UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

Or

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

For the transition period from to

Commission file number 001-35817

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 ☒

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: ☒

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: ☒ 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: ☒ 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. ☒

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	☒
		Emerging growth company	☐

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $20.6 million on June 30, 2018, the last business day of the registrant's most recently completed second fiscal quarter, based on the closing price of $0.89 on that date.

Indicate the number of shares outstanding of each of the registrant's classes of common equity, as of March 27, 2019:

Class	Number of Shares
Common Stock, $.0001 par value	**56,276,222**

Documents incorporated by reference

Portions of the registrant's proxy statement for the 2019 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year ended December 31, 2018, 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,” “believes,” “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 extend, and 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.

PART I

Item 1. Business.

Overview

We are an emerging leader in enabling precision medicine in oncology by providing multi-disciplinary diagnostic and data solutions, facilitating individualized therapies through our diagnostic 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 and immuno-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 unique disease-focused tests aim to provide actionable

information that can guide patient management decisions, potentially resulting in decreased costs for patients while streamlining 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 250 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 50 biotechnology and pharmaceutical companies across four continents in over 100 studies and trials with highly specialized development, clinical and preclinical research. Over the past 15 years, vivoPharm has also generated an extensive library of human xenograft and syngeneic tumor models, including subcutaneous, orthotopic and metastatic models. vivoPharm offers services in assessment of safety, toxicology and bioanalytic services for small and bio-molecules.

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, DNA- and RNA-extraction and customized assay development and trial design consultation.
Clinical Services	• Hospitals • Cancer Centers • Clinics	Clinical services provide information on diagnosis, prognosis and predicting treatment outcomes (theranosis) of cancers to guide patient management.
Discovery Services	• Pharmaceutical and Biotech companies • Academic Institutions • 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 2018, we generated approximately 54% of our revenue from Biopharma Services, approximately27% from Clinical Services and approximately 19% from Discovery Services. In 2017, we generated approximately 50% of our revenue from Biopharma Services, approximately37% from Clinical Services and approximately 13% from Discovery Services, including the acquisition of vivoPharm in August of 2017.

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 and Raleigh, NC. 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 2018, the World Health Organization attributed 9.6 million deaths globally to cancer, which is about 1 in 6 deaths. 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 Agency for Healthcare Research and Quality estimated 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 2018 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 2019, the National Cancer Institute received a budget of $5.74 billion, an increase of $79 million over FY 2018, 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 Manufacturers 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 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, very few have successfully made it to market. 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.

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. We recently announced a licensing transaction with a Chinese company based in Beijing, China who will be launching our Tissue of Origin® test in China, to assist in the care of Chinese patients. We plan to continue exploring opportunities to license our proprietary tests to select business partners operating laboratory services in China, where governmental regulations prevent human samples and personal data, including health data, 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:

- 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 few have successfully made it to market. 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 biopharma business development team and our relationships with global central laboratories to expand our customer base.*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

- C*ontinue our focus on translational oncology and drive innovation and cost efficiency in diagnostics by continuing to develop next generation sequencing offerings independently and through collaborations with academic and cancer research centers 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.

- *Engage key strategic partners in the U.S. and abroad to leverage our intellectual propoerty portfolio and unique capabilities to grow our revenue.* We entered into a strategic partnership in China to license our Tissue of Origin® test in that region; we announced a supply agreement with Agilent Technologies to expand the distribution of our proprietary FHACT probe internationally, and we entered into a partnership with Cellaria in the U.S. to characterize Cellaria's pipeline of commercial and custom-developed biopharma products to create innovative models that provide detailed, and patient-specific, assessment of response to therapy.

- *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 and immuno-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 unique disease-focused tests aim to provide actionable information that can guide patient management decisions, potentially resulting in decreased costs for 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 few have successfully made it to market. 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 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:

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 to target cancers that are difficult to prognose and predict treatment outcomes through currently available mainstream techniques. We utilize an expansive range of non-proprietary tests 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).

Our comprehensive testing services for cancer are utilized in the diagnosis, prognosis and prediction of treatment outcomes (theranosis) of cancer patients 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.

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 currently the only FDA-cleared test of its kind on the market, 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 licensed pathologists and licensed 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 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 capabilities include 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 ten of the 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

Test	Targeted Cancers	Technology & Advantages
Focus::NGS® **Focus::AML™** **Focus::CLL™** **Focus::DLBCL&FL™** **Focus::Lymphoma™** **Focus::MCL™** **Focus::MDS™** **Focus::MPN™** **Focus::Myeloid™** **Focus: Myeloma™**	• Chronic Lymphocytic Leukemia (CLL) • Myeloid Cancers - Myelodysplastic Syndromes (MDS) - Acute Myeloid Leukemia (AML) - Myeloproliferative Neoplasms (MPN) • B-Cell Lymphomas • Follicular Lymphoma • 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. • 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. • 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. • 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.

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 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 - Cervical Cancer - Anal Cancer - 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. • 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. • 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. • 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. • We offer an application of FHACT® as an LDT for cervical cancer and are developing applications for additional cancer targets. • 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

Test	Targeted Cancers	Technology & Advantages
Tissue of Origin®	• Solid Tissue Cancers - Thyroid - Breast - Non-Small Cell Lung Cancer (NSCLC) - Gastric - Pancreas - Colorectal - Liver - Bladder - Kidney - Non-Hodgkin's Lymphoma - Melanoma - Ovarian - Sarcoma - Testicular Germ Cell - Prostate	• Tissue of Origin® (TOO®) is FDA-cleared, Medicare-reimbursed, and provides extensive analytical and clinical validation for statistically significant improvement in accuracy over other methods. • 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. • 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. • TOO® assesses 2,000 genes, covering 15 of the most common tumor types and 90% of all solid tumors. • In the fourth quarter of 2015, we acquired the TOO® test through our acquisition of substantially all of the assets of Response Genetics, Inc.
Focus::Oncomine™ **Oncomine Dx Target Test** **Liquid::Lung *cf*-DNA™**	• Solid Tissue Cancers - Lung - Colorectal - Melanoma - Breast - Bladder - Thyroid	• Focus::Oncomine™ is 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. • 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. • 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. • 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. • Liquid::Lung- *cf*DNA™ 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. • Liquid::Lung- *cf*DNA™ is CLIA-validated and can detect lung tumor-derived cell-free DNA (cfDNA) obtained from the plasma fraction of blood.

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. • 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. • 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 - Clear Cell Renal Cell Carcinoma (ccRCC) - Chromophobe Renal Cell Carcinoma (chrRCC) - Papillary Renal Carcinoma (pRCC) - Oncocytoma (OC) • Prostate • 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. • 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. • UroGenRA®-Kidney assesses 16 genomic regions that have diagnostic significance in the four main renal cortical neoplasm subtypes. • 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

Test	Targeted Cancers	Technology & Advantages
Focus::HERSite™ **Focus::BRCA™**	• Breast • 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. • 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. • 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. • 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.

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, with increased interest throughout 2018, 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 licensed New Jersey laboratory facility. 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:

United States	Clinical Sales	- Collaborate with leading research universities and institutions that enable the validation of our new tests. Work with community-based cancer centers that need a reliable and collaborative partner for cancer testing. - 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. Build relationships in the research and development segment to identify partners with a need for preclinical efficacy and toxicity studies and biomarker discovery studies.
	Discovery Sales	- Collaborate with preclinical development teams at pharmaceutical and biotech companies on studies involving tumor models and therapeutic candidate compound testing.
Europe and Asia Pacific	Biopharma Sales	- Leverage US-based and local companies conducting clinical trials with a component of those trials occurring in European or Asia Pacific populations. - 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 10 business development and sales professionals in the United States and 2 in Europe. We support our sales force with clinical specialists who bring deep domain knowledge in the design and use of our tests and services.

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. We do not, however, market our tests directly to individual patients or consumers.

Research and Development Collaborations

We have collaborations with leading oncology centers and community-based hospitals and use specialized knowledge to develop proprietary diagnostic tests as well as non-clinical services such as biopharmaceutical and discovery services. 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 and, together with our internal expertise, we can 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.

Collaborating Institution	Principle Investigator(s)	Focus of Collaboration
North Shore-Long Island Jewish Health System, *New York*	Dr. Kanti Rai Dr. Nicholas Chiorazzi	Clinical validation of biomarkers and signatures for CLL diagnosis and therapeutic response
Columbia University, *New York*	Dr. Azra Raza Dr. Siddhartha Mukherjee	Identification of genomic biomarkers for myeloid cancers
Keck Medicine of University of Southern California, *California*	Dr. Imran Siddiqi	Identification and evaluation of genomic biomarkers for lymphoid and myeloid malignancies
	Dr. Giri Ramsingh	Transposable elements as prognostic biomarkers in acute myeloid leukemia
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*		Analyzing 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
UCLA, *California*	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, LabCorp., 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 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 FHACT® and FDA-cleared Tissue of Origin® 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 20 issued U.S. patents, 5 pending U.S. applications, and more than 40 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 12 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.

- 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 laboratory in Rutherford, New Jersey, 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 the past, we had licensed certain intellectual property, including patents, from the University of Southern California, the National Cancer Institute for a number of extraction methodologies and related technologies for some of our solid tumor tests, and the National Cancer Institute or Stanford University for the development of diagnostic assays and predictive models. However, we no longer utilize these technologies in our consolidated facility in New Jersey.

Our success in remaining an innovator in the diagnostic services industry by continuing to develop and 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 a “best-of-breed” enterprise laboratory management system licensed from multiple business partners to support a fully-integrated system across two of our U.S.-based sites. We anticipate this system to be on-line by the end of 2019. 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.

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 manner, consistent with the privacy and security requirements of HIPAA. 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. We believe this commitment and execution of our quality systems is a key differentiator in our biopharma services business.

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 York State) in order to maintain licensures, permits and regulatory approvals 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). For additional information on our clinical laboratory licensure and permitting, please review our Risk Factors.

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 licensed and permitted 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 applicable state and federal regulations prior to being processed in the laboratory as diagnostic testing services. We provide training for all personnel as required under CLIA and applicable state clinical laboratory regulations, 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 Laboratory Improvement Amendments (CLIA), Centers for Diseases Control (CDC) 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 may be 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. In 2018, we derived approximately 8% of our total revenue from Medicare and 19% of our total revenue from other third party payors that includes managed care organizations and other health care providers. In 2017, we derived approximately 25% of our total revenue from other third party payors, including managed care organizations and other health care insurance providers, and 12% from Medicare. We are not currently reimbursed by any party for testing or clinical services performed in the European Union on samples from EU persons, and therefore we believe we are not yet subject to reimbursement and pricing requirements under European Economic Area ("EEA") or EEA member state law.

In the United States, 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, contractual terms and applicable law. 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 is consistent with Federal guidelines. In states that have so-called "direct billing" laws, which require clinical laboratories to submit invoices directly to the patient, and not through the physician or health care provider, we comply with such requirements.

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. In the United States, 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.

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 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 payor 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 payor (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 payor 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 payor rates) were 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 payors 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 payor such as CMS determines that the tests failed to meet all applicable criteria for payment. When third party payors 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 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 increased them by 0.5 percent for the remainder of 2015. Beginning on January 1, 2016, the rates are scheduled to increase 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. On July 12, 2018, CMS proposed a change to the definition of "applicable lab" in the 2019 Physician Fee Schedule Proposed Rule to include a broader category of laboratories and may alter our reimbursement in ways that are unforeseeable at this time.

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, and the administrative burden associated with these requirements 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 Medicare CLFS. The discount rate varies based on the insurance company, the testing type and the often times the specifics of the patient's insurance plan. The varying rates may affect our ability to receive reimbursement that is sufficient to cover the costs of our services.

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. It is not clear at this time the effect geographic rate variance will have on our business.

Billing Codes for Third-Party Payor Reimbursement

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 was 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 effortsA 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.

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 and state and federal law. 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.

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. Payors who currently reimburse us for our tests may decide not to in the future. We cannot predict which payors who currently cover our tests will continue to do so in the future.

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, 2018 and December 31, 2017, approximately 8% and 12%, 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 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 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 laboratory 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. Two states, New York and Washington, are CLIA-exempt, however, and as such have their own regulatory requirements to which we may be subject to. CMS deemed both New York and Washington as CLIA-exempt because their licensing and supervisory programs are more stringent than that run by CMS and the CDC. New York requires clinical laboratories who accept specimens from New York residents to have both a CLIA and New York Clinical Laboratory Evaluation Program (CLEP) permit. CLEP approval can take up to a year, and can be costly and time consuming. Washington State does not require clinical laboratories to have a CLIA permit, but does require the clinical laboratory to apply for a Washington State lab permit. In general, several state clinical laboratory laws generally require that laboratories and/or laboratory personnel meet certain qualifications. State clinical laboratory laws also generally require laboratories to develop 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 "out of state" licenses or permits 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, New Jersey laboratory is licensed and in good standing under the State Departments of Health standards for New Jersey, New York, Pennsylvania, California, 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.

Our Hershey, Pennsylvania and Melbourne, Australia research laboratory 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. Certain of such devices must undergo premarket 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 premarket 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. On August 3, 2018, FDA provided Congressional committee staff technical assistance on the discussion draft entitled the Diagnostic Accuracy and Innovation Act (DAIA). In FDA's technical assistance, FDA reiterated that it supported the goal of legislation to create pathways to market for all in vitro clinical tests (IVCTs). We are monitoring developments in Congress, and in the meantime, we maintain our CLIA accreditation, which permits the use of LDTs for diagnostics purposes.

In addition to the Draft Guidances discussed above, the FDA has taken other actions that could have an impact on our business. In 2013, the 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 an application for marketing authorization with the FDA (e.g., either a 510(k) or a PMA, depending on the nature of the particular test).

Post-market Regulation

Our Tissue of Origin® test obtained clearance under section 510(k) of the FDCA. After a device, such as our Tissue of Origin® test, is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply once the test is marketed, including FDA's current good manufacturing practice requirements. Since we do not offer our FDA-approved product in the European Economic Area ("EEA") we are not currently subject to post-market regulation in the EEA or any member state.

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;
- reconsideration of 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."*

European General Data Protection Regulation

The collection and use of personal health data in the European Union had previously been governed by the provisions of the Data Protection Directive, which has been replaced by the General Data Protection Regulation ("GRPR") which became effective on May 25, 2018 While the Data Protection Directive did not apply to organizations based outside the EU, the GDPR has expanded its reach to include any business, regardless of its location, that provides goods or services to residents in the EU. This expansion would incorporate our clinical trial activities in EU members states. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information" which includes health and genetic information of data subjects residing in the EU. GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the European Union to the United States or other regions that have not been deemed to offer "adequate" privacy protections. Failure to comply with the requirements of the GDPR and the related national data protection laws of the European Union Member States, which may deviate slightly from the GDPR, may result in fines of up to 4% of global revenues, or € 20,000,000, whichever is greater. As a result of the implementation of the GDPR, we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules.

Our research activities in the EU are currently limited to non-human preclinical studies, and as such, we do not collect, store, maintain, process, or transmit any Personal Data (as that term is defined under the GDPR) of trial subjects. However, since we currently have three employees located in the EU, our processing and transfer for employee Personal Data is subject to GDPR requirements. We have implemented a privacy and security program that is designed to adhere to the requirements of the GDPR in order to protect employee Personal Data, and in the event we progress to research or clinical trials involving humans, to protect participant Personal Data. However, there is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is not clear if the authorities will conduct random audits of companies doing business in the EU, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated. Enforcement uncertainty and the costs associated with ensuring GDPR compliance be onerous and adversely affect our

business, financial condition, results of operations and prospects. As a result, we cannot predict the impact of the GDPR regulations on our current or future business, either in the US or the EU.

Federal, State and Foreign Fraud and Abuse Laws

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. Violation of the Stark Law may also result in violation of the False Claims Act. Unlike the Anti-kickback Statute, a person does not need to have intent to violate the Stark Law; this is a strict liability statute; merely violating the Stark Law on its face may result in fines, recoupments, and exclusion from federal health care programs. Many states have comparable laws that are not limited to Medicare and Medicaid referrals.

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

Approximately thirty (30) 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, which vary among the states that have enacted them, 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 93% and 94% coming from the United States in fiscal year 2018 and 2017, respectively.

Research and Development

For the years ended December 31, 2018 and 2017, our research and development expenses were $2.5 million and $4.8 million, respectively, principally in connection with our efforts to develop our proprietary tests and validate those tests, which were relocated from our Los Angeles location to our New Jersey lab facility.

Employees

As of December 31, 2018, we had a total of 150 full-time and 18 part-time employees, with 18 employees in business development, sales and marketing, 76 employees in clinical services, 25 employees in clinical trials and 31 employees in general and administrative. During 2018, we reduced our headcount by approximately 38 as the result of consolidating our Los

Angeles, CA facility to operations in New Jersey and North Carolina. 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 April 26, 2018, we sold BioServe to Reprocell, Inc., for $1.9 million, including $1.6 million in cash at closing and up to an additional $300,000 conditioned on Reprocell meeting specified revenue targets, of which, we were paid $212,500 as the final contingent amount owed to us.

On August 15, 2017, we purchased all of the outstanding stock of vivoPharm, with its principal place of business in Victoria, Australia.

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*.

This report includes the following trademarks, service marks and trade names owned by us: MatBA®, UroGenRA®, FHACT®, FReCaD™, Expand Dx™, Summation™, Select One®, DLBCL Complete™, Cervixcyte™, Leuka™, CGI®, CLL Complete®, Focus::NGS™, Focus::Myeloid™, Focus::CLL™, Tissue of Origin®, TOO®, Powered by CGI™ and Empowering Personal Cancer Treatment®. These trademarks, service marks and trade names are the property of Cancer Genetics, Inc. and its affiliates.

Item 1A. Risk Factors.

An investment in our common stock involves a high degree of risk including the risk of a loss of your entire investment. You should carefully consider the risks and uncertainties described below and the other information contained in this report and our other reports filed with the Securities and Exchange Commission. The risks set forth below are not the only ones facing us. Additional risks and uncertainties may exist that could also adversely affect our business, operations and financial condition. If any of the following risks actually materialize, our business, financial condition and/or operations could suffer. In such event, the value of our common stock could decline, and you could lose all or a substantial portion of the money that you pay for our common stock.

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$20.4 million and $20.8 million for fiscal years ended December 31, 2018 and 2017, respectively. From our inception in April 1999 through December 31, 2018, we had an accumulated deficit of$157.7 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, 2018, 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"). We did not have sufficient cash at December 31, 2018 to fund normal operations for the next twelve months. In addition, we have been in violation of certain financial covenants under our debt agreements. While our lenders have conditionally agreed to forbear from exercising their rights and remedies resulting from existing and potential defaults, our ability to continue as a going concern is dependent on our ability to comply with the forbearance conditions and other debt agreement covenants, raise additional equity or debt capital and/or spin-off non-core assets to raise additional cash. These factors raise substantial doubt about our 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, which are subject to forbearance agreements that expire on April 15, 2019, and our asset-based revolving line of credit agreement matures on April 15, 2019. We are also in default under the Credit Agreement with NovellusDx Ltd.

We have been in violation of certain of the financial and other covenants under our asset-based revolving line of credit agreement ("ABL") with Silicon Valley Bank ("SVB") and our term loan agreement (the "Term Loan") with Partners for Growth IV, L.P. ("PFG"). On August 20, 2018, the Company received waivers from its senior lenders for the covenant violations for the months of July and August 2018. In consideration of these waivers, we agreed to reduce the maximum borrowings under the ABL from $6.0 million to $3.0 million, and agreed to enter into a binding and enforceable agreement satisfactory to each lender by August 31, 2018 with respect to a merger or other business combination transaction between the Company and an unrelated third party satisfactory to each lender (the "Transaction Condition"). While we were in violation of the Transaction Condition as of August 31, we subsequently entered into a binding and enforceable agreement satisfactory to each lender on September 18, 2018 by entering into a Merger Agreement with NovellusDx Ltd. ("Novellus") and the other

parties thereto (which was subsequently terminated in December 2018) (the "Novellus Merger Agreement"). On November 19, 2018, we obtained waivers from our lenders for the covenant violations for the months of September, October and November 2018, conditioned upon the Company raising $3,000,000 through the sale of its equity securities or issuance of subordinated debt by November 30, 2018 (the "Financing Condition").

On January 16, 2019, we entered into a Forbearance and Fifth Amendment to Amended and Restated Loan and Security Agreement (the "Forbearance and Amendment") with SVB, further amending the ABL, and a Forbearance Agreement and Modification No. 4 to Loan and Security Agreement (the "Forbearance and Modification") with PFG, further amending the Term Loan.

The Forbearance and Amendment with SVB, among other things, (i) amended the interest rate under the ABL to be 2.25% per annum above the Wall Street Journal prime rate (7.75% at December 31, 2018); (ii) requires us to comply with certain milestones in connection with progressing towards a potential strategic transaction satisfactory to SVB with an anticipated closing date of on or before April 15, 2019, similar to the Transaction Condition in our August 2018 waivers (the "Milestones"), (iii) provides for SVB's forbearance of its rights and remedies resulting from certain existing and potential events of default under the ABL stated in the Forbearance and Amendment (but not a waiver) until the earlier of (a) the occurrence of an additional event of default or (b) February 28, 2019; provided such date shall be automatically extended to April 15, 2019 so long as we are in compliance with the Milestones required as of such date and (iv) extends the Revolving Line Maturity Date (as defined in the ABL) to April 15, 2019. Absent the covenant waivers, we would be required to make monthly interest payments at the default rate (10.75%).

The Forbearance and Modification with PFG, among other things, (i) requires the Company to comply with certain milestones in connection with progress in towards a potential strategic transaction satisfactory to PFG with an anticipated closing date of on or before April 15, 2019, similar to the Transaction Condition in our August 2018 waivers (the "PFG Milestones"), (ii) provides for PFG's forbearance of its rights and remedies resulting from certain existing and potential events of default under the Term Loan stated in the Forbearance and Modification (but not a wavier) until the earlier of (a) the occurrence of an additional event of default or (b) February 28, 2019; provided such date shall be automatically extended to April 15, 2019 so long as the Company is in compliance with the PFG Milestones required as of such date. Absent the covenant waivers, we would be required to make monthly interest payments at the default rate (17.50%).

The Company will not be able to close on a strategic transaction on or before April 15, 2019. No assurance can be given that the Company will be able to extend the maturity of the ABL beyond April 15, 2019 or extend the forbearances with SVB and PFG beyond April 15, 2019. However, we are in discussions with SVB and PFG about possible extensions of the forbearance agreements.

As a result of the termination of the Novellus Merger Agreement in December 2018, pursuant to the Credit Agreement (the "Novellus Credit Agreement"), dated September 18, 2018, between us and NovellusDx Ltd., the $1.5 million advance previously made to us in connection with the signing of the Novellus Merger Agreement, plus interest thereon, would have become due and payable, but for the subordination agreements described below. The interest rate under the Novellus Credit Agreement was increased to the lesser of 21% per annum and the maximum rate permitted by applicable law. In addition, NovellusDx Ltd. has the right to convert all, but not less than all, of the outstanding balance under the Novellus Credit Agreement into shares of our common stock at a conversion price of $0.606 per share.

