA would begin to require premarket review within 12 months after the Guidance was finalized. Other high risk LDTs would be reviewed over the next four years and then lower risk tests (Class II tests) would be reviewed in the following four to nine years. The Framework Draft Guidance stated that FDA expected to issue a separate Guidance describing the criteria for its risk-based classification 18-24 months after the Guidances were finalized.

On November 18, 2016, the FDA stated that it would not be issuing final guidance on regulation of LDTs and, instead, it would outline its view of an appropriate risk-based approach to LDTs. On January 13, 2017, the FDA released a "Discussion Paper on Laboratory Developed Tests" that synthesizes the feedback that the agency received from various stakeholders on FDA regulation of LDTs "with the hope that it advances public discussion on LDT oversight." The FDA stated in the introduction to the discussion paper: "The synthesis does not represent the formal thinking of the FDA, nor is it enforceable…This document does not represent a final version of the LDT draft guidance documents that were published in 2014." Rather, its purpose is to allow for further public discussion and to give Congress a chance to develop a legislative solution. The discussion paper sets forth a prospective oversight framework that would focus on new and significantly modified high- and moderate-risk LDTs and under which LDTs marketed

before the effective date of the framework would not be expected to comply with most or all FDA regulatory requirements. Also exempt would be low-risk LDTs, LDTs for rare diseases, and others. Premarket review would be phased in over four years, and those tests introduced between the framework's effective date and their phase-in date could continue to be offered for clinical use during the period of premarket review. FDA would expand its third-party premarket review program to include LDTs and coordinate with and leverage existing programs, such as New York State's Clinical Laboratory Evaluation Program and the programs run by organizations run by CLIA to accredit laboratories.

A number of Congressional committees reportedly continue to work with various stakeholders to consider different approaches to regulation of LDTs. It is unclear at this time whether those committees and stakeholders can reach consensus around an approach and develop legislation and whether Congress would pass any such legislation. FDA Commissioner Scott Gottlieb has stated publicly that it would be preferable for Congress to develop a clear legislative framework for the FDA to implement, rather than for the FDA to regulate LDTs through guidance documents. We are monitoring developments in Congress, and in the meantime, we maintain our CLIA accreditation, which permits the use of LDTs for diagnostics purposes.

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In addition to the Draft Guidances discussed above, the FDA has taken other actions that could have an impact on our business. In 2013, FDA issued Final Guidance for industry regarding appropriate labeling and distribution practices for in vitro diagnostic products intended for research or investigational use only. FDA's guidance cautions that labeling or distribution practices that conflict with research or investigational use (e.g., use in clinical diagnostic applications) could subject products shipped with research or investigational use labeling to all applicable requirements of the FDCA as well as enforcement action. As a result of this guidance from the FDA, component suppliers for our LDTs may no longer be willing to distribute components to our clinical laboratory. If this were to occur, we could not produce our LDTs.

On August 6, 2014, the FDA also issued its Final Guidance on In Vitro Companion Diagnostic Devices. According to the Guidance, companion diagnostic devices are in vitro diagnostic devices that provide information that is essential for the safe and effective use of a corresponding therapeutic product. The Guidance notes that in most circumstances, FDA expects to approve or clear a companion diagnostic device and its corresponding therapeutic product contemporaneously, based on the label of the therapeutic product. On July 15, 2016, the FDA released the draft guidance, "Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product." This draft guidance is intended to serve as a guide to assist therapeutic sponsors and in vitro companion diagnostics sponsors in co-developing therapeutic products with an accompanying companion diagnostic, and in fulfilling the FDA's applicable regulatory requirements. If it were determined that any of our tests qualified as In Vitro Companion Diagnostic Devices then we might be required to file for either a 510(k) or a PMA, depending on the nature of the particular test and its corresponding therapeutic product.

Post-market Regulation

Our Tissue of Origin® test obtained clearance under section 510(k) of the FDC Act. After a device, such as our Tissue of Origin® test, is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a company has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for products; and/or
- criminal prosecution.

In addition, FDA could publicly issue a safety notice related to our test or request updates to our product labeling, including the addition of warnings, precautions, or contraindications.

Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH Act")

Under the administrative simplification provisions of HIPAA, as amended by the HITECH Act, the United States Department of Health and Human Services has issued regulations which establish uniform standards governing the conduct of certain electronic health care transactions and protecting the privacy and security of Protected Health Information used or disclosed by health care providers and other covered entities. For further discussion of HIPAA and the impact on our business, see the section entitled "Risk Factors-Risks Related to Our Business-We are required to comply with laws governing the transmission, security and privacy of health information that require significant compliance costs, and any failure to comply with these laws could result in material criminal and civil penalties."

Federal, State and Foreign Fraud and Abuse Laws

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The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under a governmental payor program. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, waivers of co-payments, ownership interests and providing anything at less than its fair market value. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the health care industry, the Department of Health and Human Services has issued a series of regulatory "safe harbors." These safe harbor regulations set forth certain provisions, which, if met, will assure health care providers and other parties that they will not be prosecuted under the federal Anti- Kickback Statute. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. For further discussion of the impact of federal and state health care fraud and abuse laws and regulations on our business, see the section entitled "Risk Factors-Risks Related to Our Business-We are subject to federal and state health care fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws."

In addition to the administrative simplification regulations discussed above, HIPAA also created two new federal crimes: health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from governmental payor programs such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from governmental payor programs.

Finally, another development affecting the health care industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal governmental payor program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has defrauded the federal government by submitting a false claim to the federal government and permit such individuals to share in any amounts paid by the entity to the government in fines or settlement. In addition, various states have enacted false claim laws analogous to the federal False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a governmental payor program. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties ranging from $11,181 to $22,363 for each false claim violation that occurred after January 15, 2018. (Those whose false claims violations that occurred before January 15, 2018 could be liable for treble damages plus lower civil monetary penalties.)

Additionally, in Europe various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines, for individuals and/or companies committing a bribery offense. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the new Bribery Act 2010, which went into effect in July 2011, a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act 2010. Under the new regime, an individual found in violation of the Bribery Act of 2010 faces imprisonment of up to 10 years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to

prevent bribery.

Physician Self-Referral Prohibitions

Under a federal law directed at "self-referral," commonly known as the "Stark Law," there are prohibitions, with certain exceptions, on Medicare and Medicaid payments for laboratory tests referred by physicians who personally, or through a family member, have an investment or ownership interest in, or a compensation arrangement with, the clinical laboratory performing the tests. A person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to $100,000 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law is subject to civil monetary penalties of up to $15,000 per claim submission, an assessment of up to three times the amount claimed and possible exclusion from participation in federal governmental payor programs. Claims submitted in violation of the Stark Law may not be paid by Medicare or Medicaid, and any person collecting any amounts with respect to any such prohibited claim is obligated to refund such amounts. Many states have comparable laws that are not limited to Medicare and Medicaid referrals.

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We are also subject to California's Physician Ownership and Referral Act, or PORA as well as other state laws with self-referral restrictions.

Both the Stark Law and PORA contain an exception for referrals made by physicians who hold investment interests in a publicly traded company that has stockholders' equity exceeding $75 million at the end of its most recent fiscal year or on average during the previous three fiscal years, and which satisfies certain other requirements. In addition, both the Stark Law and PORA contain an exception for compensation paid to a physician for personal services rendered by the physician. Following our acquisition of Response Genetics in the fourth quarter of 2015, we have compensation arrangements with a number of physicians for personal services, such as speaking engagements and specimen tissue preparation. These arrangements were structured with terms intended to comply with the requirements of the personal services exception to Stark Law and PORA.

However, we cannot be certain that regulators would find these arrangements to be in compliance with Stark Law, PORA or similar state laws. If we are deemed to not be in compliance by the applicable regulators, we would be required to refund any payments we receive pursuant to a referral prohibited by these laws to the patient, the payor or the Medicare program, as applicable.

Corporate Practice of Medicine

Numerous states have enacted laws prohibiting business corporations, such as us, from practicing medicine and employing or engaging physicians to practice medicine, generally referred to as the prohibition against the corporate practice of medicine. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed physician. Violation of these laws may result in civil or criminal fines, as well as sanctions imposed against us and/or the professional through licensure proceedings.

Other Regulatory Requirements

Our laboratory is subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemical, biological agents and compounds, blood and bone marrow samples and other human tissue. Typically, we use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors are licensed or otherwise qualified to handle and dispose of such waste.

OSHA has established extensive requirements relating to workplace safety for health care employers, including requirements to develop and implement programs to protect workers from exposure to blood-borne pathogens by preventing or minimizing any exposure through needle stick or similar penetrating injuries.

Segment and Geographical Information

We operate in one reportable business segment and derive revenue from multiple countries, with 94% and 96% coming from the United States in fiscal year 2017 and 2016, respectively.

Research and Development

For the years ended December 31, 2017 and 2016, our research and development expenses were $4.8 million and $6.0 million, respectively, principally in connection with our efforts to develop our proprietary tests.

Employees

As of December 31, 2017, we had a total of 218 full-time and 27 part-time employees, with 24 employees in sales and marketing, 160 employees in research and development and laboratory operations, 30 employees in quality assurance, client project and data management and logistics and 31 employees in general and administrative. None of our employees are represented by a labor union, and we consider our employee relations to be good.

Corporate and Available Information

We were incorporated in the State of Delaware on April 8, 1999. On July 16, 2014 we purchased substantially all of the assets of Gentris Corporation (“Gentris”), a laboratory specializing in pharmacogenomics profiling for therapeutic development, companion diagnostics and clinical trials. On August 18, 2014 we entered into two agreements by which we acquired BioServe Biotechnologies (India) Pvt. Ltd. (“BioServe”), a premier genomics services provider serving both the research and clinical markets in India, and as a result of the acquisition, BioServe became a subsidiary of ours. On October 9, 2015, we acquired substantially all the assets

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and assumed certain liabilities of Response Genetics, Inc. ("Response Genetics"). On August 15, 2017, we purchased all of the outstanding stock of vivoPharm, Pty Ltd. ("vivoPharm"), with its principal place of business in Victoria, Australia, in a transaction valued at approximately $1.6 million in cash, and $8.1 million in the Company's common stock based on the closing price of the stock on August 15, 2017. The Company has deposited in escrow 20% of the stock consideration until the expiration of twelve months from the closing date to serve as the initial source for any indemnification claims and adjustments.

Our principal executive offices are located at 201 Route 17 North, 2nd Floor, Rutherford, New Jersey 07070. Our telephone number is (201) 528-9200 and our corporate website address is www.cancergenetics.com. We include our website address in this annual report on Form 10-K only as an inactive textual reference and do not intend it to be an active link to our website. The information on our website is not incorporated by reference in this annual report on Form 10-K.

This annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports, as well as other documents we file with the U.S. Securities and Exchange Commission ("SEC"), are available free of charge through the Investors section of our website as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. The public can obtain documents that we file with the SEC at www.sec.gov.

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Item 1A. Risk Factors.

Risks Relating to Our Financial Condition and Capital Requirements

We have a history of net losses; we expect to incur net losses in the future, and we may never achieve sustained profitability.

We have historically incurred substantial net losses. We incurred losses of $20.9 million and $15.8 million for fiscal years ended December 31, 2017 and 2016, respectively. From our inception in April 1999 through December 31, 2017, we had an accumulated deficit of $134.8 million. We expect losses to continue principally as a result of difficulties in being able to collect cash from certain third-party payors or obtain reimbursement at adequate prices, or at all, for tests provided to our Clinical Services customers, ongoing research and development expenses and sales and marketing costs. These losses have had, and will continue to have, an adverse effect on our working capital, total assets and stockholders' equity. Because of the numerous risks and uncertainties associated with our research, development and commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows.

Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.

At December 31, 2017, our cash position and history of losses required management to assess our ability to continue operating as a going concern, according to Financial Accounting Standards Board Accounting Standards Update No. 2014-15, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (“ASU 2014-15”). The Company does not have sufficient cash at December 31, 2017 to fund normal operations for the next twelve months. In addition, the Company is in violation of certain financial covenants under its debt agreements at December 31, 2017, January 31, 2018, February 28, 2018 and March 31, 2018. The Company's ability to continue as a going concern is dependent on the Company's ability to obtain a waiver of its financial covenant violations, raise additional equity or debt capital or spin-off non-core assets to raise additional cash. These factors raise substantial doubt about the Company's ability to continue as a going concern.

We have hired Raymond James & Associates, Inc. as our financial advisor to assist with evaluating strategic alternatives. Such alternatives could include raising more capital, the acquisition of another company and/or complementary assets, the sale of the Company or another type of strategic partnership. We can provide no assurances that our current actions will be successful or that additional sources of financing with be available to us on favorable terms, if at all.

The consolidated financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

We are in default of financial covenants in the credit agreements with our senior lenders and need to obtain a waiver or amendment.

On March 22, 2017, we restructured our debt with Silicon Valley Bank, by repaying the outstanding term loan and entering into a new two year $6.0 million asset-based revolving line of credit agreement. We concurrently entered into a new $6.0 million term loan agreement with Partners for Growth, which, on the day of closing, increased our indebtedness from $4.4 million to $6.0 million and, increased our available cash by $1.6 million. We may be able to borrow up to $6.0 million on the revolver, based on a formula tied to eligible accounts receivable. However, due to the

terms of the revolver, we have reached the borrowing limit based on eligible accounts receivable at December 31, 2017. In addition, as a result of the significant increase in our bad debt allowance in the fourth quarter of 2017 and other factors, as of December 31, 2017, January 31, 2018, February 28, 2018 and March 31, 2018, we were in violation of the financial covenants under the loan agreements. We are in discussion with PFG and SVB to amend the terms of the loan agreement which would, among other modifications, cure the default and reset the financial covenants. However, no assurances can be given that the lenders will agree to any such waiver or amendment, nor as to the cost or consequences to us of the terms of any such waiver or amendment if one is reached. If our lenders were to declare a default and seek repayment of the loans we would not have adequate capital to make such payment and continue to operate our business.

We will need to raise additional capital to fund our existing operations, to develop, validate and commercialize new tests and technologies, to expand our operations and to repay indebtedness.

We will need to raise additional financing to fund our operations, to develop, validate and commercialize new tests and technologies, to expand our operations and to repay indebtedness. At December 31, 2017, we had unrestricted cash and cash

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equivalents of $9.5 million. Net cash used in operating activities was $13.6 million and $17.9 million for the years ended December 31, 2017 and 2016.

The Company has retained Raymond James & Associates, Inc. as a financial advisor to assist the Company in its evaluation of a broad range of financial and strategic alternatives to enhance shareholder value, including additional capital raising transactions, the acquisition of another company or complementary assets or the potential sale or merger of the Company or another type of strategic partnership. There is no assurance that the review of strategic alternatives will result in the Company changing its business plan, pursuing any particular transaction, if any, or, if it pursues any such transaction, that it will be completed. The Company does not expect to make further public comment regarding the strategic review until the Board of Directors has approved a specific transaction or otherwise deems disclosure of significant developments is appropriate.

We believe that our current cash and availability under our revolving line of credit will support operations for approximately 6 months from the date of this report. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all, when needed. Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative, sales and marketing and research and development activities are forward-looking statements and involve risks and uncertainties. Absent sufficient additional financing, we may be unable to remain a going concern.

Additional financing may be from the sale of equity or convertible or other debt securities in a public or private offering, from an additional or new credit facility or from a strategic partnership coupled with an investment in us or a combination of forms. We continue to evaluate our operations and take steps to improve our operating cash flow. We can provide no assurances that our current actions will be successful or that any additional sources of financing will be available to us on favorable terms, if at all, when needed. Furthermore, certain provisions of the securities purchase agreements we entered into in May 2016 and September 2016, may limit our ability to raise additional capital on favorable terms, or at all, including a prohibition on entering into variable rate transactions, such as an equity line, while the 5-year warrants issued in May and September 2016 remain outstanding. Our failure to raise additional capital and in sufficient amounts when needed may significantly impact our ability to operate our business. For further discussion of our liquidity requirements, see the section titled “Liquidity and Capital Resources-Capital Resources and Expenditure Requirements.”

We also may need to raise capital to expand our business to meet our long-term business objectives, including to:

- increase our sales and marketing efforts to drive market adoption and address competitive developments;
- fund development, validation and marketing efforts of current and future tests;
- comply with current and evolving regulatory requirements;
- further expand our clinical laboratory operations;
- expand our technologies into other types of cancer;
- acquire, license or invest in technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

Our present and future funding requirements and our forecast of the period of time through which our current financial resources will be adequate to support our operations will depend on many factors, including:

- our ability to achieve revenue growth;
- our ability to amend our credit agreements;
- our ability to continue to reduce our costs and improve our operational efficiency;

- our ability to develop and obtain approvals for our new diagnostic tests and the costs associated with such research and development activities;
- our ability to execute on our marketing and sales strategy for our tests and services and gain acceptance of our tests and services in the market;
- our ability to obtain adequate reimbursement from governmental and other third-party payors for our tests and services;
- the costs, scope, progress, results, timing and outcomes of the clinical trials of our diagnostic tests;
- the costs of operating and enhancing our laboratory facilities;
- the costs of additional general and administrative personnel;
- the timing of and the costs involved in regulatory compliance, particularly if the regulations relating to laboratory developed tests ("LDTs") change;
- the timing of and costs involved in regulatory compliance, particularly if the regulations relating the PPACA (Patient Protection and Affordable Care Act) change;

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- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the effect of competing technological and market developments;
- costs related to international expansion; and
- our ability to secure financing and the amount thereof.

The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also could provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, those debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations and increase our interest expense. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or tests, or grant licenses on terms that are not favorable to us.

Additional equity or debt financing might not be available on reasonable terms, if at all. If we cannot secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or sales and marketing initiatives. In addition, we may have to work with a partner on one or more of our development programs, which could lower the economic value of those programs to us.

We identified a material weakness in our internal control over financial reporting. If we are not able to remediate the material weakness and otherwise maintain an effective system of internal control over financial reporting, the reliability of our financial reporting, investor confidence in us and the value of our common stock could be adversely affected.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of SOX, or Section 404, requires that we evaluate and determine the effectiveness of our internal controls over financial reporting and provide a management report on internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

During the fourth quarter of 2017, we identified a material weakness in our internal control over financial reporting related to our controls over accounting for uncollectible Clinical Services revenue, which prevented the Company from identifying and properly recording contractual allowances during the fourth quarter. As a result, amounts that should have been reported as reductions in revenue were instead reported as bad debt expense. We are committed to remediating the material weakness in a timely fashion. We have begun the process of implementing changes to our internal control over financial reporting to remediate the control deficiencies that gave rise to the material weakness, including further improvements in our processes and analyses that support the estimate of the allowance for doubtful accounts and the related bad debt expense and performing a comprehensive review of the need for additional corporate accounting and financial personnel, supplemented by external resources as appropriate, with the requisite skill and technical expertise. We expect this deficiency to be corrected as part of the implementation of ASU 2014-09 effective January 1, 2018.

If our steps are insufficient to successfully remediate the material weakness and otherwise establish and maintain an effective system of internal control over financial reporting, the reliability of our financial reporting, investor confidence in us and the value of our common stock could be materially and adversely affected. Effective internal control over financial reporting is necessary for us to provide reliable and timely financial reports and, together with adequate disclosure controls and procedures, are designed to reasonably detect and prevent fraud. Any failure to

implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. For as long as we are an “emerging growth company” under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an “emerging growth company” until December 31, 2018, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $1.07 billion, (ii) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three year period. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

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Moreover, we do not expect that disclosure controls or internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Failure of our control systems to prevent error or fraud could materially adversely impact us.

Our outstanding warrants and stock options may have an adverse effect on the market price of shares of our common stock

As of March 9, 2018, we had issued and outstanding warrants to purchase 10,054,990 shares of our common stock at a weighted-average exercise price of $3.80 per share. We also have outstanding options to purchase an aggregate of 2,599,023 shares of our common stock. The sale, or even the possibility of sale, and the uncertainty with respect to the timing of any sales, of the shares underlying these securities, particularly the warrants, could have an adverse effect on the market price of our common stock and on our ability to obtain future financing at prices we deem satisfactory, or at all. If and to what extent these warrants and/or options are exercised, you may experience dilution to your holdings.

Risks Relating to Our Business and Strategy

If we are unable to increase sales of our tests and services or to successfully develop and commercialize other proprietary tests, our revenues will be insufficient for us to achieve profitability.

We currently derive substantially all of our revenues from our testing services and laboratory and CRO services. We have only recently begun offering our proprietary Focus::NGS® panels through our CLIA-certified, CAP-accredited and state licensed laboratories. We are in varying stages of research and development for other diagnostic tests that we may offer.

Biopharma Services are services and tests provided to pharmaceutical and biotech companies and clinical research organizations in connection with phase I, phase II or phase III studies for development of therapeutic drugs. The nature of these services is that they tend to come in relatively large projects but episodically, rather than providing steady sources of revenues. It is unclear at this stage of our development whether we will be able to maintain and grow the number of pharmaceutical and biotech companies and clinical research organizations who will avail themselves of our services, or how regular a flow of drug development projects we will be able to obtain from existing customers.

Discovery Services are services that include proprietary preclinical test systems supporting our clinical diagnostic and prognostic offerings at early stages, supporting the pharmaceutical industry, biotechnology companies and academic research centers. In particular, our preclinical development of biomarker detection methods, response to immuno-oncology directed novel treatments and early prediction of clinical outcome is supported by our extended portfolio of orthotopic, xenografts and syngeneic tumor test systems. Since this acquisition if relatively new, it is unclear whether we will be able to maintain and grow the number of pharmaceutical and biotech companies and clinical research organizations who will avail themselves of our services, or how regular a flow of drug development projects we will be able to obtain from existing customers.

If we are unable to increase sales of our tests and services or to successfully develop, validate and commercialize other diagnostic tests, we will not produce sufficient revenues to become profitable.

If pathologists and oncologists decide not to order our diagnostic tests and/or pharmaceutical and biotech companies and clinical research organizations decide not to use our diagnostic tests and services and our CRO services in connection with their clinical trials, we may be unable to generate sufficient revenue to sustain our business.

To generate demand for our Clinical Services, we will need to educate oncologists and pathologists on the clinical utility, benefits and value of each type of test we provide through published papers, presentations at scientific conferences and one-on-one education sessions by members of our sales force. In addition, we will need to assure oncologists and pathologists of our ability to obtain and maintain coverage and adequate reimbursement from third-party payors. To generate demand for our Biopharma Services and Discovery Services, we need to educate pharmaceutical and biotech companies and clinical research organizations on the utility of our tests and services to improve the outcomes of clinical trials for new oncology drugs and more rapidly advance targeted therapies through the clinical development process through published papers, presentations at scientific conferences and one-on-one education sessions by members of our sales force. We may need to hire additional commercial, scientific, technical and other personnel to support this process. If we cannot convince medical practitioners, pharmaceutical and biotech companies or clinical research organizations to order our diagnostic tests or other future tests we develop, we will likely be unable to create demand for our tests in sufficient volume for us to achieve sustained profitability.

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The potential loss or delay of our large contracts or of multiple contracts could adversely affect our results.

Most of our Discovery Services customers can terminate our contracts upon 30 to 90 days notice. These customers may delay, terminate or reduce the scope of our contracts for a variety of reasons beyond our control, including but not limited to:

- decisions to forego or terminate a particular clinical trial;
- lack of available financing, budgetary limits or changing priorities;
- production problems resulting in shortages of the drug being tested;
- failure of products being tested to satisfy safety requirements or efficacy criteria;
- unexpected or undesired clinical results for products;
- shift of business to a competitor or internal resources; or
- shut down of manufacturing facilities.

As a result, contract terminations, delays and alterations are a possible outcome in our Discovery Services business. In the event of termination, our contracts often provide for fees for winding down the project, but these fees may not be sufficient for us to maintain our margins, and termination may result in lower resource utilization rates. In addition, we may not realize the full benefits of our backlog of contractually committed services if our customers cancel, delay or reduce their commitments under our contracts with them, which may occur if, among other things, a customer decides to shift its business to a competitor or revoke our status as a preferred provider. Thus, the loss or delay of a large contract or the loss or delay of multiple contracts could adversely affect our revenues and profitability. We believe the risk of loss or delay of multiple contracts potentially has greater effect where we are party to broader partnering arrangements with global biopharmaceutical companies.

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

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

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

Uncertainty surrounds third-party payor coverage and reimbursement of any test incorporating new technology, including tests developed using our NGS panels. Technology assessments of new medical tests and devices conducted by research centers and other entities may be disseminated to interested parties for informational purposes. Third-party payors and health care providers may use such technology assessments as grounds to deny coverage for a test or procedure.

Because each payor generally determines for its own enrollees or insured patients whether to cover or otherwise establish a policy to reimburse our diagnostic tests, seeking payor approvals is a time-consuming and costly process. We cannot be certain that coverage for our tests will be provided in the future by additional third-party payors or that

existing contracts, agreements or policy decisions or reimbursement levels will remain in place or be fulfilled under existing terms and provisions. If we cannot obtain coverage and reimbursement from private and governmental payors such as Medicare and Medicaid for our current tests, or new tests or test enhancements that we may develop in the future, our ability to generate revenues from our clinical services could be limited, which may have a material adverse effect on our financial condition, results of operations and cash flow. Further, we have experienced in the past, and will likely experience in the future, delays and temporary interruptions in the receipt of payments from third-party payors due to missing documentation and other issues, which could cause delay in collecting our revenue.

Our quarterly operating results may be subject to significant fluctuations and may be difficult to forecast.

In recent years, we have been expanding our Biopharma Services business. The nature of these services is that they tend to come in relatively large projects but episodically, rather than providing steady sources of revenues. The timing, size and duration of our contracts with pharmaceutical and biotech companies and clinical research organizations depend on the size,

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pace and duration of such customer's clinical trial, over which we have no control and sometimes limited visibility. In addition, our expense levels are based, in part, on expectation of future revenue levels. A shortfall in expected revenue could, therefore, result in a disproportionate decrease in our net income. As a result, our quarterly operating results may be subject to significant fluctuations and may be difficult to forecast.

If we are unable to successfully validate our laboratory tests and services, we will not be able to increase revenues.

Pathologists and oncologists may not order our proprietary tests, and third-party payors may not reimburse for our tests, unless we are able to provide compelling evidence that the tests are useful to patient treatment and produce actionable information with respect to the diagnosis, prognosis and theranosis of the various cancers on which our work is focused. In addition, pharmaceutical and biotech companies and clinical research organizations may not order our proprietary tests unless we are able to provide compelling evidence that such tests improve the outcomes of clinical trials for new oncology drugs and allow pharmaceutical and biotech companies to more rapidly advance targeted therapeutics. While we have validated all of the tests that we currently offer, we believe that we will need to finance and successfully complete additional and more powerful studies, and then effectively disseminate the results of those studies, to drive widespread adoption of our tests and thereby increase our revenues.

If the market for our tests and services does not experience significant growth or if our tests and services do not achieve broad acceptance, our operations will suffer.

We cannot accurately predict the future growth rate or the size of the market for our tests and services. The expansion of this market depends on a number of factors, such as:

- the results of clinical trials;
- the cost, performance and reliability of our tests and services, and the tests and services offered by competitors;
- customers' perceptions regarding the benefits of our tests and services;
- customers' satisfaction with our tests and services; and
- marketing efforts and publicity regarding our tests and services.

Our financial results may be adversely affected if we underprice our contracts, overrun our cost estimates or fail to receive approval for or experience delays in documenting change orders.

Most of our Discovery Services contracts are either fee for service contracts or fixed-fee contracts. Our past financial results have been, and our future financial results may be, adversely impacted if we initially underprice our contracts or otherwise overrun our cost estimates and are unable to successfully negotiate a change order. Change orders typically occur when the scope of work we perform needs to be modified from that originally contemplated by our contract with the customer. Modifications can occur, for example, when there is a change in a key clinical trial assumption or parameter or a significant change in timing. Where we are not successful in converting out-of-scope work into change orders under our current contracts, we bear the cost of the additional work. Such underpricing, significant cost overruns or delay in documentation of change orders could have a material adverse effect on our business, results of operations, financial condition or cash flows.

If we fail to perform our services in accordance with contractual requirements, regulatory standards and ethical considerations, we could be subject to significant costs or liability and our reputation could be harmed.

In connection with our Discovery Services business, we contract with biopharmaceutical companies to provide specialized services to assist them in planning and conducting unique, specialized studies to guide drug discovery and development programs with a concentration in oncology and immuno-oncology. Our services include monitoring

clinical trials, data and laboratory analysis, electronic data capture and other related services. Such services are complex and subject to contractual requirements, regulatory standards and ethical considerations. If we fail to perform our services in accordance with these requirements, regulatory agencies may take action against us for failure to comply with applicable regulations governing clinical trials. Customers may also bring claims against us for breach of our contractual obligations. Any such action could have a material adverse effect on our results of operations, financial condition and reputation.

Such consequences could arise if, among other things, the following occur:

Improper performance of our services. The performance of clinical development services is complex and time-consuming. For example, we may make mistakes in conducting a clinical trial that could negatively impact or obviate the usefulness of the clinical trial or cause the results of the clinical trial to be reported improperly. If the clinical trial results are compromised, we

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could be subject to significant costs or liability, which could have an adverse impact on our ability to perform our services. As examples:

- non-compliance generally could result in the termination of ongoing clinical trials or sales and marketing projects or the disqualification of data for submission to regulatory authorities;
- compromise of data from a particular clinical trial, such as failure to verify that informed consent was obtained from patients, could require us to repeat the clinical trial under the terms of our contract at no further cost to our customer, but at a substantial cost to us; and
- breach of a contractual term could result in liability for damages or termination of the contract.

While we endeavor to contractually limit our exposure to such risks, improper performance of our services could have an adverse effect on our financial condition, damage our reputation and result in the cancellation of current contracts by or failure to obtain future contracts from the affected customer or other customers.

Investigation of customers. From time to time, one or more of our customers are audited or investigated by regulatory authorities or enforcement agencies with respect to regulatory compliance of their clinical trials, programs or the marketing and sale of their drugs. In these situations, we have often provided services to our customers with respect to the clinical trials, programs or activities being audited or investigated, and we are called upon to respond to requests for information by the authorities and agencies. There is a risk that either our customers or regulatory authorities could claim that we performed our services improperly or that we are responsible for clinical trial or program compliance. If our customers or regulatory authorities make such claims against us and prove them, we could be subject to damages, fines or penalties. In addition, negative publicity regarding regulatory compliance of our customers' clinical trials, programs or drugs could have an adverse effect on our business and reputation.

If we fail to perform our Biopharma Services in accordance with contractual and regulatory requirements, and ethical considerations, we could be subject to significant costs or liability.

Through our Biopharma Services offering, we contract with pharmaceutical and biotech companies to perform a wide range of services to assist them in bringing new therapeutics to market. Our services include monitoring clinical trials, data and laboratory analysis, clinical trial design consulting, data capture and other related services. Such services are complex and subject to contractual requirements, regulatory standards and ethical considerations. For example, our services are subject to regulation by the FDA, and comparable foreign regulatory authorities relating to our activities in conducting clinical trials. If we fail to perform our services in accordance with these requirements, regulatory authorities may take action against us or our customers. Such actions may include failure of such regulatory authority to grant marketing approval of our customers' products, imposition of holds or delays, suspension or withdrawal of approvals, rejection of data collected, laboratory license revocation, product recalls, operational restrictions, civil or criminal penalties or prosecutions, damages or fines. Any such action could have a material adverse effect on our business.

If we are unable to attract suitable investigators and patients for our clinical trials, our clinical development business might suffer.

The timely recruitment of investigators and patients for clinical trials is essential to our CRO services business. Investigators are typically located at hospitals, clinics or other sites and supervise the administration of the investigational drug to patients during the course of a clinical trial. Patients generally include people from the communities in which the clinical trials are conducted. Our CRO services business could be adversely affected if we are unable to attract suitable and willing investigators or patients for clinical trials on a consistent basis. For example, if we are unable to engage investigators to conduct clinical trials as planned or enroll sufficient patients in clinical trials, we might need to expend additional funds to obtain access to resources or else be compelled to delay or modify

the clinical trial plans, which may result in additional costs to us.