Pursuant to subordination agreements entered into in connection with the Novellus Credit Agreement on September 18, 2018, NovellusDx Ltd.'s ability to be repaid under the Novellus Credit Agreement is subject to subordination to the ABL and the Term Loan. Novellus has asserted that its obligation to standstill under its subordination agreements will not be applicable at a time when the Company attains certain levels of unrestricted cash, as a result of the Company purportedly having improperly terminated the Novellus Merger Agreement. The Company does not believe it improperly terminated the Novellus Merger Agreement.

Our default under the Novellus Credit Agreement may also be deemed to be a default under the obligations to SVB and PFG.

Any default under any financing agreement or material agreement of ours (other than the Novellus Credit Agreement) may also be deemed to be a default under the obligations due under the Convertible Promissory Note (the "Iliad Note"), dated July 17, 2018, in the aggregate principal amount of $2,625,000.00 to Iliad Research and Trading, L.P. ("Iliad").

Pursuant to subordination agreements entered into in connection with the Iliad Note on July 17, 2018, Iliad's ability to be repaid under the Iliad Note is subject to subordination to the ABL and the Term Loan. However, the Iliad Note and the subordination agreements between Iliad and our senior lenders provide that on an Event of Default (as defined in the Iliad

Note), Iliad may obtain injunctive relief that would prohibit the Company from issuing any equity securities unless the outstanding balance due to Iliad is paid in full simultaneously with such issuance. On February 15, 2019, the Company entered into a standstill agreement with Iliad. The standstill agreement, among other things, (i) provided that Iliad would not seek to redeem any portion of the Iliad Note until March 10, 2019 (the "Standstill"); (ii) increased the outstanding balance of the Iliad Note by approximately $139,000, representing a fee to Iliad for such Standstill; and (iii) allowed the Company the option to elect that Iliad not seek to redeem any portion of the Iliad Note until April 15, 2019, provided that upon such election the outstanding balance of the Iliad Note would increase again by approximately $63,000. The Company elected to extend the Standstill until April 15, 2019.

We currently have limited funds and we will need to raise additional capital to fund our operations.

We will need to raise additional financing to fund our operations. AtDecember 31, 2018, we had unrestricted cash and cash equivalents of$0.2 million. Net cash used in operating activities was $12.6 million and $13.6 million for the years endedDecember 31, 2018 and 2017, respectively. We have continued to have negative cash flow in the first quarter of 2019.

Even with the net proceeds of approximately $5.4 million received in our offerings of common stock that were consummated on January 14, 2019 and January 31, 2019 (the "Offering Proceeds"), we have limited availability under our asset-based revolving line of credit agreement with Silicon Valley Bank.

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, disposition of non-core assets, 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, together with the Offering Proceeds, will support operations for approximately 3 months from the date of this report, assuming we are able to negotiate an extension of the maturity date of the ABL and an extension of the forbearances with SVB and PFG. 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 convertible debt facility entered into in July 2018 has a similar limitation on variable rate financings. 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 extend and 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;
- 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 capital 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. 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 had expected this deficiency to be corrected as part of the implementation of ASU 2014-09 effective January 1, 2018.

However, during the fourth quarter of 2018, we noted that the material weakness in our revenue and cash receipts process has continued in 2018 as our remediation efforts were not adequate. As a result, additional amounts had to be recorded as bad debt expense for older balances. Based on a change in financial leadership in late November 2018, we have demonstrated a commitment to remediate 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. We have noted 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 by the end of 2019.

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 a "smaller reporting company" under the U.S. securities laws, 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. 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.

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.

We are engaged in shareholder litigation.

Following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted against companies. On April 5, 2018 and April 12, 2018, purported stockholders of the Company filed nearly identical putative class action lawsuits in the U.S. District Court for the District of New Jersey, against the Company, Panna L. Sharma, John A. Roberts, and Igor Gitelman, captioned *Ben Phetteplace v. Cancer Genetics, Inc. et al*, No. 2:18-cv-05612 and *Ruo Fen Zhang v. Cancer Genetics, Inc. et al.*, No. 2:18-06353, respectively. The complaints alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 based on allegedly false and misleading statements and omissions regarding our business, operational, and financial results. The lawsuits sought, among other things, unspecified compensatory damages in connection with purchases of our stock between March 23, 2017 and April 2, 2018, as well as interest, attorneys' fees, and costs. On August 28, 2018, the Court consolidated the two actions in one action captioned *In re Cancer Genetics, Inc. Securities Litigation* (the "Securities Litigation") and appointed shareholder Randy Clark as the lead plaintiff. On October 30, 2018, the lead plaintiff filed an amended complaint, adding Edward Sitar as a defendant and seeking, among other things, compensatory damages in connection with purchases of CGI stock between March 10, 2016 and April 2, 2018. On December 31, 2018, Defendants filed a motion to dismiss the amended complaint for failure to state a claim. The Company is unable to predict the ultimate outcome of the Securities Litigation and therefore cannot estimate possible losses or ranges of losses, if any.

In addition, on June 1, 2018, September 20, 2018, and September 25, 2018, purported stockholders of the Company filed nearly identical derivative lawsuits on behalf of the Company in the U.S. District Court for the District of New Jersey against the Company (as a nominal defendant) and current and former members of the Company's Board of Directors and current and former officers of the Company. The three cases are captioned: *Bell v. Sharma et al*., No. 2:18-cv-10009-CCC-MF, *McNeece v. Pappajohn et al*., No. 2:18-cv-14093, and *Workman v. Pappajohn, et al*., No. 2:18-cv-14259 (the "Derivative Litigation"). The complaints allege claims for breach of fiduciary duty, violations of Section 14(a) of the Securities Exchange Act of 1934 (premised upon alleged omissions in the Company's 2017 proxy statement), and unjust enrichment, and allege that the individual defendants failed to implement and maintain adequate controls, which resulted in ineffective disclosure controls and procedures, and conspired to conceal this alleged failure. The lawsuits seek, among other things, damages and/or restitution to the Company, appropriate equitable relief to remedy the alleged breaches of fiduciary duty, and attorneys' fees and costs. On November 9, 2018, the Court in the *Bell v. Sharma* action entered a stipulation filed by the parties staying the *Bell* action until

the Securities Litigation is dismissed, with prejudice, and all appeals have been exhausted; or the defendants' motion to dismiss in the Securities Litigation is denied in whole or in part; or either of the parties in the *Bell* action gives 30 days' notice that they no longer consent to the stay. On December 10, 2018, the parties in the *McNeece* action filed a stipulation that is substantially identical to the *Bell* stipulation. On February 1, 2019, the Court in the Workman action granted a stipulation that is substantially identical to the Bell stipulation. The Company is unable to predict the ultimate outcome of the Derivative Litigation and therefore cannot estimate possible losses or ranges of losses, if any.

Additional shareholder lawsuits may be filed in the future. We may not be successful in defending ourselves in litigation or arbitration which may result in large judgments or settlements against us, any of which could have a negative effect on our business, financial condition, cash flows and results of operations. Additionally, lawsuits can be expensive to defend, whether or not they have merit, and the defense of these actions may divert the attention of our management and other resources that would otherwise be engaged in managing our business. Our liability insurance coverage may not be sufficient to satisfy, or may not cover, any expenses or liabilities that may arise.

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

As of March 11, 2019, we had issued and outstanding warrants to purchase 12,053,541 shares of our common stock at a weighted-average exercise price of $3.14 per share and outstanding options to purchase an aggregate of 2,344,171 shares of our common stock at a weighted-average exercise price of $4.79 per share. We also had approximately 3,745,800 shares issuable upon the conversion of the Iliad Note, at a conversion price of $0.80 per share, and approximately 2,661,364 shares issuable upon the conversion of the outstanding balance under the Novellus Credit Agreement at a conversion price of $0.606 per share. 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.

We are not currently in compliance with the continued listing requirements for the Nasdaq Capital Market. If we do not regain compliance and continue to meet the continued listing requirements, our common stock may be delisted from the Nasdaq Capital Market, which could affect the market price and liquidity for our common stock and reduce our ability to raise additional capital.

Our common stock is listed on the Nasdaq Capital Market. In order to maintain that listing, we must satisfy minimum financial and other requirements including, without limitation, a requirement that our closing bid price be at least $1.00 per share, and that we hold an annual meeting of stockholders within twelve months of the end of our fiscal year.

On January 29, 2019, the Company received written notice from the Listing Qualifications Staff of The Nasdaq Stock Market ("Nasdaq") notifying the Company that it was required to seek stockholder approval of the execution of the Novellus Credit Agreement, under which the Company was advanced $1.5 million, the outstanding balance of which, including interest, is convertible, at the option of Novellus, into shares of common stock at a conversion price of $0.606 per share, due to the potential for the Company, upon a conversion of such outstanding balance, with interest, to be required to issue common stock at a discount to the market price of the common stock on the day of execution of such agreement in excess of 20% of the pre-transaction outstanding shares of common stock, pursuant to Nasdaq Listing Rule 5635(d) (the "Approval Requirement"). The obligation was convertible into 2,475,248 shares (or approximately 8.9% of the Company's outstanding common stock) on the date of entry into the Novellus Credit Agreement. The Company had contemplated that the Novellus Credit Agreement would be paid off or otherwise retired in advance of any time at which the outstanding balance under such agreement could have been convertible into common stock in excess of the 20% threshold, due to both the Novellus Merger Agreement and the Novellus Credit Agreement having end dates of March 31, 2019. However, as the Novellus Merger Agreement was terminated in December 2018 before shareholder approval was sought, the Company potentially may be required to issue shares of common stock upon conversion under such agreement in excess of such threshold at a future date.

Nasdaq's notice had no immediate effect on the listing of the common stock on the Nasdaq Capital Market. Under Nasdaq Listing Rule 5810(c)(2)(C), the Company had 45 calendar days from January 29, 2019, or until March 15, 2019, to submit to Nasdaq a plan to regain compliance with the Approval Requirement, which the Company submitted on March 15, 2019. If Nasdaq accepts the Company's plan, Nasdaq may grant an extension of up to 180 calendar days from January 29, 2019, or July 28, 2019, to regain compliance. If Nasdaq does not accept the Company's plan, the Company will have the right to appeal such decision to a Nasdaq hearings panel. There can be no assurance that Nasdaq will accept the Company's plan or that the Company will be able to regain compliance with the Approval Requirement or maintain compliance with any other Nasdaq requirement in the future.

On January 3, 2019, we received written notice from the Listing Qualifications Staff Nasdaq notifying us that we no longer comply with Nasdaq Listing Rule 5620(a) due to our failure to hold an annual meeting of stockholders within twelve months of the end of our fiscal year ended December 31, 2017 (the "Annual Meeting Requirement"). We had contemplated holding our 2018 annual meeting of stockholders simultaneously with seeking stockholder approval of the Novellus Merger Agreement. As the Novellus Merger Agreement was terminated in December 2018 before any approval was sought, we still need to schedule an annual meeting.

Nasdaq's notice had no immediate effect on the listing of our common stock on the Nasdaq Capital Market. Under Nasdaq Listing Rule 5810(c)(2)(G), we had 45 calendar days from January 3, 2019, or until February 19, 2019, to submit to Nasdaq a plan to regain compliance with the Annual Meeting Requirement, which we submitted on February 19, 2019. If Nasdaq accepts our plan, Nasdaq may grant an extension of up to 180 calendar days from December 31, 2018, the date of our fiscal year end for our last fiscal year, or July 1, 2019, to regain compliance. If Nasdaq does not accept our plan, we will have the right to appeal such decision to a Nasdaq hearings panel.

There can be no assurance that Nasdaq will accept our plan or that we will be able to regain compliance with the Annual Meeting Requirement or maintain compliance with any other Nasdaq requirement in the future.

On November 13, 2018, we received a written notice from Nasdaq indicating that we are not in compliance with the minimum bid price requirement for continued listing on the Nasdaq Capital Market. We have 180 calendar days in which to regain compliance, or until May 13, 2019. We can regain compliance if at any time during this 180 day period the bid price of our common stock closes at or above $1.00 per share for a minimum of ten consecutive business days.

We intend to monitor the closing bid price of our common stock and consider our available options to resolve our noncompliance with the minimum bid price requirement, which may include submitting for approval by our stockholders a proposal to grant discretionary authority to our board of directors to amend our certificate of incorporation to effect a reverse split of our outstanding shares of common stock within an appropriate range, with the exact reverse split ratio to be decided and publicly announced by the board of directors prior to the effective time of the amendment to our certificate of incorporation. No determination regarding our response has been made at this time. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or we will otherwise be in compliance with other Nasdaq listing criteria.

If we fail to regain compliance with the minimum bid requirement, the Annual Meeting Requirement or the Approval Requirement or to meet the other applicable continued listing requirements for the Nasdaq Capital Market in the future and Nasdaq determines to delist our common stock, the delisting could adversely affect the market price and liquidity of our common stock and reduce our ability to raise additional capital. In addition, if our common stock is delisted from Nasdaq and the trading price remains below $5.00 per share, trading in our common stock might also become subject to the requirements of certain rules promulgated under the Exchange Act, which require additional disclosure by broker-dealers in connection with any trade involving a stock defined as a "penny stock" (generally, any equity security not listed on a national securities exchange or quoted on Nasdaq that has a market price of less than $5.00 per share, subject to certain exceptions).

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 at the premarket stage. 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.

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;
- failure of products being tested to satisfy safety requirements or efficacy criteria;
- unexpected or undesired clinical results for products; or
- shift of business to a competitor or internal resources.

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. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our molecular diagnostic tests. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. 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. Even if we obtain marketing clearance or approval to market molecular diagnostic tests, or where we have acquired the rights to already cleared or approved products, our future revenues will depend upon the size of any markets in which our product candidates and acquired products have received clearance or approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for our product candidates and acquired products in those markets.

Third-party payors and health care providers may use such technology assessments as grounds to deny coverage for a test or procedure. For example, on March 16, 2018, the Centers for Medicare and Medicaid Services ("CMS") finalized a National Coverage Determination ("NCD") that covers diagnostic laboratory tests using Next Generation Sequencing ("NGS") for patients with advanced cancer (i.e., recurrent, metastatic, relapsed, refractory, or stages III or IV cancer). Under the NCD, CMS will cover FDA-approved or cleared companion in vitro diagnostics when the test has an FDA-approved or cleared indication for use in that patient's cancer and results are provided to the treating physician for management of the patient using a report template to specify treatment options. Tests that gain FDA approval or clearance as an in vitro companion diagnostic will automatically receive full coverage under this final NCD, provided other coverage criteria are also met. However, coverage determinations for other diagnostic laboratory tests (i.e. not companion diagnostics) using NGS for Medicare patients with advanced cancer will be made by local Medicare Administrative Contractors ("MACs"). Local coverage determinations will vary, and may affect reimbursement rates, if any, that may be offered for tests developed using our NGS panels.

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. For our FDA-approved Tissue of Origin ® test, we are currently working with CMS to negotiate an increased CFLS rate for our FDA-approved test, and are exploring additional reimbursement arrangement with third-party payors. We cannot be certain that coverage for our tests (FDA-cleared/approved or LDT) 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, 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 successfully validated all of the tests that we currently offer through: the FDA for our FDA-cleared TOO® test, and CAP, CLIA, the New York Clinical Lab Evaluation Program (CLEP) Validation Unit, through our pharmaceutical clients and partners for our lab-developed tests,

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 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. 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 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. 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 clearances or 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 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.

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 business strategy focuses on discovering, developing and commercializing molecular, genomic and genetic diagnostic tests and services. We believe the long-term 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 or may develop, 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. Additionally, if the supply of reagents or equipment on which our tests in development or commercial tests rely becomes unavailable and we have to source replacement reagents or equipment for our tests, additional validation activities will be required and we may need to obtain regulatory clearances or approvals for the modified tests.

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 subsequently shut down Response Genetics operations in California and moved them to New Jersey and North Carolina and we are in the process of completing our commitments thereby ending the need for our joint venture with Mayo. We also purchased a business in India in August 2014 which we sold in April 2018. 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.

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) under the U.S. Food and Drug Administration's ("FDA's") enforcement framework. Although the 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 more recent draft 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 or that its application and enforcement of its authorities will not change, 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. Further, our LDT may be subject to approval by the New York State Clinical Lab Evaluation Program ("CLEP"). New York state's clinical laboratory regulatory program is exempt from CLIA, and maintains its own policies and procedures for evaluating and approving commercial LDTs for use in New York or on individuals residing in New York. New York LDT approval can be lengthy processes, which could delay our ability to market our tests to doctors and patients in this state.

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 premarket marketing authorization from the FDA, which is generally either FDA clearance of a 510(k) premarket notification or premarket approval of a PMA application. 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 premarket marketing authorization (generally referred to as premarket clearance or premarket approval throughout this document) from the FDA. We have not yet applied for clearance or approval from the 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 the 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.

Our laboratory may also require an out-of-state laboratory operations permit to accept and perform diagnostic tests on specimens from residents of California, Florida, Maryland, Massachusetts, Pennsylvania, Rhode Island, New Jersey and New York. Failure to obtain a permit to operate as an out-of-state laboratory in any of these or other locations could result in fines, refusal by the relevant state regulatory authority to issue a permit in the future, and adversely affect our ability to market our products in the future. The laboratory permitting application and approval process can be lengthy, which may further delay our ability to market our lab services and products in these states.

We do not have immediate plans to market our tests for commercial use in the European Union and as a result, at this time we do not believe we are subject to EU or EU member state post-market regulations related to our tests.

The FDA 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. 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. A number of Congressional committees of the 115th Congress reportedly are working with various stakeholders to consider different approaches to regulation of LDTs. On August 3, 2018, FDA provided Congressional committee staff technical assistance on the discussion draft entitled the Diagnostic Accuracy and Innovation Act (DAIA). In FDA’s technical assistance, FDA reiterated that it supported the goal of legislation to create pathways to market for all in vitro clinical tests (IVCTs). 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 CGI’s 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.”

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.

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.

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, then our Chief Operating Officer and Executive Vice President, Finance, succeeded him as our interim chief executive officer and was subsequently appointed our President and 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 March 27, 2019, we had approximately $2.4 million of indebtedness for borrowed money under our credit facility with Silicon Valley Bank, due April 15, 2019 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 while we have obtained amendments, waivers and most recently forbearance, the forbearance is only through April 15, 2019, and no assurances can be given that such lenders will agree to waive or amend such covenants and continue to forbear from calling our loan, which would have a material adverse effect on our ability to continue as a going concern. Further, no assurances can be given than the ABL will be extended beyond its maturity date of April 15, 2019.

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. 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:

- 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, and Morrisville, North Carolina. 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 key researchers, collaborators, and customers, 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 currently qualify as LDTs. If we are required to find a third-party laboratory to conduct our testing services, we believe the FDA would consider such 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, Interpace Diagnostics, BioCept, 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), Invitae Corp., LabCorp, NeoGenomics, Inc., Quest Diagnostics, BioCept and Interpace 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 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. During the year ended December 31, 2018, no Biopharma client accounted for more than 10% of our revenue. During the year ended December 31, 2017 one Biopharma client accounted for approximately 11% 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. 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, 2018, our research and development expenses were $2.5 million, which was 9% of our revenue and our sales and marketing expenses were $5.3 million, which was 19% of revenue. For the year ended December 31, 2017, our research and development expenses were $4.8 million, which was 16% of our net revenue and our sales and marketing expenses were $5.0 million, which was 17% of revenue. We expect our research and development expenses to continue to decrease, in absolute dollars, for the foreseeable future as we focus our business strategy on expanding our biopharma business. This change in focus however, does not change our need to validate the clinical utility of our diagnostic tests to obtain adoption or to secure reimbursement for our diagnostic tests from third party payers. We continue to require generating significant revenues in order to achieve sustained profitability.

We depend on certain third parties for the supply of certain tissue samples and biological materials that we use in our research and development services and efforts. If the costs of such collaborations increase or the third parties terminate their relationships 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 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 collaboration arrangements with Mayo Clinic, North Shore-Long Island Jewish Health System, the National Cancer Institute, 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 parties, and in many of the cases in which the arrangements are in writing, our relationships are terminable on 30 days' notice or less. If one or more third parties terminate their relationship with us, we will need to identify other third parties to supply 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 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.

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 (as that term is defined at 45 C.F.R. §160.103), 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. As of October 2018, these penalties include civil monetary penalties of $155 to $57,051per violation, up to an annual, per violation cap of $1,711,533. A single breach incident can result

in violations of multiple standards, resulting in possible penalties potentially in excess of $1,711,533. 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. California recently passed the California Consumer Privacy Act ("CCPA"), which will become effective on January 1, 2020. We may need to alter our security and privacy practices in order to comply with CCPA, but we have not yet fully evaluated CCPA's impact on our business. It is possible that this law, and other 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 state to state and 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.

The collection and use of personal data in the European Union is governed by the General Data Protection Regulation ("GRPR") which became effective on May 25, 2018. The GDPR applies to any business, regardless of its location, that provides goods or services to residents in the EU. This expansion may incorporate our future clinical trial activities in EU members states. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information" which includes health and genetic information of data subjects residing in the EU. GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the European Union to the United States or other regions that have not been deemed to offer "adequate" privacy protections.

Our research activities in the EU are currently limited to non-human preclinical studies, and as such, we do not collect, store, maintain, process, or transmit any Personal Data (as that term is defined under the GDPR) of trial subjects. However, since we currently have three employees located in the EU, our processing and transfer for employee Personal Data is subject to GDPR requirements. We have implemented a privacy and security program that is designed to adhere to the requirements of the GDPR in order to protect employee Personal Data, and in the event we progress to research or clinical trials involving humans, to protect participant Personal Data. However, there is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is not clear if the authorities will conduct random audits of companies doing business in the EU, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated. Enforcement uncertainty and the costs associated with ensuring GDPR compliance be onerous and adversely affect our business, financial condition, results of operations and prospects. As a result, we cannot predict the impact of the GDPR regulations on our current or future business, either in the US or the EU. However, failure to comply with the requirements of the GDPR (when applicable to our business) and the related national data protection laws of the European Union Member States, which may deviate slightly from the GDPR, may result in fines of up to 4% of global revenues, or € 20,000,000, whichever is greater. As a result of the implementation of the GDPR, we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules.

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 the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing clearance or approval of our clinical laboratory services and NGS products, restrict or regulate commercial activities and affect our ability to profitably sell any products for which we obtain marketing clearance or approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or our third party collaborators, suppliers or customers may receive for any approved products.

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 made a number of substantial changes in the way health care is financed by both governmental and private insurers. Among other things, the PPACA required 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.

Since the implementation of the PPACA, legislative and regulatory changes have been proposed and adopted, including aggregate reductions to Medicare Part B payments to providers of up to 2% per fiscal year, which became effective on April 1, 2013 and will remain in effect through 2027 unless additional congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. The full impact of these laws, as well as other new laws and reform measures that may be proposed and adopted in the future remains uncertain, but may result in additional reductions in Medicare and other health care funding, or higher production costs which could have a material adverse effect on our customers and, accordingly, our financial operations.

Members of the U.S. Congress and the Trump administration have expressed an intent to pass legislation or adopt executive orders to fundamentally change or repeal parts of the Affordable Care Act or to seek its invalidation through judicial action. While Congress has not passed repeal legislation to date, the 2017 Tax Cuts and Jobs Act includes a provision repealing the individual insurance coverage mandate included in the Affordable Care Act, effective January 1, 2019. On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the Affordable Care Act. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and our business, are not yet known. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

Legislative and regulatory proposals may also impact our regulatory and commercial prospects, expand marketing requirements, and restrict sales and promotional activities. We cannot be sure whether additional legislative changes will be enacted, or whether regulations, guidance or interpretations will be changed, or what the impact of such changes on the

marketing clearance or approval of our product candidates, if any, may be. For instance, the President also signed an Executive Order directing federal agencies to waive, defer, grant exemptions from or delay the implementation of provisions of the ACA that would impose a fiscal or regulatory burden on states, individuals, health care providers, health insurers, and manufacturers of drugs and devices, among others, and Congress may again attempt to repeal and possibly replace parts of the ACA. We do not know whether the ACA reform efforts will be successful or what they will ultimately look like. Accordingly, at this time it is difficult to determine the full impact of these efforts on our business. In addition, increased scrutiny by the U.S. Congress of the FDA's clearance or approval process may significantly delay or prevent marketing clearance or approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. Compliance with new requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may need to change our current manner of operation, which could have a material adverse effect on our business, financial condition, and results of operations. We expect federal and state healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from our testing products and clinical services, decreased potential returns from our development efforts, and in additional downward pressure on the price that we receive for any product for which we may we may gain clearance or approval. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our testing products.

Further, in April 2014, Congress passed the Protecting Access to Medicare Act (PAMA) overhauling the Medicare Part B Clinical Laboratory Fee Schedule (CLFS). CLFS is the nationally set reimbursement rate for clinical diagnostic tests established by Section 1833(h) of the Social Security Act. In the first massive overhaul of the CLFS since it was established in 1984, PAMA mandates the Centers for Medicare and Medicaid (CMS) to update the CLFS to reflect true market rates. 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. For any rates that are reduced, a phase-in of the reduction will occur through 2022. Between calendar years 2018-2020 the reduction for any given test cannot exceed 10% per year, and between calendar years 2021-2022, the reduction cannot be greater than 15% per year. 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. We are currently working with CMS to negotiate an increased CFLS rate for our FDA-cleared test, and are exploring additional reimbursement arrangements with third-party payors.

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 ("Quality Payment Program"). In addition, it extended the current Medicare Physician Fee Schedule rates through June 2015, and then increases them by 0.5% for the remainder of 2015. Beginning on January 1, 2016, the rates will increase 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. CMS releases its Final Physician Fee Schedule Rule annually. The Schedule changes on a year-to-year basis, and it is difficult to predict what rates our services and tests will receive. For example, the Final Fee Schedule Rule for 2017 reduced payments for flow cytometry by approximately 19% from the 2016 rate, and increases the professional component of the immunohistochemistry by approximately 9% over the 2016 rate. In 2018, there was another reduction in rates for flow cytometry codes 88185-TC and 88189-26, with the technical side cut by 23.1% to $30.60 and the professional interpretation cut by 4.1% to $88.92. Rates for the professional component of immunohistochemistry increased again but only slightly (0.3%) to $29.87 up from $29.79 in 2017.

On July 12, 2018, CMS issued a proposed rule that includes proposals to update payment policies, payment rates, and quality provisions for services furnished under the Medicare Physician Fee Schedule (PFS) on or after January 1, 2019. CMS has proposed a change to the way Medicare Advantage payments are treated in the definition of "applicable laboratory." If CMS were to finalize the proposed change, additional laboratories of all types serving a significant population of beneficiaries enrolled in Medicare Part C could meet the majority of Medicare revenues threshold and potentially qualify as an applicable laboratory and report data to CMS. It is not clear at this time what affect this change to the definition of "applicable laboratory" would have, if any, on our reporting obligations or reimbursement.

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 directed that the tests be gap-filled by the local contracts until 2018. For a new CDLT that is assigned a new or substantially revised HCPCS code on or after January 1, 2018, CMS determines the payment amount based on crosswalking if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code, or uses gap-filling if no comparable existing CDLT is available. 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.

In 2018, we derived approximately 19% of our total revenue from other third party payors, including managed care organizations and other health care insurance providers and 8% from Medicare. 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 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. For example, California is just one of several states that require out-of-state laboratories to have a state laboratory license to perform diagnostic tests on samples originating from California residents. Other states may have similar requirements or may adopt similar requirements in the future. Additionally, both New York and Washington State are exempt from CLIA and have their own stricter clinical laboratory regulatory programs. We could be required to comply with those states' programs in the event we accept specimens from New York or Washington. 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 we perform testing on samples originating in a state where we require a license, but do not currently have one, we could be subject to fines, sanctions, and may be denied permits or licenses in the future.

If the FDA were to begin requiring approval or clearance of our tests, we could incur substantial costs and time delays associated with meeting requirements for premarket 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, premarket 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 premarket review by FDA. However, our LDTs may be subject to approval by the New York State Clinical Lab Evaluation Program ("CLEP"). New York state's clinical laboratory regulatory program is exempt from CLIA, and maintains its own policies and procedures for evaluating and approving commercial LDTs for use in New York or on individuals residing in New York. New York LDT approval can be lengthy processes, which could delay our ability to market our tests to doctors and patients in this state. 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, generally, either premarket clearance or approval of LDTs, depending upon the risk-based approach FDA adopts. The public 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. 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. A number of Congressional committees of

the 115th Congress reportedly are working with various stakeholders to consider different approaches to regulation of LDTs. On August 3, 2018, FDA provided Congressional committee staff technical assistance on the discussion draft entitled the Diagnostic Accuracy and Innovation Act (DAIA). In FDA's technical assistance, FDA reiterated that it supported the goal of legislation to create pathways to market for all in vitro clinical tests (IVCTs). 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 likely 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 premarket 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.

An 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 premarket 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 premarket review, our tests may not be cleared or approved on a timely basis, if at all. We may also decide voluntarily to pursue FDA premarket review of our tests if we determine that doing so would be appropriate.

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 marketing application (e.g., 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, including reproducibility between labs, before we can submit an application for FDA approval or clearance. If the supply of reagents or equipment on which our tests in development or commercial tests rely becomes unavailable and we have to source replacement reagents or equipment for our tests, additional validation activities will be required and we may need to obtain regulatory clearances or approvals for the modified tests.

Additionally, if we commercialize any of our lab developed tests, we may also be required to submit such tests for approval by the New York State Clinical Laboratory Evaluation Program. 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 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.

Healthcare providers, physicians, and others will play a primary role in the ordering of our testing products and clinical services. Our arrangements with such persons and third-party payors, including price reporting obligations imposed by federal health care programs, will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell, and distribute our tests, if we require or obtain marketing approval. Even though we do not and will not control referrals of healthcare services or directly bill to Medicare, Medicaid, or other third party payors, certain federal and state healthcare laws, and regulations pertaining to fraud and abuse and to patients' rights are and will be applicable to our business. 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 knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, in cash or in kind, to induce or to reward inducement either the referral of an individual for, or the purchase or lease, order or recommendation of, any item, good, facility or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. The term ''remuneration'' has been interpreted broadly to include anything of value;
- 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" (including clinical laboratory 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;
- the beneficiary inducement provision of 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;
- the civil monetary penalties statute also imposes fines against any person who is determined to have knowingly presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent;
- federal civil False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program; knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay money to the federal government; and knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal

government. Any demand for payment, such as an invoice, that includes items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim under the False Claims Act;

- the criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the civil False Claims Act, requires proof of intent to submit a false claim; 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. The Physician Payment Sunshine Act (Section 6002 of the PPACA) states that 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.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations could be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, debarment from governmental contracting and refusal of orders under existing contracts, and exclusion from government funded healthcare programs, such as Medicare and Medicaid, any of which could substantially disrupt our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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 ("PHI") by "covered entities," which includes health plans, healthcare clearinghouses, and health care providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards. It also sets forth certain rights that an individual has with respect to his or her PPHI maintained by a covered entity, including the right to access or amend certain records containing PHI or to request restrictions on the use or disclosure of PHI. 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 PHI, which is electronically transmitted or 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, which may be more stringent than HIPAA. 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.

Certain state laws may also affect our other privacy and security practices. For example, California recently passed the California Consumer Privacy Act ("CCPA"), which will become effective on January 1, 2020. Although HIPAA-protected information is exempt from CCPA, additional information we may maintain on our customers and employees may be subject to additional security and privacy protections. Other states have specific protections for certain types of information. We may need to alter our security and privacy practices in order to comply with CCPA, but we have not yet fully evaluated CCPA's impact on our business.

HIPAA contains 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 have taken commercially reasonable and industry standard 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.*"

Our operations are subject to environmental, health and safety laws and regulations, with which compliance may be costly

Our business is subject to federal, state, and local laws and regulations relating to the protection of the environment, worker health and safety and the use, management, storage, and disposal of hazardous substances and wastes. Failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions. In addition, environmental laws and regulations could require us to pay for environmental remediation and response costs, or subject us to third party claims for personal injury, natural resource or property damage, relating to environmental contamination. Liability may be imposed whether or not we knew of, or were responsible for, such environmental contamination. The cost of defending against environmental claims, of compliance with environmental, health and safety regulatory requirements or of remediating contamination could materially adversely affect our business, assets or results of operations.

Intellectual Property Risks Relating 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.

Third parties 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 third parties to provide us with tissue samples and biological materials that we use to develop our tests. In some cases we have written agreements with third parties that may require us to negotiate ownership and commercial rights with the third party if our use of such third party'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 third party supplier's materials where required, or if disputes otherwise arise with respect to the intellectual property developed with the use of a third party'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 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 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 third party collaborators or suppliers, 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, suppliers or customers.

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

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, 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;
- being subject to additional privacy and cybersecurity laws, including the Australian Privacy Act of 1988;
- 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 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 may operate in jurisdictions 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

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, 2018, 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 $0.20 per share in the fourth quarter of 2018. 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 our relationship with key collaborators, suppliers, customers and third parties;
- 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.

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 15.2% of our outstanding common stock, based on the number of shares outstanding on March 27, 2019. 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;
- 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 incurring significantly increased costs and devote substantial management time as a result of operating as a public company.

As a public company, we are incurring significant legal, accounting and other expenses that we did not incur as a private company. For example, in addition to being required to comply with certain requirements of the Sarbanes-Oxley Act of 2002, we are 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 continue to 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 continue to 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, if we lose our status as 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 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:

- authorize our board of directors to issue, without stockholder approoval, 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of December 31, 2018, 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 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 2018, we had a lease agreement for approximately 19,100 square feet of laboratory space in Los Angeles, California which expired on December 31, 2018. At December 31, 2018, we owed approximately $164,000 in overdue rent and related expenses to the Los Angeles landlord, and are in active negotiations to finalize our financial obligations related to his property.

Item 3. Legal Proceedings

On April 5, 2018 and April 12, 2018, purported stockholders of the Company filed nearly identical putative class action lawsuits in the U.S. District Court for the District of New Jersey, against the Company, Panna L. Sharma, John A. Roberts, and Igor Gitelman, captioned *Ben Phetteplace v. Cancer Genetics, Inc. et al*, No. 2:18-cv-05612 and *Ruo Fen Zhang v. Cancer Genetics, Inc. et al*, No. 2:18-06353, respectively. The complaints alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 based on allegedly false and misleading statements and omissions regarding our business, operational, and financial results. The lawsuits sought, among other things, unspecified compensatory damages in connection with purchases of our stock between March 23, 2017 and April 2, 2018, as well as interest, attorneys' fees, and costs. On August 28, 2018, the Court consolidated the two actions in one action captioned *In re Cancer Genetics, Inc. Securities Litigation* (the "Securities Litigation") and appointed shareholder Randy Clark as the lead plaintiff. On October 30, 2018, the lead plaintiff filed an amended complaint, adding Edward Sitar as a defendant and seeking, among other things, compensatory damages in connection with purchases of CGI stock between March 10, 2016 and April 2, 2018. On December 31, 2018, Defendants filed a motion to dismiss the amended complaint for failure to state a claim. The Company is unable to predict the ultimate outcome of the Securities Litigation and therefore cannot estimate possible losses or ranges of losses, if any.

In addition, on June 1, 2018, September 20, 2018, and September 25, 2018, purported stockholders of the Company filed nearly identical derivative lawsuits on behalf of the Company in the U.S. District Court for the District of New Jersey against the Company (as a nominal defendant) and current and former members of the Company's Board of Directors and current and former officers of the Company. The three cases are captioned: *Bell v. Sharma et al*., No. 2:18-cv-10009-CCC-MF, *McNeece v. Pappajohn et al*., No. 2:18-cv-14093, and *Workman v. Pappajohn, et al*., No. 2:18-cv-14259 (the "Derivative Litigation"). The complaints allege claims for breach of fiduciary duty, violations of Section 14(a) of the Securities Exchange Act of 1934 (premised upon alleged omissions in the Company's 2017 proxy statement), and unjust enrichment, and allege that the individual defendants failed to implement and maintain adequate controls, which resulted in ineffective disclosure controls and procedures, and conspired to conceal this alleged failure. The lawsuits seek, among other things, damages and/or restitution to the Company, appropriate equitable relief to remedy the alleged breaches of fiduciary duty, and attorneys' fees and costs. On November 9, 2018, the Court in the *Bell v. Sharma* action entered a stipulation filed by the parties staying the *Bell* action until the Securities Litigation is dismissed, with prejudice, and all appeals have been exhausted; or the defendants' motion to dismiss in the Securities Litigation is denied in whole or in part; or either of the parties in the *Bell* action gives 30 days' notice that they no longer consent to the stay. On December 10, 2018, the parties in the *McNeece* action filed a stipulation that is substantially identical to the *Bell* stipulation. On February 1, 2019, the Court in the Workman action granted a stipulation that is substantially identical to the Bell stipulation. The Company is unable to predict the ultimate outcome of the Derivative Litigation and therefore cannot estimate possible losses or ranges of losses, if any.

Item 4. Mine Safety Disclosures

Not applicable.

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 2018	$ 1.05	$ 0.20
3rd Quarter 2018	$ 1.30	$ 0.85
2nd Quarter 2018	$ 1.75	$ 0.82
1st Quarter 2018	$ 2.20	$ 1.55
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

Holders

As of December 31, 2018, 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 ofDecember 31, 2018 and 2017, 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, 2016, 2015 and 2014 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.

	Year Ended December 31,				
	2018	2017	2016	2015	2014
	(in thousands, expect per share data)				
Consolidated Statements of Operations Data:					
Revenue	**$ 27,470**	$ 29,121	$ 27,049	$ 18,040	$ 10,199
Cost of revenues	**18,724**	18,070	17,104	14,098	8,453
Gross profit (loss)	**8,746**	11,051	9,945	3,942	1,746
Operating expenses:					
Research and development	**2,488**	4,789	5,967	5,483	4,622
General and administrative	**19,184**	19,894	16,034	14,567	12,369
Sales and marketing	**5,268**	4,990	4,668	5,269	3,964
Restructuring costs	**2,320**	—	—	—	—
Merger costs	**1,464**	—	—	—	—
Total operating expenses	**30,724**	29,673	26,669	25,319	20,955
Loss from operations	**(21,978)**	(18,622)	(16,724)	(21,377)	(19,209)
Other income (expense):					
Interest expense	**(2,120)**	(2,128)	(454)	(344)	(473)
Interest income	**21**	63	23	49	74
Change in fair value of warrant liability	**3,732**	(1,964)	1,525	35	417
Change in fair value of acquisition note payable	**136**	(42)	152	269	198
Other expense	**(78)**	(266)	(325)	—	—
Total other income (expense)	**1,605**	(4,337)	921	9	216
Loss before income taxes	**(20,373)**	(22,959)	(15,803)	(21,368)	(18,993)
Income tax (benefit)	**—**	(2,079)	—	(1,184)	(2,350)
Net (loss)	**$ (20,373)**	$ (20,880)	$ (15,803)	$ (20,184)	$ (16,643)
Basic net (loss) per share	**$ (0.75)**	$ (1.01)	$ (1.00)	$ (1.96)	$ (1.76)
Diluted net (loss) per share	**$ (0.75)**	$ (1.01)	$ (1.00)	$ (1.96)	$ (1.80)
Basic weighted average shares outstanding	**27,291**	20,663	15,861	10,298	9,449
Diluted weighted average shares outstanding	**27,291**	20,663	15,861	10,299	9,462

	Year Ended December 31,				
	2018	2017	2016	2015	2014
Consolidated Balance Sheet Data:		*(in thousands)*			
Cash and cash equivalents	**$ 161**	$ 9,541	$ 9,502	$ 19,459	$ 25,554
Working capital (deficit)	**(17,946)**	3,566	12,378	18,333	27,389
Total assets	**35,406**	52,221	42,434	48,884	47,105
Debt, excluding current portion	**—**	—	2,654	4,642	6,000
Accumulated deficit	**(157,716)**	(134,834)	(113,954)	(98,151)	(77,967)
Total stockholders' equity	**$ 6,802**	$ 26,765	$ 25,624	$ 33,017	$ 34,554

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 enabling precision medicine in oncology by providing multi-disciplinary diagnostic and data solutions, facilitating individualized therapies through our diagnostic 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. 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. 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.

Net cash used in operating activities was $12.6 million and $13.6 million for the years ended December 31, 2018 and 2017, respectively, and the Company had unrestricted cash and cash equivalents of $0.2 million at December 31, 2018, a reduction from $9.5 million at December 31, 2017. The Company has negative working capital at December 31, 2018 of $17.9 million.

The Company currently requires a significant amount of additional capital to fund operations and pay its accounts payable, and its ability to continue as a going concern is dependent upon its ability to raise such additional capital and achieve profitability. If the Company is not able to raise such additional capital on a timely basis or on favorable terms, the Company may need to scale back or, in extreme cases, discontinue its operations or liquidate its assets.

While we have implemented an aggressive consolidation strategy to reduce our operating costs in 2018, including the closure of our California laboratory and facility, we expect to continue to incur material losses for the near future. We incurred losses of $20.4 million and $20.9 million for fiscal years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of $157.7 million. We need to raise additional capital or execute on our plans to execute a strategic transaction. The report of our independent registered public accounting firm with respect to our financial statements appearing in Part II Item 8 of this annual report on 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, or that we will complete a strategic transaction. In addition, we are in default of certain financial covenants in our credit agreements with our senior lenders and our ABL matures on April 15, 2019. While we have negotiated forbearance agreements with both lenders through April 15, 2019, we will not be able to close on a strategic transaction on or before April 15, 2019, and there is no assurance that will be able to extend the forbearance periods or the term of the ABL.

Sale of India Subsidiary

On April 26, 2018, we sold our India subsidiary, BioServe Biotechnologies (India) Private Limited ("BioServe") to Reprocell, Inc., for $1.9 million, including $1.6 million in cash at closing and up to an additional $0.3 million, which was contingent upon the India subsidiary meeting a specified revenue target through August 31, 2018. The contingent consideration was reduced to $0.2 million and received in November 2018. As a result of this transaction, we recognized a loss of approximately $0.1 million on the disposal of BioServe, which is included in other income (expense) in our Consolidated Statements of Operations and Other Comprehensive Loss.

Restructuring

In 2018, the Company adopted a plan to migrate its California operations to its New Jersey and North Carolina locations and to permanently close its California laboratory. The Company incurred approximately $2.3 million of restructuring costs during the year ended December 31, 2018 as the result of this consolidation of our operations.

Merger Agreement

On September 18, 2018, we entered into an agreement and plan of merger (the "Merger Agreement") with NovellusDx, Ltd., a privately-held company formed under the law of the State of Israel ("NDX"), in regards to Wogolos Ltd., our wholly-owned subsidiary company formed under the laws of the State of Israel. Subject to satisfaction or waiver of the conditions set forth in the Merger Agreement, Wogolos Ltd. would have merged with and into NDX, with NDX becoming a wholly-owned subsidiary of us and the surviving company. In connection with the signing of the Merger Agreement, we entered into a credit agreement with NDX, pursuant to which NDX loaned us $1.5 million ("Advance from NDX").

On December 15, 2018, we terminated the Merger Agreement. As a result, the Advance from NDX, plus interest thereon, became due and payable on March 15, 2019. In addition, the interest rate was increased beginning on December 15, 2018 to 21% due to an event of default. The default also gives NDX the right to convert all, but not less than all, of the outstanding balance into shares of the Company's common stock at a conversion price of $0.606 per share.

Acquisition

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 shares of the Company's common stock, valued at $8.1 million 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 or acquire technology solutions to accelerate the penetration into the Biopharma community to achieve more revenue supporting clinical trials and develop and commercialize unique or proprietary services and tests to achieve sustainable organic growth. Our unique and proprietary tests include CGH microarrays, NGS panels, and DNA FISH probes. We continue to develop additional unique and 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 generated through our Biopharma Services, Discovery Services and Clinical Services. 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. Our 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.

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 their oncology patients or as part of a clinical trial sponsored by a pharmaceutical or biotechnology company in which the patient is being enrolled.

During the year ended December 31, 2018, no Biopharma clients accounted for more than 10% of our revenue. During the year ended December 31, 2017, one Biopharma client accounted for approximately 11% of our revenue.

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. For the year ended December 31, 2018, Medicare and other third party payors accounted for approximately 8% and 19% of our total revenue, respectively.

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, 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, including other consolidations of operations and further reductions in headcount.

Operating Expenses

We classify our operating expenses into five categories: research and development, sales and marketing, general and administrative; restructuring costs and merger costs. 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. 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 only modest 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 decrease as we expand into existing geographies and customize clinical tests and services.

Restructuring Costs. In alignment with our strategic plan to migrate our California operations to our New Jersey and North Carolina locations and to permanently close our California laboratory, we experienced various expenses associated with exiting a facility, transition of lab equipment and supplies, disposal of assets and termination benefits associated with displaced employees. We consider this expense to be one time in nature and subject to board approved strategic initiatives.

Merger Costs. In the pursuit of various strategic options for the Company, legal and other professional costs are incurred while evaluating, negotiating, executing and implementing merger and acquisition alternatives. While this expense is a non-recurring cost, until such time as we complete a strategic transaction, we expect to incur these expenses in the near term.