If we are unable to manage growth in our business, our prospects may be limited and our future results of operations may be adversely affected.

We intend to continue with our research and development activities, our sales and marketing programs and other activities as needed to meet future demand. Any significant expansion may strain our managerial, financial and other resources. If we are unable to manage such growth, our business, operating results and financial condition could be adversely affected. We will need to improve continually our operations, financial and other internal systems to manage its growth effectively, and any failure to do so may lead to inefficiencies and redundancies, and result in reduced growth prospects and diminished operational results.

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

Part of our current business strategy focuses on discovering, developing and commercializing molecular, genomic and genetic diagnostic tests and services. We believe the success of our business depends on our ability to fully validate and commercialize our existing diagnostic tests and services and to develop and commercialize new diagnostic tests. We have multiple tests we are currently offering and in development, but research, development and commercialization of diagnostic tests is time-consuming, uncertain and complex.

Tests we currently offer in our laboratory, or any additional technologies that we may develop, may not succeed in reliably diagnosing or predicting the recurrence of cancers with the sensitivity and specificity necessary to be clinically useful, and thus may not succeed commercially. In addition, prior to or an in continuing in conjunction with commercializing our diagnostic tests, we must undertake time-consuming and costly development activities, including clinical studies, and obtain regulatory clearance or approval, which may be denied. This development process involves a high degree of risk, substantial expenditures and will occur over several years. Our development efforts may fail for many reasons, including:

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

Tests that appear promising in early development may fail to be validated in subsequent studies, and even if we achieve positive results, we may ultimately fail to obtain the necessary regulatory clearances or approvals. There is substantial risk that our research and development projects will not result in commercial tests, and that success in early clinical trials will not be replicated in later studies. At any point, we may abandon development of a test or be required to expend considerable resources repeating clinical trials, which would adversely impact the timing for generating potential revenues from that test. In addition, as we develop tests, we will have to make significant investments in research, development and marketing resources. If a clinical validation study of a particular test then fails to demonstrate the outlined goals of the study, we might choose to abandon the development of that test. Further, our ability to develop and launch diagnostic tests will likely depend on our receipt of additional funding. If our discovery and development programs yield fewer commercial tests than we expect, we may be unable to execute our business plan, which may adversely affect our business, financial condition and results of operations.

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

As part of our business strategy, we may pursue other acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our offerings or distribution. For example, we acquired vivoPharm in 2017, Response Genetics, Inc. in 2015 and Gentris Corporation in 2014, and we entered into a joint venture in May 2013 with Mayo Foundation for Education and Research. We have developed experience with acquiring other companies and forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies,

which could have a material negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

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

We conduct business in a heavily regulated industry, and if we are unable to obtain regulatory clearance or approvals in the United States, if we experience delays in receiving clearance or approvals, or if we do not gain acceptance from other laboratories of any cleared or approved diagnostic tests at their facilities, our growth strategy may not be successful.

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We currently offer our proprietary tests in conjunction with our comprehensive panel of laboratory services in our CLIA-certified and CAP-accredited laboratory. Because we currently offer these tests and services solely for use within our laboratory, we believe we may market the tests as laboratory developed tests (LDTs), which are tests designed, manufactured and used within a single laboratory. Although the Food and Drug Administration (“FDA”) has statutory authority to assure that medical devices, including LDTs, are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to LDTs. Specifically, under current FDA enforcement policies and guidance, LDTs generally do not require FDA premarket clearance or approval before commercialization, and we have marketed our LDTs on that basis. While we believe that we are currently in material compliance with applicable laws and regulations as historically enforced by the FDA, we cannot assure you that the FDA will agree with our determination, and a determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations or financial condition.

If we were to offer our tests through third-party laboratories, these tests would most likely not be subject to the FDA's current exercise of enforcement discretion over LDTs, and would be subject to the applicable medical device regulations. For example, these tests could become subject to the FDA's requirements for premarket review. Unless an exemption applies, generally, before a new medical device or a new use for a medical device may be sold or distributed in the United States, the medical device must receive either FDA clearance of a 510(k) pre-market notification or pre-market approval. As a result, before we can market or distribute our tests in the United States for use by other clinical testing laboratories, we must first obtain pre-market clearance or pre-market approval from FDA. We have not yet applied for clearance or approval from FDA, and would need to complete additional validations before we are ready to apply. We believe it would likely take two years or more to conduct the studies and trials necessary to obtain approval from FDA to commercially launch any of our proprietary products outside of our clinical laboratory. Once we do apply, we may not receive FDA clearance or approval for the commercial use of our tests on a timely basis, or at all. If we are unable to obtain clearance or approval or if clinical diagnostic laboratories do not accept our tests, our ability to grow our business by deploying our tests could be compromised.

The Federal Food and Drug Administration may impose additional regulatory obligations and costs upon our business.

On October 3, 2014 the FDA issued two draft guidance documents regarding its intent to modify its policy of enforcement discretion and increase oversight over LDTs. The two draft guidance documents are entitled “Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)” (the “Framework Draft Guidance”) and “FDA Notification and Medical Device Reporting for Laboratory Developed Test (LDTs)" (the "Notification Draft Guidance”). In the Framework Draft Guidance, FDA stated that after the Guidances are finalized, it no longer would exercise enforcement discretion with respect to most LDTs and instead would regulate them in a risk-based manner consistent with the existing classification of medical devices. The Framework Draft Guidance stated that within six months after the Guidances were finalized, all laboratories would be required to give notice to the FDA and provide basic information concerning the nature of the LDTs offered. The FDA then would begin a phased-in review of the LDTs available, based on the risk associated with the tests. For the highest risk LDTs, which the FDA classifies as Class III devices, the Framework Draft Guidance stated that the FDA would begin to require premarket review within 12 months after the Guidance was finalized. Other high risk LDTs would be reviewed over the next four years and then lower risk tests (Class II tests) would be reviewed in the following four to nine years. The Framework Draft Guidance stated that FDA expected to issue a separate Guidance describing the criteria for its risk-based classification 18-24 months after the Guidances were finalized.

On November 18, 2016, the FDA stated that it would not be issuing final guidance on regulation of LDTs and, instead, it would outline its view of an appropriate risk-based approach to LDTs. On January 13, 2017, the FDA released a “Discussion Paper on Laboratory Developed Tests” that synthesizes the feedback that the agency received from various stakeholders on FDA regulation of LDTs “with the hope that it advances public discussion on LDT

oversight." The FDA stated in the introduction to the discussion paper: "The synthesis does not represent the formal thinking of the FDA, nor is it enforceable…This document does not represent a final version of the LDT draft guidance documents that were published in 2014." Rather, its purpose is to allow for further public discussion and to give Congress a chance to develop a legislative solution. As the 115th Congress gets underway, a number of Congressional committees reportedly are working with various stakeholders to consider different approaches to regulation of LDTs. It is unclear at this time whether those committees and stakeholders can reach consensus around an approach and develop legislation and whether Congress would pass any such legislation.

If we and our tests become subject to FDA's enforcement of its medical device regulations with respect to LDTs, we may be subject to significant and onerous regulatory obligations. See section entitled "Risk Factors-Regulatory Risks Relating to Our Business-If the FDA regulates LDTs as proposed, then it would classify LDTs according to the current system used to regulate medical devices. Under that system, there are three different classes of medical devices, with the requirements becoming more stringent depending on the Class."

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

Although we believe that our tests represent promising commercial opportunities, our tests may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or profits for us. We need to continue to develop a market for our tests through physician education and awareness programs. Gaining acceptance in medical communities requires that we perform additional studies after validating the efficacy of our tests and services for the diagnosis, prognosis and treatment of cancer, and that we obtain acceptance of the results of those studies using our tests for publication in leading peer-reviewed medical journals. The results of any studies are always uncertain and even if we believe such studies demonstrate the value of our tests, they process of publication in leading medical journals is subject to a peer review process and peer reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our studies published in peer-reviewed journals would limit the adoption of our tests. Our ability to successfully market the tests that we may develop will depend on numerous factors, including:

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

Failure to achieve widespread market acceptance of our diagnostic tests would materially harm our business, financial condition and results of operations.

Our agreement with Mayo Clinic may not proceed successfully.

In November 2011, we entered into an affiliation agreement with the Mayo Foundation for Medical Education and Research, subsequently amended. Under the agreement, we formed a joint venture in May 2013 to focus on developing oncology diagnostic services and tests utilizing next generation sequencing. We have made $2.0 million in capital contributions to that joint venture through December 31, 2017. We do not expect to make additional capital contributions to the joint venture entity’s operational activities. The operation of the joint venture may also divert management time from operating our business. No assurances can be given that we will be able to fully fund our obligations under the joint venture agreement, or that, even if funded, the joint venture will ever achieve the research, development and commercial objectives currently contemplated by the parties, such as the discovery and commercialization of new diagnostic tests utilizing next-generation sequencing. If the development efforts of the joint venture do not result in commercially successful tests or services, it will have an adverse effect on our business, financial condition and results of operations.

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

In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. There are several new cancer drugs under development that may increase patient survival time. There have also been advances in methods used to analyze very large amounts of genomic information. We must continuously develop new tests and enhance our existing tests to keep pace with evolving standards of care. Our existing tests could become obsolete unless we continually innovate and expand them to demonstrate benefit in patients treated with new therapies. New cancer therapies typically have only a few years of clinical data associated with them, which limits our ability to perform clinical studies and correlate sets of genes to a new treatment's effectiveness. If we cannot

adequately demonstrate the applicability of our tests to new treatments, sales of our tests and services could decline, which would have a material adverse effect on our business, financial condition and results of operations.

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

Our success depends on the market's confidence that we can continue to provide reliable, high-quality diagnostic tests. We believe that our customers are likely to be particularly sensitive to test defects and errors. As a result, the failure of our tests or services to perform as expected would significantly impair our reputation and the public image of our tests and services, and we may be subject to legal claims arising from any defects or errors.

There is a scarcity of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite technical skills, we may be unable to successfully execute our business strategy.

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The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field. Our future success depends upon our ability to attract and retain highly skilled personnel (including medical, scientific, technical, commercial, business, regulatory and administrative personnel) necessary to support our anticipated growth, develop our business and perform certain contractual obligations. Given the scarcity of professionals with the scientific knowledge that we require and the competition for qualified personnel among life science businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations. The loss of a key employee, the failure of a key employee to perform in his or her current position or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy.

The loss or transition of any member of our senior management team or our inability to attract and retain highly skilled scientists, clinicians, and salespeople could adversely affect our business.

Our success depends on the skills, experience, and performance of key members of our senior management team. The individual and collective efforts of these employees will be important as we continue to develop our tests and services, and as we expand our commercial activities. The loss or incapacity of existing members of our senior management team could adversely affect our operations if we experience difficulties in hiring qualified successors.

In February 2018, Panna Sharma resigned as our chief executive officer and John A. Roberts, our Chief Operating Officer and Executive Vice President, Finance, succeeded him as our interim chief executive officer. The complexity inherent in integrating a new key member of the senior management team with existing senior management may limit the effectiveness of any such successor or otherwise adversely affect our business. Leadership transitions can be inherently difficult to manage and may cause uncertainty or a disruption to our business or may increase the likelihood of turnover of other key officers and employees. Specifically, a leadership transition in the commercial team may cause uncertainty about or a disruption to our commercial organization, which may impact our ability to achieve sales and revenue targets.

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

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

We have indebtedness with restrictive covenants that limit our ability to obtain additional debt financing and that requires us to comply with certain financial covenants, which could have a material adverse effect on our financial condition, our ability to fund operations, and react to changes in our business.

As of April 2, 2018, we had approximately $4.1 million of indebtedness for borrowed money under our credit facility with Silicon Valley Bank and $6.0 million under our term loan with Partners for Growth due on March 22, 2020. Repayments of amounts borrowed under the credit facility may be accelerated if an event of default occurs, which includes, among other things, a violation of financial covenants and negative covenants We are currently in default with respect to certain financial covenants with such lenders, and no assurances can be given that such lenders will agree to waive or amend such covenants and forbear from calling our loan, which would have a material adverse effect on our ability to continue as a going concern. Even if we successfully negotiate a waiver or amendment, the agreements restrict us from, among other things, paying cash dividends, incurring debt and entering into certain transactions without the prior consent of the lenders. Any waiver or amendment which we may reach with our lenders may impose additional restrictions on our operations or uses of cash. Our debt and related covenants could limit our ability to satisfy our obligations, limit our ability to operate our business and impair our competitive position. For example, it could:

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- require us to dedicate a substantial portion of our cash flow from operations to payments on our debt, reducing the availability of our cash flow from operations to fund working capital, capital expenditures or other general corporate purposes;
- limit our flexibility in planning for, or reacting to, changes in our business and industry;
- place us at a disadvantage compared to competitors that may have proportionately less debt; and
- increase our cost of borrowing.

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

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

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

Further, if any of our laboratories became inoperable we may not be able to license or transfer our proprietary technology to a third-party, with established state licensure and CLIA certification under the scope of which our diagnostic tests could be performed following validation and other required procedures, to perform the tests. Even if we find a third-party with such qualifications to perform our tests, such party may not be willing to perform the tests for us on commercially reasonable terms. Moreover, we believe our tests are currently subject to an exercise of enforcement discretion by the FDA because the tests are considered LDTs. If we are required to find a third-party laboratory to conduct our testing services, we believe the FDA would consider our tests to be medical devices that are no longer subject to its exercise of enforcement discretion for LDTs. In that case, we may be required to obtain premarket clearance or approval prior to offering our tests, which would be time-consuming and costly and could result in delays in our ability to sell or offer our tests.

If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenues or achieve and sustain profitability.

We face competition from mainstream diagnostic methods that pathologists and oncologists use and have used for many years. It may be difficult to change the methods or behavior of the referring pathologists and oncologists to incorporate our molecular diagnostic testing in their practices. We believe that we can introduce our diagnostic tests successfully due to their clinical utility and the desire of pathologists and oncologists to find solutions for more accurate diagnosis, prognosis and personalized treatment options for cancer patients.

We also face competition from companies that currently offer or are developing products to profile genes, gene expression or protein biomarkers in various cancers. Precision medicine is a new area of science, and we cannot

predict what tests others will develop that may compete with or provide results superior to the results we are able to achieve with the tests we develop. Our competitors include public companies such as Abbott Laboratories, Inc., bioTheranostics, Inc., Foundation Medicine, Inc., Genomic Health, Inc., Invitae Corp., Johnson & Johnson, Myriad Genetics Inc., Nant Health, NeoGenomics, Inc., Quest Diagnostics, Roche Molecular Systems, Inc., and many private companies. We expect that pharmaceutical and biotech companies will increasingly focus attention and resources on the personalized diagnostic sector as the potential and prevalence increases for molecularly targeted oncology therapies approved by FDA along with companion diagnostics.

With respect to our clinical laboratory business we face competition from companies such as Bio-Reference Laboratories, Inc. (a division of Opko), Genoptix Medical Laboratory, Invitae Corp., LabCorp, NeoGenomics, Inc., and Quest Diagnostics. With respect to our Discovery Services, including our CRO services, we face competition from companies that offer or are developing animal models for tumors and that have capabilities in toxicology and pharmacology testing. Our competitors in our

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

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

Due to the early stage nature of our business and our limited sales and marketing activities to date, we have historically derived a significant portion of our revenue from a limited number of test ordering sites, although the test ordering sites that generate a significant portion of our revenue may change from period to period. Our test ordering sites are largely hospitals, cancer centers, reference laboratories and physician offices, as well as pharmaceutical and biotech companies as part of a clinical trial. Oncologists and pathologists at these sites order the tests on behalf of the needs of their oncology patients or as part of a clinical trial sponsored by a pharmaceutical and biotech company in which the patient is being enrolled. The top five test ordering clients during 2017 and 2016 accounted for 38% and 31%, respectively, of our testing volumes. During the year ended December 31, 2017, one Biopharma client accounted for approximately 11% of our revenue. During the year ended December 31, 2016 one Biopharma client accounted for approximately 16% of our revenue.

If we fail to perform our Biopharma Services in accordance with contractual and regulatory requirements, and ethical considerations, we could be subject to significant costs or liability.

Through our Biopharma Services offering, we contract with pharmaceutical and biotech companies to perform a wide range of services to assist them in bringing new therapeutics to market. Our services include monitoring clinical trials, data and laboratory analysis, clinical trial design consulting, data capture and other related services. Such services are complex and subject to contractual requirements, regulatory standards and ethical considerations. For example, we are subject to regulation by the FDA, and comparable foreign regulatory authorities relating to our activities in conducting pre-clinical studies and clinical trials. If we fail to perform our services in accordance with these requirements, regulatory authorities may take action against us or our customers. Such actions may include failure of such regulatory authority to grant marketing approval of our customers' products, imposition of holds or delays, suspension or withdrawal of approvals, rejection of data collected, laboratory license revocation, product recalls, operational restrictions, civil or criminal penalties or prosecutions, damages or fines. Any such action could have a material adverse effect on our business.

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

In recent years, we have incurred significant costs in connection with the development of our diagnostic tests. For the year ended December 31, 2017, our research and development expenses were $4.8 million, which was 16% of our revenue and our sales and marketing expenses were $5.0 million, which was 17% of revenue. For the year ended December 31, 2016, our research and development expenses were $6.0 million, which was 22% of our net revenue

and our sales and marketing expenses were $4.7 million, which was 17% of revenue. We expect our expenses to continue to increase, in absolute dollars, for the foreseeable future as we seek to expand the clinical utility of our diagnostic tests, drive adoption of and reimbursement for our diagnostic tests and develop new tests. As a result, we will need to generate significant revenues in order to achieve sustained profitability.

We depend on certain collaborations with third parties for the supply of certain tissue samples and biological materials that we use in our research and development efforts. If the costs of such collaborations increase or our third party collaborators terminate their relationship with us, our business may be materially harmed.

Under standard clinical practice in the United States, tumor biopsies removed from patients are chemically preserved, embedded in paraffin wax and stored. Our clinical development relies on our ability to access these archived tumor biopsy samples, as well as information pertaining to their associated clinical outcomes. Other companies often compete with us for

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access. Additionally, the process of negotiating access to archived samples is lengthy, because it typically involves numerous parties and approvals to resolve complex issues such as usage rights, institutional review board approval, privacy rights, publication rights, intellectual property ownership and research parameters.

We have collaborative relationships with Memorial Sloan-Kettering Cancer Center, Mayo Clinic, North Shore-Long Island Jewish Health System, the National Cancer Institute, the Cleveland Clinic and other institutions who provide us with tissue samples and other biological materials that we use in developing and validating our tests. We do not have any written arrangement with certain third party collaborators, and in many of the cases in which the arrangements are in writing, our collaborative relationships are terminable on 30 days' notice or less. If one or more collaborators terminate their relationship with us, we will need to identify other third parties to provide us with tissue samples and biological materials, which could result in a delay in our research and development activities and negatively affect our business.

We currently rely on a limited number of suppliers for the reagents and chemistry related to our NGS panels. Any problems, such as disruption of the supply chain or lack of visibility, experienced by these suppliers could result in a delay or interruption in the supply of our NGS panels to us until the problem is cured or until we locate and qualify an alternative source of supply.

The design of our NGS panels is currently optimized using certain reagents and chemistry, which we have incorporated into our processes, equipment and protocols. We currently purchase these components from a limited number of suppliers. If one or more of these suppliers were to delay or stop producing the required reagents, or if the prices charged us were to increase significantly, we would need to identify another supplier and optimize our NGS panels using new reagents. We could experience delays in performing the NGS panels while finding other acceptable suppliers, which could impact our results of operations.

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

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

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

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

Our activities currently require the controlled use of potentially harmful biological materials and hazardous materials and chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject to, on an ongoing basis, federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with

these laws and regulations may become significant and could have a material adverse effect on our financial condition, results of operations and cash flows. In the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines.

Our Biopharma Services business could subject us to potential liability that may adversely affect our results of operations and financial condition.

Our Biopharma Services business involves the testing of new drugs on patients in clinical trials and, if marketing approval is granted, the availability of these drugs to be prescribed to patients. Our involvement in the clinical trials and development process creates a risk of liability for personal injury to or death of patients, particularly those with life-threatening illnesses, resulting from adverse reactions to the drugs administered during testing or after product launch, respectively. For example, we have from time to time been sued and may be sued in the future by individuals alleging personal injury due to their participation in clinical trials and seeking damages from us under a variety of legal theories. Although we maintain the types

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and amounts of insurance we view as customary in the industries and countries in which we operate, if we are required to pay damages or incur defense costs in connection with any personal injury claim that is outside the scope of indemnification agreements we have with our customers, if any indemnification agreement is not performed in accordance with its terms or if our liability exceeds the amount of any applicable indemnification limits or available insurance coverage, our financial condition, results of operations and reputation could be materially and adversely affected. We maintain professional liability insurance, including liability for completed operations coverage. In the future, we may not be able to get adequate insurance for these types of risks at reasonable rates.

Our Discovery Services customers face intense competition from lower cost generic products, which may lower the amount that they spend on our services.

Our Discovery Services customers face increasing competition from lower cost generic products, which in turn may affect their ability to pursue research and development activities with us. In the United States, EU and Japan, political pressure to reduce spending on prescription drugs has led to legislation and other measures which encourages the use of generic products. In addition, proposals emerge from time to time in the United States and other countries for legislation to further encourage the early and rapid approval of generic drugs. Loss of patent protection for a product typically is followed promptly by generic substitutes, reducing our customers' sales of that product and their overall profitability. Availability of generic substitutes for our customers' drugs may adversely affect their results of operations and cash flow, which in turn may mean that they would not have surplus capital to invest in research and development and drug commercialization, including in our services. If competition from generic products impacts our customers' finances such that they decide to curtail our services, our revenues may decline and this could have a material adverse effect on our business.

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

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

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

We depend on information technology and telecommunications systems for significant aspects of our operations. In addition, our third-party billing and collections provider depends upon telecommunications and data systems provided by outside vendors and information we provide on a regular basis. These information technology and telecommunications systems support a variety of functions, including test processing, sample tracking, quality control, customer service and support, billing and reimbursement, research and development activities and our general and

administrative activities. Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from processing tests, providing test results to pathologists, oncologists, billing payors, processing reimbursement appeals, handling patient or physician inquiries, conducting research and development activities and managing the administrative aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business.

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Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to fines, penalties, liability, and adverse effects to our business and our reputation.

In the ordinary course of our business, we and our third-party billing and collections provider collect and store sensitive data, including legally protected health information, personally identifiable information, intellectual property, and proprietary business information owned or controlled by ourselves or our customers, payors, and pharmaceutical and biotech partners. The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third-party billing and collections provider, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance, or other disruptions. Any such breach or interruption could compromise our networks, and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Any such improper access or disclosure, or loss of information could require us to provide notice to the affected individuals, the press, and regulatory bodies, result in legal claims or proceedings, liability, fines and penalties under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), the Health Information Technology for Economic and Clinical Health Act (“HITECH Act”), their implementing regulations, and similar state laws. Unauthorized access, loss, or dissemination could also disrupt our operations, including our ability to conduct our analyses, provide test results, bill payors or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process, and prepare company financial information, provide information about our products and other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business, and damage our reputation, any of which could adversely affect our business.

The U.S. Department of Health and Human Services Office for Civil Rights (“OCR”) may impose penalties on a covered entity, such as us, for a failure to comply with a requirement of HIPAA. Penalties will vary significantly depending on factors such as the date of the violation, whether the covered entity knew or should have known of the failure to comply, or whether the covered entity's failure to comply was due to willful neglect. These penalties include civil monetary penalties of $100 to $50,000 per violation, up to an annual, per violation cap of $1,500,000. A single breach incident can result in violations of multiple standards, resulting in possible penalties potentially in excess of $1,500,000. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to $50,000 and up to one year imprisonment. The criminal penalties increase to $100,000 and up to five years imprisonment if the wrongful conduct involves false pretenses, and to $250,000 and up to 10 years imprisonment if the wrongful conduct involves the intent to sell, transfer, or use identifiable health information for commercial advantage, personal gain, or malicious harm. The U.S. Department of Justice is responsible for criminal prosecutions under HIPAA.

HIPAA authorizes state attorneys general to file suit under HIPAA on behalf of state residents. Courts can award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for HIPAA violations, its standards have been used as the basis for a duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of Protected Health Information.

In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA covered entities for compliance with the HIPAA privacy and security regulations. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured Protected Health Information may receive a percentage of the Civil Monetary Penalty fine paid by the violator.

HIPAA further requires covered entities to notify affected individuals "without unreasonable delay and in no case later than 60 calendar days after discovery of the breach" if their unsecured Protected Health Information is subject to an unauthorized access, use or disclosure. If a breach affects 500 patients or more, it must be reported to HHS and local media without unreasonable delay, and HHS will post the name of the breaching entity on its public website. If a breach affects fewer than 500 individuals, the covered entity must log it and notify HHS at least annually.

In addition, the interpretation and application of consumer, health-related, and data protection laws in the United States, Europe, and elsewhere are often uncertain, contradictory, and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

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Our results of operations may be adversely affected if we fail to realize the full value of our goodwill and intangible assets.

We assess the realizable condition of our indefinite-lived intangible assets and goodwill annually and conduct an interim evaluation whenever events or changes in circumstances, such as operating losses or a significant decline in earnings associated with the acquired business or asset, indicate that these assets may be impaired. Our ability to realize the value of the goodwill and indefinite-lived intangible assets will depend on the future cash flows of the businesses we have acquired, which in turn depend in part on how well we have integrated these businesses into our own business. If we are not able to realize the value of the goodwill and indefinite-lived intangible assets, we may be required to incur material charges relating to the impairment of those assets. Such impairment charges could materially and adversely affect our operating results and financial condition.

Regulatory Risks Relating to Our Business

Changes in health care law, regulations and policy may have a material adverse effect on our financial condition, results of operations and cash flows.

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

- Requires each medical device manufacturer to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices, beginning in 2013. This tax may apply to some or all of our current products and products which are in development.
- Mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule (“CLFS”) of 1.75% for the years 2011 through 2015. In addition, a productivity adjustment is made to the fee schedule payment amount. These changes in payments apply to some or all of the clinical laboratory test services we furnish to Medicare beneficiaries.
- Establishes an Independent Payment Advisory Board to reduce the per capita rate of growth in Medicare spending. The Independent Payment Advisory Board has broad discretion to propose policies, which may have a negative impact on payment rates for services, including clinical laboratory services, beginning in 2016, and for hospital services beginning in 2020.

Although some of these provisions may negatively impact payment rates for clinical laboratory services, the PPACA also extends coverage to approximately 32 million previously uninsured people, which may result in an increase in the demand for our tests and services. The mandatory purchase of insurance has been strenuously opposed by a number of state governors, resulting in lawsuits challenging the constitutionality of certain provisions of the PPACA. On June 28, 2012, the Supreme Court upheld the constitutionality of the health care reform law, with the exception of certain provisions dealing with the expansion of Medicaid coverage under the law. While most of the law's provisions went into effect in 2013 and 2014, Congress has proposed a number of legislative initiatives, including possible repeal of the PPACA. On June 25, 2015, the Supreme Court affirmed the Fourth Circuit Court of Appeals in King v. Burwell, which allows the federal government to continue to extend tax subsidies to those individuals who purchased coverage through federal exchanges, in addition to the exchanges established by individual states.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of PPACA. 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 PPACA. The Budget Resolution is not a law; however, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of PPACA.

Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of PPACA that are repealed. Because of the continued uncertainty about the implementation of PPACA, including the potential for further legal challenges or repeal of PPACA, we cannot quantify or predict with any certainty the likely impact of the PPACA or its repeal on our business, prospects, financial condition or results of operations. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the “two-for-one” provisions. We cannot predict what impact the “two-for-one” provisions may have on our business.

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In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year, starting in 2013. This 2% sequester was recently extended through 2024.

In addition, on February 22, 2012, President Obama signed the Middle Class Tax Relief and Job Creation Act of 2012 (“MCTRJCA”), which, among other things, mandated an additional change in Medicare reimbursement for clinical laboratory services. This legislation requires a rebasing of the Medicare CLFS to effect a 2% reduction in payment rates otherwise determined for 2013. This will serve as a base for 2014 and subsequent years. As a result of the changes mandated by PPACA and MCTRJCA, the Centers for Medicare & Medicaid Services (“CMS”) projects laboratory services for 2015 will be reduced by approximately 0.25%.

Further, in 2014, Congress passed the Protecting Access to Medicare Act or PAMA which also makes significant changes in the way the Medicare will pay for laboratory services. Under PAMA and its implementing regulations, certain laboratories are required to report the amount that they are paid by third party payors for each test beginning in January 2017. CMS will use this data to calculate a weighted median for each test. That new price is supposed to effective on January 1, 2018, although any resulting reductions in excess of 10% will be phased in over time. This data reporting process will be repeated every three years for most tests, although laboratories offering Advanced Diagnostic Laboratory Tests (ADLTs) will have to report private payor data on those tests annually. It is possible that some of our tests may qualify as Advanced Diagnostic Laboratory Tests, which will require us to submit pricing annually for those tests. In addition, under PAMA, we also may be required to obtain new unique codes from CMS or any entity it designates, for our tests that do not currently have unique codes. If PAMA results in a significant reduction in the prices for our tests, it could have a significant impact on our revenues and it is not known at this time how the implementation of PAMA will affect our reimbursement.

Certain of our laboratory services are paid under the Medicare Physician Fee Schedule and, under the current statutory formula, the rates for these services are updated annually. For the past several years, the application of the statutory formula would have resulted in substantial payment reductions if Congress failed to intervene. In the past, Congress passed interim legislation to prevent the decreases. On April 16, 2015, President Obama signed the Medicare and CHIP Reauthorization Act (“MACRA”), which had previously been passed by both houses of Congress. MACRA repealed the provisions related to the Medicare Sustainable Growth Rate (SGR) formula and implements a new physician payment system that is designed to reward the quality of care. In addition, it extends the current Medicare Physician Fee Schedule rates through June 2015, and then increases them by 0.5%t for the remainder of 2015. Beginning on January 1, 2016, the rates will be increased annually by 0.5%, through 2019. For 2020 through 2025 payments will be frozen, although payment will be adjusted to account for performance on certain quality metrics under the Merit-Based Incentive Payment Systems (“MIPS”) or to reflect physician participation in alternative payment models (“APMs”). For 2026 and subsequent years, qualified APM participants receive an annual 0.75% update on Medicare physician payment rates, while those not participating receive a 0.25% annual payment update, plus any applicable MIPS-based payment adjustments. At this time, it is too early to determine how these changes may impact our business beyond 2015. It is unclear what impact, if any, MACRA will have on our business and operating results, but any resulting decrease in payment may result in reduced demand for our services, which could adversely impact our revenues and results of operations.

On November 2, 2016, CMS issued its Final Physician Fee Schedule Rule for 2017, which set out policies that were effective January 2017. Among those policy changes are reductions in the payments for flow cytometry by approximately 19% and an increase in the professional component of immunohistochemistry by approximately 9%,

two types of tests that we frequently perform. At this time, we are still assessing the potential impact of these changes.

In addition, many of the Current Procedure Terminology (“CPT”) procedure codes that we use to bill our tests were revised by the AMA, effective January 1, 2013. In the Final Physician Fee Schedule Rule for 2013, CMS announced that it has decided to keep the new molecular codes on the CLFS, rather than move them to the Medicare Physician Fee Schedule as some stakeholders had urged. CMS also announced that for 2013 it would price the new codes using a "gapfilling" process by which it will refer the codes to the Medicare contractors to allow them to determine an appropriate price. Those prices were determined and became effective January 1, 2014. In addition, CMS also stated that it would not recognize certain of the new codes for Multi-Analyte Assays with Algorithmic Assays (“MAAAs”) because it does not believe they qualify as clinical laboratory tests. However, more recently, it has determined that the individual contractors may determine whether to pay for MAAA tests on a case by case basis. On September 25, 2015, CMS released its Preliminary Determinations for new CPT codes effective in 2016, including several new MAAA CPT codes. CMS had proposed "crosswalking" these codes to an unrelated test, resulting in a significant cut in their reimbursement. However, on November 17, 2015, CMS reversed its policy and

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directed that the tests be gapfilled by the local contracts. It is expected that when PAMA is fully implemented, many of the MAAA codes could qualify to be reimbursed as Advanced Diagnostic Laboratory Tests (“ADLTs”), although it is unclear whether laboratories offering such tests voluntarily will apply for the ADLT designation for those tests. There can be no guarantees that Medicare and other payors will establish positive or adequate coverage policies or reimbursement rates.

We cannot predict whether future health care initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. The taxes imposed by the new federal legislation and the expansion of government's role in the U.S. health care industry as well as changes to the reimbursement amounts paid by payors for our products or our medical procedure volumes may reduce our profits and have a materially adverse effect on our business, financial condition, results of operations and cash flows. Moreover, Congress has proposed on several occasions to impose a 20% coinsurance on patients for clinical laboratory tests reimbursed under the CLFS, which would require us to bill patients for these amounts. Because of the relatively low reimbursement for many clinical laboratory tests, in the event that Congress were to ever enact such legislation, the cost of billing and collecting for these services would often exceed the amount actually received from the patient and effectively increase our costs of billing and collecting.

We depend on Medicare and a limited number of private payors for a significant portion of our revenues and if these or other payors do not provide or stop providing reimbursement or decrease the amount of reimbursement for our tests, our revenues could decline.

For the year ended December 31, 2017, we derived approximately 20% of our total revenue from private insurance, including managed care organizations and other health care insurance providers, 12% from Medicare and 5% from other health care facilities billed directly. Medicare and other third-party payors may withdraw their coverage policies or cancel their contracts with us at any time, review and adjust the rate of reimbursement or stop paying for our tests altogether, which would reduce our total revenues.

Payors have increased their efforts to control the cost, utilization and delivery of health care services. In the past, measures have been undertaken to reduce payment rates for and decrease utilization of the clinical laboratory industry generally. Because of the cost-trimming trends, third-party payors that currently cover and provide reimbursement for our tests may suspend, revoke or discontinue coverage at any time, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues, which may have a material adverse effect on our financial condition, results of operations and cash flows.

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

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

Under current Medicare billing rules, claims for our tests performed on Medicare beneficiaries who were hospital inpatients when the tumor tissue samples were obtained and whose tests were ordered less than 14 days from discharge must be incorporated in the payment that the hospital receives for the inpatient services provided. Accordingly, we must bill individual hospitals for tests performed on Medicare beneficiaries during these timeframes

in order to receive payment for our tests. Because we generally do not have a written agreement in place with these hospitals that purchase these tests, we may not be paid for our tests or may have to pursue payment from the hospital on a case-by-case basis. In addition, until 2012, we were permitted to bill globally for certain anatomic pathology services we furnished to certain hospitals, i.e. we billed both the technical component and the professional component to Medicare. As part of the Middle Class Tax Relief and Job Creation Act of 2012, Congress terminated the special provision for "grandfathered" hospitals as of July 1, 2012. Therefore, as of that date we were required to bill all hospitals for the technical component of all anatomic pathology services we furnish to their patients, which may be difficult and/or costly for us.

Further, the Medicare Administrative Contractors who process claims for Medicare also can impose their own rules related to coverage and payment for laboratory services provided in their jurisdiction. In 2013, Palmetto GBA, the Medicare Administrative Contractor for North Carolina, South Carolina, Virginia and West Virginia, announced a comprehensive new billing policy and a coverage policy applicable to molecular diagnostic tests, such as ours. Under coverage policy, Palmetto will deny payment for molecular diagnostic tests, unless it has issued a positive coverage determination for the test. Other Medicare contractors are also adopting policies similar to Palmetto's. If any of our tests are subject to the Palmetto policy and/or the

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Palmetto policy is adopted by other contractors that process claims with hospitals or laboratories that purchase and bill for our tests, our business could be adversely impacted.

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

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

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

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

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

Although FDA maintains that it has authority to regulate the development and use of LDTs, such as ours, as medical devices, it has not exercised its authority with respect to most LDTs as a matter of enforcement discretion. FDA does not generally extend its enforcement discretion to reagents or software provided by third parties and used to perform LDTs, and therefore these products must typically comply with FDA medical device regulations, which are wide-ranging and govern, among other things: product design and development, product testing, product labeling, product storage, pre-market clearance or approval, advertising and promotion and product sales and distribution.

We believe that our proprietary tests, as utilized in our laboratory testing, are LDTs. As a result, we believe that pursuant to FDA's current policies and guidance that FDA does not require that we obtain regulatory clearances or approvals for our LDTs. The container we provide for collection and transport of tumor samples from a pathology laboratory to our clinical reference laboratory may be a medical device subject to FDA's enforcement of its medical device regulations but we believe it is currently exempt from pre-market review by FDA. While we believe that we are currently in material compliance with applicable laws and regulations, we cannot assure you that FDA or other regulatory agencies would agree with our determination, and a determination that we have violated these laws, or a public announcement that we are being investigated for possible violations of these laws, could adversely affect our business, prospects, results of operations or financial condition.

Moreover, FDA guidance and policy pertaining to diagnostic testing is continuing to evolve and is subject to ongoing review and revision. A significant change in any of the laws, regulations or policies may require us to change our business model in order to maintain regulatory compliance. At various times since 2006, FDA has issued guidance documents or announced draft guidance regarding initiatives that may require varying levels of FDA oversight of our tests. For example, in June 2010, FDA announced a public meeting to discuss the agency's oversight of LDTs prompted by the increased complexity of LDTs and their increasingly important role in clinical decision-making and disease management, particularly in the context of personalized medicine. FDA indicated that it was considering a risk-based application of oversight to LDTs and that, following public input and discussion, it might issue separate draft guidance on the regulation of LDTs, which ultimately could require that we seek and obtain either pre-market clearance or approval of LDTs, depending upon the risk-based approach FDA adopts. The public

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meeting was held in July 2010 and further public comments were submitted to FDA through September 2010. Section 1143 of the Food and Drug Administration Safety and Innovation Act, signed by the U.S. President on July 9, 2012, required FDA to notify U.S. Congress at least 60 days prior to issuing a draft or final guidance regulating LDTs and provide details of the anticipated action.

On July 31, 2014, FDA notified Congress pursuant to the FDASIA that it intended to issue draft Guidances that would modify its policy of enforcement discretion with respect to LDTs and begin to enforce the applicable medical device regulations with respect to such products and tests. On October 3, 2014, the FDA issued two separate draft guidances: "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" ("The Framework Draft Guidance") and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests" (the "Notification Draft Guidance"). In the Framework Draft Guidance, FDA stated that after the Guidances are finalized, it no longer would exercise enforcement discretion with respect to most LDTs and instead would regulate them in a risk-based manner consistent with the existing classification of medical devices. The Framework Draft Guidance stated that within six months after the Guidances were finalized, all laboratories would be required to give notice to the FDA and provide basic information concerning the nature of the LDTs offered. The FDA then would begin a phased-in review of the LDTs available, based on the risk associated with the tests. For the highest risk LDTs, which the FDA classifies as Class III devices, the Framework Draft Guidance stated that the FDA would begin to require premarket review within 12 months after the Guidance was finalized. Other high risk LDTs would be reviewed over the next four years and then lower risk tests (Class II tests) would be reviewed in the following four to nine years. The Framework Draft Guidance stated that FDA expected to issue a separate Guidance describing the criteria for its risk-based classification 18-24 months after the Guidances were finalized.

On November 18, 2016, the FDA stated that it would not be issuing final guidance on regulation of LDTs and, instead, it would outline its view of an appropriate risk-based approach to LDTs. On January 13, 2017, the FDA released a "Discussion Paper on Laboratory Developed Tests" that synthesizes the feedback that the agency received from various stakeholders on FDA regulation of LDTs "with the hope that it advances public discussion on LDT oversight." The FDA stated in the introduction to the discussion paper: "The synthesis does not represent the formal thinking of the FDA, nor is it enforceable…This document does not represent a final version of the LDT draft guidance documents that were published in 2014." Rather, its purpose is to allow for further public discussion and to give Congress a chance to develop a legislative solution. As the 115th Congress gets underway, a number of Congressional committees reportedly are working with various stakeholders to consider different approaches to regulation of LDTs. It is unclear at this time whether those committees and stakeholders can reach consensus around an approach and develop legislation and whether Congress would pass any such legislation.

If the FDA regulates LDTs as proposed, then it would classify LDTs according to the current system used to regulate medical devices. Under that system, there are three different classes of medical devices, with the requirements becoming more stringent depending on the Class.

We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our tests, whether through guidance issued by FDA, new enforcement policies adopted by FDA or new legislation enacted by Congress. We believe it is possible that legislation will be enacted into law or guidance could be issued by FDA, which may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new tests. Given the attention Congress continues to give to these issues, legislation affecting this area may be enacted into law and may result in increased regulatory burdens on us as we continue to offer our tests and to develop and introduce new tests.

In addition, the former Secretary of the Department of Health and Human Services requested that its Advisory Committee on Genetics, Health and Society make recommendations about the oversight of genetic testing. A final report was published in April 2008. If the report's recommendations for increased oversight of genetic testing were to

result in further regulatory burdens, they could negatively affect our business and delay the commercialization of tests in development.

A FDA requirement that LDTs undergo premarket review could negatively affect our business until such review is completed and clearance or approval to market is obtained. FDA could require that we stop selling our tests pending pre-market clearance or approval. If FDA allows our tests to remain on the market but there is uncertainty about our tests, if they are labeled investigational by FDA or if labeling claims FDA allows us to make are very limited, orders or reimbursement may decline. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and making a 510(k) submission, or filing a PMA application with FDA. If FDA requires pre-market review, our tests may not be cleared or approved on a timely basis, if at all. We may also decide voluntarily to pursue FDA pre-market review of our tests if we determine that doing so would be appropriate.

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Additionally, should future regulatory actions affect any of the reagents we obtain from vendors and use in conducting our tests, our business could be adversely affected in the form of increased costs of testing or delays, limits or prohibitions on the purchase of reagents necessary to perform our testing.

If we were required to conduct additional clinical trials prior to continuing to offer our proprietary tests or any other tests that we may develop as LDTs, those trials could lead to delays or failure to obtain necessary regulatory approval, which could cause significant delays in commercializing any future products and harm our ability to achieve sustained profitability.

If the FDA decides to require that we obtain clearance or approvals to commercialize our proprietary tests, we may be required to conduct additional clinical testing prior to submitting a 510(k) premarket notification or PMA application for commercial sales. In addition, as part of our long-term strategy we plan to seek FDA clearance or approval so we can sell our proprietary tests outside our laboratory; however, we need to conduct additional clinical validation activities on our proprietary tests before we can submit an application for FDA approval or clearance. Clinical trials must be conducted in compliance with FDA regulations or FDA may take enforcement action or reject the data. The data collected from these clinical trials may ultimately be used to support market clearance or approval for our tests. Once commenced, we believe it would likely take two years or more to conduct the studies and trials necessary to obtain clearance or approval from FDA to commercially launch any of our proprietary tests outside of our clinical laboratory. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our test claims or that FDA or foreign authorities will agree with our conclusions regarding our test results. Success in early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and studies. If we are required to conduct clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our test development costs, delay commercialization, and interrupt sales of our current products and 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. Moreover, the clinical trial process may fail to demonstrate that our tests are effective for the proposed indicated uses, which could cause us to abandon a test candidate and may delay development of other tests.

We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the trials properly. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests or to achieve sustained profitability.

We are subject to federal and state health care fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

We are subject to health care fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. These health care laws and regulations include, for example:

- the federal Anti-kickback Statute, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, in return for or to induce either the referral of an individual for, or the purchase order or recommendation of, any item or services for which payment may be made under a federal health care program such as the Medicare and Medicaid programs;
- the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of "designated health services" with whom the physician or a member of the physician's immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies;
- HIPAA, which established federal crimes for knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services;

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- the federal civil monetary penalties law, which prohibits, among other things, offering or transferring remuneration, including waivers of co-payments and deductible amounts (or any part thereof), to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- federal false claims laws, which, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Further, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes.

The PPACA, among other things, also imposed new reporting requirements on manufacturers of certain devices, drugs and biologics for certain payments and transfers of value by them and in some cases their distributors to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information timely, completely and accurately for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1.0 million per year for “knowing failures”). Manufacturers must submit reports by the 90th day of each calendar year. Any failure to comply with these reporting requirements could result in significant fines and penalties. Because we manufacture our own LDTs solely for use by or within our own laboratory, we believe that we are exempt from these reporting requirements. We cannot assure you, however, that the government will agree with our determination, and a determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations or financial condition.

We have adopted policies and procedures designed to comply with these laws, including policies and procedures relating to financial arrangements between us and physicians who refer patients to us. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance is also subject to governmental review. The government alleged that we engaged in improper billing practices in the past and we may be the subject of such allegations in the future as the growth of our business and sales organization may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these laws and regulations is further increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations.

Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, and/or exclusion from participation in Medicare, Medi-Cal or other state or federal health care programs, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

We are required to comply with laws governing the transmission, security and privacy of health information that require significant compliance costs, and any failure to comply with these laws could result in material criminal and civil penalties.

Under the administrative simplification provisions of HIPAA, the U.S. Department of Health and Human Services has issued regulations which establish uniform standards governing the conduct of certain electronic health care transactions and protecting the privacy and security of Protected Health Information used or disclosed by health care providers and other covered entities. Three principal regulations with which we are currently required to comply have been issued in final form under HIPAA: privacy regulations, security regulations and standards for electronic transactions.

The privacy regulations cover the use and disclosure of Protected Health Information by health care providers. It also sets forth certain rights that an individual has with respect to his or her Protected Health Information maintained by a health care provider, including the right to access or amend certain records containing Protected Health Information or to request restrictions on the use or disclosure of Protected Health Information. We have implemented policies, procedures and standards in an effort to comply appropriately with the final HIPAA security regulations, which establish requirements for safeguarding the confidentiality, integrity and availability of Protected Health Information, which is electronically transmitted or

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electronically stored. The HIPAA privacy and security regulations establish a uniform federal "floor" and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing Protected Health Information. As a result, we are required to comply with both HIPAA privacy regulations and varying state privacy and security laws. Moreover, HITECH, among other things, established certain health information security breach notification requirements. Under HIPAA, a covered entity must notify any individual "without unreasonable delay and in no case later than 60 calendar days after discovery of the breach" if their unsecured Protected Health Information is subject to an unauthorized access, use or disclosure. If a breach affects 500 patients or more, it must be reported to HHS and local media without unreasonable delay, and HHS will post the name of the breaching entity on its public website. If a breach affects fewer than 500 individuals, the covered entity must log it and notify HHS at least annually.

These laws contain significant fines and other penalties for wrongful use or disclosure of Protected Health Information. We have implemented practices and procedures to meet the requirements of the HIPAA privacy regulations and state privacy laws. In addition, we are in the process of taking necessary steps to comply with HIPAA's standards for electronic transactions, which establish standards for common health care transactions. Given the complexity of the HIPAA, HITECH and state privacy restrictions, the possibility that the regulations may change, and the fact that the regulations are subject to changing and potentially conflicting interpretation, our ability to comply with the HIPAA, HITECH and state privacy requirements is uncertain and the costs of compliance are significant. To the extent that we submit electronic health care claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied. Additionally, the costs of complying with any changes to the HIPAA, HITECH and state privacy restrictions may have a negative impact on our operations. We could be subject to criminal penalties and civil sanctions for failing to comply with the HIPAA, HITECH and state privacy restrictions, which could result in the incurrence of significant monetary penalties. For further discussion of HIPAA and the impact on our business, see the section entitled "Risk Factors-Risks Related to Our Business and Strategy-Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to fines, penalties, liability, and adverse effects to our business and our reputation."

Intellectual Property Risks Related to Our Business

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

Our ability to market certain of our tests and services, domestically and/or internationally, is in part derived from licenses to intellectual property which is owned by third parties. As such, we may not be able to continue selling our tests and services if we lose our existing licensed rights or sell new tests and services if we cannot obtain such licensed rights on reasonable terms. In particular, we currently in-license a biomarker from the National Cancer Institute used in our FHACT probe. Further, we may also need to license other technologies to commercialize future products. As may be expected, our business may suffer if (i) these licenses terminate; (ii) if the licensors fail to abide by the terms of the license, properly maintain the licensed intellectual property or fail to prevent infringement of such intellectual property by third parties; (iii) if the licensed patents or other intellectual property rights are found to be invalid or (iv) if we are unable to enter into necessary licenses on reasonable terms or at all. In return for the use of a third-party's technology, we may agree to pay the licensor royalties based on sales of our products as well as other fees. Such royalties and fees are a component of cost of product revenues and will impact the margins on our tests.

Our collaborators may assert ownership or commercial rights to inventions we develop from our use of the biological materials they provide to us.

We rely on certain collaborators to provide us with tissue samples and biological materials that we use to develop our tests. In some cases we have written agreements with collaborators that may require us to negotiate ownership and commercial rights with the collaborator if our use of such collaborator's materials results in an invention. Other agreements may limit our use of those materials to research/not for profit use. In other cases, we may not have written agreements, or the written agreements we have may not clearly deal with intellectual property rights. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from our use of a collaborator's materials where required, or if disputes otherwise arise with respect to the intellectual property developed with the use of a collaborator's samples, we may be limited in our ability to capitalize on the market potential of these inventions.

The U.S. government may have "march-in rights" to certain of our probe related intellectual property.

Because federal grant monies were used in support of the research and development activities that resulted in our two issued U.S. patents, the federal government retains what are referred to as "march-in rights" to these patents. In particular, the National

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Cancer Institute and the National Institutes of Health, each of which administered grant monies to us, technically retain the right to require us, under certain specific circumstances, to grant the U.S. government either a nonexclusive, partially exclusive, or exclusive license to the patented invention in any field of use, upon terms that are reasonable for a particular situation. Circumstances that trigger march-in rights include, for example, failure to take, within a reasonable time, effective steps to achieve practical application of the invention in a field of use, failure to satisfy the health and safety needs of the public, and failure to meet requirements of public use specified by federal regulations. The National Cancer Institute and the National Institutes of Health can elect to exercise these march-in rights on their own initiative or at the request of a third-party.

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

Our ability to protect our proprietary discoveries and technologies affects our ability to compete and to achieve sustained profitability. Currently, we rely on a combination of U.S. and foreign patents and patent applications, copyrights, trademarks and trademark applications, confidentiality or non-disclosure agreements, material transfer agreements, licenses, work-for-hire agreements and invention assignment agreements to protect our intellectual property rights. We also maintain as trade secrets certain company know-how and technological innovations designed to provide us with a competitive advantage in the marketplace. Currently, including both U.S. and foreign patent applications, we have only two issued U.S. patents and twelve pending patent applications relating to various aspects of our technology. While we intend to pursue additional patent applications, it is possible that our pending patent applications and any future applications may not result in issued patents. Even if patents are issued, third parties may independently develop similar or competing technology that avoids our patents. Further, we cannot be certain that the steps we have taken will prevent the misappropriation of our trade secrets and other confidential information and technology, particularly in foreign countries where we do not have intellectual property rights.

From time to time the U.S. Supreme Court, other federal courts, the U.S. Congress or the U.S. Patent and Trademark Office (“USPTO”) may change the standards of patentability. Any such changes could have a negative impact on our business. For instance, on October 30, 2008, the Court of Appeals for the Federal Circuit issued a decision that methods or processes cannot be patented unless they are tied to a machine or involve a physical transformation. The U.S. Supreme Court later reversed that decision in Bilski v. Kappos, finding that the "machine-or-transformation" test is not the only test for determining patent eligibility. The Court, however, declined to specify how and when processes are patentable. Most recently, on March 20, 2012, in the case Mayo v. Prometheus, the U.S. Supreme Court reversed the Federal Circuit's application of Bilski and invalidated a patent focused on a diagnostic process because the patent claim embodied a law of nature. On July 3, 2012, the USPTO issued its Interim Guidelines for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature in view of the Prometheus decision. It remains to be seen how these guidelines play out in the actual prosecution of diagnostic claims. Similarly, it remains to be seen lower courts will interpret the Prometheus decision. Some aspects of our technology involve processes that may be subject to this evolving standard, and we cannot guarantee that any of our pending process claims will be patentable as a result of such evolving standards.

The U.S. Supreme Court's June 14, 2013 decision in Association for Molecular Pathology v. Myriad will likely have an impact on the entire biotechnology industry. Specifically, the case involved certain of Myriad Genetics, Inc.'s U.S. patents related to the breast cancer susceptibility genes BRCA1 and BRCA2. Plaintiffs asserted that the breast cancer genes were not patentable subject matter. The Supreme Court unanimously held that the isolated form of naturally occurring DNA molecules does not rise to the level of patent-eligible subject matter. But the Court also held that claims directed to complementary DNA (cDNA) molecules were patent-eligible because cDNA is not naturally occurring. The Supreme Court focused on the informational content of the isolated DNA and determined that the information contained in the isolated DNA molecule was not markedly different from that naturally found in the human chromosome. Yet, in holding isolated cDNA molecules patent-eligible, the Court recognized the differences between human chromosomal DNA and the corresponding cDNA. Because the non-coding regions of naturally

occurring chromosomal DNA have been removed in cDNA, the Court accepted that cDNA is not a product of nature and, therefore, is patent-eligible subject matter.

It does not appear that the Supreme Court's ruling in Myriad will adversely affect our current patent portfolio which, unlike the claims at issue in Myriad, centers on algorithmic methods associating chromosomal markers to specific clinical end-points. Nevertheless, we of course need to remain mindful that this is an evolving area of law.

In addition, on February 5, 2010, the Secretary's Advisory Committee on Genetics, Health and Society voted to approve a report entitled “Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests.” That report defines "patent claims on genes" broadly to include claims to isolated nucleic acid molecules as well as methods of detecting particular sequences or mutations. The report also contains six recommendations, including the creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale or selling a test developed under the patent for patient care purposes, or for anyone using the patent-protected genes in the pursuit of research. The report also recommended that the Secretary should explore, identify and implement mechanisms that will encourage more voluntary

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adherence to current guidelines that promote nonexclusive in-licensing of diagnostic genetic and genomic technologies. It is unclear whether the U.S. Department of Health and Human Services will act upon these recommendations, or if the recommendations would result in a change in law or process that could negatively impact our patent portfolio or future research and development efforts.

We may become involved in lawsuits or other proceedings to protect or enforce our patents or other intellectual property rights, which could be time-consuming and costly to defend, and could result in our loss of significant rights and the assessment of treble damages.

From time to time we may face intellectual property infringement (or misappropriation) claims from third parties. Some of these claims may lead to litigation. The outcome of any such litigation can never be guaranteed, and an adverse outcome could affect us negatively. For example, were a third-party to succeed on an infringement claim against us, we may be required to pay substantial damages (including up to treble damages if such infringement were found to be willful). In addition, we could face an injunction, barring us from conducting the allegedly infringing activity. The outcome of the litigation could require us to enter into a license agreement which may not be pursuant to acceptable or commercially reasonable or practical terms or which may not be available at all. It is also possible that an adverse finding of infringement against us may require us to dedicate substantial resources and time in developing non-infringing alternatives, which may or may not be possible. In the case of diagnostic tests, we would also need to include non-infringing technologies which would require us to re-validate our tests. Any such re-validation, in addition to being costly and time consuming, may be unsuccessful.

Furthermore, we may initiate claims to assert or defend our own intellectual property against third parties. Any intellectual property litigation, irrespective of whether we are the plaintiff or the defendant, and regardless of the outcome, is expensive and time-consuming, and could divert our management's attention from our business and negatively affect our operating results or financial condition. We may not be able to prevent, alone or with our collaborators, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States. In addition, interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our current or future collaborators.

Finally, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our financial condition.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our technologies in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our technologies in jurisdictions where we do not have any issued patents and our patent claims or other intellectual rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Relating to our International Operations

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International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Our business strategy incorporates international expansion, including our recent acquisitions which have provided us with facilities in Australia, India and China, and the possibility of establishing and maintaining clinician marketing and education capabilities in other locations outside of the United States and expanding our relationships with distributors and manufacturers. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax and transfer pricing laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the sale or use of our tests in various countries, including failure to achieve "CE Marking", a conformity mark which is required to market in vitro diagnostic medical devices in the European Economic Area and which is broadly accepted in other international markets;
- difficulties in managing foreign operations;
- complexities associated with managing multiple payor-reimbursement regimes or self-pay systems;
- logistics and regulations associated with shipping tissue samples, including infrastructure conditions and transportation delays;
- limits on our ability to penetrate international markets if our diagnostic tests cannot be processed by an appropriately qualified local laboratory;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales and distributors' activities.

Any of these risks, if encountered, could significantly harm our future international expansion and operations and, consequently, have a material adverse effect on our financial condition, results of operations and cash flows.

Our operations are subject to risks associated with emerging markets, including Australia, China and India.

Emerging markets are a significant focus of our growth strategy. The developing nature of these markets presents several risks, including deterioration of social, political, labor, or economic conditions in a country or region, and difficulties in staffing and managing foreign operations. Perceived risks associated with investing in emerging markets such as China and India, or a general disruption in the development of such markets could materially and adversely affect our business, operating results and financial condition.

A portion of our assets and operations are located in China and we are subject to regulatory, economic, political and other uncertainties in China.

The Chinese government has the ability to exercise significant influence and control over our operations in China. In recent years, the Chinese government has implemented measures for economic reform, the reduction of state ownership of productive assets and the establishment of corporate governance practices in business enterprises. However, many productive assets in China are still owned by the Chinese government. In addition, the government continues to play a significant role in regulating industrial development by imposing business regulations. It also exercises significant control over the country's economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies.

There can be no assurance that China's economic, political or legal systems will not develop in a way that becomes detrimental to our business, results of operations and financial condition. Our activities may be materially and adversely affected by changes in China's economic and social conditions and by changes in the policies of the government, such as measures to control inflation, changes in the rates or method of taxation and the imposition of additional restrictions on currency conversion.

Additional factors that we may experience in connection with having operations in China or other foreign countries that may adversely affect our business and results of operations include:

- our inability to enforce or obtain a remedy under any material agreements;

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- Chinese restrictions on foreign investment that could impair our ability to conduct our business or acquire or contract with other entities in the future;
- restrictions on currency exchange that may limit our ability to use cash flow most effectively or to repatriate our investment;
- fluctuations in currency values;
- cultural, language and managerial differences that may reduce our overall performance; and
- political instability.

A portion of our assets and operations are located in India and we are subject to regulatory, economic, political and other uncertainties in India.

Our Indian subsidiary serves both the research and clinical markets and is based in Hyderabad, India. In the past, the Indian economy has experienced many of the problems that commonly confront the economies of developing countries, including high inflation, erratic gross domestic product growth and shortages of foreign exchange. The Indian government has exercised, and continues to exercise, significant influence over many aspects of the Indian economy through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries, and Indian government actions concerning the economy could have a material adverse effect on private sector entities like us.

India has experienced significant economic growth over the last several years, but faces major challenges in sustaining that growth in the years ahead. These challenges include the need for substantial infrastructure development. India has also recently experienced civil unrest and terrorism and has been involved in conflicts with neighboring countries. In recent years, there have been military confrontations between India and Pakistan that have occurred in the region of Kashmir and along the India-Pakistan border. If India becomes engaged in armed hostilities, particularly if these hostilities are protracted or involve the threat of or use of weapons of mass destruction, it is likely that our operations would be materially adversely affected.

Our financial performance may be adversely affected by general economic conditions and economic and fiscal policy in India, including changes in exchange rates and controls, interest rates and taxation policies, as well as social stability and political, economic or diplomatic developments affecting India in the future.

Our operating results may be adversely affected by fluctuations in foreign currency exchange rates and restrictions on the deployment of cash across our global operations.

Although we report our operating results in U.S. dollars, a portion of our revenues and expenses are or will be denominated in currencies other than the U.S. dollar. Fluctuations in foreign currency exchange rates can have a number of adverse effects on us. Because our consolidated financial statements are presented in U.S. dollars, we must translate revenues, expenses and income, as well as assets and liabilities, into U.S. dollars at exchange rates in effect during or at the end of each reporting period. Therefore, changes in the value of the U.S. dollar against other currencies will affect our revenues, income from operations, other income (expense), net and the value of balance sheet items originally denominated in other currencies. There is no guarantee that our financial results will not be adversely affected by currency exchange rate fluctuations. In addition, in some countries we could be subject to strict restrictions on the movement of cash and the exchange of foreign currencies, which could limit our ability to use these funds across our global operations.

We could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act and other worldwide anti-bribery laws.

The FCPA and anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business or other commercial advantage. Our policies mandate compliance with these anti-bribery laws, which often carry substantial penalties, including criminal and civil fines, potential loss of export licenses, possible suspension of the ability to do business with the federal government, denial of government reimbursement for products and exclusion from participation in government health care programs. We operate in jurisdictions such as India and China that have experienced governmental and private sector corruption to some degree, and, in certain circumstances, strict compliance with anti-bribery laws may conflict with certain local customs and practices. We cannot assure that our internal control policies and procedures always will protect us from reckless or other inappropriate acts committed by our affiliates, employees or agents. Violations of these laws, or allegations of such violations, could have a material adverse effect on our business, financial position and results of operations.

Risks Relating to Our Common Stock

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The price of our common stock has been and could remain volatile, and the market price of our common stock may decrease.

The market price of our common stock has historically experienced and may continue to experience significant volatility. From January 2015 through December 31, 2017, the market price of our common stock has fluctuated from a high of $12.75 per share in the third quarter of 2015, to a low of $1.10 per share in the fourth quarter of 2016. Market prices for securities of development-stage life sciences companies have historically been particularly volatile. The factors that may cause the market price of our common stock to fluctuate include, but are not limited to:

- progress, or lack of progress, in developing and commercializing our proprietary tests;
- favorable or unfavorable decisions about our tests or services from government regulators, insurance companies or other third-party payors;
- our ability to recruit and retain qualified regulatory and research and development personnel;
- changes in investors' and securities analysts' perception of the business risks and conditions of our business;
- changes in our relationship with key collaborators;
- changes in the market valuation or earnings of our competitors or companies viewed as similar to us;
- changes in key personnel;
- depth of the trading market in our common stock;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the granting or exercise of employee stock options or other equity awards;
- realization of any of the risks described under this section titled “Risk Factors”; and
- general market and economic conditions.

In addition, the equity markets have experienced significant price and volume fluctuations that have affected the market prices for the securities of newly public companies for a number of reasons, including reasons that may be unrelated to our business or operating performance. These broad market fluctuations may result in a material decline in the market price of our common stock and you may not be able to sell your shares at prices you deem acceptable. In the past, following periods of volatility in the equity markets, securities class action lawsuits have been instituted against public companies. Such litigation, if instituted against us, could result in substantial cost and the diversion of management attention.

Our stockholders may be diluted by exercises of outstanding options and warrants.

As of March 9, 2018 we had outstanding options to purchase an aggregate of 2,599,023 shares of our common stock at a weighted average exercise price of $7.20 per share and warrants to purchase an aggregate of 10,054,990 shares of our common stock at a weighted average exercise price of $3.80 per share. The exercise of such outstanding options and warrants will result in dilution of the value of our shares.

Reports published by securities or industry analysts, including projections in those reports that exceed our actual results, could adversely affect our common stock price and trading volume.

Securities research analysts establish and publish their own periodic projections for our business. These projections may vary widely from one another and may not accurately predict the results we actually achieve. Our stock price may decline if our actual results do not match securities research analysts' projections. Similarly, if one or more of the analysts who writes reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price could decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, our stock price or trading volume could decline. While we expect securities research analyst coverage, if no securities or industry analysts begin to cover us, the trading price for our stock and the trading volume could be adversely affected.