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, 2018 and 2017

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

	Year Ended December 31,		Change	
	2018	2017	**$**	**%**
(dollars in thousands)				
Revenue	**$ 27,470**	$ 29,121	$ (1,651)	-6 %
Cost of revenues	**18,724**	18,070	654	4 %
Research and development expenses	**2,488**	4,789	(2,301)	-48 %
General and administrative expenses	**19,184**	19,894	(710)	-4 %
Sales and marketing expenses	**5,268**	4,990	278	6 %
Restructuring costs	**2,320**	—	2,320	N/A
Merger costs	**1,464**	—	1,464	N/A
Total operating loss	**(21,978)**	(18,622)	(3,356)	18 %
Interest (expense), net	**(2,099)**	(2,065)	(34)	2 %
Change in fair value of warrant liability	**3,732**	(1,964)	5,696	-290 %
Change in fair value of other derivatives	**(86)**	—	(86)	N/A
Change in fair value of acquisition note payable	**136**	(42)	178	-424 %
Other expense	**(78)**	(266)	188	-71 %
Loss before income taxes	**(20,373)**	(22,959)	2,586	-11 %
Income tax (benefit)	**—**	(2,079)	2,079	N/A
Net loss	**$ (20,373)**	$ (20,880)	$ 507	-2 %

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,	
	2018	2017
Reconciliation of net (loss):		
Net (loss)	**$ (20,373)**	$ (20,880)
Adjustments:		
Change in fair value of acquisition note payable	**(136)**	42
Change in fair value of other derivatives	**86**	—
Change in fair value of warrant liability	**(3,732)**	1,964
Adjusted net (loss)	**$ (24,155)**	$ (18,874)
Reconciliation of basic and diluted net (loss) per share:		
Basic and diluted net (loss) per share	**$ (0.75)**	$ (1.01)
Adjustments to net (loss)	**(0.14)**	0.10
Adjusted basic and diluted net (loss) per share	**$ (0.89)**	$ (0.91)
Basic and diluted weighted-average shares outstanding	**27,291**	20,663

Adjusted net (loss) increased 28% to $24.2 million during the year ended December 31, 2018, from an adjusted net (loss) of $18.9 million during the year ended December 31, 2017. Adjusted basic and diluted net (loss) per share decreased 2% to $0.89 during the year ended December 31, 2018, down from $0.91 during the year ended December 31, 2017.

Revenue

The breakdown of our revenue is as follows:

	Year Ended December 31,				Change	
	2018		2017			
(dollars in thousands)	$	%	$	%	$	%
Biopharma Services	**14,828**	**54%**	14,629	50%	199	1 %
Clinical Services	**7,429**	**27%**	10,774	37%	(3,345)	(31)%
Discovery Services	**5,213**	**19%**	3,718	13%	1,495	40 %
Total Revenue	**27,470**	**100%**	29,121	100%	(1,651)	(6)%

Revenue decreased 6%, or $1.7 million, to $27.5 million for the year ended December 31, 2018, from $29.1 million for the year ended December 31, 2017, principally due to lower realization on third party and direct billings in our Clinical Services and the effects of the adoption of the new revenue recognition standard, which is directly the result of actual cash collection trends, offset in part by an increase in our Discovery Services.

Revenue from Biopharma Services increased 1%, or $0.2 million, to $14.8 million for the year ended December 31, 2018, from $14.6 million for the year ended December 31, 2017, principally due to the variability of timing related to project start dates and patient recruitment into clinical trials by our customers. Revenue from Clinical Services customers decreased 31%, or $3.3 million, to $7.4 million for the year ended December 31, 2018, from $10.8 million for the year ended December 31, 2017, principally due to lower realization on third party and direct billings and the effects of the adoption of the new revenue recognition standard. Revenue from Discovery Services increased $1.5 million, to $5.2 million for the year ended December 31, 2018, from $3.7 million for the year ended December 31, 2017 due to a full year of operations at vivoPharm, which was acquired in August 2017.

Cost of Revenues

Cost of revenues increased 4%, or $0.7 million, to $18.7 million for the year ended December 31, 2018, from $18.1 million for the year ended December 31, 2017, principally due to increased shipping and payroll costs of $1.0 million and $1.1 million, respectively, as a result of a full year of operations at vivoPharm, offset, in part, by a decrease in lab supplies of $1.2 million and a decrease of $0.4 million in depreciation and amortization. Gross margin declined from 38% to 32% during the year ended December 31, 2018. The decline in gross margin was caused by the challenges of cash collections in our clinical services business, which reduced our recorded revenue in the period. In addition, we recognized an out of measurement period adjustment associated with the vivoPharm acquisition and a corresponding change in estimate of the contract obligations for the remaining portfolio of contracts.

Operating Expenses

Research and Development Expenses. Research and development expenses decreased 48%, or $2.3 million, to $2.5 million for the year ended December 31, 2018, from $4.8 million for the year ended December 31, 2017. The decrease relates primarily to reduced payroll and benefits costs of $1.7 million and decreased lab supplies of $0.6 million.

General and Administrative Expenses. General and administrative expenses decreased 4%, or $0.7 million to $19.2 million for the year ended December 31, 2018, from $19.9 million for the year ended December 31, 2017. The decrease primarily relates to a decline in our bad debt expense of $2.8 million due to the adoption of the new revenue recognition standard, which requires implicit price concessions to be recorded as a reduction of revenue, and large write-offs of Clinical Services revenue in 2017 related to challenges faced at our California location during the period October 2015 through December 2017. We also reduced our legal and accounting costs by $0.5 million, travel costs by $0.2 million and office supplies by $0.1 million due to expense control measures and optimizing use of legal counsel. These reductions were partially offset by an increase in professional services of $0.7 million, an increase in medical billings expense of $0.5 million, an increase in payroll and other benefits of $0.6 million, an increase in depreciation and amortization of $0.2 million due to a full year of operations at

vivoPharm, an increase in business licenses of $0.2 million, an increase in taxes of $0.3 million and an increase in software and maintenance of $0.2 million.

Sales and Marketing Expenses. Sales and marketing expenses increased 6%, or $0.3 million, to $5.3 million for the year ended December 31, 2018, from $5.0 million for the year ended December 31, 2017, principally due to increased compensation and related benefits of $0.2 million due to the effect of a full year of operating expenses related to the vivoPharm acquisition and increased rent expense of $0.1 million.

Restructuring Costs: Restructuring costs of $2.3 million were incurred during the year ended December 31, 2018, primarily associated with the closure of the California laboratory and operations.

Merger Costs. Merger costs of $1.5 million were incurred during the year ended December 31, 2018, principally due to the evaluation and pursuit of strategic options, including the terminated merger with NDX.

Interest Expense, Net

Interest expense, net remained consistent during the year ended December 31, 2018 as compared to the year ended December 31, 2017.

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 income of $3.7 million for the year ended December 31, 2018, as compared to non-cash expense of $2.0 million for the year ended December 31, 2017, 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 Other Derivatives

The change in fair value of other derivatives resulted in $0.1 million of non-cash expense due to provisions in our convertible note and Advance from NDX agreements that qualify as derivatives. We considered the probabilities of the occurrence or non-occurrence of various scenarios, as well as any potential changes in interest rates, in determining the valuation of these derivatives.

Change in Fair Value of Acquisition Note Payable

The change in fair value of the acquisition note payable resulted in $0.1 million in non-cash income for the year ended December 31, 2018, as compared to non-cash expense $42,000 for the year ended December 31, 2017 as a result of fluctuations in our stock price.

Other Expense

During the year ended December 31, 2018, we recognized a loss on the sale of our India subsidiary of approximately $0.1 million. During the year ended December 31, 2017, we incurred $0.3 million of aggregate expense resulting from the issuance of derivative warrants as part of a debt refinancing and the 2017 Offering (as defined below).

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, 2018. However, we received $0.5 million of net proceeds from the sale of state NOL's and state research and development credits on April 12, 2019.

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. On April 26, 2018, we sold our India subsidiary for $1.9 million, including $1.6 million in cash at closing and up to an additional $0.3 million, which was contingent upon the India subsidiary meeting a specified revenue target through August 31, 2018. The contingent consideration was reduced to $0.2 million and received in November 2018. In general, our primary uses of cash are providing for operating expenses, working capital purposes and servicing debt.

Line of Credit and Term Note

On March 22, 2017, we entered into a two year asset-based revolving line of credit agreement with Silicon Valley Bank ("SVB"). The SVB credit facility provided 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 required monthly interest payments at the Wall Street Journal prime rate plus 1.5% (7.0% at December 31, 2018) and was scheduled to mature on March 22, 2019. We pay a fee of 0.25% per year on the average unused portion of the ABL. In August 2018, the maximum borrowings were reduced from $6.0 million to $3.0 million. Subsequent to year-end, the interest rate was adjusted to the Wall Street Journal prime rate plus 2.25% and the maturity date was extended through April 15, 2019, subject to the Company satisfying certain milestones of the forbearance agreement discussed below. At December 31, 2018, we had borrowed $2.6 million on the ABL, which was the maximum amount allowed based on eligible accounts receivable at the time and timing related to cash collections of accounts receivable.

On March 22, 2017, we concurrently entered into a 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. At December 31, 2018, the PFG Term Note had a principal balance of $6.0 million.

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 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, 2018, January 31, 2019, February 28, 2019 and March 31, 2019, we were in violation of certain financial covenants in the loan agreements. In January 2019, we entered into forbearance agreements with both lenders that, among other things, (i) require us to comply with certain milestones in connection with a potential strategic transaction satisfactory to PFG and SVB with an anticipated closing date of on or before April 15, 2019 (the "Milestones"), (ii) provide for PFG and SVB's forbearance of their respective rights and remedies resulting from existing and stated potential events of default under the PFG Term Note and ABL until the earlier of (a) the occurrence of an additional event of default or (b) February 15, 2019; provided such date shall be automatically extended to (1) February 28, 2019 and then to (2) April 15, 2019 so long as we are in compliance with the Milestones required as of such dates and (iii) extend the maturity date of the ABL until April 15, 2019. The Company will not be able to close on a strategic transaction on or before April 15, 2019. No assurance can be given that the Company will be able to extend the maturity of the ABL beyond April 15, 2019 or extend the forbearances with SVB and PFG beyond April 15, 2019.

Convertible Debt

On July 17, 2018, the Company entered into a convertible note with Iliad Research and Trading, L.P. ("Iliad"), with an initial principal amount of $2.6 million ("Convertible Note"). The Convertible Note has an 18 month term and carries interest at 10% per annum. The note is convertible into shares of the Company's common stock at a conversion price of $0.80 per share upon 5 trading days' notice, subject to certain adjustments (standard dilution) and ownership limitations specified in the Convertible Note.

Advance from NDX

On September 18, 2018, NDX loaned us $1.5 million. The Advance from NDX bears interest at 10.75% and is payable on March 15, 2019. The interest rate was increased to 21% on December 15, 2018 due to the termination of the Merger Agreement, which was an event of default. The default also gives NDX the right to convert all, but not less than all, of the outstanding balance into shares of the Company's common stock at a conversion price of $0.606 per share.

2019 Offerings

On January 9, 2019, we entered into an underwriting agreement with H.C. Wainwright & Co., LLC ("H.C. Wainwright"), relating to an underwritten public offering of 13,333,334 shares of our common stock for $0.225 per share. We received proceeds from the offering of approximately $2.4 million, net of expenses and discounts of approximately $0.6 million. We also issued warrants to purchase 933,334 shares of common stock to H.C. Wainwright in connection with this offering. The warrants are exercisable for five years from the date of issuance at a per share price of $0.2475.

On January 26, 2019, we issued 15,217,392 shares of common stock at a public offering price of $0.23 per share. We received proceeds from the offering of approximately $3.0 million, net of expenses and discounts of approximately $0.5 million. We also issued warrants to purchase 1,065,217 shares of common stock to the underwriter, H.C. Wainwright, in connection with this offering. The warrants are exercisable for five years from the date of issuance at a per share price of $0.253.

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. Subject to certain ownership limitations, these warrants were 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 24-month 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.

As of December 31, 2018, the Company has sold 1,000,000 shares under this agreement at $3.00 per share, resulting in proceeds of approximately $3.0 million, 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.

Cash Flows

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

	Year Ended December 31,	
	2018	2017
(in thousands)		
Cash provided by (used in):		
Operating activities	**$ (12,552)**	$ (13,564)
Investing activities	**1,084**	(2,701)
Financing activities	**2,147**	16,338
Effect of foreign exchange rates on cash and cash equivalents and restricted cash	**(59)**	16
Net increase (decrease) in cash and cash equivalents and restricted cash	**$ (9,380)**	$ 89

We had cash and cash equivalents and restricted cash of $0.5 million and $9.9 million at December 31, 2018 and 2017, respectively.

The $9.4 million decrease in cash and cash equivalents and restricted cash was principally the result of $12.6 million of net cash used to fund operations and $1.5 million used to repay debt. These uses were offset by net proceeds of $2.5 million and $1.5 million received from Iliad and NDX, respectively, and net proceeds of $1.8 million received from the sale of our India subsidiary.

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.

Cash Used in Operating Activities

Net cash used in operating activities was $12.6 million for the year ended December 31, 2018. We used $17.6 million in net cash to run our core operations, including losses from operations and $1.3 million in cash paid for interest. These uses were partially offset by a net decrease in accounts receivable of $1.0 million, a net increase in accounts payable, accrued expenses and deferred revenue of $3.8 million and a net decrease in other current assets of $0.3 million.

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.

Cash Used in Investing Activities

Net cash provided by investing activities was $1.1 million for the year ended December 31, 2018. During 2018, we received net proceeds of $1.8 million from the sale of our India subsidiary. These proceeds were partially offset by $0.7 million of fixed asset additions.

Net cash used in investing activities was $2.7 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, and $0.2 million used in a cost method investment.

Cash Used/Provided by Financing Activities

Net cash provided by financing activities was $2.1 million for the year ended December 31, 2018 and principally resulted from net proceeds received from the Convertible Note of $2.5 million and proceeds received from NDX of $1.5 million, offset, in part, by net repayments on our ABL of $1.5 million and capital lease payments of $0.3 million.

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.

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 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 ABL, we have reached the borrowing limit based on eligible accounts receivable at December 31, 2018. In addition, we were in violation of certain financial covenants with SVB and PFG as of December 31, 2018, January 31, 2019, February 28, 2019 and March 31, 2019. We have negotiated forbearance agreements with both lenders, as discussed above. However, we will not be able to close on a strategic transaction on or before April 15, 2019, and no assurance can be given that we will be able to extend the maturity of the ABL beyond April 15, 2019 or extend the forbearances

beyond April 15, 2019. If our lenders were to 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, 2018 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 extend our forbearance agreements and the ABL;
- 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.”

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, 2018 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 consolidated 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 ofDecember 31, 2018. 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, 2018. 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	$ 13,054	$ 13,054	$ —	$ —	$ —
Capital lease obligations, including interest, for equipment	777	394	370	13	—
Operating lease obligations relating to corporate headquarters and clinical laboratories	3,612	1,388	1,567	657	—
Total	$ 17,443	$ 14,836	$ 1,937	$ 670	$ —

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 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.

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;
- Warrant liabilities and other derivatives; and
- Impairment of intangibles and long-lived assets.

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 Australia (vivoPharm Pty Ltd.) and through our subsidiary in Italy (Cancer Genetics Italia, S.r.l.). For the years ended December 31, 2018 and 2017, approximately 7% and 6%, 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 Australia Dollar or Euro to United States dollars. We currently do not hedge currency risk. The translation adjustments for the years ended December 31, 2018 and 2017 were not significant.

Interest Rate Risk

At December 31, 2018, we had interest rate risk primarily related to borrowings of $2.6 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% (7.0% at December 31, 2018). If interest rates increased by 1.0%, interest expense on our current borrowings would increase by approximately $7,500, calculated based on the current maturity date of April 15, 2019.

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.

Item 8. Financial Statements and Supplementary Data

INDEX TO FINANCIAL STATEMENTS

Cancer Genetics, Inc. and Subsidiaries

Consolidated Financial Report December 31, 2018

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, 2018 and 2017, 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, 2018 and 2017, 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, and has 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.

Change in Accounting Principle
As discussed in Note 3 to the consolidated financial statements, the Company has changed its method of accounting for recognizing revenue effective January 1, 2018 due to the adoption of Accounting Standards Update No. 2014-09, “Revenue from Contracts with Customers”.

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 consolidated 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 consolidated 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 consolidated 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 15, 2019

CANCER GENETICS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(in thousands, except par value)

	December 31,	
	2018	2017
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	**$ 161**	$ 9,541
Accounts receivable, net of allowance for doubtful accounts of 2018 $3,462; 2017 $6,539	**7,038**	10,958
Other current assets	**2,148**	2,707
Total current assets	**9,347**	23,206
FIXED ASSETS, net of accumulated depreciation	**4,056**	5,550
OTHER ASSETS		
Restricted cash	**350**	350
Patents and other intangible assets, net of accumulated amortization	**4,004**	4,478
Investment in joint venture	**92**	246
Goodwill	**17,257**	17,992
Other	**300**	399
Total other assets	**22,003**	23,465
Total Assets	**$ 35,406**	$ 52,221
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	**$ 13,067**	$ 8,715
Obligations under capital leases, current portion	**330**	272
Deferred revenue	**2,173**	516
Line of credit	**2,621**	4,137
Term note	**6,000**	6,000
Convertible note, net	**2,481**	—
Advance from NovellusDx, Ltd., net	**535**	—
Other derivatives	**86**	—
Total current liabilities	**27,293**	19,640
Obligations under capital leases	**379**	624
Deferred rent payable and other	**305**	360
Warrant liability	**248**	4,403
Deferred revenue, long-term	**379**	429
Total Liabilities	**28,604**	25,456
STOCKHOLDERS' EQUITY		
Preferred stock, authorized 9,764 shares $0.0001 par value, none issued	**—**	—
Common stock, authorized 100,000 shares, $0.0001 par value, 27,726 and 27,754 shares issued and outstanding as of December 31, 2018 and 2017, respectively	**3**	3
Additional paid-in capital	**164,455**	161,527
Accumulated other comprehensive income	**60**	69
Accumulated deficit	**(157,716)**	(134,834)
Total Stockholders' Equity	**6,802**	26,765
Total Liabilities and Stockholders' Equity	**$ 35,406**	$ 52,221

See Notes to Consolidated Financial Statements.

CANCER GENETICS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Other Comprehensive Loss

(in thousands, except per share amounts)

	Years Ended December 31,	
	2018	2017
Revenue	**$ 27,470**	$ 29,121
Cost of revenues	**18,724**	18,070
Gross profit	**8,746**	11,051
Operating expenses:		
Research and development	**2,488**	4,789
General and administrative	**19,184**	19,894
Sales and marketing	**5,268**	4,990
Restructuring costs	**2,320**	—
Merger costs	**1,464**	—
Total operating expenses	**30,724**	29,673
Loss from operations	**(21,978)**	(18,622)
Other income (expense):		
Interest expense	**(2,120)**	(2,128)
Interest income	**21**	63
Change in fair value of warrant liability	**3,732**	(1,964)
Change in fair value of other derivatives	**(86)**	—
Change in fair value of acquisition note payable	**136**	(42)
Other expense	**(78)**	(266)
Total other income (expense)	**1,605**	(4,337)
Loss before income taxes	**(20,373)**	(22,959)
Income tax (benefit)	**—**	(2,079)
Net (loss)	**$ (20,373)**	$ (20,880)
Basic and diluted net (loss) per share	**$ (0.75)**	$ (1.01)
Basic and diluted weighted average shares outstanding	**27,291**	20,663
Net (loss)	**(20,373)**	(20,880)
Unrealized gain (loss) on foreign currency translation	**(9)**	69
Total comprehensive (loss)	**$ (20,382)**	$ (20,811)

See Notes to Consolidated Financial Statements.

CANCER GENETICS, INC. AND SUBSIDIARIES

Consolidated Statements of Changes in Stockholders' Equity
Years Ended December 31, 2018 and 2017
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount				
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
Stock based compensation—employees	(28)	—	921	—		921
Fair value of warrants reclassified from liabilities to equity	—	—	423	—	—	423
Warrant modification costs	—	—	83	—	—	83
Beneficial conversion feature on Convertible Note	—	—	328	—	—	328
Beneficial conversion feature on Advance from NovellusDx, Ltd.	—	—	1,173	—	—	1,173
Transition adjustment for adoption of Accounting Standards Codification Topic 606	—	—	—	—	(2,509)	(2,509)
Unrealized loss on foreign currency translation	—	—	—	(9)	—	(9)
Net loss	—	—	—	—	(20,373)	(20,373)
Balance, December 31, 2018	27,726	$ 3	$ 164,455	$ 60	$ (157,716)	$ 6,802

See Notes to Consolidated Financial Statements.

CANCER GENETICS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(in thousands)

	Years Ended December 31,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	**$ (20,373)**	$ (20,880)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**1,602**	1,799
Amortization	**512**	366
Provision for bad debts	**2,514**	5,278
Stock-based compensation	**921**	1,895
Stock issued for consulting services	**—**	5
Change in fair value of warrant liability, acquisition note payable and other derivatives	**(3,782)**	2,006
Amortization of discount of debt and debt issuance costs	**517**	1,299
Loss on disposal of fixed assets and sale of India subsidiary	**204**	—
Modification of 2017 Debt warrants	**83**	—
Loss in equity-method investment	**154**	22
Loss on extinguishment of debt	**—**	78
Change in working capital components:		
Accounts receivable	**1,041**	(3,583)
Other current assets	**330**	(159)
Other non-current assets	**1**	—
Accounts payable, accrued expenses and deferred revenue	**3,766**	(1,538)
Deferred rent and other	**(42)**	(152)
Net cash (used in) operating activities	**(12,552)**	(13,564)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of fixed assets	**(649)**	(1,284)
Patent costs	**(31)**	(126)
Purchase of cost method investment	**—**	(200)
Cash received in the sale of India subsidiary, net of cash transferred	**1,764**	—
Cash used in acquisition of vivoPharm, Pty Ltd., net of cash received	**—**	(1,091)
Net cash provided by (used in) investing activities	**1,084**	(2,701)
CASH FLOWS FROM FINANCING ACTIVITIES		
Principal payments on capital lease obligations	**(337)**	(230)
Proceeds from warrant and option exercises	**—**	1,834
Proceeds from offerings of equity and derivative warrants, net of certain offering costs	**—**	6,586
Proceeds from borrowings on Silicon Valley Bank line of credit	**12,055**	4,137
Repayments of borrowings on Silicon Valley Bank line of credit	**(13,571)**	—
Proceeds from Convertible Note	**2,500**	—
Advance from NovellusDx, Ltd.	**1,500**	—
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 Silicon Valley Bank term note	**—**	(4,667)
Net cash provided by financing activities	**2,147**	16,338
Effect of foreign currency exchange rates on cash and cash equivalents	**(59)**	16
Net increase (decrease) in cash and cash equivalents	**(9,380)**	89
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH		
Beginning	**9,891**	9,802
Ending	**$ 511**	$ 9,891
SUPPLEMENTAL CASH FLOW DISCLOSURE		
Cash paid for interest	**$ 1,271**	$ 871
SUPPLEMENTAL DISCLOSURE OF NONCASH		
INVESTING AND FINANCING ACTIVITIES		
Fixed assets acquired through capital lease arrangements	**$ 150**	$ 567
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
Fair value of warrants reclassified from liabilities to equity	**423**	—

Beneficial conversion feature on Convertible Note	**328**	—
Beneficial conversion feature on Advance from NovelluxDx, Ltd.	**1,173**	—
Sale of India subsidiary:		
Accounts receivable, net	**$ 365**	$ —
Other current assets	**229**	—
Fixed assets, net	**608**	—
Goodwill	**735**	—
Other noncurrent assets	**98**	—
Accounts payable, accrued expenses and deferred revenue	**(180)**	—
Deferred rent and other	**(13)**	—
Loss on sale of India subsidiary	**(78)**	—
Cash received in the sale of India subsidiary, net of cash transferred	**$ 1,764**	$ —

See Notes to Consolidated Financial Statements.

CANCER GENETICS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Note 1. Organization, Description of Business, Sale of India Subsidiary, Restructuring, Financing, Merger and Offerings

We are an emerging leader in enabling precision medicine in oncology by providing multi-disciplinary diagnostic and data solutions, facilitating individualized therapies through our diagnostic 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 currently have offices and state-of-the-art laboratories located in New Jersey, North Carolina, Pennsylvania, and Australia. Our laboratories comply with the highest regulatory standards as appropriate for the services they deliver including CLIA, CAP, and NY State. 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.

Sale of India Subsidiary

On April 26, 2018, we sold our India subsidiary, BioServe Biotechnologies (India) Private Limited ("BioServe") to Reprocell, Inc., for $1.9 million, including $1.6 million in cash at closing and up to an additional $300,000, which was contingent upon the India subsidiary meeting a specified revenue target through August 31, 2018. The contingent consideration was reduced to $213,000 and received in November 2018. As a result of this transaction, we recognized a loss of approximately $78,000 on the disposal of BioServe, which is included in other income (expense) in our Consolidated Statements of Operations and Other Comprehensive Loss.

Restructuring

In 2018, the Company adopted a plan to migrate its California operations to its New Jersey and North Carolina locations and to permanently close its California laboratory. The Company incurred and paid approximately $2,320,000 of restructuring costs during the the year ended December 31, 2018, which are summarized in the table below (in thousands).

Disposal activity costs	$	705
Costs to consolidate facilities		766
Contract termination costs		371
Employee termination costs		478
	$	2,320

Convertible Debt

On July 17, 2018, the Company issued a convertible promissory note to an institutional accredited investor in the initial principal amount of $2,625,000 ("Convertible Note"), as described in Note 7. The Convertible Note has an 18 month term and carries interest at 10% per annum. The note is convertible into shares of the Company's common stock at a conversion price

of $0.80 per share upon 5 trading days' notice, subject to certain adjustments (standard dilution) and ownership limitations specified in the Convertible Note. The note provides that in the event of default, the lender may, at its option, elect to increase the outstanding balance by applying the default effect (defined as outstanding balance at date of default multiplied by 15% plus outstanding amount) by providing written notice to the Company. Additionally, the lender may elect to increase the interest rate to 22% in the event of default.

Merger with NovellusDx, Ltd.

On September 18, 2018, we entered into an agreement and plan of merger (the "Merger Agreement") with NovellusDx, Ltd., a privately-held company formed under the law of the State of Israel ("NDX"), in regards to Wogolos Ltd., our wholly-owned subsidiary company formed under the laws of the State of Israel. Subject to satisfaction or waiver of the conditions set forth in the Merger Agreement, Wogolos Ltd. would have merged with and into NDX, with NDX becoming a wholly-owned subsidiary of us and the surviving company. In connection with the signing of the Merger Agreement, we entered into a credit agreement with NDX, pursuant to which NDX loaned us $1,500,000 ("Advance from NDX"), as described in Note 7.

On December 15, 2018, we terminated the Merger Agreement. As a result, the Advance from NDX, plus interest thereon, became due and payable on March 15, 2019. In addition, the interest rate was increased on December 15, 2018 to 21% due to an event of default. The default also gives NDX the right to convert all, but not less than all, of the outstanding balance into shares of the Company's common stock at a conversion price of $0.606 per share.

2019 Offerings

In January 2019, we closed two public offerings and issued an aggregate of 28,550,726 shares of common stock for approximately $5,412,000, net of expenses and discounts of approximately $1,088,000 ("2019 Offerings"). The Company also issued 1,998,551 warrants to its underwriters in conjunction with these offerings. See Note 21 for additional information.

Note 2. Going Concern

At December 31, 2018, 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 ("FASB") 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, 2018 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, 2018, January 31, 2019, February 28, 2019 and March 31, 2019. In January 2019, the Company was able to secure forbearance agreements with both of its senior lenders and raise approximately $5,412,000, net of expenses and discounts of $1,088,000, through two public offerings. The Company's ability to continue as a going concern is dependent on the Company's ability to meet the milestones outlined in its forbearance agreements, extend the forbearance agreements and the term of the ABL beyond April 15, 2019, 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 non-core assets, 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 2018 or 2017.

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.

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, 2018 and 2017, our restricted cash collateralizes a $350,000 letter of credit in favor of our landlord, pursuant to the terms of the lease for our Rutherford facility. Effective January 1, 2018, we adopted ASU 2016-18, which requires companies to include restricted cash accounts with cash and cash equivalents when reconciling the beginning of period and end of period total amounts shown on the Consolidated Statements of Cash Flows.

Revenue recognition under ASC 606: Effective January 1, 2018, the Company recognizes revenue in accordance with FASB Accounting Standards Codification ("ASC") 606. We adopted the new standard using the modified retrospective method. We recognized the cumulative effect of initially applying the new revenue standard as an adjustment to the opening balance of accumulated deficit. Financial information for the year ended December 31, 2017 has not been restated and continues to be reported under the accounting standards in effect for that period.

The transition adjustment resulted in a net reduction to the opening balance of accumulated deficit of$2.5 million on January 1, 2018 and increased deferred revenue associated with Biopharma Services and Discovery Services by $1.9 million and $0.6 million, respectively, due to a change in our policies for recognized revenue for performance obligations fulfilled over time. In our Clinical Services area, the majority of the amounts historically charged as a provision for bad debts are now considered an implicit price concession in determining net revenue under ASC 606. Accordingly, we now report uncollectible balances as a reduction in the transaction price, and therefore, as a reduction in net revenues rather than a component of selling, general and administrative expenses.

The following tables present the amounts by which each financial statement line item was affected by adopting the new revenue recognition guidance (in thousands):

	Year Ended December 31, 2018		
	As Reported	ASC 606 Adjustments	Balances Without Adoption
Consolidated Statements of Operations and Other Comprehensive Loss			
Revenue:			
Biopharma Services	$ 14,828	$ (832)	$ 13,996
Clinical Services	7,429	3,954	11,383
Discovery Services	5,213	(650)	4,563
	$ 27,470	$ 2,472	$ 29,942

	December 31, 2018		
	As Reported	ASC 606 Adjustments	Balances Without Adoption
Consolidated Balance Sheets			
CURRENT ASSETS			
Accounts receivable, net of allowance for doubtful accounts	$ 7,038	$ 3,954	$ 10,992
CURRENT LIABILITIES			
Deferred revenue			
Biopharma Services	$ 959	$ (899)	$ 60
Clinical Services	—	—	—
Discovery Services	1,214	—	1,214
	$ 2,173	$ (899)	$ 1,274
NON-CURRENT LIABILITIES			
Deferred revenue			
Biopharma Services	$ 379	$ (128)	$ 251
Clinical Services	—	—	—
Discovery Services	—	—	—
	$ 379	$ (128)	$ 251
STOCKHOLDERS' EQUITY			
Accumulated (deficit)	$ (157,716)	$ 4,981	$ (152,735)

The adoption of ASC 606 had no impact on our total cash flows from operations.

We record deferred revenues (contract liabilities) when cash payments are received or due in advance of our performance, including amounts which are refundable.

The allowance for doubtful accounts does not reflect any adjustments related to the ASC 606 adjustment for accounts receivable.

Performance Obligations:

	Biopharma Services	Clinical Services	Discovery Services
Performance Obligation Satisfaction and Revenue Recognition:	Performance obligations are satisfied at a point in time as the Company processes samples delivered by the customer. Project level activities, including study setup and project management, are satisfied over the life of the contract. Revenues are recognized at a point in time when the test results or other deliverables are reported to the customer. Project level fee revenue is recognized ratably over the life of the contract.	Performance obligations are satisfied at a point in time when the tests are reported to the customer. Revenues are recognized at a point in time when the test results are reported to the ordering site.	Performance obligations are satisfied over time and as study data is transmitted to the customer. Revenue is recognized using the time elapsed method and at a point in time as the Company delivers study results to the customers.
Significant Payment Terms:	Monthly invoices at a contractual rate are generated as services are delivered for work completed during the prior month. Some contracts have prepayments prior to services being rendered that are recorded as deferred revenue.	The Company invoices at its list price or contractually negotiated price. Payments realized vary from amounts invoiced. Accordingly, the Company estimates the variable consideration it expects to collect.	As results are delivered, the invoices are generated based on contractual rates. Some contracts have prepayments prior to services being rendered that are recorded as deferred revenue.
Nature of Services:	Biopharma testing services, study setup and study management	Clinical testing services	Discovery services

Remaining Performance Obligations:

Services offered under the Biopharma and Discovery Services frequently take time to complete under their respective contacts. These times vary depending on specific contract arrangements including the length of the study and how samples are delivered to us for processing. In the case of Clinical Services and Discovery Services, the duration of performance obligation is less than one year. As of December 31, 2018, the Company had approximately$34.8 million in remaining performance obligations in the Biopharma Services area. We expect to recognize the remaining performance obligations over the next two to three years.

Practical Expedients:

Our customer arrangements in Biopharma Services and Discovery Services do not contain any significant financing component (interest). We have not recognized the financing component in the case of Clinical Services, as the payment plans we may grant to our self-pay customers do not to exceed six months.

We incur incremental costs on our Biopharma clients but have elected the practical expedient afforded by the new revenue standard to expense such costs as incurred.

We exclude from the measurement of the transaction price all taxes that we collect from customers that are assessed by governmental authorities and are both imposed on and concurrent with specific revenue-producing transactions.

Revenue recognition under ASC 605: Prior to 2018, the Company recognized revenue in accordance with FASB 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 required that four basic criteria be met before revenue could 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 was fixed or determinable, we considered payment limits imposed by insurance carriers and Medicare, and the amount of revenue recorded took into account the historical percentage of revenue we had collected for each type of test for each payor category. Periodically, an adjustment was 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. 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 was recorded based upon the contractually agreed upon fee schedule. When assessing collectability, we considered whether we had sufficient payment history to reliably estimate a payor’s individual payment patterns. We did not bill customers for shipping and handling fees, other than reimbursement of such expenses we incur on behalf of our Biopharma clients, and we did 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. After the adoption of ASC 606 on January 1, 2018, revenue is recorded at the amount expected to be collected, which includes implicit price concessions. Under the new standard, the majority of the amounts historically charged as a provision for bad debts are now considered an implicit price concession.

Prior to the adoption of ASC 606, revenue was 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 were written off against the allowance for doubtful accounts. Since the Company only recognized revenue to the extent it expected to collect such amounts, bad debt expense related to receivables from patient service revenue was recorded in general and administrative expense in the Consolidated Statements of Operations and Other Comprehensive Loss. Recoveries of accounts receivable previously written off were 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 would not likely be collectible. Accordingly, the Company recorded approximately $5,278,000 of bad debt expense 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 determined that an additional $2,514,000 of bad debt was required for the year ended December 31, 2018 and specifically an additional $647,000 in fourth quarter 2018 beyond the previous quarter levels associated with typical collection windows of third party claims due to continued challenges associated with collections.

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, software developed for internal use 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. The cost of computer software developed for internal use, which consists of our lab information system that is still in its configuration and implementation stages, is capitalized and will be amortized on a straight-line basis over its estimated useful life of ten years when complete. 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 and Other Comprehensive Loss.

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 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 in 2014, the purchase of certain assets of Response Genetics in 2015 and the purchase of vivoPharm, Pty Ltd. (“vivoPharm”) in 2017. 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 endedDecember 31, 2018 and 2017.

Goodwill (in thousands)		
Balance, January 1, 2017	$	12,029
Purchased through acquisition of vivoPharm		5,960
Foreign currency translation adjustment		3
Balance, December 31, 2017		17,992
Reduced by sale of our India subsidiary, BioServe		(735)
Balance, December 31, 2018	$	17,257

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 issued warrants during the 2016 Offerings and the 2017 Offering that contain a contingent net cash settlement feature, which are described herein as derivative warrants. We also issued warrants that were subject to a 20% reduction if we achieved certain financial milestones as part of our 2017 debt refinancing described in Note 7. At December 31, 2017, these warrants were also classified as derivative warrants but were reclassified as equity during 2018 when the number of shares issuable under the agreement became fixed. Derivative warrants are recorded as liabilities in the accompanying Consolidated Balance Sheets. 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 (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.

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, 2018 and 2017; therefore, we have not recognized any deferred 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, 2018 and 2017 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, 2018 or 2017, 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, 2018 or 2017.

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 2018 or 2017.

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, the note payable to VenturEast and other derivatives are described in Notes 15 and 16.

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 $154,000 and $22,000 for the years ended December 31, 2018 and 2017, 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, 2018 and 2017, which is included in other assets in the Consolidated Balance Sheets. See additional information in Note 19.

Subsequent events: We have evaluated potential subsequent events through the date the financial statements were issued.

Recent Accounting Pronouncements: In February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, "Leases (Topic 842)," to increase transparency and comparability among organizations by requiring recognition of right-of-use assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements (with the exception of short-term leases). The standard will become effective for interim periods beginning after December 15, 2018, with early adoption permitted. In July 2018, the FASB issued ASU 2018-11, "Leases (Topic 842): *Targeted Improvements*" that allows entities to recognize a cumulative-effect adjustment to the opening balance of accumulated deficit in the period of adoption. We plan to adopt this guidance on January 1, 2019 using this new transition guidance. We currently expect to use the package of practical expedients which allows us to not (1) reassess whether any expired or existing contracts are considered a lease; (2) reassess the lease classification for any expired or existing leases; and (3) reassess the initial direct costs for any existing leases. We also expect to elect not to apply the recognition requirements for short-term leases and to include both the lease and non-lease components as a single component for all classes of assets. We are substantially complete with our implementation assessment and estimate the adoption will result in the addition of approximately $2,900,000 of assets and liabilities to our Consolidated Balance Sheet, with no significant changes to our Consolidated Statements of Operations and Other Comprehensive Loss or Cash Flows.

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

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 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.

In June 2018, the FASB issued ASU 2018-07, Compensation - Stock Compensation (Topic 718): "*Improvements to Nonemployee Share-Based Payment Accounting*," which simplifies the accounting for nonemployee share-based payment transactions. Under the new guidance, equity-classified share-based payment awards issued to nonemployees will now be measured on the grant date, instead of the previous requirement to remeasure the awards through the performance completion date. Awards that include performance conditions will recognize compensation cost when the achievement of the performance condition is probable, rather than upon achievement of the performance condition. Finally, the current requirement to reassess the classification (equity or liability) for nonemployee awards will be eliminated, except for awards in the form of convertible instruments. The ASU is effective for annual periods beginning after December 15, 2018, but no earlier than the adoption of ASC 606. We plan to adopt the guidance on January 1, 2019. The adoption of ASU 2018-07 is not expected to have a material impact on our consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, Intangibles - Goodwill and Other-Internal-Use Software (Subtopic 350-40): "*Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that is a Service Contract*," which clarifies the accounting for implementation costs in cloud computing arrangements. The update will become effective for interim and annual periods beginning after December 15, 2019 and may be adopted either retrospectively or prospectively. Early adoption is permitted. We plan to adopt the guidance on the effective date and are currently evaluating the impacts of the adoption of this ASU 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):

	2018	2017
Numerator:		
Net (loss) for basic and dilutive earnings per share	**$ (20,373)**	$ (20,880)
Denominator:		
Weighted-average basic and dilutive common shares outstanding	**27,291**	20,663
Basic and dilutive net loss per share	**$ (0.75)**	$ (1.01)

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

	2018	2017
Common stock purchase warrants	**10,055**	10,055
Stock options	**3,004**	2,844
Restricted shares of common stock	**29**	705
Convertible note	**3,077**	—
Advance from NovellusDx, Ltd.	**2,562**	—
	18,727	13,604

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):

	2018	2017
Biopharma Services	**$ 14,828**	$ 14,629
Clinical Services	**7,429**	10,774
Discovery Services	**5,213**	3,718
	$ 27,470	$ 29,121

The table above includes approximately $4,932,000 and $2,717,000 of Discovery Services revenue from our acquisition of vivoPharm for the year ended December 31, 2018 and 2017, respectively.

Accounts receivable by service type at December 31, 2018 and 2017 consists of the following (in thousands):

	2018	2017
Biopharma Services	**$ 3,692**	$ 3,746
Clinical Services	**6,031**	12,205
Discovery Services	**777**	1,546
Allowance for doubtful accounts	**(3,462)**	(6,539)
	$ 7,038	$ 10,958

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:

	2018	2017
Medicare	**8 %**	12 %
Other third party payors	**19 %**	25 %
Total Clinical Services	**27 %**	37 %

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.

During the year ended December 31, 2018, no Biopharma clients accounted for more than 10% of our revenue. During the year ended December 31, 2017, one Biopharma client accounted for approximately 11% of our revenue.

Note 5. Other Current Assets

At December 31, 2018 and 2017, other current assets consisted of the following (in thousands):

	2018	2017
Inventory	**$ 144**	$ 144
Lab supplies	**1,294**	1,690
Prepaid expenses	**710**	873
	$ 2,148	$ 2,707

Note 6. Lease Commitments

We lease our laboratory, research facility and administrative office space under various operating leases. At December 31, 2018, we have approximately 17,900 square feet of office and laboratory space in Rutherford, New Jersey, 24,900 square feet in Morrisville, North Carolina, 5,800 square feet in Hershey, Pennsylvania, and 1,959 square feet in Bundoora, Australia. During 2018, we had a lease agreement for approximately 19,100 square feet of laboratory space in Los Angeles, California which expired on December 31, 2018. At December 31, 2018, we owed the California landlord approximately $164,000. For a portion of 2018, we also had 10,000 square feet in Hyderabad, India, which was vacated in April 2018. We have escalating lease agreements for our New Jersey, North Carolina, Pennsylvania and Australia spaces, which expire February 2023, May 2020, November 2020 and June 2021, respectively. These leases require monthly rent with periodic rent increases that vary from $0.32 to $0.85 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 $1,493,579 and accumulated depreciation of $623,867, as of December 31, 2018.

Minimum future lease payments under all capital and operating leases as of December 31, 2018 are as follows (in thousands):

	Capital Leases	Operating Leases	Total
December 31,			
2019	$ 394	$ 1,388	$ 1,782
2020	249	969	1,218
2021	121	598	719
2022	13	563	576
2023	—	94	94
Total minimum lease payments	$ 777	$ 3,612	$ 4,389
Less amount representing interest	68		
Present value of net minimum obligations	709		
Less current obligation under capital lease	330		
Long-term obligation under capital lease	$ 379		

Rent expense for the years ended December 31, 2018 and 2017 was approximately $1.76 million and $1.79 million, respectively.

Note 7. Financing

Line of Credit and Term Note

On March 22, 2017, we entered into a new two year asset-based revolving line of credit agreement with Silicon Valley Bank (“SVB”). The SVB credit facility provided 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 required monthly interest payments at the Wall Street Journal prime rate plus 1.5% (7.0% at December 31, 2018) and was scheduled to mature on March 22, 2019. We paid to SVB a $30,000 commitment fee at closing and pay a fee of 0.25% per year on the average unused portion of the ABL. In August 2018, the maximum borrowings were reduced from $6.0 million to $3.0 million. At December 31, 2018 and 2017, the ABL had a principal balance of $2,620,984 and $4,136,907, respectively, which is the maximum amount allowed based on eligible accounts receivable at the time and the timing of cash collections from accounts receivable. Subsequent to year-end, the interest rate was adjusted to the Wall Street Journal prime rate plus 2.25% and the maturity date was extended through April 15, 2019, subject to the Company satisfying certain milestones of the forbearance agreement discussed in Note 21.

On March 22, 2017, we concurrently entered into a 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. 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, 2018 and 2017, the PFG Term Note had a principal balance of $6,000,000.

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 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, 2018, January 31, 2019, February 28, 2019 and March 31, 2019, we were in violation of certain financial covenants. In January 2019, we entered into forbearance agreements with both lenders, as discussed in Note 21. However, we will not be able to close on a strategic transaction on or before April 15, 2019, and no assurance can be given that we will be able to extend the maturity of the ABL beyond April 15, 2019 or extend the forbearances beyond April 15, 2019, their current expiration date. We are in discussions with SVB and PFG about possible extensions of the forbearance agreements.

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, initially valued at $1,004,000. These warrants were subject to a 20% reduction if we achieved certain financial milestones. These warrants were initially recorded as a warrant liability, and all subsequent changes in their fair value were recognized in earnings until April 2, 2018, when the number of shares of common stock issuable upon exercise of the warrants became fixed. See Notes 14 and 15. On June 30, 2018, the warrants were modified to adjust the exercise price from $2.82 per share to $0.92 per share.

At December 31, 2018, the principal amount of the PFG Term Note of $6,000,000 was due in 2020; however, due to the forbearance agreement, the debt is now considered due on demand and is presented as a current liability. As a result of financial covenant violations at December 31, 2017, we fully amortized debt issuance costs on the PFG Term Note and the ABL, resulting in additional interest expense of approximately $220,000, as well as approximately $796,000 of interest expense to accrete the remaining discount on debt on the PFG Term Note.

Convertible Note

On July 17, 2018, the Company entered into the Convertible Note with Iliad Research and Trading, L.P. ("Iliad"), with an initial principal amount of $2,625,000. The Company received consideration of $2,500,000, reflecting an original issue discount of $100,000 and expenses payable by the Company of $25,000. The Convertible Note has an 18 month term and carries interest at 10% per annum. The note is convertible into shares of the Company's common stock at a conversion price of $0.80 per share upon 5 trading days' notice, subject to certain adjustments (standard dilution) and ownership limitations specified in the Convertible Note and resulted in a beneficial conversion feature discount of approximately $328,000. At December 31, 2018, the principal amount of the Convertible Note was $2,625,000.

Iliad may redeem any portion of the Convertible Note, at any time after six months from the issue date upon 5 trading days' notice, subject to a maximum monthly redemption amount of $650,000, with the Company having the option to pay such redemptions in cash, the Company's common stock at the Conversion Price, or by a combination thereof, subject to certain conditions, including that the stock price is $1.00 per share or higher. Subsequent to year-end, the Company entered into a standstill agreement with Iliad to delay Iliad's right to request monthly redemptions for an additional three months, as described in Note 21. The Company may prepay the outstanding balance of the Convertible Note, in part or in full, at a 10% premium to

par value if prior to the one year anniversary of the date of issuance and at par if prepaid thereafter. At maturity, the Company may pay the outstanding balance in cash, the Company's common stock at the Conversion Price, or by a combination thereof, subject to certain conditions. The note provides that in the event of default, the lender may, at its option, elect to increase the outstanding balance applying the default effect (defined as outstanding balance at date of default multiplied by 15% plus outstanding amount) by providing written notice to the Company. In addition, the interest rate increases to 22% upon default. The default effect and default interest rate provisions qualify as embedded derivatives with an estimated fair value of $55,000 at December 31, 2018.