Our directors and executive officers have substantial influence over us and could delay or prevent a change in corporate control.

Our directors and executive officers, together with their affiliates, in the aggregate beneficially own approximately 22% of our outstanding common stock, based on the number of shares outstanding on December 31, 2017. These stockholders, acting together, have significant influence over the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, have significant influence over our management and affairs. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in control;

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- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

We are an “emerging growth company,” and any decision on our part to comply only with certain reduced disclosure requirements applicable to “emerging growth companies” could make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and, for as long as we continue to be an “emerging growth company,” we intend to take advantage of exemptions from various reporting requirements applicable to other public companies but not to “emerging growth companies,” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as discussed below, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.07 billion or more; (ii) December 31, 2018, which is the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; and (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We have irrevocably chosen to "opt out" of the extended transition periods available under the JOBS Act for complying with new or revised accounting standards. We intend to take advantage of certain exemptions from various reporting requirements including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved, and if we do take advantage of these exemptions, we cannot predict if investors will find our common stock less attractive as a result. If some investors find our common stock less attractive as a result of any choices to take advantage of these reduced disclosure obligations, there may be a less active trading market for our common stock and our stock price may be more volatile.

We are incurring significantly increased costs and devote substantial management time as a result of operating as a public company particularly after we are no longer an “emerging growth company.”

As a public company and particularly after we cease to be an “emerging growth company,” we are incurring significant legal, accounting and other expenses that we did not incur as a private company and which may increase after we are no longer an "emerging growth company." For example, in addition to being required to comply with certain requirements of the Sarbanes-Oxley Act of 2002, we will be required to comply with certain requirements of the Dodd Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time consuming and costly. In addition, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these public company requirements.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. In addition, after we are no longer an “emerging growth company,” provided that we are not then still a “smaller reporting company,” we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting. Our compliance with Section 404 of the Sarbanes-Oxley Act, as applicable, requires us to incur substantial accounting expense and expend significant management efforts. We currently do not have an internal

audit group, and we will need to continue to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to successfully implement our business plan and maintain compliance with Section 404, as applicable, requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. If

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we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results, and current and potential stockholders may lose confidence in our financial reporting. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

Anti-takeover provisions of our certificate of incorporation, our bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove the current members of our board and management.

Certain provisions of our amended and restated certificate of incorporation and bylaws could discourage, delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove members of our board of directors. These provisions also could limit the price that investors might be willing to pay in the future for our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions, among other things:

- allow the authorized number of directors to be changed only by resolution of our board of directors;
- authorize our board of directors to issue, without stockholder approval, preferred stock, the rights of which will be determined at the discretion of the board of directors and that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our board of directors does not approve;
- establish advance notice requirements for stockholder nominations to our board of directors or for stockholder proposals that can be acted on at stockholder meetings; and
- limit who may call a stockholder meeting.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time.

Because we do not expect to pay cash dividends for the foreseeable future, you must rely on appreciation of our common stock price for any return on your investment. Even if we change that policy, we may be restricted from paying dividends on our common stock.

We do not intend to pay cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial performance, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. Accordingly, you will have to rely on capital appreciation, if any, to earn a return on your investment in our common stock. Investors seeking cash dividends in the foreseeable future should not purchase our common stock.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Our ability to utilize our federal net operating loss, carryforwards and federal tax credits are limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. The limitations apply since we have experienced an “ownership change,” as defined by Section 382, as a result of the Company's securities offerings. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect “five percent shareholders” changes by more than 50 percentage points over their lowest ownership percentage at any time during the applicable testing period (typically three years). Since we have experienced an “ownership change”, our NOL carryforwards and federal tax credits are subject to limitations as to our ability to utilize

them to offset taxable income and related income taxes. In addition, future changes in our stock ownership, which may be outside of our control, may trigger further “ownership changes” which would further limit their utilization. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset United States federal taxable income and related income taxes are subject to limitations, which could potentially result in increased future tax liability to us.

U.S. federal income tax reform could materially affect our tax obligations and effective tax rate.

On December 22, 2017, the Tax Cuts and Jobs Act, or the Tax Act, was signed into law, significantly reforming the tax code. The Tax Act, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, limits net operating loss (NOL) deductions, allows for the expensing of capital expenditures, puts into effect the migration from a “worldwide” system of taxation to a territorial system and modifies or repeals many business deductions and credits. The estimated impact of the Tax Act is based on our management’s current knowledge and assumptions,

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and recognized impacts could be materially different from current estimates based on our actual results and our further analysis of the new law. While we have not yet completed our assessment of the effects of the Tax Act, we are able to determine reasonable estimates for the impacts of certain key items, thus we have reported provisional amounts for these items. We will continue to calculate the impact of the Tax Act and will record any resulting tax adjustments during 2018, prior to the permitted remeasurement date. On a provisional basis, we are electing to use tax NOLs to offset any inclusion to U.S. taxable income prescribed by the guidance in new Internal Revenue Code Section 965 ("Section 965"). Given the availability to use NOLs to offset this income inclusion, at this time the Company does not expect to pay any one-time transition tax over the eight-year installment period as prescribed by Section 965. This conclusion is subject to change as we refine the provisional estimate of our total post-1986 E&P, cash position and other related calculations.

We continue to examine the impact this tax reform legislation may have on our business. The Tax Act requires complex computations not previously provided in U.S. tax law. As such, the application of accounting guidance for such items is currently uncertain. Further, compliance with the Tax Act and the accounting for such provisions require accumulation of information not previously required or regularly produced. As additional regulatory guidance is issued by the applicable taxing authorities, as accounting treatment is clarified, as we perform additional analysis on the application of the law, and as we refine estimates in calculating the effect, our final analysis, which will be recorded in the period completed, may be different from our current provisional amounts, which could materially affect our tax obligations and effective tax rate.

Our failure to meet the continued listing requirements of The NASDAQ Capital Market could result in a de-listing of our common stock.

If we fail to satisfy the continued listing requirements of The NASDAQ Capital Market, such as the corporate governance requirements or the minimum closing bid price requirement, NASDAQ may take steps to de-list our common stock. Such a de-listing would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with NASDAQ's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the NASDAQ minimum bid price requirement or prevent future non-compliance with NASDAQ listing requirements.

## Item 1B. Unresolved Staff Comments

None.

## Item 2. Properties

As of December 31, 2017, we had a lease for approximately 17,900 square feet of office and laboratory space in Rutherford, New Jersey, 24,900 square feet of laboratory space located in Research Triangle Park (RTP) in Morrisville, North Carolina, 5,800 square feet in Hershey, Pennsylvania, 10,000 square feet of laboratory space in Hyderabad, India and 1,959 square feet in Bundoora, Australia. These lease agreements have escalating lease payments and expire in February 2023, May 2020, November 2020 and July 2021, respectively. During 2017, we vacated our 2,700 square feet of laboratory space in Shanghai, China. We also have approximately 19,100 square feet of laboratory space in Los Angeles, California; the California lease expires in December 2018.

## Item 3. Legal Proceedings

In the normal course of business, the Company may be involved in legal proceedings or threatened legal proceedings. We are not party to any legal proceedings or aware of any threatened legal proceedings which are expected to have a material adverse effect on our financial condition, results of operations or liquidity.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

The following table sets forth, for the periods indicated, the reported high and low sales prices of our common stock on The NASDAQ Capital Market.

| | High | Low |
|---|---|---|
| 4th Quarter 2017 | $3.50 | $1.75 |
| 3rd Quarter 2017 | $4.25 | $2.60 |
| 2nd Quarter 2017 | $4.78 | $3.00 |
| 1st Quarter 2017 | $5.30 | $1.35 |
| | | |
| 4th Quarter 2016 | $1.98 | $1.10 |
| 3rd Quarter 2016 | $2.73 | $1.72 |
| 2nd Quarter 2016 | $2.93 | $1.82 |
| 1st Quarter 2016 | $3.38 | $1.90 |

Holders

As of December 31, 2017, we had approximately 100 holders of record of our common stock. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies. The transfer agent of our common stock is Continental Stock Transfer & Trust, 17 Battery Place, 8th Floor, New York, New York, 10004.

Dividends

We have never declared dividends on our equity securities, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. Our loan agreements prohibit us from paying cash dividends on our common stock and the terms of any future loan agreement we enter into or any debt securities we may issue are likely to contain similar restrictions on the payment of dividends. Subject to the foregoing, the payment of cash dividends in the future, if any, will be at the discretion of our board of directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our board of directors.

Item 6. Selected Financial Data.

The selected financial data set forth below as of December 31, 2017 and 2016, and for the years then ended has been derived from the audited consolidated financial statements of the Company, which are included elsewhere in this Annual Report on Form 10-K. We derived the consolidated financial data as of and for the years ended December 31, 2015, 2014 and 2013 from our audited consolidated financial statements that are not included elsewhere in this Annual Report on Form 10-K.

The information set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the audited consolidated financial statements, and the notes thereto, and other financial information included herein. Our historical results are not necessarily indicative of our future results.

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| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2017 | 2016 | 2015 | 2014 | 2013 |
| | (in thousands, expect per share data) | | | | |
| Consolidated Statements of Operations Data: | | | | | |
| Revenue | $29,121 | $27,049 | $18,040 | $10,199 | $6,610 |
| Cost of revenues | 18,070 | 17,104 | 14,098 | 8,453 | 4,925 |
| Gross profit (loss) | 11,051 | 9,945 | 3,942 | 1,746 | 1,685 |
| Operating expenses: | | | | | |
| Research and development | 4,789 | 5,967 | 5,483 | 4,622 | 2,190 |
| General and administrative | 19,894 | 16,034 | 14,567 | 12,369 | 6,115 |
| Sales and marketing | 4,990 | 4,668 | 5,269 | 3,964 | 1,842 |
| Total operating expenses | 29,673 | 26,669 | 25,319 | 20,955 | 10,147 |
| Loss from operations | (18,622) | (16,724) | (21,377) | (19,209) | (8,462) |
| Other income (expense): | | | | | |
| Interest expense | (2,128) | (454) | (344) | (473) | (2,388) |
| Interest income | 63 | 23 | 49 | 74 | 30 |
| Change in fair value of warrant liability | (1,964) | 1,525 | 35 | 417 | 4,633 |
| Change in fair value of acquisition note payable | (42) | 152 | 269 | 198 | — |
| Other expense | (266) | (325) | — | — | (6,850) |
| Total other income (expense) | (4,337) | 921 | 9 | 216 | (4,575) |
| Loss before income taxes | (22,959) | (15,803) | (21,368) | (18,993) | (13,037) |
| Income tax (benefit) | (2,079) | — | (1,184) | (2,350) | (664) |
| Net (loss) | $(20,880) | $(15,803) | $(20,184) | $(16,643) | $(12,373) |
| Basic net (loss) per share | $(1.01) | $(1.00) | $(1.96) | $(1.76) | $(2.65) |
| Diluted net (loss) per share | $(1.01) | $(1.00) | $(1.96) | $(1.80) | $(3.64) |
| Basic weighted average shares outstanding | 20,663 | 15,861 | 10,298 | 9,449 | 4,665 |
| Diluted weighted average shares outstanding | 20,663 | 15,861 | 10,299 | 9,462 | 4,676 |

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2017 | 2016 | 2015 | 2014 | 2013 |
| Consolidated Balance Sheet Data: | (in thousands) | | | | |
| Cash and cash equivalents | $9,541 | $9,502 | $19,459 | $25,554 | $49,460 |
| Working capital | 3,566 | 12,378 | 18,333 | 27,389 | 43,272 |
| Total assets | 52,221 | 42,434 | 48,884 | 47,105 | 55,157 |
| Debt, excluding current portion | — | 2,654 | 4,642 | 6,000 | — |
| Accumulated deficit | (134,834) | (113,954) | (98,151) | (77,967) | (61,325) |
| Total stockholders' equity | $26,765 | $25,624 | $33,017 | $34,554 | $45,463 |

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Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

As used herein, the "Company," "we," "us," "our" or similar terms, refer to Cancer Genetics, Inc. and its wholly owned subsidiaries: Cancer Genetics Italia, S.r.l., Gentris, LLC, BioServe Biotechnologies (India) Private Limited and vivoPharm Pty, Ltd., except as expressly indicated or unless the context otherwise requires. The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to help facilitate an understanding of our financial condition and our historical results of operations for the periods presented. This MD&A should be read in conjunction with the audited consolidated financial statements and notes thereto included in this annual report on Form10-K. This MD&A may contain forward-looking statements that involve risks and uncertainties. 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.

Overview

We are an emerging leader in the field of precision medicine, enabling individualized therapies in the field of oncology through tests, services and molecular markers. We develop, commercialize and provide molecular- and biomarker-based tests and services, including proprietary preclinical oncology and immuno-oncology services, that enable biotech and pharmaceutical companies engaged in oncology trials to better select candidate populations and reduce adverse drug reactions by providing information regarding genomic factors influencing subject responses to therapeutics. Through our clinical services, we enable physicians to personalize the clinical management of each individual patient by providing genomic information to better diagnose, monitor and inform cancer treatment. We have a comprehensive, disease-focused oncology testing portfolio, and an extensive set of anti-tumor referenced data based on predictive xenograft and syngeneic tumor models. Our tests and techniques target a wide range of indications, covering all ten of the top cancers in prevalence in the United States, with additional unique capabilities offered by our FDA-cleared Tissue of Origin® test for identifying difficult to diagnose tumor types or poorly differentiated metastatic disease.

We are currently executing a strategy of partnering with pharmaceutical and biotech companies and clinicians as oncology diagnostic specialists by supporting therapeutic discovery, development and patient care from bench to bedside. Pharmaceutical and biotech companies are increasingly attracted to work with us to provide molecular profiles on clinical trial participants. Similarly, we believe the oncology industry is undergoing a rapid evolution in its approach to diagnostic, prognostic and treatment outcomes (theranostic) testing, embracing precision medicine and individualized testing as a means to drive higher standards of patient treatment and disease management. These profiles may help identify biomarker and genomic variations that may be responsible for differing responses to oncology therapies, thereby increasing the efficiency of trials while lowering costs. We believe tailored and combination therapies can revolutionize oncology care through molecular- and biomarker-based testing services, enabling physicians and researchers to target the factors that make each patient and disease unique.

We believe the next shift in cancer management will bring together testing capabilities for germline, or inherited mutations, and somatic mutations that arise in tissues over the course of a lifetime. We have created a unique position in the industry by providing both targeted somatic analysis of tumor sample cells alongside germline analysis of an individual's non-cancerous cells' molecular profile as we attempt to continue achieving milestones in precision medicine.

Our clinical offerings include our portfolio of proprietary tests targeting hematological, urogenital and HPV-associated cancers, in conjunction with ancillary non-proprietary tests. Our proprietary tests target cancers that are difficult to prognose and predict treatment outcomes through currently available mainstream techniques. We provide our proprietary tests and services, along with a comprehensive range of non-proprietary oncology-focused

tests and laboratory services, to oncologists and pathologists at hospitals, cancer centers, and physician offices, as well as biotech and pharmaceutical companies to support their clinical trials. Our proprietary tests are based principally on our expertise in specific cancer types, test development methodologies and proprietary algorithms correlating genetic events with disease specific information. Our portfolio primarily includes comparative genomic hybridization (CGH) microarrays and next generation sequencing (NGS) panels, gene expression tests, and DNA fluorescent in situ hybridization (FISH) probes.

The non-proprietary testing services we offer are focused in part on specific oncology categories where we are developing our proprietary tests. We believe that there is significant synergy in developing and marketing a complete set of tests and services that are disease focused and delivering those tests and services in a comprehensive manner to help with treatment decisions. The insight that we develop in delivering the non-proprietary services are often leveraged in the development of our proprietary programs and now increasingly in the validation of our proprietary programs, such as MatBA and Focus::NGS.

We expect to continue to incur material losses for the near future. We incurred losses of $20.9 million and $15.8 million for fiscal years ended December 31, 2017 and 2016, respectively. As of December 31, 2017, we had an accumulated deficit of

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$134.8 million. We need to raise additional capital. The report of our independent registered public accounting firm with respect to our financial statements appearing in our Form 10-K contains an explanatory paragraph stating that our operating losses and negative cash flows from operations, raise substantial doubt about our ability to continue as a going concern. There can be no assurance that additional capital will be available to us on acceptable terms, if at all. In addition, we are in default of certain financial covenants in our credit agreements with our senior lenders, and while we are in negotiations with such lenders and believe we will be able to secure relief with respect to such defaults, there is no assurance that we will be successful in negotiating for waivers of such defaults or amendments of such covenants.

Acquisitions

On August 15, 2017, we purchased all of the outstanding stock of vivoPharm, with its principal place of business in Victoria, Australia, in a transaction valued at approximately $1.6 million in cash and $8.1 million in the Company's common stock based on the closing price of the stock on August 15, 2017.

Key Factors Affecting our Results of Operations and Financial Condition

Our overall long-term growth plan is predicated on our ability to develop and commercialize our proprietary tests, penetrate the Pharmaceutical and Biotechnology (Biopharma) community to achieve more revenue supporting clinical trials and develop and penetrate the Indian market. Our proprietary tests include CGH microarrays, NGS panels, gene expression tests and DNA FISH probes. We continue to develop additional proprietary tests. To facilitate market adoption of our proprietary tests, we anticipate having to successfully complete additional studies with clinical samples and publish our results in peer-reviewed scientific journals. Our ability to complete such studies is dependent upon our ability to leverage our collaborative relationships with leading institutions to facilitate our research and obtain data for our quality assurance and test validation efforts.

We believe that the factors discussed in the following paragraphs have had and are expected to continue to have a material impact on our results of operations and financial condition.

Revenues

Our revenue is primarily generated through our Clinical Services and Biopharma Services. Clinical Services can be billed to Medicare, another third party insurer or the referring community hospital or other healthcare facility or patients in accordance with state and federal law. Biopharma Services are billed to the customer directly. While we have agreements with our Biopharma clients, volumes from these clients are subject to the progression and continuation of the clinical trials which can impact testing volume. We also derive revenue from Discovery Services, which are services provided in the development of new testing assays and methods and include pre-clinical toxicology and efficacy studies. Discovery Services are billed directly to the customer.

We have historically derived a significant portion of our revenue from a limited number of test ordering sites, although the test ordering sites that generate a significant portion of our revenue have changed from period to period. Test ordering sites account for all of our Clinical Services revenue along with a portion of the Biopharma Services revenue. Our test ordering sites are hospitals, cancer centers, reference laboratories, physician offices, and pharmaceutical and biotechnology companies. Oncologists and pathologists at these sites order the tests on behalf of the needs of their oncology patients or as part of a clinical trial sponsored by a pharmaceutical or biotechnology company in which the patient is being enrolled.

The top five test ordering clients during 2017 and 2016 accounted for 38% and 31%, respectively, of our testing volumes. During the year ended December 31, 2017, one Biopharma client accounted for approximately 11% of our

revenue. During the year ended December 31, 2016 one Biopharma client accounted for approximately 16% of our revenue. The loss of our largest client would materially adversely affect our results of operations; however, the loss of any other test ordering client would not materially adversely affect our results of operations.

We receive revenue for our Clinical Services from Medicare, other insurance carriers and other healthcare facilities. Some of our customers choose, generally at the beginning of our relationship, to pay for laboratory services directly as opposed to having patients (or their insurers) pay for those services and providing us with the patients' insurance information. A hospital may elect to be a direct bill customer and pay our bills directly, or may provide us with patient information so that their patients pay our bills, in which case we generally expect payment from their private insurance carrier or Medicare. In a few instances, we have arrangements where a hospital may have two accounts with us, so that certain tests are billed directly to the hospital, and certain tests are billed to and paid by a patient's insurer. The billing arrangements generally are dictated by our customers and in accordance with state and federal law.

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For the year ended December 31, 2017, Medicare accounted for approximately 12% of our total revenue, other insurance accounted for approximately 20% of our total revenue and other healthcare facilities accounted for 5% of our total revenue. On average, we generate less revenue per test from other healthcare facilities billed directly, than from other insurance payors.

Cost of Revenues

Our cost of revenues consists principally of internal personnel costs, including non-cash stock-based compensation, laboratory consumables, shipping costs, overhead and other direct expenses, such as specimen procurement and third party validation studies. We are pursuing various strategies to reduce and control our cost of revenues, including automating our processes through more efficient technology and attempting to negotiate improved terms with our suppliers. In 2017, we purchased all of the outstanding stock of vivoPharm. Overall, with four acquisitions completed, we have made significant progress with integrating our resources and services and leveraging enterprise wide purchasing power to gain supplier discounts, in an effort to reduce costs. We will continue to assess other possible advantages to help us improve our cost structure.

Operating Expenses

We classify our operating expenses into three categories: research and development, sales and marketing, and general and administrative. Our operating expenses principally consist of personnel costs, including non-cash stock-based compensation, outside services, laboratory consumables and overhead, development costs, marketing program costs and legal and accounting fees.

Research and Development Expenses. We incur research and development expenses principally in connection with our efforts to develop our proprietary tests. Our primary research and development expenses consist of direct personnel costs, laboratory equipment and consumables and overhead expenses. In 2013, we entered into a joint venture with the Mayo Foundation for Medical Education and Research, with a focus on developing oncology diagnostic services and tests utilizing next generation sequencing. These efforts continued throughout 2016 and 2017. All research and development expenses are charged to operations in the periods they are incurred.

General and Administrative Expenses. General and administrative expenses consist principally of personnel-related expenses, professional fees, such as legal, accounting and business consultants, occupancy costs, bad debt and other general expenses. We have incurred increases in our general and administrative expenses and anticipate further increases as we expand our business operations.

Sales and Marketing Expenses. Our sales and marketing expenses consist principally of personnel and related overhead costs for our sales team and their support personnel, travel and entertainment expenses, and other selling costs including sales collaterals and trade shows. We expect our sales and marketing expenses to increase as we expand into new geographies and add new clinical tests and services.

Seasonality

Our business experiences decreased demand during spring vacation season, summer months and the December holiday season when patients are less likely to visit their health care providers. We expect this trend in seasonality to continue for the foreseeable future.

Results of Operations

Years Ended December 31, 2017 and 2016

The following table sets forth certain information concerning our results of operations for the periods shown:

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| | Year Ended December 31, | | Change | |
|---|---|---|---|---|
| | 2017 | 2016 | $ | % |
| (dollars in thousands) | | | | |
| Revenue | $ 29,121 | $ 27,049 | $2,072 | 8 % |
| Cost of revenues | 18,070 | 17,104 | 966 | 6 % |
| Research and development expenses | 4,789 | 5,967 | (1,178) | -20 % |
| General and administrative expenses | 19,894 | 16,034 | 3,860 | 24 % |
| Sales and marketing expenses | 4,990 | 4,668 | 322 | 7 % |
| Total operating loss | $ (18,622) | $ (16,724) | $(1,898) | 11 % |
| Interest (expense), net | (2,065) | (431) | (1,634) | 379 % |
| Change in fair value of warrant liability | (1,964) | 1,525 | (3,489) | -229 % |
| Change in fair value of acquisition note payable | (42) | 152 | (194) | -128 % |
| Other expense | (266) | (325) | 59 | -18 % |
| Loss before income taxes | (22,959) | (15,803) | (7,156) | 45 % |
| Income tax (benefit) | (2,079) | — | (2,079) | N/A |
| Net loss | $ (20,880) | $ (15,803) | $(5,077) | 32 % |

Non-GAAP Financial Information

In addition to disclosing financial results in accordance with United States generally accepted accounting principles ("GAAP"), the table below contains non-GAAP financial measures that we believe are helpful in understanding and comparing our past financial performance and our future results. The non-GAAP financial measures disclosed by the Company exclude the non- operating changes in the fair value of derivative instruments. These non-GAAP financial measures should not be considered a substitute for, or superior to, financial measures calculated in accordance with GAAP, and the financial results calculated in accordance with GAAP and reconciliations from these results should be carefully evaluated. Management believes that these non-GAAP measures provide useful information about the Company's core operating results and thus are appropriate to enhance the overall understanding of the Company's past financial performance and its prospects for the future. The non-GAAP financial measures in the table below include adjusted net (loss) and the related adjusted basic and diluted net (loss) per share amounts.

Reconciliation from GAAP to Non-GAAP Results (in thousands, except per share amounts):

| | Year Ended December 31, | |
|---|---|---|
| | 2017 | 2016 |
| Reconciliation of net (loss): | | |
| Net (loss) | $(20,880) | $(15,803) |
| Adjustments: | | |
| Change in fair value of acquisition note payable | 42 | (152) |
| Change in fair value of warrant liability | 1,964 | (1,525) |
| Adjusted net (loss) | $(18,874) | $(17,480) |
| Reconciliation of basic and diluted net (loss) per share: | | |
| Basic and diluted net (loss) per share | $(1.01) | $(1.00) |
| Adjustments to net (loss) | 0.10 | (0.10) |
| Adjusted basic and diluted net (loss) per share | $(0.91) | $(1.10) |
| Basic and diluted weighted-average shares outstanding | 20,663 | 15,861 |

Adjusted net (loss) increased 8% to $18.9 million during the year ended December 31, 2017, from an adjusted net (loss) of $17.5 million during the year ended December 31, 2016. Adjusted basic and diluted net (loss) per share decreased 17% to $0.91 during the year ended December 31, 2017, down from $1.10 during the year ended

December 31, 2016.

Revenue

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The breakdown of our revenue is as follows:

| | Year Ended December 31, | | | | Change | |
|---|---|---|---|---|---|---|
| | 2017 | | 2016 | | | |
| (dollars in thousands) | $ | % | $ | % | $ | % |
| Biopharma Services | 14,629 | 50 % | 15,321 | 57 % | (692) | (5)% |
| Clinical Services | 10,774 | 37 % | 10,651 | 39 % | 123 | 1 % |
| Discovery Services | 3,718 | 13 % | 1,077 | 4 % | 2,641 | 245 % |
| Total Revenue | 29,121 | 100% | 27,049 | 100% | 2,072 | 8 % |

Revenue increased 8%, or $2.1 million, to $29.1 million for the year ended December 31, 2017, from $27.0 million for the year ended December 31, 2016, principally due to our acquisition of vivoPharm, which accounted for $2.7 million of the increase. Our average revenue (excluding probe revenue) per test decreased to $363 per test for the year ended December 31, 2017 from $421 per test for the year ended December 31, 2016, principally due to the increased volume from our California facility at lower average revenue per test. Overall test volumes increased by 7% from 48,427 tests for the year ended December 31, 2016 to 51,999 tests for the year ended December 31, 2017.

Revenue from Biopharma Services decreased 5%, or $0.7 million, to $14.6 million for the year ended December 31, 2017, from $15.3 million for the year ended December 31, 2016, principally due to fluctuations in the start-up and patient enrollment timing of our clinical study projects with pharmaceutical and biotechnology customers. Revenue from Clinical Services customers increased 1%, or $0.1 million, to $10.8 million for the year ended December 31, 2017, from $10.7 million for the year ended December 31, 2016, principally due to increased test volumes. Revenue from Discovery Services increased $2.6 million, to $3.7 million for the year ended December 31, 2017, from $1.1 million for the year ended December 31, 2016 due to revenue contributed by the acquisition of vivoPharm in the third quarter of 2017, which accounted for all of the increase.

Cost of Revenues

Cost of revenues increased 6%, or $1.0 million, to $18.1 million for the year ended December 31, 2017, from $17.1 million for the year ended December 31, 2016, principally due to the following: increased lab supplies expense of $0.4 million as a result of higher test volumes and a higher concentration of next generation sequencing test volume in the second half of 2017, increased payroll and other benefits of $0.2 million, increased professional services of $0.3 million to support clinical capabilities and increases in shipping costs of $0.3 million as the Company shipped samples between laboratory facilities to meet customer demands. These increases were partially offset by a decrease in outsourced labor of $0.1 million, and a reduction in depreciation expense of $0.2 million.

Operating Expenses

Research and Development Expenses. Research and development expenses decreased 20%, or $1.2 million, to $4.8 million for the year ended December 31, 2017, from $6.0 million for the year ended December 31, 2016. The decrease relates primarily to a reduced payroll and benefits costs of $0.5 million, decreased facility cost of $0.2 million, and a reduction of $0.4 million in lab supplies due to fewer validations of diagnostic tests as we partnered with our biopharma customers to complete the development of new test capabilities in support of their clinical trials. In addition, our share of the loss from Oncospire, our joint venture with Mayo Clinic, decreased by $0.1 million.

General and Administrative Expenses. General and administrative expenses increased 24%, or $3.9 million to $19.9 million for the year ended December 31, 2017, from $16.0 million for the year ended December 31, 2016. The increase primarily relates to an increase in our bad debt expense of $4.6 million due to challenges with the integration of the lab management system into the billing platform from the Response Genetics acquisition in California for the periods from October 2015 to September 30, 2017 and low collections experience due to the lack of coverage for

certain of our next generation sequencing tests by Medicare and most third-party managed care plans. We also experienced an increase in professional fees of $0.4 million as we prepare for the impacts of conforming to new revenue recognition guidance in accordance with ASC 606, partially offset by a $0.8 million decrease in facility costs primarily resulting from the elimination of building management fees at our North Carolina location. We also experienced reduced legal, accounting and other financial consulting fees of $0.2 million and decreased franchise and property taxes of $0.3 million.

Sales and Marketing Expenses. Sales and marketing expenses increased 7%, or $0.3 million, to $5.0 million for the year ended December 31, 2017, from $4.7 million for the year ended December 31, 2016, principally due to the following: compensation

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costs increased by $0.6 million as a result of an increase in our Clinical Services sales force and related increase in commission payments, offset by decreased travel and entertainment costs of $0.1 million, reduced professional fees of $0.1 million and decreased facility costs of $0.1 million primarily resulting from the elimination of building management fees at our North Carolina location.

Interest Expense, Net

Interest expense increased 379%, or $1.6 million, to $2.1 million for the year ended December 31, 2017, from $0.4 million for the year ended December 31, 2016, principally due to accelerating the amortization of debt issuance costs and the discount on debt as a result of violating certain financial covenants. The acceleration of these costs resulted in additional interest expense of approximately $1.0 million. In addition, the debt we refinanced in March 2017 resulted in increased borrowings and also bears a higher interest rate.

Change in Fair Value of Warrant Liability

Changes in fair value of some of our common stock warrants may impact our results. Accounting rules require us to record certain of our warrants as a liability, measure the fair value of these warrants each quarter and record changes in that value in earnings. We recognized non-cash expense of $2.0 million for the year ended December 31, 2017, as compared to non-cash income of $1.5 million for the year ended December 31, 2016, as a result of fluctuations in our stock price. In the future, if our stock price increases, we would record a non-cash charge as a result of changes in the fair value of our common stock warrants. Consequently, we may be exposed to non-cash charges, or we may record non-cash income, as a result of this warrant exposure in future periods.

Change in Fair Value of Acquisition Note Payable

The change in fair value of the acquisition note payable resulted in $42,000 in non-cash expense for the year ended December 31, 2017, as compared to non-cash income $0.2 million for the year ended December 31, 2016 as a result of fluctuations in our stock price.

Other Expense

During the year ended December 31, 2017, we recognized $0.3 million of aggregate expense resulting from the issuance of derivative warrants as part of a debt refinancing and the 2017 Offering. During the year ended December 31, 2016, we incurred $0.3 million of expense resulting from the issuance of derivative warrants as part of the 2016 Offerings.

Income Taxes

During 2017, we received approximately $2.1 million of net proceeds from the sale of state NOL’s and state research and development credits. No NOL’s or research and development tax credits were sold during the year ended December 31, 2016.

Liquidity and Capital Resources

Sources of Liquidity

Our primary sources of liquidity have been funds generated from our debt financings and equity financings. In addition, we have generated funds from the following sources: (i) cash collections from customers and (ii) cash received from sale of state NOL’s.