The Convertible Note is the general unsecured obligation of the Company and is subordinated in right of payment to the ABL and PFG Term Note. The following is a summary of the Convertible Note balance at December 31, 2018 (in thousands):

Convertible Note, net of discounts of $136	$	2,489
Less unamortized debt issuance costs		8
Convertible Note, net	$	2,481

Advance from NDX

In connection with signing the Merger Agreement described in Note 1, NDX agreed to loan us $1,500,000. Interest originally accrued on the outstanding balance at 10.75% per annum, and the advance was to mature upon the earlier of March 31, 2019 or the date on which the Merger Agreement was terminated in accordance with its terms (or ninety days thereafter in the case of certain causes for termination). Upon certain events of default, NDX would be able to convert all, but not less than all, of the outstanding balance into shares of the Company's common stock at a conversion price of $0.606 per share, which qualified as a contingent beneficial conversion feature that would only be recognized if a default occurs.

On December 15, 2018, we terminated the Merger Agreement. As a result, the Advance from NDX, plus interest thereon, became due and payable on March 15, 2019, and the interest rate was increased on December 15, 2018 to 21% due to an event of default. As a result of the default, the Company recognized the beneficial conversion feature discount of approximately $1,173,000. The default interest rate provision qualifies as an embedded derivative with an estimated fair value of $31,000 at December 31, 2018. At December 31, 2018, the principal balance of the Credit Agreement was $1,500,000, which is presented net of the unamortized beneficial conversion feature of approximately $965,000 in the Consolidated Balance Sheet.

The Advance from NDX is the general unsecured obligation of the Company and is subordinated in right of payment to the ABL and PFG Term Note, provided that NDX has asserted that its obligation to standstill under its subordination agreements will not be applicable at a time when the Company attains certain levels of unrestricted cash, as a result of the Company having improperly terminated the Merger Agreement. The Company does not believe it improperly terminated the Merger Agreement.

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, 2018 and 2017, 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):

	2018	2017
Equipment	**$ 9,858**	$ 11,030
Furniture and fixtures	**1,130**	1,076
Leasehold improvements	**1,077**	924
Internal use software	**1,172**	675
	13,237	13,705
Less accumulated depreciation	**(9,181)**	(8,155)
Net fixed assets	**$ 4,056**	$ 5,550

Note 10. Patents and Other Intangible Assets

Patents and other intangible assets consist of the following at December 31, 2018 and 2017:

	(in thousands) 2018	(in thousands) 2017	Weighted-Average Remaining Amortization Period
Patents	**$ 1,800**	$ 1,769	**4 years**
Software	**446**	446	**0 years**
Customer list - vivoPharm acquisition	**2,738**	2,738	**9 years**
Trade name - vivoPharm acquisition	**477**	477	**9 years**
	5,461	5,430	
Less accumulated amortization	**(1,457)**	(952)	
Net patent and other intangible assets	**$ 4,004**	$ 4,478	

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. Foreign currency translation adjustments were de minimus during the year ended December 31, 2018.

Future amortization expense for legally approved patents (excluding patent applications in progress of approximately$601,000 as of December 31, 2018) and other intangible assets, is estimated as follows (in thousands):

2019	$ 488
2020	482
2021	479
2022	411
2023	347
Thereafter	1,196
Total	$ 3,403

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 impacted 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 as of December 31, 2017. There was 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 adoption of ASC 606 primarily resulted in a deceleration of revenue as of December 31, 2017, which in turn increased our existing deferred tax asset for amounts that had previously been included in revenue. As we have provided a full valuation allowance against our net deferred tax assets, the aggregate impact of adopting ASC 606 was offset by a corresponding increase to the valuation allowance.

The provision (benefit) for income taxes for the years endedDecember 31, 2018 and 2017 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:

	For the Year Ended December 31, 2018		For the Year Ended December 31, 2017	
	Amount (in thousands)	% of Pretax Loss	Amount (in thousands)	% of Pretax Loss
Income tax benefit at federal statutory rate	$ (4,278)	21.0 %	$ (8,036)	35.0 %
State tax provision, net of federal tax benefit	226	(1.1)%	(707)	3.1 %
Tax credits	(60)	0.3 %	(545)	2.4 %
Stock based compensation	211	(1.0)%	2,333	(10.2)%
Derivative warrants	(766)	3.7 %	687	(3.0)%
Change in valuation allowance	4,048	(19.9)%	(11,551)	50.3 %
Foreign operations	508	(2.5)%	15	(0.1)%
Remeasurement of deferred taxes under TCJA	—	— %	15,205	(66.2)%
Other	111	(0.5)%	520	(2.3)%
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, 2018 and 2017 (in thousands):

	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$ 25,999	$ 23,135
Accruals and reserves	4,328	2,656
Stock based compensation	1,020	1,052
Research and development tax credits	1,936	1,876
Derivative warrant liability	17	17
Investment in joint venture	162	161
Other	6	5
Total deferred tax assets	33,468	28,902
Less valuation allowance	(31,783)	(27,083)
Net deferred tax assets	1,685	1,819
Deferred tax liabilities		
Fixed assets	(352)	(379)
Goodwill and intangible assets	(1,333)	(1,440)
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, 2018 and 2017. Therefore, we have recorded a full valuation allowance on our deferred tax assets. As a result of the TCJA, the federal net operating losses incurred after 2017 will have an indefinite carryforward. At December 31, 2018, we have net operating loss carryforwards for federal income tax purposes of approximately $118 million, of which approximately $99 million could expire over time, beginning in 2027, if not used. Utilization of these carryforwards is subject to limitation due to ownership changes that may delay the utilization of a portion of the carryforwards.

Note 12. Capital Stock

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 were 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.

2019 Offerings

In January 2019, we closed two public offerings and issued an aggregate of 28,550,726 shares of common stock for approximately $5,412,000, net of expenses and discounts of $1,088,000. See Note 21 for additional information.

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 24-month 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.

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. No shares were sold during 2018 under the Purchase 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 Consultant

On October 3, 2017, we issued 2,000 shares of common stock to a 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, 2018 and 2017, 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. Effective April 9, 2018, the Company is no longer able to issue options from the 2008 Plan. Prior to April 9, 2018, we were authorized to issue incentive stock options or non-statutory stock options to eligible participants, as defined in the 2008 Plan.

At December 31, 2018, we have 36,000 options outstanding that were issued outside of the Stock Option Plans.

At December 31, 2018, 215,988 shares remain available for future awards under the 2011 Plan.

As of December 31, 2018, no stock appreciation rights and 363,334 shares of restricted stock had been awarded under the Stock Option Plans.

A summary of employee and non-employee stock option activity for the years ended December 31, 2018 and 2017 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, 2017	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
Granted	857	0.84		
Cancelled or expired	(697)	4.74		
Outstanding December 31, 2018	3,004	$ 5.77	5.70	$ —
Exercisable, December 31, 2018	1,868	$ 8.36	3.65	$ —

Aggregate intrinsic value represents the difference between the fair value of our common stock and the exercise price of outstanding, in-the-money options. During the year ended December 31, 2018, no options were exercised. We received $6,500 from the exercise of options during the year ended December 31, 2017.

As of December 31, 2018, total unrecognized compensation cost related to non-vested stock options granted to employees was $987,659, which we expect to recognize over the next 3.06 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. We record forfeitures of unvested stock options when they occur. 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,	
	2018	2017
Volatility	**77.79%**	74.58%
Risk free interest rate	**2.88%**	1.98%
Dividend yield	**—**	—
Term (years)	**6.45**	5.92
Weighted-average fair value of options granted during the period	**$ 0.59**	$ 1.87

In May 2014, we issued 200,000 options to a Director, with an exercise price of $15.89. See Note 20 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 year ended December 31, 2017.

Volatility	75.59%
Risk free interest rate	2.24%
Dividend yield	—
Term (years)	6.76

Restricted stock awards have been granted to employees, directors and consultants as compensation for services. At December 31, 2018, there was $62,737 of unrecognized compensation cost related to non-vested restricted stock granted to employees; we expect to recognize the cost over 0.69 years.

The following table summarizes the activities for our non-vested restricted stock awards for the years ended December 31, 2018 and 2017:

	Non-vested Restricted Stock Awards	
	Number of Shares (in thousands)	Weighted-Average Grant Date Fair Value
Non-vested at January 1, 2017	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
Vested	(40)	3.36
Forfeited/cancelled	(22)	6.77
Non-vested at December 31, 2018	29	$ 3.43

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,	
	2018	2017
Cost of revenues	**$ 285**	$ 346
Research and development	**54**	133
General and administrative	**515**	1,299
Sales and marketing	**67**	117
Total stock-based compensation	**$ 921**	$ 1,895

Note 14. Warrants

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 were subject to a 20% reduction if we achieved certain financial milestones as part of our debt refinancing in March 2017 (identified as 2017 Debt in the table below). These warrants were recorded as a warrant liability, and all subsequent changes in their fair value were recognized in earnings until April 2, 2018, when the number of shares of common stock issuable upon exercise of the warrants became fixed. On June 30, 2018, the 2017 Debt warrants were modified to adjust the exercise price from $2.82 per share to $0.92 per share.

A certain number of our warrants are held by Mr. Pappajohn, the Chairman of our Board of Directors and stockholder. See Note 20 for additional details on these warrants.

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 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 warrants. On June 30, 2018, the 2017 Debt warrants were modified to adjust the exercise price from $2.82 per common share to $0.92 per common share.

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.

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 six months from the issuance date and are exercisable for twelve 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.

In January 2019, we issued warrants to purchase 933,334 and 1,065,217 shares of our common stock a $0.2475 and $0.253 per share, respectively, in conjunction with our 2019 Offerings described in Note 21.

The following table summarizes the warrant activity for the years ending December 31, 2018 and 2017 (in thousands, except exercise price):

Issued With / For	Exercise Price		Warrants Outstanding January 1, 2017	2017 Warrants Issued	2017 Warrants Exercised	2017 Warrants Expired	Warrants Outstanding December 31, 2017	Transfer Between Derivative Warrants and Non-Derivative Warrants	Warrants Outstanding December 31, 2018
Non-Derivative Warrants:									
Financing	$ 10.00		243	—	—	—	243	—	243
Financing	15.00		361	—	—	(85)	276	—	276
Debt Guarantee	15.00		109	—	—	(109)	—	—	—
2015 Offering	5.00		3,450	—	—	—	3,450	—	3,450
2017 Debt	0.92	A	—	—	—	—	—	443	443
	5.49	C	4,163	—	—	(194)	3,969	443	4,412
Derivative Warrants:									
2016 Offerings	2.25	B	2,870	—	(902)	—	1,968		1,968
2017 Debt	0.92	A	—	443	—	—	443	(443)	—
2017 Offering	2.35	B	—	3,500	—	—	3,500	—	3,500
2017 Offering	2.50	B	—	175	—	—	175	—	175
	2.32	C	2,870	4,118	(902)	—	6,086	(443)	5,643
	$ 3.71	C	7,033	4,118	(902)	(194)	10,055	—	10,055

A These warrants were subject to fair value accounting until the number of shares issuable upon the exercise of the warrants became fixed on April 2, 2018. Effective June 30, 2018, the exercise price was reduced from $2.82 per share to $0.92 per share. See Note 15.

B These warrants are subject to fair value accounting and contain a contingent net cash settlement feature. See Note 15.

C Weighted average exercise prices are as of December 31, 2018.

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 were valued using a Monte Carlo model. The derivative warrants issued in conjunction with the 2017 Offering are 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 December 31, 2018 and 2017, and the fair value of derivative warrants issued, exercised and reclassified during the years then ended.

2016 Offerings	As of December 31, 2018	As of December 31, 2017	Exercised During the Year Ended December 31, 2017
Exercise price	$ 2.25	$ 2.25	$ 2.25
Expected life (years)	3.08	4.08	4.78
Expected volatility	100.51%	73.44%	76.24%
Risk-free interest rate	2.46%	2.11%	1.94%
Expected dividend yield	0.00%	0.00%	0.00%

2017 Debt	Reclassified to Equity During the Year Ended December 31, 2018	As of December 31, 2017	Issued During the Year Ended December 31, 2017
Exercise price	$ 2.82	$ 2.82	$ 2.82
Expected life (years)	5.97	6.22	7.00
Expected volatility	73.40%	74.18%	74.61%
Risk-free interest rate	2.55%	2.33%	2.22%
Expected dividend yield	0.00%	0.00%	0.00%

2017 Offering	As of December 31, 2018	As of December 31, 2017	Issued During the Year Ended December 31, 2017
Exercise price	$ 2.36	$ 2.36	$ 2.36
Expected life (years)	0.44	1.43	1.50
Expected volatility	172.50%	77.55%	76.03%
Risk-free interest rate	2.56%	1.83%	1.73%
Expected dividend yield	0.00%	0.00%	0.00%

The range of Company stock prices used in computing the warrant fair value for warrants issued during the year ended December 31,2017 was $1.95—$2.90. The range of Company stock prices used in computing the fair value for warrants exercised during 2017 was $3.55—$5.05. The Company stock price used in computing the fair value for warrants reclassified to equity during 2018 was $1.65. In determining the fair value of warrants outstanding at each reporting date, the Company stock price was$0.24 and $1.85 (the closing price on the NASDAQ Capital Market) at December 31, 2018 and 2017, respectively.

The following table summarizes the derivative warrant activity subject to fair value accounting for the years endedDecember 31, 2018 and 2017 (in thousands):

	Issued with 2016 Offerings	Issued with 2017 Debt	Issued with 2017 Offering	Total
Fair value of warrants outstanding as of January 1, 2017	$ 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
Fair value of warrants reclassified to equity	—	(423)	—	(423)
Change in fair value of warrants	(1,704)	(78)	(1,950)	(3,732)
Fair value of warrants outstanding as of December 31, 2018	$ 225	$ —	$ 23	$ 248

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):

	2018			
	Total	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Warrant liability	**$ 248**	**$ —**	**$ —**	**$ 248**
Notes payable	**20**	—	—	**20**
Other derivatives	**86**	—	—	**86**
	$ 354	**$ —**	**$ —**	**$ 354**

	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

At December 31, 2018, the warrant liability consists of stock warrants issued as part of the 2016 Offerings and 2017 Offering that contain contingent redemption features. 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, 2018 and 2017, 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, 2018 and 2017, we recognized a gain of $136,000 and loss of $42,000, 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	Other Derivatives
Fair value at January 1, 2017	$ 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	—
Change in fair value	(136)	(3,732)	—
Fair value of warrants reclassified to equity	—	(423)	—
Fair value of certain default provisions	—	—	86
Fair value at December 31, 2018	$ 20	$ 248	$ 86

Note 17. Contingencies

On April 5, 2018 and April 12, 2018, purported stockholders of the Company filed nearly identical putative class action lawsuits in the U.S. District Court for the District of New Jersey, against the Company, Panna L. Sharma, John A. Roberts, and Igor Gitelman, captioned *Ben Phetteplace v. Cancer Genetics, Inc. et al*, No. 2:18-cv-05612 and *Ruo Fen Zhang v. Cancer Genetics, Inc. et al*, No. 2:18-06353, respectively. The complaints alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 based on allegedly false and misleading statements and omissions regarding our business, operational, and financial results. The lawsuits sought, among other things, unspecified compensatory damages in connection with purchases of our stock between March 23, 2017 and April 2, 2018, as well as interest, attorneys' fees, and costs. On August 28, 2018, the Court consolidated the two actions in one action captioned *In re Cancer Genetics, Inc. Securities Litigation* (the "Securities Litigation") and appointed shareholder Randy Clark as the lead plaintiff. On October 30, 2018, the lead plaintiff filed an amended complaint, adding Edward Sitar as a defendant and seeking, among other things, compensatory damages in connection with purchases of CGI stock between March 10, 2016 and April 2, 2018. On December 31, 2018, Defendants filed a motion to dismiss the amended complaint for failure to state a claim. The Company is unable to predict the ultimate outcome of the Securities Litigation and therefore cannot estimate possible losses or ranges of losses, if any.

In addition, on June 1, 2018, September 20, 2018, and September 25, 2018, purported stockholders of the Company filed nearly identical derivative lawsuits on behalf of the Company in the U.S. District Court for the District of New Jersey against the Company (as a nominal defendant) and current and former members of the Company's Board of Directors and current and former officers of the Company. The three cases are captioned: *Bell v. Sharma et al*., No. 2:18-cv-10009-CCC-MF, *McNeece v. Pappajohn et al*., No. 2:18-cv-14093, and *Workman v. Pappajohn, et al*., No. 2:18-cv-14259 (the "Derivative Litigation"). The complaints allege claims for breach of fiduciary duty, violations of Section 14(a) of the Securities Exchange Act of 1934 (premised upon alleged omissions in the Company's 2017 proxy statement), and unjust enrichment, and allege that the individual defendants failed to implement and maintain adequate controls, which resulted in ineffective disclosure controls and procedures, and conspired to conceal this alleged failure. The lawsuits seek, among other things, damages and/or restitution to the Company, appropriate equitable relief to remedy the alleged breaches of fiduciary duty, and attorneys' fees and costs. On November 9, 2018, the Court in the *Bell v. Sharma* action entered a stipulation filed by the parties staying the *Bell* action until the Securities Litigation is dismissed, with prejudice, and all appeals have been exhausted; or the defendants' motion to dismiss in the Securities Litigation is denied in whole or in part; or either of the parties in the *Bell* action gives 30 days' notice that they no longer consent to the stay. On December 10, 2018, the parties in the *McNeece* action filed a stipulation that is substantially identical to the *Bell* stipulation. On February 1, 2019, the Court in the Workman action granted a stipulation that is substantially identical to the Bell stipulation. The Company is unable to predict the ultimate outcome of the Derivative Litigation and therefore cannot estimate possible losses or ranges of losses, if any.

Note 18. Acquisition of vivoPharm Pty, Ltd.

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 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 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. On August 15, 2018, the escrowed shares were released. The Company 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.

The measurement period expired on August 15, 2018 and the final valuation was deemed consistent with the preliminary valuation completed during the acquisition diligence phase, specifically concerning lab supplies, deferred revenue and deferred taxes. Subsequent to the measurement period expiration, a review of deferred revenue surfaced a refinement in contract completion estimate of $0.2 million associated with the acquisition valuation and accordingly the current revenue offset was recorded in the statement of operations during the year ended December 31, 2018.

The final 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 2017 pro forma financial information for the Company as if the acquisition of vivoPharm discussed above occurred on January 1, 2017 (in thousands except per share amounts):

	Unaudited Year Ended December 31, 2017
Revenue	**$ 32,880**
Net income (loss)	**(20,961)**
Basic and dilutive net loss per share	**$ (0.92)**

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.

Note 19. 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.

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. During 2018, we received a cash distribution from the JV of $150,000, and we are in the process of winding down the JV.

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 20. 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, 2018, 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, 2018.

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, 2018 and 2017 related to this agreement. At December 31, 2018 and 2017, we owed EDI $70,000 and $10,000, 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. 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 year ended December 31, 2017 was $69,250.

As further described in Note 21, subsequent to year-end the Company closed two public offerings, in which various executives and directors purchased shares at the public offering price. On January 14, 2019, John Pappajohn, John Roberts, our President and Chief Executive Officer, and Geoffrey Harris, a Director, purchased 1,000,000 shares, 100,000 shares and 100,000 shares, respectively, at the public offering price of $0.225 per share. On January 31, 2019, John Pappajohn, John Roberts, Edmund Cannon, a Director, and M. Glenn Miles, our Chief Financial Officer, purchased 1,000,000 shares, 185,436 shares, 43,479 shares and 150,000 shares, respectively, at the public offering price of $0.23 per share.

Note 21. Subsequent Events

2019 Offerings

On January 9, 2019, we entered into an underwriting agreement with H.C. Wainwright & Co., LLC ("H.C. Wainwright"), relating to an underwritten public offering of 13,333,334 shares of our common stock for $0.225 per share. We received proceeds from the offering of approximately $2,437,000, net of expenses and discounts of approximately $563,000. We also issued warrants to purchase 933,334 shares of common stock to H.C. Wainwright in connection with this offering. The warrants are exercisable for five years from the date of issuance at a per share price of $0.2475.

On January 26, 2019, we issued 15,217,392 shares of common stock at a public offering price of $0.23 per share. We received proceeds from the offering of approximately $2,975,000, net of expenses and discounts of approximately $525,000. We also issued warrants to purchase 1,065,217 shares of common stock to the underwriter, H.C. Wainwright, in connection with this offering. The warrants are exercisable for five years from the date of issuance at a per share price of $0.253.

As disclosed in Note 20, certain of our directors and executives purchased shares during the 2019 Offerings at the public offering price.

Forbearance Agreements

On January 16, 2019, we entered into forbearance agreements with both PFG and SVB that among other things, (i) require us to comply with certain milestones in connection with a potential strategic transaction satisfactory to PFG and SVB with an anticipated closing date of on or before April 15, 2019 (the "Milestones"), (ii) provide for PFG and SVB's forbearance of their respective rights and remedies resulting from existing and stated potential events of default under the PFG Term Note and ABL until the earlier of (a) the occurrence of an additional event of default or (b) February 15, 2019; provided such date shall be automatically extended to (1) February 28, 2019 and then to (2) April 15, 2019 so long as we are in compliance with the Milestones required as of such dates. In addition, the ABL interest rate was increased to 2.25% over the Wall Street Journal prime rate, and the maturity date was extended until April 15, 2019.

Standstill Agreement

On February 15, 2019, we entered into a standstill agreement with Iliad, related to the Convertible Note dated July 17, 2018. The standstill agreement, among other things, (i) provides that Iliad will not seek to redeem any portion of the Convertible Note until March 10, 2019 (the "Standstill"); (ii) increases the outstanding balance of the Convertible Note by approximately $139,000, representing a fee to Iliad for such Standstill; and (iii) allows us the option to elect that Iliad not seek to redeem any portion of the Convertible Note until April 15, 2019, provided that upon such election the outstanding balance of the Convertible Note would increase again by approximately $63,000. We elected to extend the Standstill until April 15, 2019.

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, 2018, 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, 2018 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, 2018. 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 report the material weakness, as described below, in our internal control over financial reporting as of December 31, 2018. This material weakness was initially reported in our filings for December 31, 2017 and subsequent quarterly filings. 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 described below, and based on management's assessment, as of December 31, 2018, 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 of 2017, management revised its estimation process and as a result of the low collection patterns during the fourth quarter of 2017 principally related to clinical service revenues from claims generated by the Los Angeles location, a determination was made to significantly increase the allowance for doubtful accounts to reflect this change in estimate, and recorded audit adjustments in 2017 pertaining to contractual allowances. Further, in 2018, management reviewed collection patterns across the year as part of the year end process, and upon a further detailed review of its accounts receivable balances noted that its procedures and controls did not provide accurate aging for its uncollectible accounts receivable from previous years and recorded significant adjustments. 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. Our management has determined that this control deficiency constitutes a material weakness at December 31, 2018.

Remediation plan and procedures: Management is committed to remediating the material weakness. We began 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 and supplemented by external resources as appropriate, with the requisite skill and technical expertise during 2018. However, management's focus on ensuring funding to continue operations, closure of its California location, consolidation of its clinical services operations, strategic initiatives and adoption of revenue recognition standard impaired its ability to sufficiently remediate the process. While resource constraints, staff turnover, the departure of the previous chief accounting officer, and the appointment of a new principal financial officer (November 2018) has occurred amidst efforts to address the control environment, the material weakness continued as of December 31, 2018. In 2019, management plans to include additional reconciliations between its general ledger and billing systems to enhance its remediation efforts. The Company expects this deficiency to be corrected by the end of 2019.