In general, our primary uses of cash are providing for operating expenses, working capital purposes and servicing debt. On March 22, 2017, we restructured our debt with Silicon Valley Bank, by repaying the outstanding term loan and entering into a new two-year $6.0 million asset-based revolving line of credit agreement. We concurrently entered into a new $6.0 million term loan agreement with Partners for Growth, which, on the day of closing, increased our indebtedness from $4.4 million to $6.0 million and increased our available cash by $1.6 million. We may be able to borrow up to $6.0 million on the revolver, based on a formula tied to eligible accounts receivable, which will increase our indebtedness dollar for dollar. At December 31, 2017, we have borrowed $4.1 million of the maximum $6.0 million on the revolving line of credit. Due to the terms of the revolver, we have reached the borrowing limit based on eligible accounts receivable at December 31, 2017. In connection with such debt restructuring we issued warrants to such lenders to purchase an aggregate of 443,262 shares of our common stock.

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Both loan agreements require us to comply with certain financial covenants, including minimum adjusted EBITDA, revenue and liquidity covenants, and restrict us from, among other things, paying cash dividends, incurring debt and entering into certain transactions without the prior consent of the lenders. Repayment of amounts borrowed under the new loan agreements may be accelerated if an event of default occurs, which includes, among other things, a violation of such financial covenants and negative covenants. As of December 31, 2017, January 31, 2018, February 28, 2018 and March 31, 2018, we were in default of certain financial covenants in our credit agreements with PFG and SVB as a result of the significant increase in our bad debt allowance in the fourth quarter of 2017 and other factors. We are currently in negotiations with our lenders with respect to waivers of the covenant defaults or amendments of the covenants. However, no assurances can be given that the lenders will agree to any such waivers or amendments, nor as to the cost or consequences to us of the terms of any such waivers or amendments if they are reached. If our lenders were to declare a default and seek repayment of the loans we would not have adequate capital to make such payment and continue to operate our business.

Our largest source of operating cash flow is cash collections from our customers.

Offerings

2016 Offerings

On May 25, 2016, we sold 2,467,820 shares of common stock in a public offering and warrants to purchase 1,233,910 shares of common stock in a concurrent private placement. These offerings resulted in gross proceeds of $5 million. We sold 2,150,000 shares of common stock and warrants to purchase 1,075,000 shares of common stock to certain institutional investors at a combined offering price of $2.00 per common share, and our Chairman of the Board, John Pappajohn, purchased 317,820 shares of common stock and warrants to purchase 158,910 shares of common stock at a combined offering price of $2.2025 per common share. In addition, we issued warrants to purchase an aggregate of 123,391 shares of common stock to the placement agent. Subject to certain ownership limitations, the warrants were initially exercisable commencing six months from the issuance date at an exercise price equal to $2.25 per share of common stock. The warrants are exercisable for five years from the initial exercise date.

On September 14, 2016, we sold 2,750,000 shares of common stock in a public offering and warrants to purchase 1,375,000 shares of common stock in a concurrent private placement at a combined price of $2.00 per common share. These offerings resulted in gross proceeds of $5.5 million. In addition, we issued warrants to purchase an aggregate of 137,500 shares of common stock to the placement agent. Subject to certain ownership restrictions, the warrants will be initially exercisable six months from the issuance date at an exercise price of $2.25 per share of common stock. The warrants are exercisable for five years from the initial exercise date.

2017 Offering

On December 8, 2017, we sold 3,500,000 shares of our common stock and warrants to purchase 3,500,000 shares of common stock in a public offering (the “2017 Offering”). The offering resulted in gross proceeds of $7.0 million. The 2017 Offering warrants have an exercise price of $2.35 per share of common stock. In addition, we issued warrants to purchase an aggregate of 175,000 shares of common stock at $2.50 per share to the placement agent (“Wainwright Warrants”). Subject to certain ownership limitations, these warrants will be initially exercisable 6 months from the issuance date and are exercisable for 12 months from the initial exercise date.

Common Stock Purchase Agreement with Aspire Capital

On August 14, 2017, we entered into a Common Stock Purchase Agreement (the “Purchase Agreement”) with Aspire Capital Fund, LLC, an Illinois limited liability company (“Aspire Capital”), which provides that Aspire Capital is

committed to purchase up to an aggregate of $16 million of our common stock (the “Purchase Shares”) from time to time over the term of the Purchase Agreement. Aspire Capital made an initial purchase of 1,000,000 Purchase Shares (the “Initial Purchase”) at a purchase price of $3.00 per share on the commencement date of the agreement.

After the commencement date, on any business day over the 24-month term of the Purchase Agreement, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice (each, a “Purchase Notice”) directing Aspire Capital to purchase up to 33,333 Purchase Shares per business day, provided that Aspire Capital will not be required to buy Purchase Shares pursuant to a Purchase Notice that was received by Aspire Capital on any business day on which the last closing trade price of our common stock on the NASDAQ Capital Market is below $3.00. The Company and Aspire Capital also may mutually agree to increase the number of shares that may be sold to as much as an additional 2,000,000 Purchase Shares per

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business day. The Purchase Agreement provides for a purchase price per Purchase Share of $3.00. As consideration for entering into the Purchase Agreement, we issued 320,000 shares of our common stock to Aspire Capital ("Commitment Shares").

The number of Purchase Shares covered by and timing of each Purchase Notice are determined by us, at our sole discretion. The aggregate number of shares that we can sell to Aspire Capital under the Purchase Agreement may in no case exceed 3,938,213 shares of our common stock (which is equal to approximately 19.9% of the common stock outstanding on the date of the Purchase Agreement), including the 320,000 Commitment Shares and the 1,000,000 Initial Purchase Shares, unless shareholder approval is obtained to issue additional shares.

Our net proceeds will depend on several factors, including the frequency of our sales of Purchase Shares to Aspire Capital and the frequency at which the last closing trade price of our common stock is below $3.00, subject to a maximum of $16 million in gross proceeds, including the Initial Purchase. Our delivery of Purchase Notices will be made subject to market conditions, in light of our capital needs from time to time and under the limitations contained in the Purchase Agreement.

As of December 31, 2017, the Company has sold 1,000,000 shares under this agreement at $3.00 per share, resulting in proceeds of approximately $2,965,000, net of offering costs of approximately $35,000. The Company has also issued 320,000 shares as consideration for entering into the Purchase Agreement. The Company has not deferred any offering costs associated with this agreement. Due to the price of the Company's stock being lower than the $3.00 per share, the Company does not expect to sell more shares under the Purchase Agreement in the foreseeable future.

Credit Facility

On March 22, 2017, we refinanced our debt with SVB, by repaying the SVB Term Note, which was scheduled to mature in April 2019, and entered into a new two year asset-based revolving line of credit agreement. The new SVB credit facility provides for an asset-based line of credit ("ABL") for an amount not to exceed the lesser of (a) $6.0 million or (b) an amount equal to 80% of eligible accounts receivable plus the lesser of 50% of the net collectible value of third party accounts receivable or three times the average monthly collection amount of third party accounts receivable over the previous quarter. The ABL requires monthly interest payments at the Wall Street Journal prime rate plus 1.5% (6.0% at December 31, 2017) and matures on March 22, 2019. We paid to SVB a $30,000 commitment fee at closing and will pay a fee of 0.25% per year on the average unused portion of the ABL. At December 31, 2017, the ABL had a principal balance of $4,136,907 and represented the maximum we could borrow based on eligible accounts receivable.

We concurrently entered into a new three year $6.0 million term loan agreement ("PFG Term Note") with Partners for Growth IV, L.P. ("PFG"). The PFG Term Note is an interest only loan with the full principal and any outstanding interest due at maturity on March 22, 2020. Interest is payable monthly at a rate of 11.5% per annum, with the possibility of reducing to 11.0% in 2018 based on achieving certain financial milestones set forth by PFG. We may prepay the PFG Term Note in whole or in part at any time without penalty. We paid PFG a commitment fee of $120,000 at closing. At December 31, 2017, the PFG Term Note had a principal balance of $6,000,000.

As discussed above, as of December 31, 2017, January 31, 2018, February 28, 2018 and March 31, 2018, we are in breach of certain financial covenants in our credit agreements with SVB and PFG and are currently attempting to negotiate waivers of such breaches or amendments of the covenants.

Cash Flows

Our net cash flow from operating, investing and financing activities for the periods below were as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2017 | 2016 |
| (in thousands) | | |
| Cash provided by (used in): | | |
| Operating activities | $(13,564) | $(17,851) |
| Investing activities | (2,751) | (609) |
| Financing activities | 16,338 | 8,503 |
| Effect of foreign exchange rates on cash and cash equivalents | 16 | — |
| Net increase (decrease) in cash and cash equivalents | $39 | $(9,957) |

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We had cash and cash equivalents of $9.5 million at both December 31, 2017 and 2016.

The primary uses of cash during 2017 include $13.6 million of net cash used to fund operations, $1.3 million of net cash used to invest in fixed assets, $1.1 million of net cash used to acquire vivoPharm and $4.7 million used to repay debt. These uses were offset by $6.6 million of net proceeds from the 2017 Offering, $3.0 million of net proceeds from Aspire Capital stock purchases, $1.8 million of proceeds from warrant exercises and $10.1 million in aggregate borrowings from our PFG Term Note and the ABL.

The $10.0 million decrease in cash and cash equivalents for the year ended December 31, 2016 was principally the result of the use of $17.9 million of net cash in operations and repaying $1.3 million of debt, offset by $10.0 million in net proceeds from the 2016 Offerings.

Cash Used in Operating Activities

Net cash used in operating activities was $13.6 million for the year ended December 31, 2017. We used $8.1 million in net cash to run our core operations, including losses from operations and $0.9 million in cash paid for interest. We incurred additional uses of cash when adjusting for working capital items as follows: a net increase in accounts receivable of $3.6 million, a net increase in other current assets of $0.2 million, a net decrease in accounts payable, accrued expenses and deferred revenue of $1.5 million and a net decrease in deferred rent and other of $0.2 million.

Net cash used in operating activities was $17.9 million for the year ended December 31, 2016. We used $12.2 million in net cash to run our core operations, including losses from operations and $0.3 million in cash paid for interest. We incurred additional uses of cash when adjusting for working capital items as follows: a net increase in accounts receivable of $5.9 million and a combined increase in other current and non-current assets of $0.1 million. All of these uses of cash were partially offset by a net increase in accounts payable, accrued expenses and deferred revenue of $0.4 million.

Cash Used in Investing Activities

Net cash used in investing activities was $2.8 million for the year ended December 31, 2017 and principally resulted from the purchase of fixed assets for $1.3 million, net cash used in the acquisition of vivoPharm of $1.1 million, patent costs of $0.1 million, $0.2 million used in a cost method investment and an increase in our restricted cash of $0.1 million.

Net cash used in investing activities was $0.6 million for the year ended December 31, 2016 and principally resulted from the purchase of fixed assets for $0.5 million and patent costs of $0.1 million.

Cash Used/Provided by Financing Activities

Net cash provided by financing activities was $16.3 million for the year ended December 31, 2017 and principally resulted from the 2017 Offering, which resulted in $6.6 million in net proceeds, aggregate borrowings on our PFG Term Note and ABL of $10.1 million, proceeds from warrant exercises of $1.8 million and net proceeds from Aspire Capital stock proceeds of $3.0 million, offset by the repayment of $4.7 million in indebtedness, debt issuances costs of $0.3 million and capital lease payments of $0.2 million.

Net cash provided by financing activities was $8.5 million for the year ended December 31, 2016 and principally resulted from the 2016 Offerings, which resulted in $10.0 million in net proceeds, offset by the repayment of $1.3 million in indebtedness and capital lease payments of $0.1 million.

Capital Resources, Acquisitions and Expenditure Requirements

We expect to continue to incur material operating losses in the future. It may take several years, if ever, to achieve positive operational cash flow. We may need to raise additional capital to fund our current operations, to repay certain outstanding indebtedness and to fund expansion of our business to meet our long-term business objectives through public or private equity offerings, debt financings, borrowings or strategic partnerships coupled with an investment in our company or a combination thereof. If we raise additional funds through the issuance of convertible debt securities, or other debt securities, these securities could be secured and could have rights senior to those of our common stock. In addition, any new debt incurred by the Company could impose covenants that restrict our operations and increase our interest expense. The issuance of any new equity securities will also dilute the interest of our current stockholders. Given the risks associated with our business, including our unprofitable operating history and our ability to develop additional proprietary tests, additional capital may not be available when needed on acceptable terms, or at all. If adequate funds are not available, we will need to curb our expansion plans or

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limit our research and development activities, which may have a material adverse impact on our business prospects and results of operations. Due to the terms of the revolver, we have reached the borrowing limit based on eligible accounts receivable at December 31, 2017. In addition, we were in violation of certain financial covenants with SVB and PFG as of December 31, 2017, January 31, 2018, February 28, 2018 and March 31, 2018. We are currently in negotiations with our lenders with respect to waivers of the covenant defaults or amendments of the covenants. However, no assurances can be given that the lenders will agree to any such waivers or amendments, nor as to the cost or consequences to us of the terms of any such waivers or amendments if they are reached. If our lenders were to declare a default and seek repayment of the loans we would likely not have adequate capital to make such payment and continue to operate our business.

We do not believe that our current cash will support operations for at least the next 12 months from the date of this report unless we raise additional equity or debt capital or spin-off non-core assets to raise additional cash. We have hired Raymond James & Associates Inc. as our financial advisor to assist with evaluating strategic alternatives. Such alternatives could include raising more capital, the acquisition of another company and / or complementary assets, the sale of the Company or another type of strategic partnership. There is no assurance that the review of strategic alternatives will result in the Company changing its business plan, pursuing any particular transaction, if any, or, if it pursues any such transaction, that it will be completed.

Meanwhile we are taking steps to improve our operating cash flow. We can provide no assurances that our current actions will be successful or that any additional sources of financing will be available to us on favorable terms, if at all, when needed. Our cash position, recurring losses from operations and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern, and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2017 with respect to this uncertainty. This going concern opinion, and any future going concern opinion, could materially limit our ability to raise additional capital. The perception that we may not be able to continue as a going concern may cause potential partners or investors to choose not to deal with us due to concerns about our ability to meet our contractual and financial obligations. If we cannot continue as a going concern, our stockholders may lose their entire investment in our common stock.

Our forecast of the period of time through which our current financial resources will be adequate to support our operations and our expected operating expenses are forward-looking statements and involve risks and uncertainties. Actual results could vary materially and negatively as a result of a number of factors, including:

- our ability to negotiate a waiver or amendment of the financial covenants in our credit agreements with our senior lenders;
- our ability to achieve revenue growth and profitability;
- our ability to secure financing and the amount thereof;
- the costs for funding the operations we recently acquired and our ability to realize anticipated benefits from the vivoPharm acquisition;
- our ability to improve efficiency of billing and collection processes;
- our ability to obtain approvals for our new diagnostic tests;
- our ability to execute on our marketing and sales strategy for our tests and gain acceptance of our tests in the market;
- our ability to obtain adequate reimbursement from governmental and other third-party payors for our tests and services;
- our ability to maintain our present customer base and obtain new customers;
- our ability to clinically validate our pipeline of tests currently in development;
- the costs of operating and enhancing our laboratory facilities;
- our ability to succeed with our cost control initiative;
-

- our ability to satisfy US (FDA) and international regulatory regiments with respect to our tests and services, many of which are new and still evolving;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- our ability to manage the costs of manufacturing our tests;
- our rate of progress in, and cost of research and development activities associated with, products in research and early development;
- the effect of competing technological and market developments;
- costs related to expansion; and
- other risks discussed in the section entitled “Risk Factors.”

We expect that our operating expenses and capital expenditures may increase in the future as we expand our business. We plan to take steps to decrease our sales and marketing expenses related to our clinical tests and services, and will continue our

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research and development expenditures associated with performing work with research collaborators, to expand our pipeline and to perform work associated with our research collaborations. For example, in 2011 we entered into an affiliation agreement to form a joint venture with the Mayo Foundation for Medical Education and Research pursuant to which we made an initial $1.0 million capital contribution in October 2013 and $1.0 million in the third quarter of 2014. We do not expect to make additional capital contributions to the joint venture entity's operational activities. Until we can generate a sufficient amount of revenues to finance our cash requirements, which we may never do, we may need to raise additional capital to fund our operations.

Subject to the availability of future financing, we may use significant cash to fund acquisitions. On August 15, 2017, we purchased all of the outstanding stock of vivoPharm, with its principal place of business in Victoria, Australia, in a transaction valued at approximately $1.6 million in cash and $8.1 million in the Company's common stock based on the closing price of the stock on August 15, 2017.

The consolidated financial statements for the year ended December 31, 2017 were prepared on the basis of a going concern, which contemplates that the Company will be able to realize assets and discharge liabilities in the normal course of business. Accordingly, they do not give effect to adjustments that would be necessary should the Company be required to liquidate its assets. The ability of the Company to meet its obligations, and to continue as a going concern is dependent upon the availability of future funding and the continued growth in revenues. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Future Contractual Obligations

The following table reflects a summary of our estimates of future contractual obligations as of December 31, 2017. The information in the table reflects future unconditional payments and is based on the terms of the relevant agreements, appropriate classification of items under U.S. GAAP as currently in effect and certain assumptions, such as the interest rate on our variable debt that was in effect as of December 31, 2017. Future events could cause actual payments to differ from these amounts.

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| Contractual Obligations | Total | Less than 1 Year | 1-3 Years | 3-5 Years | More than 5 years |
| (dollars in thousands) | | | | | |
| Principal and interest under notes payable and lines of credit | $10,372 | $10,372 | $— | $— | $ — |
| Capital Lease obligations, including interest, for equipment | 1,026 | 363 | 538 | 125 | — |
| Operating lease obligations relating to corporate headquarters and clinical laboratories | 5,313 | 1,583 | 2,354 | 1,282 | 94 |
| Total | $16,711 | $12,318 | $2,892 | $1,407 | $ 94 |

Income Taxes

Over the past several years we have generated operating losses in all jurisdictions in which we may be subject to income taxes. As a result, we have accumulated significant net operating losses and other deferred tax assets. Because of our history of losses and the uncertainty as to the realization of those deferred tax assets, a full valuation allowance has been recognized. We do not expect to report a benefit related to the deferred tax assets until we have a history of earnings, if ever, that would support the realization of our deferred tax assets.

Off-Balance Sheet Arrangements

Since inception, we have not engaged in any off balance sheet activities as defined in Item 303(a)(4) of Regulation S-K.

Critical Accounting Policies and Significant Judgment and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates based on

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historical experience and make various assumptions, which management believes to be reasonable under the circumstances, which form the basis for judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Section 107 of the JOBS Act provides that an "emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we have chosen to "opt out" of such extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

The notes to our audited consolidated financial statements contain a summary of our significant accounting policies. We consider the following accounting policies critical to the understanding of the results of our operations:

- Revenue recognition;
- Accounts receivable and bad debts;
- Stock-based compensation; and
- Warrant liability.

Recent Accounting Pronouncements

The notes to our audited consolidated financial statements contain a summary of recent accounting pronouncements.

Item 7A. Qualitative and Quantitative Disclosures about Market Risk

We have exposure to financial market risks, including changes in foreign currency exchange rates and interest rates, and risk associated with how we invest our cash.

Foreign Exchange Risk

We conduct business in foreign markets through our subsidiary in India (BioServe Biotechnologies (India) Private Limited), in Australia through our subsidiary (vivoPharm Pty Ltd.) and in Italy through our subsidiary (Cancer Genetics Italia, S.r.l.). For the years ended December 31, 2017 and 2016, approximately 6% and 4%, respectively, of our revenues were earned outside the United States and collected in local currency. We are subject to risk for exchange rate fluctuations between such local currencies and the United States dollar and the subsequent translation of the Indian Rupee, Australia Dollar or Euro to United States dollars. We currently do not hedge currency risk. The translation adjustments for the years ended December 31, 2017 and 2016 were not significant.

Interest Rate Risk

At December 31, 2017, we had interest rate risk primarily related to borrowings of $4.1 million on the asset-based line of credit with Silicon Valley Bank ("ABL"). The ABL requires monthly interest payments at the Wall Street Journal prime rate plus 1.5% (6.0% at December 31, 2017). If interest rates increased by 1.0%, interest expense in 2018 on our current borrowings would increase by approximately $41,000.

Investment of Cash

We invest our cash primarily in money market funds. Because of the short-term nature of these investments, we do not believe we have material exposure due to market risk. The impact to our financial position and results of operations from likely changes in interest rates is not material.

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Item 8. Financial Statements and Supplementary Data

INDEX TO FINANCIAL STATEMENTS

Cancer Genetics, Inc. and Subsidiaries

Consolidated Financial Report December 31, 2017

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Cancer Genetics, Inc. and Subsidiaries

Opinion on the Financial Statements
We have audited the accompanying consolidated balance sheets of Cancer Genetics, Inc. and its subsidiaries (the Company) as of December 31, 2017 and 2016, and the related consolidated statements of operations and other comprehensive loss, changes in stockholders' equity and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern
The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses, an accumulated deficit and negative cash flows from operations. The Company is also in violation of certain debt covenants. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ RSM US LLP

We have served as the Company's auditor since 2010.

New York, New York
April 2, 2018

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CANCER GENETICS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
(in thousands, except par value)

| | December 31, | |
|---|---|---|
| | 2017 | 2016 |
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | $9,541 | $9,502 |
| Accounts receivable, net of allowance for doubtful accounts of 2017 $6,539; 2016 $1,387 | 10,958 | 11,748 |
| Other current assets | 2,707 | 2,174 |
| Total current assets | 23,206 | 23,424 |
| FIXED ASSETS, net of accumulated depreciation | 5,550 | 4,738 |
| OTHER ASSETS | | |
| Restricted cash | 350 | 300 |
| Patents and other intangible assets, net of accumulated amortization | 4,478 | 1,503 |
| Investment in joint venture | 246 | 268 |
| Goodwill | 17,992 | 12,029 |
| Other | 399 | 172 |
| Total other assets | 23,465 | 14,272 |
| Total Assets | $52,221 | $42,434 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES | | |
| Accounts payable and accrued expenses | $8,715 | $8,148 |
| Obligations under capital leases, current portion | 272 | 109 |
| Deferred revenue | 516 | 789 |
| Line of credit | 4,137 | — |
| Bank term note, current portion | 6,000 | 2,000 |
| Total current liabilities | 19,640 | 11,046 |
| Bank term note | — | 2,654 |
| Obligations under capital leases | 624 | 374 |
| Deferred rent payable and other | 360 | 290 |
| Warrant liability | 4,403 | 2,018 |
| Deferred revenue, long-term | 429 | 428 |
| Total Liabilities | 25,456 | 16,810 |
| STOCKHOLDERS' EQUITY | | |
| Preferred stock, authorized 9,764 shares $0.0001 par value, none issued | — | — |
| Common stock, authorized 100,000 shares, $0.0001 par value, 27,754 and 18,936 shares issued and outstanding as of December 31, 2017 and 2016, respectively | 3 | 2 |
| Additional paid-in capital | 161,527 | 139,576 |
| Accumulated other comprehensive income | 69 | — |
| Accumulated deficit | (134,834) | (113,954) |
| Total Stockholders' Equity | 26,765 | 25,624 |
| Total Liabilities and Stockholders' Equity | $52,221 | $42,434 |

See Notes to Consolidated Financial Statements.

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CANCER GENETICS, INC. AND SUBSIDIARIES
Consolidated Statements of Operations and Other Comprehensive Loss
(in thousands, except per share amounts)

| | Years Ended December 31, | |
|---|---|---|
| | 2017 | 2016 |
| Revenue | $29,121 | $27,049 |
| Cost of revenues | 18,070 | 17,104 |
| Gross profit | 11,051 | 9,945 |
| Operating expenses: | | |
| Research and development | 4,789 | 5,967 |
| General and administrative | 19,894 | 16,034 |
| Sales and marketing | 4,990 | 4,668 |
| Total operating expenses | 29,673 | 26,669 |
| Loss from operations | (18,622) | (16,724) |
| Other income (expense): | | |
| Interest expense | (2,128) | (454) |
| Interest income | 63 | 23 |
| Change in fair value of warrant liability | (1,964) | 1,525 |
| Change in fair value of acquisition note payable | (42) | 152 |
| Other expense | (266) | (325) |
| Total other income (expense) | (4,337) | 921 |
| Loss before income taxes | (22,959) | (15,803) |
| Income tax (benefit) | (2,079) | — |
| Net (loss) | $(20,880) | $(15,803) |
| Basic and diluted net (loss) per share | $(1.01) | $(1.00) |
| Basic and diluted weighted average shares outstanding | 20,663 | 15,861 |
| | | |
| Net (loss) | (20,880) | (15,803) |
| Unrealized gain on foreign currency translation | 69 | — |
| Total comprehensive (loss) | $(20,811) | $(15,803) |

See Notes to Consolidated Financial Statements.

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CANCER GENETICS, INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders' Equity
Years Ended December 31, 2017 and 2016
(in thousands)

| | Common Stock | | Additional Paid-in | Accumulated Other | Accumulated | Total |
|---|---|---|---|---|---|---|
| | Shares | Amount | Capital | Comprehensive Income | Deficit | |
| Balance, December 31, 2015 | 13,652 | 1 | 131,167 | — | (98,151) | 33,017 |
| Stock based compensation - employees | 16 | — | 1,978 | — | — | 1,978 |
| Stock based compensation - non-employees | — | — | 38 | — | — | 38 |
| Issuance of stock - consultant | 50 | — | 75 | — | — | 75 |
| Issuance of stock - 2016 Offerings | 5,218 | 1 | 6,318 | — | — | 6,319 |
| Net loss | — | — | — | — | (15,803) | (15,803) |
| Balance, December 31, 2016 | 18,936 | 2 | 139,576 | — | (113,954) | 25,624 |
| Stock based compensation—employees | 68 | — | 1,826 | — | | 1,826 |
| Stock based compensation—non-employees | — | — | 69 | — | — | 69 |
| Exercise of warrants | 857 | — | 4,609 | — | — | 4,609 |
| Exercise of options | 3 | — | 7 | — | — | 7 |
| Issuance of stock - consultant | 2 | — | 5 | — | — | 5 |
| Issuance of stock - acquisition of vivoPharm, Pty Ltd. | 3,068 | — | 8,084 | — | — | 8,084 |
| Issuance of stock - Aspire Capital | 1,320 | — | 2,965 | — | — | 2,965 |
| Issuance of stock - 2017 Offering | 3,500 | 1 | 4,386 | — | — | 4,387 |
| Unrealized gain on foreign currency translation | — | — | — | 69 | — | 69 |
| Net loss | — | — | — | — | (20,880) | (20,880) |
| Balance, December 31, 2017 | 27,754 | $ 3 | $ 161,527 | $ 69 | $ (134,834) | $ 26,765 |

See Notes to Consolidated Financial Statements.

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CANCER GENETICS, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
(in thousands)

| | Years Ended December 31, | |
|---|---|---|
| | 2017 | 2016 |
| CASH FLOWS FROM OPERATING ACTIVITIES | | |
| Net loss | $(20,880) | $(15,803) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 1,799 | 2,032 |
| Amortization | 366 | 343 |
| Provision for bad debts | 5,278 | 723 |
| Stock-based compensation | 1,895 | 2,016 |
| Stock issued for consulting services | 5 | 75 |
| Change in fair value of acquisition note payable | 42 | (152) |
| Change in fair value of warrant liability | 1,964 | (1,525) |
| Amortization of debt issuance costs | 295 | 12 |
| Accretion of discount on debt | 1,004 | — |
| Loss in equity-method investment | 22 | 73 |
| Loss on extinguishment of debt | 78 | — |
| Change in working capital components: | | |
| Accounts receivable | (3,583) | (5,850) |
| Other current assets | (159) | (56) |
| Other non-current assets | — | (69) |
| Accounts payable, accrued expenses and deferred revenue | (1,538) | 355 |
| Deferred rent and other | (152) | (25) |
| Net cash (used in) operating activities | (13,564) | (17,851) |
| CASH FLOWS FROM INVESTING ACTIVITIES | | |
| Purchase of fixed assets | (1,284) | (490) |
| Increase in restricted cash | (50) | — |
| Patent costs | (126) | (119) |
| Purchase of cost method investment | (200) | — |
| Cash used in acquisition of vivoPharm, Pty Ltd., net of cash received | (1,091) | — |
| Net cash (used in) investing activities | (2,751) | (609) |
| CASH FLOWS FROM FINANCING ACTIVITIES | | |
| Principal payments on capital lease obligations | (230) | (126) |
| Proceeds from warrant exercises | 1,827 | — |
| Proceeds from option exercises | 7 | — |
| Proceeds from offerings of equity and derivative warrants, net of certain offering costs | 6,586 | 9,962 |
| Proceeds from borrowings on Silicon Valley Bank line of credit | 4,137 | — |
| Proceeds from Partners for Growth IV, L.P. term note | 6,000 | — |
| Proceeds from Aspire Capital common stock purchase, net of certain offering costs | 2,965 | — |
| Payment of debt issuance costs | (287) | — |
| Principal payments on notes payable | (4,667) | (1,333) |
| Net cash provided by financing activities | 16,338 | 8,503 |
| Effect of foreign currency exchange rates on cash and cash equivalents | 16 | — |
| Net increase (decrease) in cash and cash equivalents | 39 | (9,957) |
| CASH AND CASH EQUIVALENTS | | |
| Beginning | 9,502 | 19,459 |

| | | |
|---|---|---|
| Ending | $9,541 | $9,502 |
| | | |
| SUPPLEMENTAL CASH FLOW DISCLOSURE | | |
| Cash paid for interest | $871 | $333 |
| SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES | | |
| Fixed assets acquired through capital lease arrangements | $567 | $211 |
| Derivative warrants issued with debt | 1,004 | — |
| Value of shares issued as partial consideration to purchase vivoPharm, Pty Ltd. | 8,084 | — |
| Derivative warrants issued with common stock | 2,199 | — |

See Notes to Consolidated Financial Statements.

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CANCER GENETICS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements
Note 1. Organization, Description of Business, Acquisition and Offerings

We are an emerging leader in the field of precision medicine, enabling individualized therapies in the field of oncology through our tests, services and molecular markers. We develop, commercialize and provide molecular- and biomarker-based tests and services, including proprietary preclinical oncology and immuno-oncology services, that enable biotech and pharmaceutical companies engaged in oncology and immuno-oncology trials to better select candidate populations and reduce adverse drug reactions by providing information regarding genomic and molecular factors influencing subject responses to therapeutics. Through our clinical services, we enable physicians to personalize the clinical management of each individual patient by providing genomic information to better diagnose, monitor and inform cancer treatment. We have a comprehensive, disease-focused oncology testing portfolio, and extensive set of anti-tumor referenced data based on predictive xenograft and syngeneic tumor models. Our tests and techniques target a wide range of indications, covering all ten of the top cancers in prevalence in the United States, with additional unique capabilities offered by our FDA-cleared Tissue of Origin® test for identifying difficult to diagnose tumor types or poorly differentiated metastatic disease. Following the acquisition of vivoPharm, Pty Ltd. (“vivoPharm”) we provide contract research services, focused primarily on unique specialized studies to guide drug discovery and development programs in the oncology and immuno-oncology fields.

We were incorporated in the State of Delaware on April 8, 1999 and have offices and state-of-the-art laboratories located in California, New Jersey, North Carolina, Pennsylvania, Australia, and Hyderabad (India). Our laboratories comply with the highest regulatory standards as appropriate for the services they deliver including CLIA, CAP, NY State, California State and NABL (India). Our services are built on a foundation of world-class scientific knowledge and intellectual property in solid and blood-borne cancers, as well as strong academic relationships with major cancer centers such as Memorial Sloan-Kettering, Mayo Clinic, and the National Cancer Institute. We offer preclinical services such as predictive tumor models, human orthotopic xenografts and syngeneic immuno-oncology relevant tumor models in our Hershey PA facility, and a leader in the field of immuno-oncology preclinical services in the United States. This service is supplemented with GLP toxicology and extended bioanalytical services in our Australian based facility in Bundoora VIC.

Acquisition of vivoPharm Pty, Ltd.

On August 15, 2017, we purchased all of the outstanding stock of vivoPharm, Pty Ltd. (“vivoPharm”), with its principal place of business in Victoria, Australia, in a transaction valued at approximately $1.6 million in cash and shares of the Company's common stock, valued at $8.1 million based on the closing price of the stock on August 15, 2017. The Company has deposited in escrow 20% of the stock consideration until the expiration of twelve months from the closing date to serve as the initial source for any indemnification claims and adjustments. The Company has incurred approximately $135,000 in transaction costs associated with the purchase of vivoPharm, which were expensed during the year ended December 31, 2017.

Prior to the acquisition, vivoPharm was a contract research organization (“CRO”) that specialized in planning and conducting unique, specialized studies to guide drug discovery and development programs with a concentration in oncology and immuno-oncology. The transaction is being accounted for using the acquisition method of accounting for business combinations. Under this method, the total consideration transferred to consummate the acquisition is being allocated to the identifiable tangible and intangible assets acquired and liabilities assumed based on their respective fair values as of the closing date of the acquisition. Goodwill arising from the acquisition of vivoPharm relates to expected growth and synergies, as well as an assembled workforce. Goodwill is not deductible for income tax purposes.

The acquisition method of accounting requires extensive use of estimates and judgments to allocate the consideration transferred to the identifiable tangible and intangible assets acquired and liabilities assumed. Accordingly, the allocation of the consideration transferred is preliminary and will be adjusted upon completion of the final valuation of the assets acquired and liabilities assumed. The final valuation is expected to be completed as soon as practicable but no later than twelve months after the closing date of the acquisition. As of December 31, 2017, the valuation of the lab supplies, deferred revenue and deferred taxes is provisional.

The Company made revisions to the preliminary valuation of certain assets and liabilities acquired which decreased lab supplies by approximately $908,000, decreased prepaid expenses and other current assets by approximately $41,000, decreased fixed assets by approximately $184,000, decreased intangible assets by approximately $3,854,000, increased goodwill by approximately $3,831,000, increased deferred rent and other by approximately $222,000 and decreased capital lease obligations by $41,000.

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The estimated allocation of the purchase price as of August 15, 2017 consists of the following (in thousands):

| | Amount |
|---|---|
| Cash | $544 |
| Accounts receivable | 905 |
| Lab supplies | 350 |
| Prepaid expenses and other current assets | 60 |
| Fixed assets | 765 |
| Intangible assets | 3,160 |
| Goodwill | 5,960 |
| Accounts payable | (913) |
| Deferred revenue | (814) |
| Deferred rent and other | (222) |
| Obligations under capital lease | (76) |
| Total purchase price | $9,719 |

The following table provides certain pro forma financial information for the Company as if the acquisition of vivoPharm discussed above occurred on January 1, 2016 (in thousands except per share amounts):

| | Unaudited Year Ended December 31, | |
|---|---|---|
| | 2017 | 2016 |
| Revenue | $32,880 | $31,981 |
| Net income (loss) | (20,961) | (16,493) |
| Basic and dilutive net loss per share | $(0.92) | $(0.87) |

The pro forma numbers above are derived from historical numbers of the Company and vivoPharm and reflect adjustments for pro forma amortization and certain operating expenses. The Company's results of operations for the year ended December 31, 2017 include the operations of vivoPharm from August 15, 2017, with revenues of approximately $2,717,000. The net income (loss) of vivoPharm cannot be determined, as its operations were integrated with Cancer Genetics.

2016 Offerings

May Offering

On May 25, 2016, we sold 2,467,820 shares of common stock in a public offering and warrants to purchase 1,233,910 shares of common stock in a concurrent private placement. These offerings resulted in gross proceeds of $5 million. We sold 2,150,000 shares of common stock and warrants to purchase 1,075,000 shares of common stock to certain institutional investors at a combined offering price of $2.00 per common share, and our Chairman of the Board, John Pappajohn, purchased 317,820 shares of common stock and warrants to purchase 158,910 shares of common stock at a combined offering price of $2.2025 per common share. In addition, we issued warrants to purchase an aggregate of 123,391 shares of common stock to the placement agent. Subject to certain ownership limitations, the warrants were initially exercisable commencing six months from the issuance date at an exercise price equal to $2.25 per share of common stock. The warrants are exercisable for five years from the initial exercise date. All references to the sales of common stock with warrants mentioned in this paragraph, along with the September Offering below, are referred to as

the “2016 Offerings.”

September Offering

On September 14, 2016, we sold 2,750,000 shares of common stock in a public offering and warrants to purchase 1,375,000 shares of common stock in a concurrent private placement at a combined price of $2.00 per common share. These offerings

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resulted in gross proceeds of $5.5 million. In addition, we issued warrants to purchase an aggregate of 137,500 shares of common stock to the placement agent. Subject to certain ownership restrictions, the warrants will be initially exercisable six months from the issuance date at an exercise price of $2.25 per share of common stock. The warrants are exercisable for five years from the initial exercise date. All references to the sales of common stock with warrants mentioned in this paragraph, along with the May Offering above, are referred to as the "2016 Offerings."

2017 Offering

On December 8, 2017, we sold 3,500,000 shares of our common stock and warrants to purchase 3,500,000 shares of common stock in a public offering ("2017 Offering"). The offering resulted in gross proceeds of $7.0 million. The 2017 Offering warrants have an exercise price of $2.35 per share of common stock. In addition, we issued warrants to purchase an aggregate of 175,000 shares of common stock at $2.50 per share to the placement agent ("Wainwright Warrants"). Subject to certain ownership limitations, these warrants will be initially exercisable 6 months from the issuance date and are exercisable for 12 months from the initial exercise date.

Common Stock Purchase Agreement with Aspire Capital

On August 14, 2017, we entered into a Common Stock Purchase Agreement (the "Purchase Agreement") with Aspire Capital Fund, LLC, an Illinois limited liability company ("Aspire Capital"), which provides that Aspire Capital is committed to purchase up to an aggregate of $16 million of our common stock (the "Purchase Shares") from time to time over the term of the Purchase Agreement. Aspire Capital made an initial purchase of 1,000,000 Purchase Shares (the "Initial Purchase") at a purchase price of $3.00 per share on the commencement date of the agreement.

After the commencement date, on any business day over the 24-month term of the Purchase Agreement, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice (each, a "Purchase Notice") directing Aspire Capital to purchase up to 33,333 Purchase Shares per business day, provided that Aspire Capital will not be required to buy Purchase Shares pursuant to a Purchase Notice that was received by Aspire Capital on any business day on which the last closing trade price of our common stock on the NASDAQ Capital Market is below $3.00. The Company and Aspire Capital also may mutually agree to increase the number of shares that may be sold to as much as an additional 2,000,000 Purchase Shares per business day. The Purchase Agreement provides for a purchase price per Purchase Share of $3.00. As consideration for entering into the Purchase Agreement, we issued 320,000 shares of our common stock to Aspire Capital ("Commitment Shares").

The number of Purchase Shares covered by and timing of each Purchase Notice are determined by us, at our sole discretion. The aggregate number of shares that we can sell to Aspire Capital under the Purchase Agreement may in no case exceed 3,938,213 shares of our common stock (which is equal to approximately 19.9% of the common stock outstanding on the date of the Purchase Agreement), including the 320,000 Commitment Shares and the 1,000,000 Initial Purchase Shares, unless shareholder approval is obtained to issue additional shares.

Our net proceeds will depend on several factors, including the frequency of our sales of Purchase Shares to Aspire Capital and the frequency at which the last closing trade price of our common stock is below $3.00, subject to a maximum of $16 million in gross proceeds, including the Initial Purchase. Our delivery of Purchase Notices will be made subject to market conditions, in light of our capital needs from time to time and under the limitations contained in the Purchase Agreement. We currently intend to use the net proceeds from sales of Purchase Shares for general corporate purposes and working capital requirements.

As of December 31, 2017, the Company has sold 1,000,000 shares under this agreement at $3.00 per share, resulting in proceeds of approximately $2,965,000, net of offering costs of approximately $35,000. The Company has also issued 320,000 shares as consideration for entering into the Purchase Agreement. The Company has not deferred any

offering costs associated with this agreement. Due to the price of the Company's stock being lower than the $3.00 per share, the Company does not expect to sell more shares under the Purchase Agreement in the foreseeable future.

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Note 2. Going Concern

At December 31, 2017, our cash position and history of losses required management to assess our ability to continue operating as a going concern, according to Financial Accounting Standards Board Accounting Standards Update No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern ("ASU 2014-15"). The Company does not have sufficient cash at December 31, 2017 to fund normal operations for the next twelve months. In addition, the Company is in violation of certain financial covenants under its debt agreements at December 31, 2017, January 31, 2018, February 28, 2018 and March 31, 2018. The Company's ability to continue as a going concern is dependent on the Company's ability to obtain a waiver of its financial covenant violations, raise additional equity or debt capital or spin-off non-core assets to raise additional cash. These factors raise substantial doubt about the Company's ability to continue as a going concern.

We have hired Raymond James & Associates, Inc. as our financial advisor to assist with evaluating strategic alternatives. Such alternatives could include raising more capital, the acquisition of another company and/or complementary assets, the sale of the Company or another type of strategic partnership. We can provide no assurances that our current actions will be successful or that additional sources of financing with be available to us on favorable terms, if at all.

The consolidated financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

Note 3. Significant Accounting Policies

Basis of presentation: We prepare our financial statements on the accrual basis of accounting in accordance with accounting principles generally accepted in the United States of America.
Segment reporting: Operating segments are defined as components of an enterprise about which separate discrete information is used by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. We view our operations and manage our business in one operating segment, which is the business of developing and selling diagnostic tests and services.

Principles of consolidation: The accompanying consolidated financial statements include the accounts of Cancer Genetics, Inc. and our wholly owned subsidiaries.
All significant intercompany account balances and transactions have been eliminated in consolidation.
Foreign currency: We translate the financial statements of our foreign subsidiaries, which have a functional currency in the respective country's local currency, to U.S. dollars using month-end exchange rates for assets and liabilities and average exchange rates for revenue, costs and expenses. Translation gains and losses are recorded in accumulated other comprehensive income as a component of stockholders' equity. Gains and losses resulting from foreign currency transactions that are denominated in currencies other than the entity's functional currency are included within the consolidated statements of operations and other comprehensive loss and were not significant during 2017 or 2016.
Use of estimates and assumptions: The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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. Significant estimates made by management include, among others, realization of amounts billed, realization of long-lived assets, realization of intangible assets, accruals for litigation and registration payments, assumptions used to value stock options, warrants and goodwill and the valuation of assets acquired and liabilities assumed from acquisitions. Actual results could differ from those estimates.
Risks and uncertainties: We operate in an industry that is subject to intense competition, government regulation and rapid technological change. Our operations are subject to significant risk and uncertainties including financial,

operational, technological, regulatory, foreign operations, and other risks, including the potential risk of business failure.

Cash and cash equivalents: Highly liquid investments with original maturities of three months or less when purchased are considered to be cash equivalents. Financial instruments which potentially subject us to concentrations of credit risk consist primarily of cash and cash equivalents. We maintain cash and cash equivalents with high-credit quality financial institutions. At times, such amounts may exceed insured limits. We have not experienced any losses in such accounts and believe we are not exposed to any significant credit risk on our cash and cash equivalents.

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Restricted cash: Represents cash held at financial institutions which we may not withdraw and which collateralizes certain of our financial commitments. All of our restricted cash is invested in interest bearing certificates of deposit. At December 31, 2017 and 2016, our restricted cash collateralizes a $350,000 and $300,000, respectively, letter of credit in favor of our landlord, pursuant to the terms of the lease for our Rutherford facility.

Revenue recognition: The Company recognizes revenue in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 605, as well as SEC Staff Accounting Bulletin 104, for its Biopharma and Discovery Services, and ASC 954-605, Health Care Entities, Revenue Recognition for its Clinical Services. These standards generally require that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred and title and the risks and rewards of ownership have been transferred to the customer or services have been rendered; (3) the price is fixed or determinable; and (4) collectability is reasonably assured. In determining whether the price is fixed or determinable, we consider payment limits imposed by insurance carriers and Medicare, and the amount of revenue recorded takes into account the historical percentage of revenue we have collected for each type of test for each payor category. Periodically, an adjustment is made to Clinical Services revenue to record differences between our anticipated cash receipts from third parties, such as insurance carriers and Medicare, and actual receipts from such payors. These adjustments primarily relate to contractual allowances and discount and were not significant for the year ended December 31, 2016. For the year ended December 31, 2017, the Company recorded an adjustment of approximately $1,640,000. For some Clinical Service and Biopharma customers billed directly, revenue is recorded based upon the contractually agreed upon fee schedule. When assessing collectability, we consider whether we have sufficient payment history to reliably estimate a payor's individual payment patterns. We do not bill customers for shipping and handling fees, other than reimbursement of such expenses we incur on behalf of our Biopharma clients, and we do not collect any sales or other taxes from customers.

Accounts receivable: Accounts receivable are carried at net realizable value, which is the original invoice amount less an estimate for contractual adjustments, discounts and doubtful receivables, the amounts of which are determined by an analysis of individual accounts. Our policy for assessing the collectability of receivables is dependent upon the major payor source of the underlying revenue. For Biopharma and Discovery clients, an assessment of credit worthiness is performed prior to initial engagement and is reassessed periodically. If deemed necessary, an allowance is established on receivables from direct bill clients. For Clinical Services clients, we record revenues and related receivables when the testing process is complete and the results are reported. Revenue is recorded at the expected price, taking into account the patient's ability to pay, as well as anticipated discounts, adjustments and/or contractual allowances, as applicable. After reasonable collection efforts are exhausted, amounts deemed to be uncollectible are written off against the allowance for doubtful accounts. Since the Company only recognizes revenue to the extent it expects to collect such amounts, bad debt expense related to receivables from patient service revenue is recorded in general and administrative expense in the consolidated statements of operations. Recoveries of accounts receivable previously written off are recorded when received. For the 2017 calendar year, the Company, as part of its evaluation of outstanding accounts receivable, determined that a substantial amount of its receivables will not likely be collectible. Accordingly, the Company recorded approximately $5,278,000 of bad debt expenses in its Consolidated Statements of Operations and Other Comprehensive Loss during the year ended December 31, 2017. While the Company continues with its collections efforts on all claims, the Company has determined most of its challenges in cash collections is related to the acquisition of Response Genetics, some dating back to 2015 and 2016, and was associated with the integration of invoices into CGI's billing platform. These invoices were deemed uncollectible due to delays in filing its claims, the demands by payors for copies of patient medical records or diagnosis codes which has been difficult to obtain, among other reasons that payors have declined to reimburse the Company for its services. In addition, the Company has experienced low collection rates for its next generation sequencing tests due to the lack of coverage for certain of our next generation sequencing tests by Medicare and most third-party managed care plans, along with challenges in the integration of the lab management system in its Los Angeles laboratory facility into the Company's billing system, resulting in lower collections from third-party payors.

Deferred revenue: Payments received in advance of services rendered are recorded as deferred revenue and are subsequently recognized as revenue in the period in which the services are performed.

Fixed assets: Fixed assets consist of diagnostic equipment, furniture and fixtures and leasehold improvements. Fixed assets are carried at cost and are depreciated using the straight-line method over the estimated useful lives of the assets, which generally range from five to seven years. Leasehold improvements are depreciated over the lesser of the lease term or the estimated useful lives of the improvements using the straight-line method. Repairs and maintenance are charged to expense as incurred while improvements are capitalized. Upon sale, retirement or disposal of fixed assets, the accounts are relieved of the cost and the related accumulated depreciation with any gain or loss recorded to the consolidated statements of operations.

Fixed assets are reviewed for impairment whenever changes in circumstances indicate that the carrying amount of an asset may not be recoverable. These computations utilize judgments and assumptions inherent in our estimate of future cash flows to

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determine recoverability of these assets. If our assumptions about these assets were to change as a result of events or circumstances, we may be required to record an impairment loss.

Goodwill: Goodwill resulted from the purchases of Gentris Corporation ("Gentris") and BioServe Biotechnologies (India) Pvt. Ltd. ("BioServe") in 2014, the purchase of certain assets of Response Genetics, Inc. ("Response Genetics") in 2015 and the purchase of vivoPharm in 2017, as discussed in Note 1. In accordance with ASC 350, Intangibles - Goodwill and Other, we are required to test goodwill for impairment and adjust for impairment losses, if any, at least annually and on an interim basis if an event or circumstance indicates that it is likely impairment has occurred. Our annual goodwill impairment testing date is October 1 of each year. No such losses were incurred during the years ended December 31, 2017 and 2016.

| Goodwill (in thousands) | |
|---|---|
| Balance, December 31, 2015 and 2016 | $12,029 |
| Purchased through acquisition of vivoPharm | 5,960 |
| Foreign currency translation adjustment | 3 |
| Balance, December 31, 2017 | $17,992 |

Financing fees: Financing fees are amortized using the effective interest method over the term of the related debt. Debt is recorded net of unamortized debt issuance costs.

Warrant liability: We had issued certain warrants that contained an exercise price adjustment feature in the event we issued additional equity instruments at a price lower than the exercise price of the warrant. These warrants expired unexercised during the year ended December 31, 2016. We issued warrants during the 2016 Offerings and that 2017 Offering that contain a contingent net cash settlement feature. We also issued warrants that are subject to a 20% reduction if we achieve certain financial milestones as part of our 2017 debt refinancing described in Note 7. All of these warrants are described herein as derivative warrants. We account for these derivative warrants as liabilities. These common stock purchase warrants do not trade in an active securities market, and as such, we estimate the fair value of these warrants using the binomial lattice, Black-Scholes and Monte Carlo valuation pricing models with the assumptions as follows: The risk-free interest rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve. The expected life of the warrants is based upon the contractual life of the warrants. We use the historical volatility of our common stock and the closing price of our shares on the NASDAQ Capital Market. We compute the fair value of the warrant liability at each reporting period and the change in the fair value is recorded as non-cash expense or non-cash income. The key component in the value of the warrant liability is our stock price, which is subject to significant fluctuation and is not under our control. The resulting effect on our net income (loss) is therefore subject to significant fluctuation and will continue to be so until the warrants are exercised, amended or expire. Assuming all other fair value inputs remain constant, we will record non-cash expense when the stock price increases and non-cash income when the stock price decreases.

Income taxes: Income taxes are provided for the tax effects of transactions reported in the consolidated financial statements and consist of taxes currently due plus deferred income taxes. Deferred income taxes are recognized for temporary differences between the financial statement and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future. Deferred income taxes are also recognized for net operating loss ("NOLs") carryforwards that are available to offset future taxable income and research and development credits.

On December 22, 2017, the U.S. federal government enacted legislation commonly referred to as the "Tax Cuts and Jobs Act" (the "TCJA"). The TCJA makes widespread changes to the Internal Revenue Code, including, among other items, the introduction of a new international "Global Intangible Low-Taxed Income" ("GILTI") regime effective January 1, 2018. Companies may adopt one of two views in regards to establishing deferred taxes in accordance with the new GILTI regime under ASC 740. Companies may account for the effects of GILTI either (1) in the period the entity becomes subject to GILTI, or (2) establish deferred taxes (similar to the guidance that currently exists with respect to basis differences that will reverse under current Subpart F rules) for basis differences that upon reversal will be subject to GILTI. We have elected to account for GILTI in the period we become subject to GILTI.

Pursuant to the Securities and Exchange Commission (“SEC”) Staff Accounting Bulletin No.118 (“SAB 118”), the Company is allowed a measurement period of up to one year after the enactment date of the TCJA to finalize the recording of the related tax impacts. While we have not yet completed our assessment of the effects of the TCJA, we are able to determine reasonable estimates for the impacts of certain key items, thus we have reported provisional amounts for these items. The Company will continue to calculate the impact of the TCJA and will record any resulting tax adjustments during 2018, prior to the permitted

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remeasurement date. On a provisional basis, the Company is electing to use tax NOLs to offset any inclusion to U.S. taxable income prescribed by the guidance in new Internal Revenue Code Section 965 ("Section 965"). Given the availability to use NOLs to offset this income inclusion, at this time the Company does not expect to pay any one-time transition tax over the eight-year installment period as prescribed by Section 965. This conclusion is subject to change as we refine the provisional estimate of our total post-1986 E&P, cash position and other related calculations.

Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. We have established a full valuation allowance on our deferred tax assets as of December 31, 2017 and 2016; therefore, we have not recognized any tax benefit or expense in the periods presented.

ASC 740, Income Taxes, clarifies the accounting for uncertainty in income taxes recognized in the financial statements. ASC 740 provides that a tax benefit from uncertain tax positions may be recognized when it is more-likely-than-not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. Income tax positions must meet a more-likely-than-not recognition threshold to be recognized. ASC 740 also provides guidance on measurement, de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. At December 31, 2017 and 2016 we had no uncertain tax positions.

Our policy is to recognize interest and/or penalties related to income tax matters in income tax expense. There is no accrual for interest or penalties on our consolidated balance sheets at December 31, 2017 or 2016, and we have not recognized interest and/or penalties in the Consolidated Statements of Operations and Other Comprehensive Loss for the years ended December 31, 2017 or 2016.

Patents and other intangible assets: We account for intangible assets under ASC 350-30. Patents consisting of legal fees incurred are initially recorded at cost. We have also acquired patents that are initially recorded at fair value. Patents are amortized over the useful lives of the assets, using the straight-line method. Certain patents are in the legal application process and therefore are not currently being amortized. We review the carrying value of patents at the end of each reporting period. Based upon our review, there were no patent impairments in 2017 or 2016.

Other intangible assets consist of software acquired with Response Genetics and vivoPharm's customer list and trade name, which are all amortized using the straight-line method over the estimated useful lives of the assets, which range from three to ten years.

Research and development: Research and development costs associated with service and product development include direct costs of payroll, employee benefits, stock-based compensation and supplies and an allocation of indirect costs including rent, utilities, depreciation and repairs and maintenance. All research and development costs are expensed as they are incurred.

Stock-based compensation: Stock-based compensation is accounted for in accordance with the provisions of ASC 718, Compensation-Stock Compensation, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors based on estimated fair values on the grant date. We estimate the fair value of stock-based awards on the date of grant using the Black-Scholes option pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods using the straight-line method. See additional information in Note 13.

All issuances of stock options or other issuances of equity instruments to employees as the consideration for services received by us are accounted for based on the fair value of the equity instrument issued.

We account for stock-based compensation awards to non-employees in accordance with ASC 505-50, Equity Based Payments to Non-Employees. Under ASC 505-50, we determine the fair value of the warrants or stock-based compensation awards granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. Stock-based compensation awards issued to non-employees are recorded in expense and additional paid-in capital in stockholders' equity over the applicable service periods based on the fair value of the awards or consideration received at the vesting date.

Fair value of financial instruments: The carrying amount of cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued expenses, approximate their estimated fair values due to the short term maturities of those financial instruments. The fair value of warrants recorded as derivative liabilities and the note payable to VenturEast are described in Notes 15 and 16.

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Joint venture accounted for under the equity method: The Company records its joint venture investment following the equity method of accounting, reflecting its initial investment in the joint venture and its share of the joint venture's net earnings or losses and distributions. The Company's share of the joint venture's net loss was approximately $22,000 and $73,000 for the years ended December 31, 2017 and 2016, respectively, and is included in research and development expense on the Consolidated Statements of Operations and Other Comprehensive Loss. The Company has a net receivable due from the joint venture of approximately $10,000 at both December 31, 2017 and 2016, which is included in other assets in the Consolidated Balance Sheets. See additional information in Note 18.
Subsequent events: We have evaluated potential subsequent events through the date the financial statements were issued.

Recent Accounting Pronouncements: In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606), requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. As issued and amended, ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective and permits the use of either a full retrospective or retrospective with cumulative effect transition method. We adopted this guidance as of January 1, 2018, utilizing the modified retrospective transition method only with respect to contracts that were not completed as of January 1, 2018. The adoption changes our policies for recognizing revenue for performance obligations fulfilled over time in the Biopharma Services and Discovery Services areas. This transition adjustment is expected to reduce the opening balance of accumulated deficit by less than $3.0 million as of January 1, 2018 and increase deferred revenue associated with Biopharma Services and Discovery Services by up to $2.0 million and $1.0 million, respectively. In our Clinical Services area, the majority of the amounts historically classified as a provision for bad debts related to patient responsibility and will be considered an implicit price concession in determining net revenue under ASC 606. Accordingly, we will report uncollectible balances associated with individual patients as a reduction in the transaction price, and therefore, as a reduction in net revenues when historically these amounts were classified as bad debt expense within selling, general and administrative expenses. Pursuant to our adoption of the standard we also anticipate expanding our disclosures relating to revenue recognition, assets and liabilities relating to contracts with customers, the nature of our performance obligations and the manner by which we determine and allocate transaction prices and variable consideration to our performance obligations, and the significant judgments inherent in our revenue recognition policies. We also anticipate implementing enhancements to our internal controls to support our ability to sustain compliance with the standard after adoption.

In February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, "Leases (Topic 842)," which provides guidance for accounting for leases. Under ASU 2016-02, the Company will be required to recognize the assets and liabilities for the rights and obligations created by leased assets. ASU 2016-02 will take effect for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. We plan to adopt this guidance on the effective date. We are currently evaluating the impact the provisions will have on our consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230) "Classification of Certain Cash Receipts and Cash Payments." ASU 2016-15 provides guidance on statement of cash flow presentation for eight specific cash flow issues where diversity in practice exists. We will adopt this guidance as of January 1, 2018. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): "Restricted Cash," clarifying the treatment of restricted cash accounts on the statements of cash flows. ASU 2016-18 indicates that restricted cash accounts should be included with cash and cash equivalents when reconciling the beginning of year and end of year total amounts shown on the statements of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017. We will adopt this guidance as of January 1, 2018. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, Business Combinations (Topic 805) “Clarifying the Definition of a Business.” ASU 2017-01 clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The updated standard is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. We will adopt this guidance as of January 1, 2018. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, Intangibles - Goodwill and Other (Topic 350): “Simplifying the Accounting for Goodwill Impairment,” which removes the requirement to perform a hypothetical purchase price allocation to measure goodwill impairment. A goodwill impairment will now be the amount by which a reporting unit’s carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. ASU 2017-04 is effective for annual periods beginning after December

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15, 2019, and interim periods within those annual periods. Early adoption is permitted and applied prospectively. We do not expect ASU 2017-04 to have a material impact on our consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, Compensation - Stock Compensation (Topic 718): “Scope of Modification Accounting.” This ASU clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The ASU is effective for annual reporting periods beginning after December 15, 2017 and interim periods within those annual periods. Early adoption is permitted. We will adopt this guidance as of January 1, 2018. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): “(Part 1) Accounting for Certain Financial Instruments with Down Round Features (Part 2) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception.” This guidance changes the methodology for determining the liability or equity classification of certain financial instruments with a down round feature and clarifies existing disclosure requirements for equity-classified instruments, among other things. The revised guidance is effective for annual reporting periods beginning after December 15, 2018. Early adoption is permitted and applied retrospectively. We plan to adopt the guidance on its effective date and do not expect it to have a material impact on our consolidated financial statements.

Earnings (loss) per share: Basic earnings (loss) per share is computed by dividing net income (loss) available to common stockholders by the weighted average number of common shares assumed to be outstanding during the period of computation. Diluted earnings per share is computed similar to basic earnings per share except that the numerator is adjusted for the change in fair value of the warrant liability (only if dilutive) and the denominator is increased to include the number of dilutive potential common shares outstanding during the period using the treasury stock method.

Basic net loss and diluted net loss per share data were computed as follows (in thousands, except per share amounts):

| | 2017 | 2016 |
|---|---|---|
| Numerator: | | |
| Net (loss) for basic and dilutive earnings per share | $(20,880) | $(15,803) |
| Denominator: | | |
| Weighted-average basic and dilutive common shares outstanding | 20,663 | 15,861 |
| Basic and dilutive net loss per share | $(1.01) | $(1.00) |

The following table summarizes potentially dilutive adjustments to the weighted average number of common shares which were excluded from the calculation (in thousands):

| | 2017 | 2016 |
|---|---|---|
| Common stock purchase warrants | 10,055 | 7,033 |
| Stock options | 2,844 | 2,198 |
| Restricted shares of common stock | 705 | 80 |
| | 13,604 | 9,311 |

Note 4. Revenue and Accounts Receivable

Revenue by service type for each of the years ended December 31 is comprised of the following (in thousands):

| | 2017 | 2016 |
|---|---|---|
| Biopharma Services | $14,629 | $15,321 |
| Clinical Services | 10,774 | 10,651 |
| Discovery Services | 3,718 | 1,077 |

$29,121 $27,049

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The table above includes approximately $2,717,000 of Discovery Services revenue from our acquisition of vivoPharm for the year ended December 31, 2017.

Accounts receivable by service type at December 31, 2017 and 2016 consists of the following (in thousands):

| | 2017 | 2016 |
|---|---|---|
| Biopharma Services | $3,746 | $3,683 |
| Clinical Services | 12,205 | 8,972 |
| Discovery Services | 1,546 | 480 |
| Allowance for doubtful accounts | (6,539) | (1,387) |
| | $10,958 | $11,748 |

Revenue for Biopharma Services are customized solutions for patient stratification and treatment selection through an extensive suite of DNA-based testing services. Biopharma Services are billed to pharmaceutical and biotechnology companies. Clinical Services are tests performed to provide information on diagnosis, prognosis and theranosis of cancers to guide patient management. Clinical Services tests can be billed to Medicare, another third party insurer or the referring community hospital or other healthcare facility. Discovery Services are services that provide the tools and testing methods for companies and researchers seeking to identify new DNA-based biomarkers for disease. The breakdown of our Clinical Services revenue (as a percent of total revenue) is as follows:

| | 2017 | 2016 |
|---|---|---|
| Medicare | 12% | 14% |
| Other insurers | 20% | 20% |
| Other healthcare facilities | 5 % | 5 % |
| Total Clinical Services | 37% | 39% |

We have historically derived a significant portion of our revenue from a limited number of test ordering sites. Test ordering sites account for all of our Clinical Services revenue. Our test ordering sites are largely hospitals, cancer centers, reference laboratories, physician offices and biopharmaceutical companies. Oncologists and pathologists at these sites order the tests on behalf of the needs of their oncology patients or as part of a clinical trial sponsored by a biopharmaceutical company in which the patient is being enrolled. We generally do not have formal, long-term written agreements with such test ordering sites, and, as a result, we may lose a significant test ordering site at any time.

The top five test ordering clients during 2017 and 2016 accounted for 38% and 31%, respectively, of our testing volumes. During the year ended December 31, 2017, one Biopharma client accounted for approximately 11% of our revenue. During the year ended December 31, 2016, one Biopharma client accounted for approximately 16% of our revenue.

Note 5. Other Current Assets

At December 31, 2017 and 2016, other current assets consisted of the following (in thousands):

| | 2017 | 2016 |
|---|---|---|
| Inventory | $144 | $146 |
| Lab supplies | 1,690 | 1,301 |
| Prepaid expenses | 873 | 727 |
| | $2,707 | $2,174 |

Note 6. Lease Commitments

We lease our laboratory, research facility and administrative office space under various operating leases. We have approximately 17,900 square feet of office and laboratory space in Rutherford, New Jersey, 24,900 square feet in

Morrisville, North Carolina, 19,100 square feet in Los Angeles, California, 5,800 square feet in Hershey, Pennsylvania, 10,000 square feet in Hyderabad, India, and 1,959 square feet in Bundoora, Australia. For 2016 and a portion of 2017, we also had 2,700 square

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feet in Shanghai, China, which was vacated in July 2017. We have escalating lease agreements for our New Jersey, North Carolina, Pennsylvania and Australia spaces, which expire February 2023, May 2020, November 2020 and July 2021, respectively. These leases require monthly rent with periodic rent increases that vary from $0.15 to $0.83 per square foot of the rented premises per year. The difference between minimum rent and straight-line rent is recorded as deferred rent payable. The terms of our New Jersey lease require that a $350,000 security deposit for the facility be held in a stand by letter of credit in favor of the landlord (see Note 8).