Changes in Internal Control over Financial Reporting.

Other than the continuation of the previously disclosed 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, 2018 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

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 2019 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, 2018 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 2019 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, 2018 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 2019 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, 2018 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 2019 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, 2018 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 2019 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, 2018 and is incorporated by reference herein.

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.

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 15, 2019

/s/ John A. Roberts

John A. Roberts

President and Chief Executive Officer
(Principal Executive Officer and duly authorized signatory)

Date: April 15, 2019

/s/ M. Glenn Miles

M. Glenn Miles

Chief Financial Officer
(Principal Financial and Accounting Officer)

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 M. Glenn Miles, 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 John A. Roberts	President and Chief Executive Officer *(Principal Executive Officer)*	April 15, 2019
/s/ M. Glenn Miles M. Glenn Miles	Chief Financial Officer *(Principal Financial and Accounting Officer)*	April 15, 2019
/s/ John Pappajohn John Pappajohn	Chairman of the Board of Directors	April 15, 2019
/s/ Geoffrey Harris Geoffrey Harris	Director	April 15, 2019
/s/ Edmund Cannon Edmund Cannon	Director	April 15, 2019
/s/ Howard McLeod Howard McLeod	Director	April 15, 2019
/s/ Michael J. Welsh Michael J. Welsh	Director	April 15, 2019
/s/ Raju S. K. Chaganti Raju S. K. Chaganti, Ph.D.	Director	April 15, 2019
/s/ Franklyn G. Prendergast Franklyn G. Prendergast, M.D., Ph.D.	Director	April 15, 2019
/s/ Thomas F. Widmann Thomas F. Widmann	Director	April 15, 2019

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).
2.2	Agreement and Plan of Merger, dated September 18, 2018, by and among Cancer Genetics, Inc., NovellusDx Ltd. and Wogolos Ltd. (incorporated by reference to Exhibit 2.1 to the Company's current report on Form 8-K, filed with the Securities and Exchange Commission on September 21, 2018).
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 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.
4.3	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.
4.4	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).
4.5	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 August 18, 2014 with the Securities and Exchange Commission).
4.6	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 November 6, 2015).
4.7	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).
4.8	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).
4.9	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).
4.10	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 December 8, 2017).
4.11	Omnibus Warrant Amendment to Warrant Issued to Lenders, dated as of June 30, 2018 (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 July 5, 2018).
4.12	Convertible Promissory Note, dated July 17, 2018, in favor of Iliad Research and Trading, L.P. (incorporated by reference to Exhibit 4.1 of the Company's current report on Form 8-K filed on July 18, 2018 with the Securities and Exchange Commission).
4.13	Form of Underwriter Warrants of Cancer Genetics, Inc. (incorporated by reference to Exhibit 4.1 of the Company's current report on Form 8-K filed on January 10, 2019 with the Securities and Exchange Commission).
4.14	Form of Placement Agent Warrants of Cancer Genetics, Inc. (incorporated by reference to Exhibit 4.1 of the Company's current report on Form 8-K filed on January 29, 2019 with the Securities and Exchange Commission).

Exhibit No.	Description
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. †
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.
10.16	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.

Exhibit No.	Description
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).
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).
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). †

Exhibit No.	Description
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).
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. (incorporated by reference to Exhibit 10.60 of the Company's annual report on Form 10-K, filed on April 2, 2018). †
10.61	Thirteenth Amendment to Lease Agreement by and between the University of South Carolina and Cancer Genetics, Inc., dated March 29, 2018 (incorporated by reference to Exhibit 10.61 to the Company's annual report on Form 10-K, filed on April 2, 2018).
10.62	First Amendment to Lease by and between Meadows Landmark, LLC and Cancer Genetics, Inc., dated October 30, 2017 (incorporated by reference to Exhibit 10.62 to the Company's annual report on Form 10-K, filed on April 2, 2018).
10.63	Share Purchase Agreement dated April 26, 2018 by and among BioServe Biotechnologies (India) Private Limited, Cancer Genetics, Inc. and Reprocell Incorporated (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 April 27, 2018).
10.64	Waiver and First Amendment to Amended and Restated Loan and Security Agreement by and between Silicon Valley Bank and Cancer Genetics, Inc., dated May 14, 2018 (incorporated by reference to Exhibit 10.3 to the Company's current report on Form 10-Q, filed with the Securities and Exchange Commission on May 15, 2018).
10.65	Conditional Waiver & Modification No. 1 to Loan and Security Agreement by and between Partners for Growth IV, L.P. and Cancer Genetics, Inc., dated May 14, 2018 (incorporated by reference to Exhibit 10.4 to the Company's quarterly report on Form 10-Q, filed on May 15, 2018).
10.66	Joinder and Second Amendment to Amended and Restated Loan and Security Agreement with Silicon Valley Bank, dated as of June 21, 2018 (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 June 27, 2018).

Exhibit No.	Description
10.67	Joinder and Modification No. 2 to Loan and Security Agreement with Partners for Growth IV, L.P., dated as of June 30, 2018 (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 July 5, 2018).
10.68	Securities Purchase Agreement, dated July 17, 2018, between Cancer Genetics, Inc. and Iliad Research and Trading, L.P. (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on July 18, 2018 with the Securities and Exchange Commission).
10.69	Waiver and Third Amendment to Amended and Restated Loan and Security Agreement with Silicon Valley Bank, dated as of August 20, 2018 (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 August 21, 2018).
10.70	Waiver and Modification No. 3 to Loan and Security Agreement with Partners for Growth IV, L.P., dated as of August 20, 2018 (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 August 21, 2018).
10.71	Credit Agreement, dated September 18, 2018, by and between Cancer Genetics, Inc. and NovellusDx Ltd. (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K, filed with the Securities and Exchange Commission on September 21, 2018).
10.72	Promissory Note, dated September 18, 2018, in favor of NovellusDx Ltd. (incorporated by reference to Exhibit 10.2 of the Company's current report on Form 8-K, filed with the Securities and Exchange Commission on September 21, 2018).
10.73	Registration Rights Agreement, dated September 18, 2018, by and between Cancer Genetics, Inc. and NovellusDx Ltd (incorporated by reference to Exhibit 10.3 of the Company's current report on Form 8-K, filed with the Securities and Exchange Commission on September 21, 2018).
10.74	Form of Securities Purchase Agreement, dated September 18, 2018 (incorporated by reference to Exhibit 10.7 to the Company's quarterly report on Form 10-Q, filed with the Securities and Exchange Commission on November 19, 2018.
10.75	Waiver and Fourth Amendment to Amended and Restated Loan Security Agreement with Silicon Valley Bank, dated as of November 19, 2018 (incorporated by reference to Exhibit 10.8 of the Company's quarterly report on Form 10-Q, filed with the Securities and Exchange Commission on November 19, 2018).
10.76	Waiver Under Loan Security Agreement with Partners for Growth IV, L.P., dated as of November 19, 2018 (incorporated by reference to Exhibit 10.9 to the Company's quarterly report on Form 10-Q, filed with the Securities and Exchange Commission on November 19, 2018.
10.77	Offer Letter with Glenn Miles, dated November 16, 2018 (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K/A, filed with the Securities and Exchange Commission on November 21, 2018).†
10.78	Forbearance and Fifth Amendment to Amended and Restated Loan and Security Agreement with Silicon Valley Bank, dated January 16, 2019 (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K, filed on January 16, 2019).
10.79	Forbearance Agreement and Modification No. 4 to Loan and Security Agreement with Partners for Growth IV, L.P., dated January 16, 2019 (incorporated by reference to Exhibit 10.2 to the Company's current report on Form 8-K, filed on January 16, 2019).
10.80*	Standstill Agreement, between Iliad Research and Trading, L.P. and Cancer Genetics, Inc., dated February 12, 2019.
10.81*	Employment Agreement with Ralf Brandt, dated August 15, 2017.†
10.82*	Offer Letter with Michael McCartney, dated May 14, 2018.†
10.83*	Offer Letter with William Finger, dated December 14, 2018.†
21.1*	Subsidiaries of Cancer Genetics, Inc.
23.1*	Consent of RSM US LLP.
24.1	Power of attorney (included on the signature page).

Exhibit No.	Description
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities and Exchange Act of 1934, as amended.
31.2*	Certification of 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 Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of 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, 2018, filed on April 15, 2019, 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.

† Indicates a management contract or compensation plan, contract or arrangement.

STANDSTILL AGREEMENT

This Standstill Agreement (this "**Agreement**") is entered into as of February 12, 2019 by and between Iliad Research and Trading, L.P., a Utah limited partnership ("**Lender**"), and Cancer Genetics, Inc., a Delaware corporation ("**Borrower**"). Capitalized terms used in this Agreement without definition shall have the meanings given to them in the Note (defined below).

A. Borrower previously sold and issued to Lender that certain Convertible Promissory Note dated July 17, 2018 in the original principal amount of $2,625,000.00 (the "**Note**") pursuant to that certain Securities Purchase Agreement dated July 17, 2018 by and between Lender and Borrower (the "**Purchase Agreement**," and together with the Note and all other documents entered into in conjunction therewith, the "**Transaction Documents**").

B. Borrower has requested and Lender has agreed, subject to the terms, conditions and understandings expressed in this Agreement, to refrain and forbear temporarily from making redemptions under the Note.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Recitals and Definitions. Each of the parties hereto acknowledges and agrees that the recitals set forth above in this Agreement are true and accurate, are contractual in nature, and are hereby incorporated into and made a part of this Agreement.

2. Standstill. Subject to the terms, conditions and understandings contained in this Agreement, for a period beginning as of the date hereof and ending on March 10, 2019 (the "**Standstill Period**"), Lender will not seek to redeem (whether in cash or Redemption Conversion Shares) any portion of the Note (the "**Standstill**"). Notwithstanding the foregoing, the Standstill shall immediately and automatically terminate upon the occurrence of an Event of Default under the Note or Borrower's breach of this Agreement or the Transaction Documents after the date hereof, including without limitation if Borrower fails to increase the Share Reserve (as defined in the Purchase Agreement) in accordance with the provisions of Section 4 below. Notwithstanding anything herein or in any other Transaction Documents, no default to Novellus Dx or its affiliates, including those existing today, those arising from this Agreement and those arising hereafter, shall be deemed an Event of Default under this Agreement or any other Transaction Document. In addition, the Borrower at its option may extend the Standstill Period to April 15, 2019 by delivering written notice of such election to Lender on or before March 10, 2019. In the event of such an election, Borrower agrees that the Outstanding Balance shall automatically increase in the amount of the Second Standstill Fee (as defined below).

3. Standstill Fee. As a material inducement and partial consideration for Lender's agreement to enter into this Agreement, each of Borrower and Lender acknowledges and agrees that the Outstanding Balance of the Note shall be increased by $138,765.41 (the "**Standstill Fee**") as of the date hereof and that the Standstill Fee will tack back to the Purchase Price Date for Rule 144 purposes to the extent permitted by law. Following the application of the Standstill Fee, each of Borrower and Lender acknowledges and agrees that the Outstanding Balance of the

Note (inclusive of principal and all accrued interest) is $2,914,073.63 as of the date hereof. If Borrower elects to extend the Standstill Period to April 15, 2019 pursuant to the last sentence of Paragraph 2 above, the Outstanding Balance shall be increased by an additional sum of $63,382.71 (the "**Second Standstill Fee**").

4. Increase of Share Reserve. Borrower and Lender agree that in conjunction with the Standstill granted herein, within three (3) Trading Days of the date of this Agreement, the Share Reserve shall be increased to 4,000,000 shares of Common Stock. In furtherance of the foregoing, Borrower shall take all such actions as are necessary to increase the Share Reserve as set forth herein, including without limitation executing and delivering to its transfer agent such documents and instructions as are necessary to cause its transfer agent to increase the Share Reserve to 4,000,000 shares of Common Stock.

5. Ratification of the Note. The Note shall be and remains in full force and effect in accordance with its terms, and is hereby ratified and confirmed in all respects. Borrower acknowledges that it is unconditionally obligated to pay the remaining balance of the Note in accordance with its terms and represents that such obligation is not subject to any defenses, rights of offset or counterclaims. No forbearance or waiver other than as expressly set forth herein may be implied by this Agreement. Except as expressly set forth herein, the execution, delivery, and performance of this Agreement shall not operate as a waiver of, or as an amendment to, any right, power or remedy of Lender under the Note or the Transaction Documents, as in effect prior to the date hereof.

6. Failure to Comply. Borrower understands that the Standstill shall terminate immediately upon the earliest occurrence of (a) any breach of this Agreement, or (b) any Event of Default after the date hereof, and that in any such case, Lender may seek all recourse available to it under the terms of the Note, this Agreement, any other Transaction Document, or applicable law. Upon the termination of this Agreement or the expiration of the Standstill Period, among other rights, Lender shall have the right to redeem all or any portion of the Outstanding Balance in accordance with the terms of the Note. For the avoidance of doubt, the termination of the Standstill pursuant to this Section shall not terminate, limit or modify any other provision of this Agreement (including without limitation the increase in the Share Reserve or the application of the Standstill Fee).

7. Representations, Warranties and Agreements. In order to induce Lender to enter into this Agreement, Borrower, for itself, and for its affiliates, successors and assigns, hereby acknowledges, represents, warrants and agrees as follows:

(a) Borrower has full power and authority to enter into this Agreement and to incur and perform all obligations and covenants contained herein, all of which have been duly authorized by all proper and necessary action. No consent, approval, filing or registration with or notice to any governmental authority is required as a condition to the validity of this Agreement or the performance of any of the obligations of Borrower hereunder.

(b) Any Event of Default which may have occurred under the Note has not been, is not hereby, and shall not be deemed to be waived by Lender, expressly, impliedly, through course of conduct or otherwise except upon full satisfaction of Borrower's obligations

under this Agreement or as expressly provided herein. The agreement of Lender to refrain and forbear from exercising any rights and remedies by reason of any existing default or any future default shall not constitute a waiver of, consent to, or condoning of, any other existing or future default.

(c) All understandings, representations, warranties and recitals contained or expressed in this Agreement are true, accurate, complete, and correct in all respects; and no such understanding, representation, warranty, or recital fails or omits to state or otherwise disclose any material fact or information necessary to prevent such understanding, representation, warranty, or recital from being misleading. Borrower acknowledges and agrees that Lender has been induced in part to enter into this Agreement based upon Lender's justifiable reliance on the truth, accuracy, and completeness of all understandings, representations, warranties, and recitals contained in this Agreement. There is no fact known to Borrower or which should be known to Borrower which Borrower has not disclosed to Lender on or prior to the date hereof which would or could materially and adversely affect the understandings of Lender expressed in this Agreement or any representation, warranty, or recital contained in this Agreement.

(d) Except as expressly set forth in this Agreement, Borrower acknowledges and agrees that neither the execution and delivery of this Agreement nor any of the terms, provisions, covenants, or agreements contained in this Agreement shall in any manner release, impair, lessen, modify, waive, or otherwise affect the liability and obligations of Borrower under the terms of the Note or any of the other Transaction Documents.

(e) Borrower has no defenses, affirmative or otherwise, rights of setoff, rights of recoupment, claims, counterclaims, actions or causes of action of any kind or nature whatsoever against Lender, directly or indirectly, arising out of, based upon, or in any manner connected with, the transactions contemplated hereby, whether known or unknown, which occurred, existed, was taken, permitted, or begun prior to the execution of this Agreement and occurred, existed, was taken, permitted or begun in accordance with, pursuant to, or by virtue of any of the terms or conditions of the Transaction Documents. To the extent any such defenses, affirmative or otherwise, rights of setoff, rights of recoupment, claims, counterclaims, actions or causes of action exist or existed, such defenses, rights, claims, counterclaims, actions and causes of action are hereby waived, discharged and released. Borrower hereby acknowledges and agrees that the execution of this Agreement by Lender shall not constitute an acknowledgment of or admission by Lender of the existence of any claims or of liability for any matter or precedent upon which any claim or liability may be asserted.

(f) Borrower hereby acknowledges that it has freely and voluntarily entered into this Agreement after an adequate opportunity and sufficient period of time to review, analyze, and discuss (i) all terms and conditions of this Agreement, (ii) any and all other documents executed and delivered in connection with the transactions contemplated by this Agreement, and (iii) all factual and legal matters relevant to this Agreement and/or any and all such other documents, with counsel freely and independently selected by Borrower (or had the opportunity to be represented by counsel). Borrower further acknowledges and agrees that it has actively and with full understanding participated in the negotiation of this Agreement and all other documents executed and delivered in connection with this Agreement after consultation and review with its counsel (or had the opportunity to be represented by counsel), that all of the terms and conditions

of this Agreement and the other documents executed and delivered in connection with this Agreement have been negotiated at arm's-length, and that this Agreement and all such other documents have been negotiated, prepared, and executed without fraud, duress, undue influence, or coercion of any kind or nature whatsoever having been exerted by or imposed upon any party by any other party. No provision of this Agreement or such other documents shall be construed against or interpreted to the disadvantage of any party by any court or other governmental or judicial authority by reason of such party having or being deemed to have structured, dictated, or drafted such provision.

(g) There are no proceedings or investigations pending or threatened before any court or arbitrator or before or by, any governmental, administrative, or judicial authority or agency, or arbitrator, against Borrower.

(h) There is no statute, regulation, rule, order or judgment and no provision of any mortgage, indenture, contract or other agreement binding on Borrower, which would prohibit or cause a default under or in any way prevent the execution, delivery, performance, compliance or observance of any of the terms and conditions of this Agreement and/or any of the other documents executed and delivered in connection with this Agreement.

(i) Borrower is solvent as of the date of this Agreement, and none of the terms or provisions of this Agreement shall have the effect of rendering Borrower insolvent. The terms and provisions of this Agreement and all other instruments and agreements entered into in connection herewith are being given for full and fair consideration and exchange of value.

(j) To the best of its belief, after diligent inquiry, Borrower represents and warrants that, as of the date hereof, no Event of Default under the Note (nor any breach by Borrower under any of the other Transaction Documents) exists.

8. Certain Acknowledgments. Each of the parties acknowledges and agrees that no property or cash consideration of any kind whatsoever has been or shall be given by Lender to Borrower in connection with the Standstill or any other amendment to the Note granted herein.

9. Arbitration. Each party agrees that any dispute arising out of or relating to this Agreement shall be subject to the Arbitration Provisions (as defined in the Purchase Agreement).

10. Governing Law; Venue. This Agreement shall be governed by and interpreted in accordance with the laws of the State of Utah without regard to the principles of conflict of laws. Each party agrees that the proper venue for any dispute arising out of or relating to this Agreement shall be determined in accordance with the provisions of the Purchase Agreement. **BORROWER HEREBY IRREVOCABLY WAIVES ANY RIGHT IT MAY HAVE TO, AND AGREES NOT TO REQUEST, A JURY TRIAL FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION WITH OR ARISING OUT OF THIS AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREBY.**

11. Counterparts. This Agreement may be executed in any number of counterparts with the same effect as if all signing parties had signed the same document. All counterparts shall be construed together and constitute the same instrument. The exchange of copies of this Agreement and of signature pages by facsimile transmission or other electronic transmission

Agreement and of signature pages by facsimile transmission or other electronic transmission

(including email) shall constitute effective execution and delivery of this Agreement as to the parties and may be used in lieu of the original Agreement for all purposes. Signatures of the parties transmitted by facsimile transmission or other electronic transmission (including email) shall be deemed to be their original signatures for all purposes.

12. Attorneys' Fees. In the event of any arbitration or action at law or in equity to enforce or interpret the terms of this Agreement, the parties agree that the party who is awarded the most money shall be deemed the prevailing party for all purposes and shall therefore be entitled to an additional award of the full amount of the attorneys' fees and expenses paid by such prevailing party in connection with the arbitration, litigation and/or dispute without reduction or apportionment based upon the individual claims or defenses giving rise to the fees and expenses. Nothing herein shall restrict or impair an arbitrator's or a court's power to award fees and expenses for frivolous or bad faith pleading.

13. Severability. If any part of this Agreement is construed to be in violation of any law, such part shall be modified to achieve the objective of the parties to the fullest extent permitted and the balance of this Agreement shall remain in full force and effect.

14. Entire Agreement. This Agreement, together with the Transaction Documents, and all other documents referred to herein, supersedes all other prior oral or written agreements between Borrower, Lender, its affiliates and persons acting on its behalf with respect to the matters discussed herein, and this Agreement and the instruments referenced herein contain the entire understanding of the parties with respect to the matters covered herein and therein and, except as specifically set forth herein or therein, neither Lender nor Borrower makes any representation, warranty, covenant or undertaking with respect to such matters.

15. No Reliance. Borrower acknowledges and agrees that neither Lender nor any of its officers, directors, members, managers, representatives or agents has made any representations or warranties to Borrower or any of its agents, representatives, officers, directors, stockholders, or employees except as expressly set forth in this Agreement and the Transaction Documents and, in making its decision to enter into the transactions contemplated by this Agreement and the Transaction Documents, Borrower is not relying on any representation, warranty, covenant or promise of Lender or its officers, directors, members, managers, agents or representatives other than as set forth in this Agreement and in the Transaction Documents.

16. Amendments. This Agreement may be amended, modified, or supplemented only by written agreement of the parties. No provision of this Agreement may be waived except in writing signed by the party against whom such waiver is sought to be enforced.

17. Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their respective successors and assigns. This Agreement or any of the severable rights and obligations inuring to the benefit of or to be performed by Lender hereunder may be assigned by Lender to a third party, including its financing sources, in whole or in part. Borrower may not assign this Agreement or any of its obligations herein without the prior written consent of Lender.

18. Continuing Enforceability; Conflict Between Documents. Except as otherwise modified by this Agreement, the Note and each of the other Transaction Documents shall remain in full force and effect, enforceable in accordance with all of its original terms and provisions. This Agreement shall not be effective or binding unless and until it is fully executed and delivered by Lender and Borrower. If there is any conflict between the terms of this Agreement, on the one hand, and the Note or any other Transaction Document, on the other hand, the terms of this Agreement shall prevail.

19. Time is of Essence. Time is of the essence with respect to each and every provision of this Agreement.

20. Notices. Unless otherwise specifically provided for herein, all notices, demands or requests required or permitted under this Agreement to be given to Borrower or Lender shall be given as set forth in the "Notices" section of the Purchase Agreement.

21. Further Assurances. Each party shall do and perform or cause to be done and performed, all such further acts and things, and shall execute and deliver all such other agreements, certificates, instruments and documents, as the other party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and the consummation of the transactions contemplated hereby.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the date first set forth above.

BORROWER:

CANCER GENETICS, INC.

DocuSigned by:

By: John A. Roberts

Name: 9EC776BC2026454... John A. Roberts

Title: Chief Executive Officer

LENDER:

ILIAD RESEARCH AND TRADING, L.P.

By: Iliad Management, LLC, its General Partner

By: Fife Trading, Inc., its Manager

By: _____

John M. Fife, President

CANCER GENETICS, INC.