We acquired office and scientific equipment under long term leases which have been capitalized at the present value of the minimum lease payments. The equipment under these capital leases had a cost of $1,453,797 and accumulated depreciation of $342,454, as of December 31, 2017.

Minimum future lease payments under all capital and operating leases as of December 31, 2017 are as follows (in thousands):

| | Capital Leases | Operating Leases | Total |
|---|---|---|---|
| December 31, | | | |
| 2018 | $363 | $ 1,583 | $1,946 |
| 2019 | 342 | 1,275 | 1,617 |
| 2020 | 196 | 1,079 | 1,275 |
| 2021 | 112 | 717 | 829 |
| 2022 | 13 | 565 | 578 |
| Thereafter | — | 94 | 94 |
| Total minimum lease payments | $1,026 | $ 5,313 | $6,339 |
| Less amount representing interest | 130 | | |
| Present value of net minimum obligations | 896 | | |
| Less current obligation under capital lease | 272 | | |
| Long-term obligation under capital lease | $624 | | |

Rent expense for the years ended December 31, 2017 and 2016 was approximately $1.79 million and $1.71 million, respectively.

Note 7. Bank Term Note and Line of Credit

At December 31, 2016, we had a term note with Silicon Valley Bank (“SVB”) that required monthly principal payments of approximately $167,000 and interest at the Wall Street Journal prime rate plus 2%, with a floor of 5.25% (5.75% at December 31, 2016) (“SVB Term Note”). An additional deferred interest payment of $180,000 was due at payoff. At December 31, 2016, the principal balance of the SVB Term Note was $4,666,667.

On March 22, 2017, we refinanced our debt with SVB, by repaying the SVB Term Note, which was scheduled to mature in April 2019, and entered into a new two year asset-based revolving line of credit agreement. The new SVB credit facility provides for an asset-based line of credit (“ABL”) for an amount not to exceed the lesser of (a) $6.0 million or (b) an amount equal to 80% of eligible accounts receivable plus the lesser of 50% of the net collectible value of third party accounts receivable or three times the average monthly collection amount of third party accounts receivable over the previous quarter. The ABL requires monthly interest payments at the Wall Street Journal prime rate plus 1.5% (6.0% at December 31, 2017) and matures on March 22, 2019. We paid to SVB a $30,000 commitment fee at closing and will pay a fee of 0.25% per year on the average unused portion of the ABL. At December 31, 2017, the ABL had a principal balance of $4,136,907, which is the maximum amount allowed based on eligible accounts receivable.

We concurrently entered into a new three year $6.0 million term loan agreement (“PFG Term Note”) with Partners for Growth IV, L.P. (“PFG”). The PFG Term Note is an interest only loan with the full principal and any outstanding interest due at maturity on March 22, 2020. Interest is payable monthly at a rate of 11.5% per annum, with the possibility of reducing to 11.0% in 2018 based on achieving certain financial milestones set forth by PFG. We may prepay the PFG Term Note in whole or part at any time without penalty. We paid PFG a commitment fee of $120,000 at closing. At December 31, 2017, the PFG Term Note had a principal balance of $6,000,000.

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Both loan agreements require us to comply with certain financial covenants, including minimum adjusted EBITDA, revenue and liquidity covenants, and restrict us from, among other things, paying cash dividends, incurring debt and entering into certain transactions without the prior consent of the lenders. Repayment of amounts borrowed under the new loan agreements may be accelerated if an event of default occurs, which includes, among other things, a violation of such financial covenants and negative covenants. As of December 31, 2017, January 31, 2018, February 28, 2018 and March 31, 2018, we were in violation of certain financial covenants. We are in discussion with PFG and SVB to amend the terms of the loan agreement which would, among other modifications, cure the default and reset the financial covenants.

Our obligations to SVB under the ABL facility are secured by a first priority security interest on substantially all of our assets, and our obligations under the PFG Term Note are secured by a second priority security interest subordinated to the SVB lien.
In connection with the PFG Term Note, we issued seven year warrants to the lenders to purchase an aggregate of 443,262 shares of our common stock at an exercise price of $2.82 per share, valued at $1,004,000. This amount has been recorded as a derivative warrant liability (see Note 14). The number of warrants may be reduced by 20% subject to us achieving certain financial milestones set forth by PFG.

The following is a summary of long-term debt as of December 31 (in thousands):

| | 2017 | 2016 |
|---|---|---|
| SVB Term Note, repaid in 2017 | $— | $4,667 |
| PFG Term Note | 6,000 | — |
| Less unamortized debt issuance costs | — | 13 |
| Term note, net | 6,000 | 4,654 |
| Less current maturities | $6,000 | $2,000 |
| Long-term portion | $— | $2,654 |

At December 31, 2017, the principal amount of the PFG Term Note of $6,000,000 was due in 2020; however, due to the financial covenant violations, the debt is now considered due on demand and has been reclassified as a current liability. As a result of these violations, we also recorded additional interest expense of approximately $220,000 to fully amortize debt issuance costs on the PFG Term Note and the ABL, as well as approximately $796,000 of interest expense to accrete the remaining discount on debt.

Note 8. Letter of Credit

We maintain a $350,000 letter of credit in favor of our landlord pursuant to the terms of the lease for our Rutherford facility. At December 31, 2017 and 2016, the letter of credit was fully secured by the restricted cash disclosed on our Consolidated Balance Sheets.

Note 9. Fixed Assets

Fixed assets are summarized by major classifications as follows (in thousands):

| | 2017 | 2016 |
|---|---|---|
| Equipment | $11,030 | $9,094 |
| Furniture and fixtures | 1,751 | 1,068 |
| Leasehold improvements | 924 | 932 |
| | 13,705 | 11,094 |
| Less accumulated depreciation | (8,155) | (6,356) |
| Net fixed assets | $5,550 | $4,738 |

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Note 10. Patents and Other Intangible Assets

Patents and other intangible assets consist of the following at December 31, 2017 and 2016:

| | (in thousands) 2017 | (in thousands) 2016 | Weighted-Average Remaining Amortization Period |
|---|---|---|---|
| Patents | $ 1,769 | $ 1,643 | 5 years |
| Software | 446 | 446 | 1 year |
| Customer list - vivoPharm acquisition | 2,738 | — | 10 years |
| Trade name - vivoPharm acquisition | 477 | — | 10 years |
| | 5,430 | 2,089 | |
| Less accumulated amortization | (952) | (586) | |
| Net patent and other intangible assets | $ 4,478 | $ 1,503 | |

The customer list and trade name in the table above include foreign currency translation gains of approximately $38,000 and $17,000, respectively, at December 31, 2017.

Future amortization expense for legally approved patents (excluding patent applications in progress of approximately $570,000 as of December 31, 2017) and other intangible assets, is estimated as follows (in thousands):

| | |
|---|---|
| 2018 | $522 |
| 2019 | 472 |
| 2020 | 461 |
| 2021 | 458 |
| 2022 | 439 |
| 2023 and thereafter | 1,556 |
| Total | $3,908 |

Note 11. Income Taxes

On December 22, 2017, the U.S. federal government enacted legislation commonly referred to as the “Tax Cuts and Jobs Act” (the “TCJA”). The TCJA makes widespread changes to the Internal Revenue Code, including, among other things, a reduction in the federal corporate tax rate from 35% to 21%, effective January 1, 2018. The carrying value of deferred tax assets and liabilities is also determined by the enacted U.S. corporate income tax rate. Consequently, the U.S. corporate tax rate will impact the carrying value of our deferred tax assets and liabilities. Under the new corporate tax rate of 21%, deferred income tax assets, net of deferred tax liabilities have decreased by $15.2 million. There is no net effect of the tax reform enactment on the consolidated financial statements as of December 31, 2017 due to full valuation allowance on the net deferred tax assets.

The provision (benefit) for income taxes for the years ended December 31, 2017 and 2016 differs from the approximate amount of income tax benefit determined by applying the U.S. federal income tax rate to pre-tax loss, due to the following:

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| | For the Year Ended December 31, 2017 | | For the Year Ended December 31, 2016 | |
|---|---|---|---|---|
| | Amount (in thousands) | % of Pretax Loss | Amount (in thousands) | % of Pretax Loss |
| Income tax benefit at federal statutory rate | $(8,036) | 35.0 % | $(5,531) | 35.0 % |
| State tax provision, net of federal tax benefit | (707) | 3.1 % | (777) | 4.9 % |
| Tax credits | (545) | 2.4 % | (342) | 2.2 % |
| Stock based compensation | 2,333 | (10.2)% | 206 | (1.3)% |
| Derivative warrants | 687 | (3.0)% | (534) | 3.4 % |
| Change in valuation allowance | (11,551) | 50.3 % | 7,459 | (47.2)% |
| Foreign operations | 15 | (0.1)% | 251 | (1.6)% |
| Remeasurement of deferred taxes under TCJA | 15,205 | (66.2)% | — | — % |
| Other | 520 | (2.3)% | (732) | 4.6 % |
| Income tax (benefit) provision | $(2,079) | 9.0 % | $— | — % |

In February 2017, we sold $18,177,059 of gross State of New Jersey NOL's relating to the 2014 and 2015 tax years as well as $167,572 of state research and development tax credits, resulting in the receipt of approximately $970,000, net of expenses. In December 2017, we sold $15,876,736 of gross State of New Jersey NOL's relating to the 2011 and 2016 tax years as well as $523,385 of state research and development tax credits, resulting in the receipt of approximately $1,109,000, net of expenses.

We transferred the NOL carryforwards through the Technology Business Tax Certificate Transfer Program sponsored by the New Jersey Economic Development Authority.

Approximate deferred taxes consist of the following components as of December 31, 2017 and 2016 (in thousands):

| | 2017 | 2016 |
|---|---|---|
| Deferred tax assets: | | |
| Net operating loss carryforwards | $23,135 | $32,273 |
| Accruals and reserves | 2,656 | 1,829 |
| Non-qualified stock options | 1,052 | 3,882 |
| Research and development tax credits | 1,876 | 1,331 |
| Derivative warrant liability | 17 | 26 |
| Investment in joint venture | 161 | 250 |
| Other | 5 | 8 |
| Total deferred tax assets | 28,902 | 39,599 |
| Less valuation allowance | (27,083) | (38,634) |
| Net deferred tax assets | 1,819 | 965 |
| Deferred tax liabilities | | |
| Fixed assets | (379) | (401) |
| Goodwill and intangible assets | (1,440) | (564) |
| Net deferred taxes | $— | $— |

Due to a history of losses we have generated since inception, we believe it is more-likely-than-not that all of the deferred tax assets will not be realized as of December 31, 2017 and 2016. Therefore, we have recorded a full valuation allowance on our deferred tax assets. We have net operating loss carryforwards for federal income tax purposes of approximately $99 million as of December 31, 2017. The net operating loss carryforwards will begin to expire in 2027. Utilization of these carryforwards is subject to limitation due to ownership changes that may delay the utilization of a portion of the carryforwards.

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Note 12. Capital Stock

2016 Offerings

May Offering

On May 25, 2016, we sold 2,467,820 shares of common stock in a public offering and warrants to purchase 1,233,910 shares of common stock in a concurrent private placement. These offerings resulted in gross proceeds of $5 million. We sold 2,150,000 shares of common stock and warrants to purchase 1,075,000 shares of common stock to certain institutional investors at a combined offering price of $2.00 per common share, and our Chairman of the Board, John Pappajohn, purchased 317,820 shares of common stock and warrants to purchase 158,910 shares of common stock at a combined offering price of $2.2025 per common share. In addition, we issued warrants to purchase an aggregate of 123,391 shares of common stock to the placement agent. Subject to certain ownership limitations, the warrants were initially exercisable commencing six months from the issuance date at an exercise price equal to $2.25 per share of common stock. The warrants are exercisable for five years from the initial exercise date. These warrants include a contingent net cash settlement feature, as described further in Note 14.

September Offering

On September 14, 2016, we sold 2,750,000 shares of common stock in a public offering and warrants to purchase 1,375,000 shares of common stock in a concurrent private placement at a combined price of $2.00 per common share. These offerings resulted in gross proceeds of $5.5 million. In addition, we issued warrants to purchase an aggregate of 137,500 shares of common stock to the placement agent. Subject to certain ownership restrictions, the warrants will be initially exercisable six months from the issuance date at an exercise price of $2.25 per share of common stock. The warrants are exercisable for five years from the initial exercise date. These warrants include a contingent net cash settlement feature, as described further in Note 14.

2017 Offering

On December 8, 2017, we sold 3,500,000 shares of our common stock and warrants to purchase 3,500,000 shares of common stock in a public offering (“2017 Offering”). The offering resulted in gross proceeds of $7.0 million. The 2017 Offering warrants have an exercise price of $2.35 per share of common stock. In addition, we issued warrants to purchase an aggregate of 175,000 shares of common stock at $2.50 per share to the placement agent (“Wainwright Warrants”). Subject to certain ownership limitations, these warrants will be initially exercisable 6 months from the issuance date and are exercisable for 12 months from the initial exercise date. These warrants include a contingent net cash settlement feature, as described further in Note 14.

Common Stock Purchase Agreement with Aspire Capital

On August 14, 2017, we entered into a Common Stock Purchase Agreement (the “Purchase Agreement”) with Aspire Capital Fund, LLC, an Illinois limited liability company (“Aspire Capital”), which provides that Aspire Capital is committed to purchase up to an aggregate of $16 million of our common stock (the “Purchase Shares”) from time to time over the term of the Purchase Agreement. Aspire Capital made an initial purchase of 1,000,000 Purchase Shares (the “Initial Purchase”) at a purchase price of $3.00 per share on the commencement date of the agreement.

After the commencement date, on any business day over the 24-month term of the Purchase Agreement, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice (each, a “Purchase Notice”) directing Aspire Capital to purchase up to 33,333 Purchase Shares per business day, provided that Aspire Capital will not be required to buy Purchase Shares pursuant to a Purchase Notice that was received by Aspire Capital on any business

day on which the last closing trade price of our common stock on the NASDAQ Capital Market is below $3.00. The Company and Aspire Capital also may mutually agree to increase the number of shares that may be sold to as much as an additional 2,000,000 Purchase Shares per business day. The Purchase Agreement provides for a purchase price per Purchase Share of $3.00. As consideration for entering into the Purchase Agreement, we issued 320,000 shares of our common stock to Aspire Capital (“Commitment Shares”).

The number of Purchase Shares covered by and timing of each Purchase Notice are determined by us, at our sole discretion. The aggregate number of shares that we can sell to Aspire Capital under the Purchase Agreement may in no case exceed 3,938,213 shares of our common stock (which is equal to approximately 19.9% of the common stock outstanding on the date of the Purchase Agreement), including the 320,000 Commitment Shares and the 1,000,000 Initial Purchase Shares, unless shareholder approval is obtained to issue additional shares.

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Our net proceeds will depend on several factors, including the frequency of our sales of Purchase Shares to Aspire Capital and the frequency at which the last closing trade price of our common stock is below $3.00, subject to a maximum of $16 million in gross proceeds, including the Initial Purchase. Our delivery of Purchase Notices will be made subject to market conditions, in light of our capital needs from time to time and under the limitations contained in the Purchase Agreement.

As of December 31, 2017, the Company has sold 1,000,000 shares under this agreement at $3.00 per share, resulting in proceeds of approximately $2,965,000, net of offering costs of approximately $35,000. The Company has also issued 320,000 shares as consideration for entering into the Purchase Agreement. The Company has not deferred any offering costs associated with this agreement. Due to the price of the Company's stock being lower than the $3.00 per share, the Company does not expect to sell more shares under the Purchase Agreement in the foreseeable future.

Stock Issued to Consultants

On October 24, 2016, we issued 50,000 shares of common stock to Maxim, LLC ("Maxim") at a value of $1.50 per common share in exchange for consulting services. On October 3, 2017, we issued 2,000 shares of common stock to another consultant at a value of $2.65 per common share.

Preferred Stock

We are currently authorized to issue up to 9,764,000 shares of preferred stock. As of December 31, 2017 and 2016, no shares of preferred stock were outstanding.

Note 13. Stock-Based Compensation

We have two equity incentive plans: the 2008 Stock Option Plan (the "2008 Plan") and the 2011 Equity Incentive Plan (the "2011 Plan", and together with the 2008 Plan, the "Stock Option Plans"). The Stock Option Plans are meant to provide additional incentive to officers, employees and consultants to remain in our employment. Options granted are generally exercisable for up to 10 years.

The Board of Directors adopted the 2011 Plan on June 30, 2011 and reserved 350,000 shares of common stock for issuance under the 2011 Plan. On May 22, 2014, May 14, 2015 and on October 11, 2016, the stockholders voted to increase the number of shares reserved by the plan to 2,000,000, 2,650,000, and 3,150,000 shares of common stock, respectively, under several types of equity awards including stock options, stock appreciation rights, restricted stock awards and other awards defined in the 2011 Plan.

The Board of Directors adopted the 2008 Plan on April 29, 2008 and reserved 251,475 shares of common stock for issuance under the plan. On April 1, 2010, the stockholders voted to increase the number of shares reserved by the plan to 550,000. We are authorized to issue incentive stock options or non-statutory stock options to eligible participants, as defined in the 2008 Plan.

We have also issued 48,000 options outside of the Stock Option Plans.

At December 31, 2017, 359,776 shares remain available for future awards under the 2011 Plan and 134,354 shares remain available for future awards under the 2008 Plan.
As of December 31, 2017, no stock appreciation rights and 363,334 shares of restricted stock had been awarded under the Stock Option Plans.

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A summary of employee and non-employee stock option activity for the years ended December 31, 2017 and 2016 is as follows:

| | Options Outstanding Number of Shares (in thousands) | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| Outstanding January 1, 2016 | 1,961 | $ 10.55 | 7.68 | $ — |
| Granted | 417 | 1.95 | | |
| Cancelled or expired | (180 ) | 8.44 | | |
| Outstanding December 31, 2016 | 2,198 | $ 9.09 | 7.04 | $ — |
| Granted | 902 | 2.85 | | |
| Exercised | (3 ) | 2.23 | | |
| Cancelled or expired | (253 ) | 10.34 | | |
| Outstanding December 31, 2017 | 2,844 | $ 7.00 | 6.96 | $ 4 |
| Exercisable, December 31, 2017 | 1,714 | $ 9.07 | 5.72 | $ 2 |

Aggregate intrinsic value represents the difference between the fair value of our common stock and the exercise price of outstanding, in-the-money options. We received $6,500 from the exercise of options during the year ended December 31, 2017. During the year ended December 31, 2016, no options were exercised.

As of December 31, 2017, total unrecognized compensation cost related to non-vested stock options granted to employees was $2,506,099, which we expect to recognize over the next 2.2 years.

The fair value of options granted to employees is estimated on the grant date using the Black-Scholes option valuation model. This valuation model requires us to make assumptions and judgments about the variables used in the calculation, including the expected term (the period of time that the options granted are expected to be outstanding), the volatility of our common stock, a risk-free interest rate, and expected dividends. Effective January 1, 2017, we adopted ASU 2016-09, which permits us to record forfeitures of unvested stock options when they occur. The adoption, along with the remaining provisions of ASU 2016-09, did not have a material impact on our consolidated financial statements. Prior to 2017, we estimated forfeitures of unvested stock options, and to the extent actual forfeitures differed from the estimate, the difference was recorded as a cumulative adjustment in the period the estimate was revised. No compensation cost is recorded for options that do not vest. We use the simplified calculation of expected life described in the SEC's Staff Accounting Bulletin No. 107, Share-Based Payment, and volatility is based on the historical volatility of our common stock. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option. We use an expected dividend yield of zero, as we do not anticipate paying any dividends in the foreseeable future.

The following table presents the weighted-average assumptions used to estimate the fair value of options granted to employees during the periods presented:

| | Year Ended December 31, | |
|---|---|---|
| | 2017 | 2016 |
| Volatility | 74.58 % | 73.86 % |
| Risk free interest rate | 1.98 % | 1.25 % |
| Dividend yield | — | — |
| Term (years) | 5.92 | 5.93 |
| Weighted-average fair value of options granted during the period | $ 1.87 | $ 1.26 |

In May 2014, we issued 200,000 options to a Director, with an exercise price of $15.89. See Note 19 for additional information. The following table presents the weighted-average assumptions used to estimate the fair value of options reaching their measurement date for non-employees during the periods presented:

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| | Year Ended December 31, | | | |
|---|---|---|---|---|
| | 2017 | | 2016 | |
| Volatility | 75.59 | % | 74.08 | % |
| Risk free interest rate | 2.24 | % | 1.64 | % |
| Dividend yield | — | | — | |
| Term (years) | 6.76 | | 7.76 | |

Restricted stock awards have been granted to employees, directors and consultants as compensation for services. At December 31, 2017, there was $314,481 of unrecognized compensation cost related to non-vested restricted stock granted to employees; we expect to recognize the cost over 1.3 years.

The following table summarizes the activities for our non-vested restricted stock awards for the years ended December 31, 2017 and 2016:

| | Non-vested Restricted Stock Awards | |
|---|---|---|
| | Number of Shares (in thousands) | Weighted-Average Grant Date Fair Value |
| Non-vested at January 1, 2016 | 121 | $ 8.25 |
| Granted | 18 | 1.81 |
| Vested | (57) | 8.99 |
| Forfeited/cancelled | (2) | 9.02 |
| Non-vested at December 31, 2016 | 80 | $ 6.30 |
| Granted | 70 | 3.26 |
| Vested | (57) | 5.73 |
| Forfeited/cancelled | (2) | 11.36 |
| Non-vested at December 31, 2017 | 91 | $ 4.21 |

The following table presents the effects of stock-based compensation related to stock option and restricted stock awards to employees and non-employees on our Consolidated Statements of Operations and Other Comprehensive Loss during the periods presented (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2017 | 2016 |
| Cost of revenues | $346 | $290 |
| Research and development | 133 | 172 |
| General and administrative | 1,299 | 1,446 |
| Sales and marketing | 117 | 108 |
| Total stock-based compensation | $1,895 | $2,016 |

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Note 14. Warrants

Prior to 2016, we issued certain warrants containing an exercise price adjustment (identified as Financing under the heading “derivative” in the table below). For these warrants, in the event new equity instruments were issued at a price lower than the exercise price of the warrant, the exercise price would be adjusted to the new equity instruments issued (price adjustment feature). These warrants were initially recorded as a warrant liability, with any subsequent change in their fair value recognized in earnings until the warrants were exercised, amended or expired. At December 31, 2016, all of these warrants had either been exercised or expired. During 2016 and 2017, we issued warrants containing a contingent net cash settlement feature (identified as 2016 Offerings and 2017 Offering, respectively, under the heading “derivative” in the table below). These warrants are recorded as a warrant liability, and all subsequent changes in their fair value are recognized in earnings until they are exercised, amended or expired. During 2017, we issued warrants that are subject to a 20% reduction if we achieve certain financial milestones as part of our debt refinancing in March 2017 (identified as 2017 Debt under the heading “derivative” in the table below). These warrants are recorded as a warrant liability, and all subsequent changes in their fair value are recognized in earnings until the number of shares of common stock issuable upon exercise of the warrants becomes fixed.

A certain number of our warrants are held by Mr. Pappajohn, the Chairman of our Board of Directors and stockholder. See Note 19 for additional details on these warrants.

On February 21, 2016 and March 23, 2016, 200 and 70,000 warrants expired unexercised, respectively.

On May 25, 2016, we issued 1,357,301 warrants to purchase shares of our common stock as part of our May Offering. Subject to certain ownership limitations, the warrants were initially exercisable commencing six months from the issuance date at an exercise price equal to $2.25 per share of common stock. The warrants are exercisable for five years from the initial exercise date. These warrants contain a contingent net cash settlement feature and are part of the 2016 Offerings derivative warrants in the table below.

On June 30, 2016, 86,533 warrants held by Mr. Pappajohn expired unexercised.

On September 14, 2016, we issued 1,512,500 warrants to purchase shares of our common stock as part of our September Offering. Subject to certain ownership limitations, the warrants were initially exercisable commencing six months from the issuance date at an exercise price equal to $2.25 per share of common stock. The warrants are exercisable for five years from the initial exercise date. These warrants also contain a contingent net cash settlement feature and are part of the 2016 Offerings derivative warrants in the table below.

On December 1, 2016 and December 21, 2016, 37,000 and 75,294 warrants held by Mr. Pappajohn expired unexercised, respectively.

On March 22, 2017, we issued seven year warrants to the lenders to purchase an aggregate of 443,262 shares of our common stock at an exercise price of $2.82 per share in connection with the PFG Term Note. The number of warrants may be reduced by 20% subject to us achieving certain financial milestones set forth by PFG. The warrants can be net settled in common stock using the average 90-trading day price of our common stock. These warrants are defined in the table below as 2017 Debt derivative warrants.

On March 24, 2017, warrant holders exercised warrants to purchase 375,700 shares of common stock at an exercise price of $2.25 per share, resulting in proceeds of $845,325.

On March 27, 2017, warrant holders exercised warrants to purchase 214,300 shares of common stock at an exercise price of $2.25 per share, resulting in proceeds of $482,175.

On March 28, 2017, warrant holders exercised warrants to purchase 64,200 shares of common stock at an exercise price of $2.25 per share, resulting in proceeds of $144,450.

On March 28, 2017, warrant holders exercised warrants to purchase 90,063 shares of common stock at an exercise price of $2.25 per share using the net issuance exercise method whereby 45,162 shares were surrendered as payment in full of the exercise price resulting in a net issuance of 44,901 shares.

On March 30, 2017, warrant holders exercised warrants to purchase 123,700 shares of common stock at an exercise price of $2.25 per share, resulting in proceeds of $278,325.

On May 22, 2017, warrant holders exercised warrants to purchase 9,000 shares of common stock at an exercise price of $2.25 per share, resulting in proceeds of $20,250.

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On August 9, 2017, warrant holders exercised warrants to purchase 25,000 shares of common stock at an exercise price of $2.25 per share, resulting in proceeds of $56,250.

On November 26, 2017, 194,007 warrants held by Mr. Pappajohn expired unexercised.

On December 8, 2017, we issued warrants to purchase 3,500,000 shares of our common stock at $2.35 per share and warrants to purchase 175,000 shares of our common stock at $2.50 per share to our placement agent, referred to below as the 2017 Offering. Subject to certain ownership limitations, the warrants will be initially exercisable 6 months from the issuance date and are exercisable for 12 months from the initial exercise date. These warrants contain a contingent net cash settlement feature and are part of derivative warrants in the table below.

The following table summarizes the warrant activity for the years ending December 31, 2017 and 2016 (in thousands, except exercise price):

| Issued With / For | Exercise Price | | Warrants Outstanding January 1, 2016 | 2016 Warrants Issued | 2016 Warrants Expired | Warrants Outstanding December 31, 2016 | 2017 Warrants Issued | 2017 Warrants Exercised | 2017 Warrants Expired | Warrants Outstanding December 31, 2017 |
|---|---|---|---|---|---|---|---|---|---|---|
| Non-Derivative Warrants: | | | | | | | | | | |
| Financing | $ 10.00 | | 243 | — | — | 243 | — | — | — | 243 |
| Financing | 15.00 | | 436 | — | (75) | 361 | — | — | (85) | 276 |
| Debt Guarantee | 15.00 | | 233 | — | (124) | 109 | — | — | (109) | — |
| Consulting | 10.00 | | 10 | — | (10) | — | — | — | — | — |
| 2015 Offering | 5.00 | | 3,450 | — | — | 3,450 | — | — | — | 3,450 |
| | $ 6.00 | D | 4,372 | — | (209) | 4,163 | — | — | (194) | 3,969 |
| Derivative Warrants: | | | | | | | | | | |
| Financing | $ 4.00 | A | 60 | — | (60) | — | — | — | — | — |
| 2016 Offerings | 2.25 | B | — | 2,870 | — | 2,870 | — | (902) | — | 1,968 |
| 2017 Debt | 2.82 | C | — | — | — | — | 443 | — | — | 443 |
| 2017 Offering | 2.35 | B | — | — | — | — | 3,500 | — | — | 3,500 |
| 2017 Offering | 2.50 | B | — | — | — | — | 175 | — | — | 175 |
| | $ 2.36 | D | 60 | 2,870 | (60) | 2,870 | 4,118 | (902) | — | 6,086 |
| | $ 3.80 | D | 4,432 | 2,870 | (269) | 7,033 | 4,118 | (902) | (194) | 10,055 |

A These warrants are subject to fair value accounting and contain an exercise price adjustment feature.

B These warrants are subject to fair value accounting and contain a contingent net cash settlement feature. See Note 15.

C These warrants are subject to fair value accounting until the number of shares of common stock issuable upon exercise of the warrants becomes fixed. See Note 15.

D Weighted average exercise prices are as of December 31, 2017.

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Note 15. Fair Value of Warrants

The derivative warrants issued as part of the 2016 Offerings are valued using a probability-weighted Binomial model, while the derivative warrants issued as part of the 2017 Debt refinancing are valued using a Monte Carlo model. The derivative warrants issued in conjunction with the 2017 Offering were valued using a Black-Scholes model. The following tables summarize the assumptions used in computing the fair value of derivative warrants subject to fair value accounting at the date of issue, at December 31, 2017 and 2016, and during the years then ended.

| 2016 Offerings | As of December 31, 2017 | Exercised During the Year Ended December 31, 2017 | As of December 31, 2016 | Issued During the Year Ended December 31, 2016 |
|---|---|---|---|---|
| Exercise price | $ 2.25 | $ 2.25 | $ 2.25 | $ 2.25 |
| Expected life (years) | 4.08 | 4.78 | 5.06 | 5.50 |
| Expected volatility | 73.44 % | 76.24 % | 72.82 % | 74.36 % |
| Risk-free interest rate | 2.11 % | 1.94 % | 1.93 % | 1.30 % |
| Expected dividend yield | 0.00 % | 0.00 % | 0.00 % | 0.00 % |

| 2017 Debt | As of December 31, 2017 | Issued During the Year Ended December 31, 2017 |
|---|---|---|
| Exercise price | $ 2.82 | $ 2.82 |
| Expected life (years) | 6.22 | 7.00 |
| Expected volatility | 74.18 % | 74.61 % |
| Risk-free interest rate | 2.33 % | 2.22 % |
| Expected dividend yield | 0.00 % | 0.00 % |

| 2017 Offering | As of December 31, 2017 | Issued During the Year Ended December 31, 2017 |
|---|---|---|
| Exercise price | 2.36 | $ 2.36 |
| Expected life (years) | 1.43 | 1.50 |
| Expected volatility | 77.55 % | 76.03 % |
| Risk-free interest rate | 1.83 % | 1.73 % |
| Expected dividend yield | 0.00 % | 0.00 % |

The ranges of Company stock prices used in computing the warrant fair value for warrants issued during the years were as follows: in 2017, $1.95—$2.90; in 2016, $1.90—$2.14. The range of Company stock prices used in computing the fair value for warrants exercised during 2017 was $3.55—$5.05. In determining the fair value of warrants outstanding at each reporting date, the Company stock price was $1.85 and $1.35 (the closing price on the NASDAQ Capital Market) at December 31, 2017 and 2016.

The following table summarizes the derivative warrant activity subject to fair value accounting for the years ended December 31, 2017 and 2016 (in thousands):

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| | Issued with 2016 Offerings | Issued with 2017 Debt | Issued with 2017 Offering | Total |
|---|---|---|---|---|
| Fair value of warrants outstanding as of January 1, 2016 | $ — | $— | $ — | $17 |
| Fair value of warrants issued | 3,526 | — | — | 3,526 |
| Change in fair value of warrants | (1,508 ) | — | — | (1,525 ) |
| Fair value of warrants outstanding as of December 31, 2016 | $ 2,018 | $— | $ — | $2,018 |
| Fair value of warrants issued | — | 1,004 | 2,199 | 3,203 |
| Fair value of warrants exercised | (2,782 ) | — | — | (2,782 ) |
| Change in fair value of warrants | 2,693 | (503 ) | (226 ) | 1,964 |
| Fair value of warrants outstanding as of December 31, 2017 | $ 1,929 | $501 | $ 1,973 | $4,403 |

Note 16. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. The Fair Value Measurements and Disclosures Topic of the FASB Accounting Standards Codification requires the use of valuation techniques that are consistent with the market approach, the income approach and/or the cost approach. Inputs to valuation techniques refer to the assumptions that market participants would use in pricing the asset or liability. Inputs may be observable, meaning those that reflect the assumptions market participants would use in pricing the asset or liability developed based on market data obtained from independent sources, or unobservable, meaning those that reflect our own assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. In that regard, the Topic establishes a fair value hierarchy for valuation inputs that give the highest priority to quoted prices in active markets for identical assets or liabilities and the lowest priority to unobservable inputs.

The fair value hierarchy is as follows:

Level 1: Quoted prices (unadjusted) for identical assets or liabilities in active markets that we have the ability to access as of the measurement date.

Level 2: Significant other observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data.

Level 3: Significant unobservable inputs that reflect our own assumptions about the assumptions that market participants would use in pricing an asset or liability.

The following table summarizes the financial liabilities measured at fair value on a recurring basis segregated by the level of valuation inputs within the fair value hierarchy utilized to measure fair value (in thousands):

| | 2017 | | | |
|---|---|---|---|---|
| | Total | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Warrant liability | $4,403 | — | — | $ 4,403 |
| Notes payable | $156 | — | — | 156 |
| | $4,559 | — | — | $ 4,559 |

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| | 2016 | | | |
|---|---|---|---|---|
| | Total | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Warrant liability | $2,018 | — | — | $ 2,018 |
| Notes payable | 114 | — | — | 114 |
| | $2,132 | — | — | $ 2,132 |

At December 31, 2017, the warrant liability consists of stock warrants issued as part of the 2016 Offerings and 2017 Offering that contain contingent redemption features and warrants issued as part of the 2017 debt refinancing outlined in Note 7. In accordance with derivative accounting for warrants, we calculated the fair value of warrants and the assumptions used are described in Note 15, “Fair Value of Warrants.” Realized and unrealized gains and losses related to the change in fair value of the warrant liability are included in other income (expense) on the Consolidated Statements of Operations and Other Comprehensive Loss.

At December 31, 2017 and 2016, the Company had a note payable to VenturEast from a prior acquisition. The ultimate repayment of the note will be the value of 84,278 shares of common stock at the time of payment. The value of the note payable to VenturEast was determined using the fair value of our common stock at the reporting date. During the years ended December 31, 2017 and 2016, we recognized a loss of $42,000 and gain of $152,000, respectively, due to the changes in value of the note. Realized and unrealized gains and losses related to the VenturEast note are included in other income (expense) on the Consolidated Statements of Operations and Other Comprehensive Loss.

The following table summarizes the activity of the notes payable to VenturEast and our derivative warrants, which were measured at fair value using Level 3 inputs (in thousands):

| | Note Payable to VenturEast | Warrant Liability |
|---|---|---|
| Fair value at January 1, 2016 | $ 266 | $17 |
| Change in fair value | (152) | (1,525) |
| Fair value of warrants issued | — | 3,526 |
| Fair value at December 31, 2016 | $ 114 | $2,018 |
| Change in fair value | 42 | 1,964 |
| Fair value of warrants issued | — | 3,203 |
| Fair value of warrants exercised | — | (2,782) |
| Fair value at December 31, 2017 | $ 156 | $4,403 |

Note 17. Contingencies

In the normal course of business, the Company is involved in various claims and legal proceedings. In the opinion of management, the ultimate liability or disposition thereof is not expected to have a material adverse effect on our financial condition, results of operations or liquidity.

Note 18. Joint Venture Agreement

In November 2011, we entered into an affiliation agreement with the Mayo Foundation for Medical Education and Research (“Mayo”), subsequently amended. Under the agreement, we formed a joint venture with Mayo in May 2013 to focus on developing oncology diagnostic services and tests utilizing next generation sequencing. The joint venture is a limited liability company, with each party initially holding fifty percent of the issued and outstanding membership interests of the new entity (the “JV”). In exchange for our membership interest in the JV, we made an initial capital contribution of $1.0 million in October 2013. In addition, we issued 10,000 shares of our common stock to Mayo pursuant to our affiliation agreement and recorded an expense of approximately $175,000. We also recorded additional expense of approximately $231,000 during the fourth quarter of 2013 related to shares issued to Mayo in November of 2011 as the JV achieved certain performance milestones. In the third quarter of 2014 we made an additional $1.0 million capital contribution.

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The agreement also requires aggregate total capital contributions by us of up to an additional $4.0 million. The timing of the remaining installments is subject to the JV's achievement of certain operational milestones agreed upon by the board of governors of the JV. In exchange for its membership interest, Mayo's capital contribution will take the form of cash, staff, services, hardware and software resources, laboratory space and instrumentation, the fair market value of which will be approximately equal to $6.0 million. Mayo's continued contribution will also be conditioned upon the JV's achievement of certain milestones.

The joint venture is considered a variable interest entity under ASC 810-10, but we are not the primary beneficiary as we do not have the power to direct the activities of the joint venture that most significantly impact its performance. Our evaluation of ability to impact performance is based on our equal board membership and voting rights and day to day management functions which are performed by the Mayo personnel.

Note 19. Related Party Transactions

John Pappajohn, a member of the Board of Directors and stockholder, had personally guaranteed our revolving line of credit with Wells Fargo Bank through March 31, 2014. As consideration for his guarantee, as well as each of the eight extensions of this facility through March 31, 2014, Mr. Pappajohn received warrants to purchase an aggregate of 1,051,506 shares of common stock of which Mr. Pappajohn assigned warrants to purchase 284,000 shares of common stock to certain third parties. Through December 31, 2017, warrants to purchase 440,113 shares of common stock have been exercised by Mr. Pappajohn, and the remaining warrants expired unexercised.

In addition, John Pappajohn also had loaned us an aggregate of $6,750,000 (all of which was converted into 675,000 shares of common stock at the IPO price of $10.00 per share). In connection with these loans, Mr. Pappajohn received warrants to purchase an aggregate of 202,630 shares of common stock. After adjustment pursuant to the terms of the warrants in conjunction with our IPO, the number of warrants outstanding was 275,556 at $15.00 per share at December 31, 2017.

We have a consulting agreement with Equity Dynamics, Inc. ("EDI"), an entity controlled by John Pappajohn, effective April 1, 2014 pursuant to which EDI receives a monthly fee of $10,000. We expensed $120,000 annually for the years ended December 31, 2017 and 2016 related to this agreement. At December 31, 2017 and 2016, we owed EDI $10,000 and $50,000, respectively.

Pursuant to a consulting and advisory agreement that ended December 31, 2016, Dr. Chaganti received $5,000 per month for providing consulting and technical support services. Total expenses for the year ended December 31, 2016 were $60,000. Pursuant to the terms of the consulting agreement, Dr. Chaganti received an option to purchase 200,000 shares of our common stock at a purchase price of $15.89 per share vesting over a period of four years. Total non-cash stock-based compensation recognized under this consulting agreement for the years ended December 31, 2017 and 2016 was $69,250 and $37,625, respectively. Also pursuant to the consulting agreement, Dr. Chaganti assigned to us all rights to any inventions which he may invent during the course of rendering consulting services to us. In exchange for this assignment, if the USPTO issues a patent for an invention on which Dr. Chaganti is listed as an inventor, we are required to pay Dr. Chaganti (i) a one-time payment of $50,000 and (ii)1% of any net revenues we receive from any licensed sales of the invention.

On May 25, 2016, Mr. Pappajohn purchased 317,820 shares of common stock and warrants to purchase 158,910 shares of common stock in the May Offering described in Note 12.

Note 20. Subsequent Events

On February 1, 2018, Panna Sharma resigned as our President, Chief Executive Officer and the Company appointed John A. Roberts as interim Chief Executive Officer. Mr. Sharma has agreed to provide consulting services to the Company during the transition period and will receive 12 months in base salary as severance, payable in accordance with the Company's standard payroll practices over 12 months, subject to the separation agreement and general release. In addition, Mr. Sharma will be provided with an extension through 1 year after the termination date of the exercise period for his vested stock options.

Financial Advisory Agreement

The Company has retained Raymond James & Associates, Inc. as a financial advisor to assist the Company in its evaluation of a broad range of financial and strategic alternatives to enhance shareholder value, including additional capital raising transactions, the acquisition of another company or complementary assets or the potential sale or merger of the Company or another type of strategic partnership. There is no assurance that the review of strategic alternatives will result in the Company changing its business plan, pursuing any particular transaction, if any, or, if it pursues any such transaction, that it will be

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completed. The Company does not expect to make further public comment regarding the strategic review until the Board of Directors has approved a specific transaction or otherwise deems disclosure of significant developments is appropriate.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

We evaluated, under the supervision and with the participation of our principal executive officer and principal financial officer, the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934 ("Exchange Act"), as amended) as of December 31, 2017, the end of the period covered by this report on Form 10-K. Based on this evaluation, the principal executive officer and the principal financial officer have concluded that our disclosure controls and procedures were not effective at December 31, 2017 as a result of the material weakness in internal controls described below. Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and were operating in an effective manner for the period covered by this report, and (ii) is accumulated and communicated to management, including, the principal executive officer and principal financial officer, or the person performing similar functions as appropriate, to allow timely decisions regarding required disclosures.

Management's Report on Internal Control Over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934.

The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to risk that controls may become inadequate because of changes in conditions or because of declines in the degree of compliance with policies or procedures. Our management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2017. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control-Integrated Framework (2013).

In connection with this assessment, we identified a material weakness, as described below, in our internal control over financial reporting as of December 31, 2017. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement for the annual or interim financial statements will not be prevented or detected on a timely basis. Because of the material weakness identified below, and based on management's assessment, as of December 31, 2017, the Company's internal control over financial reporting was not effective:

Accounting for uncollectible clinical services revenue: The Company's quarterly and year- end review procedures includes management's assessment of collectability and adjustment of its allowance for doubtful accounts. During the fourth quarter management revised its estimation process and as a result of the low collection patterns during the fourth quarter principally related to clinical service revenues from claims generated by the Los Angeles location, a determination was made to

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significantly increase the allowance for doubtful accounts to reflect this change in estimate, and our management has determined that this control deficiency constitutes a material weakness at December 31, 2017. However, the Company failed to identify that adjustments which pertained to contractual allowances and reduced expected collections of current quarter revenues should have been recorded as reductions in net revenue rather than bad debt expense. Accordingly, management needed to record audit adjustments to properly account for these items. Although management does perform overall review of revenue and related reserves at each reporting date, the controls designed to identify material misstatements did not operate at a sufficient level of precision to prevent or detect such errors in its determination of this significant accounting estimate.

Remediation plan: Management is committed to remediating the material weakness in a timely fashion. We have begun the process of implementing changes to our internal control over financial reporting to remediate the control deficiencies that gave rise to the material weakness, including further improvements in our processes and analyses that support the estimate of the allowance for doubtful accounts and the related bad debt expense and performing a comprehensive review of the need for additional corporate accounting and financial personnel, supplemented by external resources as appropriate, with the requisite skill and technical expertise. In addition, the Company expects this deficiency to be addressed as part of the implementation of ASU 2014-09 effective January 1, 2018.

Changes in Internal Control over Financial Reporting.

Other than the discovery of the material weakness and the remediation plan set forth above, there were no changes in our internal control over financial reporting during the three months ended December 31, 2017 that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

Item 9B. Other Information.

The Company has retained Raymond James & Associates, Inc. as a financial advisor to assist the Company in its evaluation of a broad range of financial and strategic alternatives to enhance shareholder value, including additional capital raising transactions, the acquisition of another company or complementary assets or the potential sale or merger of the Company or another type of strategic partnership. There is no assurance that the review of strategic alternatives will result in the Company changing its business plan, pursuing any particular transaction, if any, or, if it pursues any such transaction, that it will be completed. The Company does not expect to make further public comment regarding the strategic review until the Board of Directors has approved a specific transaction or otherwise deems disclosure of significant developments is appropriate.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be contained in the Proxy Statement for our 2018 Annual Meeting of Stockholders, which we anticipate will be filed no later than 120 days after the end of our fiscal year ended December 31, 2017 and is incorporated herein by reference herein.

Item 11. Executive Compensation.

The information required by this item will be contained in the Proxy Statement for our 2018 Annual Meeting of Stockholders, which we anticipate will be filed no later than 120 days after the end of our fiscal year ended December 31, 2017 and is incorporated by reference herein.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be contained in the Proxy Statement for our 2018 Annual Meeting of Stockholders, which we anticipate will be filed no later than 120 days after the end of our fiscal year ended December 31, 2017 and is incorporated by reference herein.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be contained in the Proxy Statement for our 2018 Annual Meeting of Stockholders, which we anticipate will be filed no later than 120 days after the end of our fiscal year ended December 31, 2017 and is incorporated by reference herein.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be contained in the Proxy Statement for our 2018 Annual Meeting of Stockholders, which we anticipate will be filed no later than 120 days after the end of our fiscal year ended December 31, 2017 and is incorporated by reference herein.

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PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements. The financial statements filed as part of this report are listed on the Index to the Consolidated Financial Statements.

(a)(2) Financial Statement Schedules. Schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or notes thereto.

(a)(3) Exhibits. Reference is made to the Exhibit Index. The exhibits are included, or incorporated by reference, in this annual report on Form 10-K and are numbered in accordance with Item 601 of Regulation S-K.

Item 16. Form 10-K Summary.

None.

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SIGNATURES

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

Cancer Genetics, Inc.
(Registrant)

Date: April 2, 2018 /s/ John A. Roberts
John A. Roberts
Interim Chief Executive Officer, Chief Operating Officer and Executive Vice President, Finance
(Principal Executive Officer and Principal Financial Officer and duly authorized signatory)

Date: April 2, 2018 /s/ Igor Gitelman
Igor Gitelman
Chief Accounting Officer
(Principal Accounting Officer)

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SIGNATURES AND POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints John A. Roberts and Igor Gitelman, and each of them, his true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to (i) act on, sign and file with the Securities and Exchange Commission any and all amendments to this annual report on Form 10-K together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith and, (iii) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act, this annual report on Form 10-K has been signed by the following persons in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ John A. Roberts<br>John A. Roberts | Interim Chief Executive Officer, Chief Operating Officer and Executive Vice President, Finance<br>(Principal Executive and Financial Officer) | April 2, 2018 |
| /s/ Igor Gitelman<br>Igor Gitelman | Chief Accounting Officer<br>(Principal Accounting Officer) | April 2, 2018 |
| /s/ John Pappajohn<br>John Pappajohn | Chairman of the Board of Directors | April 2, 2018 |
| /s/ Geoffrey Harris<br>Geoffrey Harris | Director | April 2, 2018 |
| /s/ Edmund Cannon<br>Edmund Cannon | Director | April 2, 2018 |
| /s/ Howard McLeod<br>Howard McLeod | Director | April 2, 2018 |
| /s/ Michael J. Welsh<br>Michael J. Welsh | Director | April 2, 2018 |
| /s/ Raju S. K. Chaganti<br>Raju S. K. Chaganti, Ph.D. | Director | April 2, 2018 |

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| /s/ Franklyn G. Prendergast<br>Franklyn G. Prendergast, M.D., Ph.D. | Director | April 2, 2018 |
| /s/ Thomas F. Widmann<br>Thomas F. Widmann | Director | April 2, 2018 |

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INDEX TO EXHIBITS

| Exhibit No. | Description |
|---|---|
| 2.1 | Stock Purchase Agreement, dated as of August 14, 2017, by and among the Company, the Trustee of The Brandt Family Trust, a trust organized under the laws of Australia, Sabine Brandt, Royal Melbourne Institute of Technology, South Australian Life Science Advancement Partnership, LP, vivoPharm Pty Ltd, Dr. Ralf Brandt, as Shareholders' Representative and the Management Parties party thereto (incorporated by reference to Exhibit 2.1 of the Company's current report on Form 8-K filed on August 16, 2017 with the Securities and Exchange Commission). |
| 3.1 | Third Amended and Restated Certificate of Incorporation of Cancer Genetics, Inc., filed as Exhibit 3.1 to quarterly report on Form 10-Q filed on May 15, 2013 and incorporated herein by reference. |
| 3.2 | Amended and Restated Bylaws of Cancer Genetics, Inc., filed as Exhibit 3.4 to Form S-1/A filed on April 30, 2012 (File No. 333-178836) and incorporated herein by reference. |
| 4.1 | Specimen Common Stock certificate of Cancer Genetics, Inc., filed as Exhibit 4.1 to Form S-1/A filed on May 16, 2012 (File No. 333-178836) and incorporated herein by reference. |
| 4.2 | Form of Short Form Cashless Exercise Warrant, filed as Exhibit 4.9 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference. |
| 4.3 | Form of Medium Form Warrant, filed as Exhibit 4.10 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference. |
| 4.4 | Form of Long Form Warrant, filed as Exhibit 4.11 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference. |
| 4.5 | Form of Bridge Financing Warrant issued by Cancer Genetics, Inc. to John Pappajohn, NNJCA Capital, LLC, Pecora and Company and DAM Holdings, LLC, filed as Exhibit 10.36 to Form S-1/A filed on March 13, 2012 (File No. 333-178836) and incorporated herein by reference. |
| 4.6 | Form of Modified Bridge Warrant issued by Cancer Genetics, Inc. to John Pappajohn and Mark Oman, filed as Exhibit 10.50 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference. |
| 4.7 | Form of October 2012 Warrant issued by Cancer Genetics, Inc. to John Pappajohn and Mark Oman, filed as Exhibit 10.53 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference. |
| 4.8 | Share Purchase Agreement, by and among Cancer Genetics (India) Private Limited, Cancer Genetics, Inc., BioServe Biotechnologies (India) Pvt. Ltd., BioServe Biotechnologies Ltd., and each of the Selling Shareholders named therein, dated May 12, 2014 (incorporated by reference to Exhibit 4.1 of the Company’s current report on Form 8-K filed on August 18, 2014 with the Securities and Exchange Commission). |
| 4.9 | Stock Purchase Agreement, by and between Cancer Genetics, Inc. and BioServe Biotechnologies Ltd., dated May 12, 2014 (incorporated by reference to Exhibit 4.2 of the Company’s current report on Form 8-K filed on |

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| | August 18, 2014 with the Securities and Exchange Commission). |
| 4.10 | Form of Warrant Agreement of Cancer Genetics, Inc. (incorporated by reference to Exhibit 4.1 of the Company's current report on Form 8-K, filed with the Securities and Exchange Commission on May 20, 2016). |
| 4.11 | Form of Warrant Agreement of Cancer Genetics, Inc. (incorporated by reference to Exhibit 4.1 to the Company's current report on Form 8-K, filed with the Securities and Exchange Commission on September 9, 2016). |
| 4.12 | Registration Rights Agreement, dated as of August 14, 2017, by and between the Company and Aspire Capital Fund, LLC (incorporated by reference to Exhibit 4.1 to the Company's current report on Form 8-K, filed with the Securities and Exchange Commission on August 16, 2017). |
| 4.13 | Form of Warrant Agreement of Cancer Genetics, Inc. (incorporated by reference to Exhibit 4.1 of the Company's current report on Form 8-K, filed with the Securities and Exchange Commission on December 8, 2017). |
| 10.1 | Amended and Restated 2008 Stock Option Plan, filed as Exhibit 10.1 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference. |
| 10.2 | Form of Notice of Stock Option Grant under 2008 Stock Option Plan, filed as Exhibit 10.2 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference. |
| 10.3 | Form of Stock Option Grant Agreement under 2008 Stock Option Plan, filed as Exhibit 10.3 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference. |

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| Exhibit No. | Description |
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| 10.4 | Form of Exercise Notice and Restricted Stock Purchase Agreement under 2008 Stock Option Plan, filed as Exhibit 10.4 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference. |
| 10.5 | Form of Stock Option Grant Agreement under 2011 Stock Option Plan, filed as Exhibit 10.6 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference. |
| 10.6 | Form of Indemnification Agreement, filed as Exhibit 10.7 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference. |
| 10.7 | Medical Director Agreement, between Cancer Genetics, Inc. and Lan Wang, M.D., dated October 9, 2009, filed as Exhibit 10.9 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference. |
| 10.8 | Employment Agreement, between Panna Sharma and Cancer Genetics, Inc., effective as of April 1, 2010, filed as Exhibit 10.17 to Form S-1/A filed on February 14, 2012 (File No. 333-178836) and incorporated herein by reference. |
| 10.9 | Office Lease Agreement, between Cancer Genetics, Inc. and Onyx Equities, LLC, dated October 9, 2007, filed as Exhibit 10.20 to Form S-1/A filed on April 23, 2012 (File No. 333-178836) and incorporated herein by reference. |
| 10.10 | Affiliation Agreement, between Cancer Genetics, Inc. and Mayo Foundation for Medical Education and Research dated November 7, 2011, filed as Exhibit 10.35 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference. |
| 10.11 | Letter Agreement, between Meadows Office, L.L.C. and Cancer Genetics, Inc., dated January 10, 2008, filed as Exhibit 10.44 to Form S-1/A filed on April 23, 2012 (File No. 333-178836) and incorporated herein by reference. |
| 10.12 | Letter of Credit from JPMorgan Chase Bank, N.A., dated April 19, 2012, filed as Exhibit 10.46 to Form S-1/A filed on April 30, 2012 (File No. 333-178836) and incorporated herein by reference. |
| 10.13 | Amendment No. 1 to Affiliation Agreement, between Cancer Genetics, Inc. and Mayo Foundation for Medical Education and Research, dated September 29, 2012, filed as Exhibit 10.49 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference. |
| 10.14 | Restated Registration Rights Agreement, between Cancer Genetics, Inc., Mark Oman and John Pappajohn, dated October 17, 2012, filed as Exhibit 10.54 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference. |
| 10.15 | Amendment No. 2 to Affiliation Agreement between Cancer Genetics, Inc. and Mayo Foundation for Medical Education and Research, dated January 4, 2013, filed as Exhibit 10.61 to Form S-1/A filed on January 8, 2013 (File No. 333-178836) and incorporated herein by reference. |
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| | Form of Letter Agreement between Cancer Genetics, Inc. and certain warrant holders waiving certain anti-dilution rights, filed as Exhibit 10.68 to Form S-1/A filed on March 4, 2013 (File No. 333-178836) and incorporated herein by reference. |
| 10.17 | Letter Amendment dated March 20, 2013 to Letter Agreement, between Meadows Office, L.L.C. and Cancer Genetics, Inc., dated April 6, 2012, filed as Exhibit 10.72 to Form S-1/A filed on March 22, 2013 (File No. 333-178836) and incorporated herein by reference. |
| 10.18 | Amendment No. 3 to Affiliation Agreement between the Company and Mayo Foundation for Medical Education and Research, dated May 21, 2013, filed as Exhibit 10.73 to Form S-1 filed on June 5, 2013 (File No. 333-189117) and incorporated herein by reference. |
| 10.19 | Limited Liability Company Agreement of OncoSpire Genomics, LLC, dated May 21, 2013, filed as Exhibit 10.74 to Form S-1/A filed on July 12, 2013 (File No. 333-189117) and incorporated herein by reference. |
| 10.20 | Joint Development Intellectual Property Agreement, among the Company, Mayo Foundation for Medical Education and Research and OncoSpire Genomics, LLC, dated May 21, 2013, filed as Exhibit 10.75 to Form S-1/A filed on July 12, 2013 (File No. 333-189117) and incorporated herein by reference. |
| 10.21 | Consulting Agreement, between Cancer Genetics, Inc. and R.S.K. Chaganti, dated February 19, 2014 (incorporated by reference to Exhibit 10.67 of the Company's Annual Report on Form 10-K for the year ended December 31, 2013). |
| 10.22 | Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated April 1, 2014 (incorporated by reference to Exhibit 10.1 of the Company’s current report on Form 8-K filed on April 4, 2014 with the Securities and Exchange Commission). |

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| Exhibit No. | Description |
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| 10.23 | Revolving Line of Credit Note, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated April 1, 2014 (incorporated by reference to Exhibit 10.2 of the Company's current report on Form 8-K filed on April 4, 2014 with the Securities and Exchange Commission). |
| 10.24 | Consulting Agreement, between Cancer Genetics Inc. and Equity Dynamics, dated November 6, 2014 and effective as of April 1, 2014 (incorporated by reference to Exhibit 10.4 of the Company's quarterly report on Form 10-Q for the period ended September 30, 2014 with the Securities and Exchange Commission). |
| 10.25 | Security Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated November 12, 2014 (incorporated by reference to Exhibit 10.5 of the Company's quarterly report on Form 10-Q for the period ended September 30, 2014 with the Securities and Exchange Commission). |
| 10.26 | First Amendment to Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated November 12, 2014. (incorporated by reference to Exhibit 10.6 of the Company's quarterly report on Form 10-Q for the period ended September 30, 2014 with the Securities and Exchange Commission). |
| 10.27 | Loan and Security Agreement, between Cancer Genetics, Inc. and Silicon Valley Bank, dated May 7, 2015.(incorporated by reference to Exhibit 10.1 of the Company's quarterly report on Form 10-Q for the period ended March 31, 2015 with the Securities and Exchange Commission). |
| 10.28 | Amended and Restated Asset Purchase Agreement By and Between Response Genetics, Inc. a Delaware Corporation, and Cancer Genetics., a Delaware Corporation, dated as of August 14, 2015 (incorporated by reference to the Company's current report on Form 8-K filed on August 21, 2015). |
| 10.29 | 2011 Equity Incentive Plan, as amended and restated effective May 14, 2015, filed as Exhibit 10.1 to Form S-8 filed on July 28, 2015 (File Number 333-205903) and incorporated herein by reference. |
| 10.30 | Employment Agreement between Dr. Shaknovich and Cancer Genetics, Inc., effective as of July 1, 2015.(incorporated by reference to the Company's current report on Form 8-K filed on July 7, 2015). |
| 10.31 | Form of Warrant Agreement of Cancer Genetics, Inc. (corrected) (incorporated by reference to Exhibit 4.1 of the Company's quarterly report on Form 10-Q for the period ended September 30, 2015 with the Securities and Exchange Commission). |
| 10.32 | Office Lease, between Response Genetics, Inc. and Health Research Association, dated September 16, 2004 (incorporated by reference to the Company's annual report on Form 10-K for the year ended December 31, 2015 with the Securities and Exchange Commission). |
| 10.33 | Tenth Amendment to Office Lease, between Response Genetics, Inc. and University of Southern California, dated June 30, 2015 (incorporated by reference to the Company's annual report on Form 10-K for the year ended December 31, 2015 with the Securities and Exchange Commission). |
| 10.44 | Consent and First Amendment to Loan and Security Agreement, between Cancer Genetics, Inc. and Silicon Valley Bank, dated January 28, 2016 (incorporated by reference to Exhibit 10.73 to the Company's annual report on Form 10-K for the year ended December 31, 2015, filed on March 10, 2016). |

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| 10.45 | Form of Securities Purchase Agreement, dated May 19, 2016, by and between Cancer Genetics, Inc. and various purchasers named therein (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the Securities and Exchange Commission on May 20, 2016). |
| 10.46 | Engagement Letter between Cancer Genetics, Inc. and Rothman & Renshaw, a unit of H.C. Wainwright & Co., LLC, dated as of May 19, 2016 (incorporated by reference to Exhibit 10.2 to the Company's current report on Form 8-K filed with the Securities and Exchange Commission on May 20, 2016). |
| 10.47 | Eleventh Amendment to Lease Agreement, dated June 10, 2016, between University of Southern California and Cancer Genetics, Inc. (incorporated by reference to Exhibit 10.1 of the Company's quarterly report on Form 10-Q for the period ended June 30, 2016). |
| 10.48 | Employment Agreement of John Roberts, dated June 27, 2016 (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on June 30, 2016). |
| 10.49 | Form of Securities Purchase Agreement, dated September 8, 2016, by and between Cancer Genetics, Inc. and various purchasers named therein (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the Securities and Exchange Commission on September 9, 2016). |
| 10.50 | Engagement Letter between Cancer Genetics, Inc. and Rothman & Renshaw, a unit of H.C. Wainwright & Co., LLC, dated as of September 8, 2016 (incorporated by reference to Exhibit 10.2 to the Company's current report on Form 8-K filed with the Securities and Exchange Commission on September 9, 2016). |

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| Exhibit No. | Description |
|---|---|
| 10.51 | Amendment, dated as of October 11, 2016, to Amended and Restated Cancer Genetics, Inc. 2011 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K, filed with the Securities and Exchange Commission on October 12, 2016). |
| 10.52 | Amended and Restated Loan and Security Agreement with Silicon Valley Bank dated as of March 22, 2017 (incorporated by reference to Exhibit 10.81 to the Company's annual report on Form 10-K for the year ended December 31, 2016, filed on March 23, 2017). |
| 10.53 | Loan and Security Agreement with Partners for Growth IV, L.P. dated as of March 22, 2017 (incorporated by reference to Exhibit 10.82 to the Company's annual report on Form 10-K for the year ended December 31, 2016, filed on March 23, 2017). |
| 10.54 | Form of Warrant issued to lenders dated March 22, 2017 (incorporated by reference to Exhibit 10.83 to the Company's annual report on Form 10-K for the year ended December 31, 2016, filed on March 23, 2017). |
| 10.55 | Release, dated February 3, 2017, between Edward Sitar and Cancer Genetics, Inc (incorporated by reference to Exhibit 10.84 to the Company's annual report on Form 10-K for the year ended December 31, 2016, filed on March 23, 2017). |
| 10.56 | Employment Agreement between Dr. Shaknovich and Cancer Genetics, Inc., effective as of May 28, 2017 (incorporated by reference to the Company's quarterly report on Form 10-Q for the period ended March 31, 2017). |
| 10.57 | Common Stock Purchase Agreement, dated as of August 14, 2017, by and between the Company and Aspire Capital Fund, LLC (incorporated by reference to the Company's current report on Form 8-K, filed with the Securities and Exchange Commission on August 16, 2017). |
| 10.58 | Form of Securities Purchase Agreement, dated December 8, 2017, by and between Cancer Genetics, Inc. and various purchasers named therein (incorporated by reference to the Company's current report on Form 8-K, filed with the Securities and Exchange Commission on December 8, 2017). |
| 10.59 | Engagement Letter between Cancer Genetics, Inc. and H.C. Wainwright & Co., LLC, dated as of December 3, 2017 (incorporated by reference to the Company's current report on Form 8-K, filed with the Securities and Exchange Commission on December 8, 2017). |
| 10.60* | Separation and General Release Agreement by and between Panna Sharma and Cancer Genetics, Inc. |
| 10.61* | Thirteenth Amendment to Lease Agreement by and between the University of South Carolina and Cancer Genetics, Inc., dated March 29, 2018. |
| 10.62* | First Amendment to Lease by and between Meadows Landmark, LLC and Cancer Genetics, Inc., dated October 30, 2017. |
| 21.1* | Subsidiaries of Cancer Genetics, Inc. |
| 23.1* | Consent of RSM US LLP. |

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| 24.1 | Power of attorney (included on the signature page). |
| 31.1* | Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities and Exchange Act of 1934, as amended. |
| 32.1** | Certification of Chief Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101* | The following financial statements from this annual report on Form 10-K of Cancer Genetics, Inc. for the year ended December 31, 2017, filed on April 2, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations and Other Comprehensive Loss, (iii) the Consolidated Statements of Cash Flows, (iv) the Consolidated Statements of Stockholders' Equity and (v) the Notes to the Consolidated Financial Statements. |

* Filed herewith.
** Furnished herewith.