EMPLOYMENT AGREEMENT

This Employment Agreement (this "Agreement") is entered into as of August 14, 2017 ("Effective Date"), by and between **Cancer Genetics, Inc.**, a Delaware corporation with its corporate headquarters at 201 Route 17 North, 2nd Floor, Rutherford, NJ 07070 (the "Company"), and **Dr. Ralf Brandt**, with an address at 148 Savannah Drive, Hummesltown PA 17036 ("Employee").

In consideration of the mutual covenants and conditions set forth herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereby agree as follows:

1. **Employment.** The Company hereby employs Employee in the capacity of the President of Discovery Services, and will serve on the Company's Clinical and Scientific Advisory Board, reporting directly to the President and Chief Executive Officer of the Company (the "CEO"). Employee accepts such employment and agrees to perform such roles and provide such management and other services for the Company as are customary to such office and such additional responsibilities, consistent with the position of President of Discovery Services, as may be assigned from time to time by the CEO. Employee will manage the activity, workflow and quality of the Company's discovery services business segment.

2. **Term.** The employment hereunder shall be for a period commencing on the close of the acquisition of *vivo*Pharm Pty Ltd by Cancer Genetics, Inc. (the "Commencement Date") and ending on the two (2)-year anniversary of the Commencement Date (the "Initial Term"), unless earlier terminated as provided in Section 4 or 5. This Agreement shall be automatically renewed for successive one (1)-year periods thereafter, commencing upon the expiration of the Initial Term, unless earlier terminated as provided in Section 4 or 5. Employee's employment following the Commencement Date will be on a full-time business basis requiring the devotion of substantially all of Employee's productive business time for the efficient and successful operation of the business of the Company.

3. **Compensation and Benefits.**

3.1 **Cash Compensation.** For the performance of Employee's duties hereunder following the Commencement Date, the Company shall pay Employee an annual salary in the amount of three hundred and thirty thousand dollars ($330,000 USD) ("Base Compensation"). The Base Compensation shall be paid in installments every two weeks over twenty-six (26) pay periods per year, based on and in accordance with Company's regular payroll procedures.

3.2 **Bonus Plan.**

(a) Employee shall be entitled to participation in the performance bonus compensation plan further defined in Section 3.2(b). Additional detail of the performance bonus compensation plan, including performance goals, targets and milestones, will be developed by the Employee, the CEO and the Company Board of Directors. Such additional detail will be finalized and provided in writing to Employee once the performance bonus

detail will be finalized and provided in writing to Employee once the performance bonus

compensation plan is adopted by the Board, which will occur within thirty (30) days after the Commencement Date. Any bonus compensation paid to Employee shall be in addition to Base Compensation.

(b) Employee shall be eligible annually for a performance-based bonus of up to thirty percent (30%) of Base Compensation per bonus period. The amount of the bonus shall be determined by the Board and the Company CEO, based on their reasonable assessments of Employee's performance and the Company's performance against appropriate goals, including growth targets based on revenue and new accounts, margin targets, customer satisfaction targets and key milestones established that ensure successful integration of *vivo*Pharm with the Company, which goals will be established within thirty (30) days following the Commencement Date by the CEO and the Board, or the Compensation Committee of the Board, after consultation with the Employee. Key milestones that ensure successful integration of the *vivo*Pharm business with the Company will count towards at least one third (1/3) of the overall bonus target. If all such goals are achieved for a given period, the amount of the bonus will be up to thirty (30%) of Base Compensation for that period. Employee and the CEO will meet for an interim assessment of the Employee's performance approximately six (6) months following the Commencement Date. The bonus amount for the first bonus period will be determined following the one (1)-year anniversary of the Commencement Date. Thereafter, each subsequent bonus period shall be measured in twelve-month periods marked by each subsequent anniversary of the Commencement Date. Employee's bonus, as earned, shall be payable in accordance with the Company's payment schedules then in effect, or (ii) upon the issuance of the independent auditors' report for the period ending when the bonus was earned.

3.3 **Stock Options and Restricted Stock Grant.**

(a) From time to time the Company may grant to employee under the Company's Stock Option Plan (or its successor stock plan) to purchase shares of the Company's common stock at a stated exercise price per share.

(b) Effective on the Commencement Date, the Company shall grant to Employee a stock option under the 2011 Stock Option Plan (the "Plan") to purchase one hundred thousand (100,000) shares of Common Stock, with the exercise price of the stock options fixed under the Plan as of the Commencement Date, with the option to be treated as an incentive stock option to the greatest extent permitted by law and a non-qualified stock option as to the balance, vesting in equal quarterly increments over a two (2)-year period beginning on October 1, 2017 as outlined in Exhibit A (the "Stock Options").

(c) Effective on the Date of Approval by the Compensation Committee the Company shall grant to Employee thirty thousand (30,000) shares of restricted stock under the 2011 Stock Option Plan (the "Plan"). The restricted stock will vest over a period of three (3) years beginning on October 1, 2017, in equal annual increments as outlined in Exhibit A (the "Restricted Stock").

3.4 **Benefits.** Employee and Employee's dependents shall continue to receive the medical/dental, disability and life insurance coverage that are currently made available to Employee through the vivoPharm, LLC Welfare Benefit Plan ("vP Plan"), through the vP Plan's expiration on August 31, 2018. Commencing September 1, 2018, Employee and Employee's dependents shall be entitled to such medical/dental/vision, disability and life insurance coverage as are made available either to Company's other senior executives or to the Company's personnel generally, whichever is greater, all in accordance with the

Company's benefits program in effect from time to time. Effective as of the

Commencement Date, Employee and Employee's dependents shall be entitled to such 401(k) plan and other retirement plan participation, vacation, sick leave and holiday benefits, if any, and any other benefits as are made available either to Company's other senior executives or to the Company's personnel generally, whichever is greater, all in accordance with the Company's benefits program in effect from time to time. The Employee is responsible for paying the employee's portion of the benefit costs consistent with other similarly situated employees of the Company, with the sole exception of Employee's coverage under the vP Plan. The medical/dental/vision, disability and life benefits provided to Employee under this Section 3.4 shall continue until, and shall terminate, three (3) months after a Termination Event pursuant to Section 4 or Section 5 hereof, except to the extent that Employee receives comparable benefits at a future employer during the three (3) months after the Termination Event, in which case the pertinent benefits from the Company shall end upon Employee's enrollment in such future employer's benefit plan.

3.5 **Reimbursement of Expenses.** Employee shall be entitled to be reimbursed for all reasonable expenses including the cost of travel for business; home office operation; business meals and entertainment, incurred by Employee in performing the tasks, duties and responsibilities of the position under Section 2 or otherwise in connection with and reasonably related to the furtherance of the Company's business. Employee shall submit expense reports and receipts documenting the expenses incurred in accordance with Company policy, and will comply with using the Company's electronic travel and expense software and travel planning systems.

3.6 **Mobile Device & Phones.** The Company shall provide a mobile phone that is compliant with the company policy and is HIPAA compliant. The Employee is welcome to use Employee's own device or phone, but it must be registered with the Information Technology department and must follow the Company's "BYOD" (Bring Your Own Device) policies in place from time to time, including but not limited to setting up of passwords, backups of information and compliance with email and communication policies.

4. Change of Control.

4.1 In the event of a termination of Employee's employment hereunder by the Company without Cause or by Employee with Good Reason (as defined below), within twelve (12) months following a Change of Control, the Company will promptly pay Employee, in lieu of the amounts required under Section 5.2(b) and in addition to the amounts required under Sections 3.5 and 5.2(a), a severance amount, payable in a lump sum immediately upon the later of such termination of employment or Employee's execution of a Release in the form attached as Exhibit B (which the Company shall execute contemporaneously), equal to the remainder of the contract term for the initial two years, or six (6) months of the Base Compensation, whichever is greater.

4.2 As used herein, a "Change of Control" of the Company shall mean any of the following:

(i) the acquisition by any person(s) (individual, entity or affiliated or unaffiliated group) in one or a series of transactions (including, without limitation, issuance of shares by the Company or through merger of the Company with another entity) of direct or indirect record or beneficial ownership of 50% or more of the voting power

with respect to matters put to the vote of the shareholders of the Company and, for

this purpose, the terms "person" and "beneficial ownership" shall have the meanings provided in Section 13(d) or 14(d) of the Securities Exchange Act of 1934 or related rules promulgated by the Securities and Exchange Commission;

(ii) the commencement of or public announcement of an intention to make a tender or exchange offer for more than 50% of the then outstanding Shares of the common stock of the Company;

(iii) a sale of all or substantially all of the assets of the Company; or

(iv) the Board, in its sole and absolute discretion, determines that there has been a sufficient change in the stock ownership of the Company to constitute a change in control of the Company. Notwithstanding the foregoing, the following acquisitions shall not constitute a "Change of Control": (1) any capital raised by the Company (not used for a redemption of outstanding shares); (2) the closing of any transaction that in good faith may be reasonably characterized as an acquisition of another entity by the Company rather than the other way around; or (3) any acquisition of the Company or its shares by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company.

5. Termination

5.1 **Termination Events.** The employment hereunder will terminate upon the occurrence of any of the following events ("the Termination Event"):

(a) Employee dies; or

(b) The Company, by written notice to Employee or his personal representative, discharges Employee due to the inability to continue to perform the duties previously assigned to Employee hereunder prior to such injury, illness or disability for a continuous period exceeding 90 consecutive days or 180 out of 360 days by reason of injury, physical or mental illness or other disability, which condition has been certified by a physician reasonably acceptable to the Company; provided, however, that prior to discharging Employee due to such disability, the Company shall give a written statement of findings to Employee or his personal representative setting forth specifically the nature of the disability and the resulting performance failures, and Employee shall have a period of thirty (30) days thereafter to respond in writing to the Company's findings, whereupon the Company shall conduct a reasonable and fair hearing with the Employee and any supporting witnesses and evidence for the Employee to reach a final determination; or

(c) Employee is discharged by the Company for "Cause". As used in this Agreement, the term "Cause" shall mean:

(i) Employee's final and unappealed conviction of (or pleading guilty or "nolo contendere" to) any felony or a major misdemeanor involving dishonesty or moral turpitude; provided, however, that prior to discharging Employee for Cause, the Company shall give a written statement of findings to Employee

Company shall give a written statement of findings to Employee setting forth specifically the grounds on which Cause is based, and

Employee shall have a period of (10) days thereafter to respond in writing to the Company's findings; or

(ii) The Employee's (1) unreasonable failure to perform his duties, as determined by the Board of Directors, (2) substantial and material breach of, or default under, this Agreement or the Proprietary Information and Invention Assignment Agreement (as defined herein), or (3) The unreasonable failure of the Company, as determined by the Board of Directors, to meet reasonable benchmarks that are in control of the Employee, as may be agreed to from time to time by the Employee and the Board of Directors. In the case of any of the conditions set forth in this Section 5.1(c)(ii), the Employee shall be given written notice of the intent of the Board of Directors to terminate the Employee's employment under this paragraph, and shall be permitted thirty (30) days from receipt of such written notice to promptly cure any such breach or default to the reasonable satisfaction of the Board.

(d) Employee is discharged by Company other than in accordance with Section 5.l(a)(c) (a termination "without Cause"), which the Company may do at any time, with at least thirty (30) days advance written notice, subject to the full performance of the obligations of the Company to the Employee pursuant to Section 4 or Section 5.2, as the case may be; or

(e) Employee voluntarily terminates his employment due to "Good Reason", which shall mean (i) a material default by the Company in the performance of any of its obligations hereunder, which default remains uncured by the Company for a period of thirty (30) days following receipt of written notice thereof to the Company from Employee; or

(f) Employee voluntarily terminates his employment without Good Reason, which Employee may do at any time with at least thirty (30) days advance notice.

5.2 **Effects of Termination.**

(a) Upon termination of Employee's employment hereunder for any reason, the Company will promptly pay Employee all Base Compensation owed to Employee and all bonuses earned, as previously defined in writing by the Company, and unpaid through the date of termination, which shall be the last day that Employee performs his duties for the Company (including, without limitation, salary and employee expenses reimbursements). Employee shall be paid for any performance bonus plan then in effect on a pro rata basis for that period of time during the fiscal year in which termination occurs, but such amount, if any shall only be paid at a commensurate time as other employees are paid their bonus amounts.

(b) Unless Section 4 applies (in which case Section 4, and not this Section 5.2(b), will be followed), and in addition to the amounts required under Sections 3.5 and 5.2(a):

(i) Upon termination of Employee's employment under Sections 5.l(a),

Company shall continue to pay the Base Compensation to the estate of the Employee for a period of three (3) months after such death.

(ii) Upon termination of Employee's employment under Section 5.l(b), the Company shall pay Employee, commencing immediately upon such termination of employment, monthly (or biweekly at the Company's discretion) amounts equal to the then applicable Base Compensation, excluding bonus, for a period of four (4) months after termination.

(c) Upon termination of Employee's employment under Section 5.l(d) or 5.1(e), the Company shall pay Employee, commencing immediately upon the later of such termination of employment or Employee's execution of a Release (which the Company shall execute contemporaneously) in the form attached as Exhibit B, monthly (or biweekly at the Company's discretion) amounts equal to the then applicable Base Compensation, excluding bonus: (i) if such termination occurs during the initial two (2)-year term of this Agreement, for a period equal to the remainder of the contract term for such initial two (2) years measured from the Commencement Date, or for a period of 6 months of Base Compensation, whichever is greater; or (ii) if such termination occurs following the initial two (2)-year term of this Agreement, for a period of six (6) months of Base Compensation.

(d) Upon termination of Employee's employment hereunder pursuant to Section 5.1(f), the Company shall pay Employee, commencing immediately upon the later of such termination of employment or Employee's execution of a Release (which the Company shall execute contemporaneously) in the form attached as Exhibit B, monthly (or biweekly at the Company's discretion) amounts equal to the then applicable Base Compensation, excluding bonus, for a period of three (3) months of Base Compensation, which amount shall be inclusive of any required notice period for such termination pursuant to Section 5.1(f).

(e) Upon termination of Employee's employment hereunder pursuant to Sections 5.l(b), 5.l(c), 5.l(d) or 5.1(f), Employee agrees as follows:

(i) Any amounts paid according to above Section 4 or Section 5, following a termination event as described therein, are paid to Employee only for so long as Employee does not provide services to any commercial firm, corporation or other business enterprise which is involved in the business of discovery, development, marketing or providing a diagnostic service offering proprietary nucleic acid and biomarker-based probe or microarray or next generation sequencing to cancer researchers or physician practitioners or biotech and pharma companies that serve the cancer markets and categories in direct competition with the Company ("Competitive Engagements"). Employee agrees not to engage in Competitive Engagements for: (i) a period equal to the remainder of the contract term, if such termination occurs during the initial two (2)-year term of this Agreement, from the Commencement Date, or (ii) for a period of six (6) months, after the date of termination, whichever is greater. Nothing in this Section 5.2(d) shall prevent Employee from accepting employment engagements, after the date of termination of his employment with the

engagements, after the date of termination of his employment with the Company, with non-commercial entities including but not limited to

research and academic institutions.

(ii) The terms of the Cancer Genetics, Inc. Confidentiality, Proprietary Information and Inventions Agreement shall remain in effect for the time periods specified in this Agreement.

(iii) Employee will not knowingly, directly and actively solicit any individual to leave the Company's then full-time employ, for any reason, to join or be employed by any employer that then employs Employee as an employee, director, consultant or advisor.

(iv) Employee will not knowingly, directly and actively induce any provider, agent, customer, supplier, distributor, or licensee of the Company to cease doing business with the Company or to breach its agreement with the Company.

(f) Employee acknowledges that monetary damages may not be sufficient to compensate the Company for any economic loss, which may be incurred by reason of breach of the restrictive covenants set forth in Section 5.2(d). Accordingly, in the event of any such breach, the Company shall, in addition to any remedies available to the Company at law, be entitled to seek equitable relief in the form of an injunction, precluding Employee from continuing to engage in such breach.

(g) If any restriction set forth in Section 5.2(d) is held to be unreasonable, then Employee and the Company agree, and hereby submit, to the reduction and limitation of such prohibition to such area or period as shall be deemed reasonable.

(h) Except as required by law, Employee agrees not to make to any person, including but not limited to customers of the Company, any statement that disparages the Company or which reflects negatively upon the Company, including but not limited to statements regarding the Company's financial condition, its officers, directors, shareholders, employees and affiliates. The Company agrees not to make to any person, including but not limited to customers of the Company, any statement that disparages Employee or which reflects negatively upon Employee, including but not limited to statements regarding his financial condition, qualifications and professional competence.

6. Conflicts of Interest

6.1 **Duty to Disclose.** Employee will provide the CEO and Board with a report on the existence of any actual conflicts of interest. In connection with any actual conflicts of interests, Employee will confidentially disclose the existence of any conflicts of interests, including his financial interest and the minimum about of facts necessary to assess the conflict of interest, to the CEO and Board or to any special committees with Board delegated powers considering the proposed transaction or arrangement. If the Board or committee has reasonable cause to believe that Employee has failed to disclose any actual conflict of interest, it shall inform Employee of the basis for such belief and afford Employee an opportunity to explain the alleged failure to disclose.

the alleged failure to disclose.

6.2 **Determining Whether a Conflict of Interest Exists.** After disclosure of the financial interest and the minimum about of facts necessary to assess the conflict of Interest, and after any discussion with the Employee, Employee shall excuse him/herself from the Board or committee meeting while the determination of whether a conflict of interest exists is discussed and voted upon. The remaining Board or committee members shall determine whether a conflict of interest exists. Notwithstanding the foregoing, however, prior approval of the Board of Directors shall not be required if the transaction falls below a *de minimis* threshold established by the Board.

6.3 **Addressing Conflict.** If the Board determines that Employee has an actual conflict of interest, the Company and Employee shall employ good faith actions to resolve the conflict of interest.

7. General Provisions.

7.1 **Assignment.** Neither party may assign or delegate any of his or its rights or obligations under this Agreement without the prior written consent of the other party.

7.2 **Entire Agreement.** This Agreement contains the entire agreement between the parties with respect to the subject matter hereof and supersedes any and all prior written and verbal agreements between the parties. This Agreement supersedes, replaces and terminates as of the Commencement Date, the prior agreement for employment between the Employee and vivoPharm Pty Ltd without further obligation of the Company or the Employee thereto.

7.3 **Modifications.** This Agreement may be changed or modified only by an agreement in writing signed by both parties hereto.

7.4 **Successors and Assigns.** The provisions of this Agreement shall inure to the benefit of, and be binding upon, the Company and its successors and permitted assigns and Employee and Employee's legal representatives, heirs, legatees, distributees, assigns and transferees by operation of law, whether or not any such person shall have become a party to this Agreement and have agreed in writing to join and be bound by the terms and conditions hereof.

7.5 **Governing Law.** This Agreement shall be governed by, construed and enforced in accordance with, the laws of the State of New Jersey, and venue and jurisdiction for any disputes hereunder shall be heard in any court of competent jurisdiction in New Jersey for all purposes.

7.6 **Severability.** If any provision of this Agreement is held by a court of competent jurisdiction to be invalid, void or unenforceable, the remaining provisions shall nevertheless continue in full force and effect.

7.7 **Further Assurances.** The parties will execute such further instruments and take such further actions as may be reasonably necessary to carry out the intent of this Agreement.

7.8 **Notices.** Any notices or other communications required or permitted hereunder shall be in writing and shall be deemed received by the recipient when delivered personally or, if mailed, five (5) days after the date of deposit in the United States mail, certified or

registered, postage prepaid and addressed, in the case of the Company, to the address set

forth above, attention CEO, and in the case of Employee, to the address shown for Employee on the signature page hereof, or to such other address as either party may later specify by at least ten (10) days advance written notice delivered to the other party in accordance herewith.

7.9 **No Waiver.** The failure of either party to enforce any provision of this Agreement shall not be construed as a waiver of that provision, nor prevent that party thereafter from enforcing that provision of any other provision of this Agreement.

7.10 **Legal Fees and Expenses.** In the event of any disputes under this Agreement, each party shall be responsible for their own legal fees and expenses which it may incur in resolving such dispute, unless otherwise provided by applicable law or a court of competent jurisdiction.

7.11 **Counterparts.** This Agreement may be executed by exchange of facsimile signature pages and/or in counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

7.12 **Insurance on Employee.** The Company shall be entitled to obtain and maintain, at the Company's sole option and at the Company's expense, key person life insurance on the life of the Employee, naming the Company as the beneficiary of such policy. Employee agrees to cooperate with the Company and take all reasonable actions necessary to obtain such insurance, such as taking usual and customary physical examinations and providing true and accurate personal, health related information for any application at no cost to Employee.

7.13 **Confidentiality, Proprietary Information and Invention Assignment Agreement.** The terms of the confidentiality, proprietary information and invention assignment agreement attached hereto as Exhibit C (the "Confidentiality, Proprietary Information and Invention Assignment Agreement") are incorporated herein by reference. If there is any conflict between the terms of the Confidentiality, Proprietary Information and Invention Assignment Agreement and the terms of this Agreement, the terms of this Agreement shall prevail.

[*Signatures on Next Page*]

IN WITNESS WHEREOF, the Company and Employee have executed this Agreement, effective as of the day and year first above written.

CANCER GENETICS, INC.

By: _____

Name: Panna Sharma
Title: CEO & President

EMPLOYEE

DocuSigned by:
Ralf Brandt
_____
Dr. Ralf Brandt

Address:

148 Savannah Drive

Hummesltown PA 17036

EXHIBIT A

NOTICE OF GRANT OF 100,000 OPTIONS TO PURCHASE SHARES
&
NOTICE OF GRANT OF 30,000 SHARES OF RESTRICTED STOCK

STOCK OPTION VESETING SCHEDULE

Date	Amount Vested
October 1, 2017	12,500 options
January 1, 2018	12,500 options
April 1, 2018	12,500 options
July 1, 2018	12,500 options
October 1, 2018	12,500 options
January 1, 2019	12,500 options
April 1, 2019	12,500 options
July 1, 2019	12,500 options

RESTRICTED STOCK VESTING SCHEDULE

Date	Amount Vested
October 1, 2017	10,000 shares
October 1, 2018	10,000 shares
October 1, 2019	10,000 shares

EXHIBIT B

RELEASE

The undersigned individual ("Releasor"), on his own behalf and on behalf of his heirs, beneficiaries and assigns, hereby releases and forever discharges Cancer Genetics, Inc. and its subsidiaries and all of their respective officers and directors, successors and assigns (collectively, "Released"), both individually and in their official capacities, from any and all liability, claims, demands, actions and causes of action of any type (collectively, "Claims") which Releasor has had in the past, now has, or might now have, through the date of your execution of this Release, in any way resulting from, arising out of or connected with your employment by Cancer Genetics, Inc. and its subsidiaries (collectively, "Company") or its termination or pursuant to any federal, state or local employment law, regulation or other requirement (including without limitation Title VII of the Civil Rights Act of 1964, as amended; the Age Discrimination in Employment Act, as amended ("ADEA"); the Americans with Disabilities Act, as amended).

The Company, on its own behalf and on behalf of the Released, hereby releases and forever discharges the Releasor and his heirs, beneficiaries and representatives and assigns, both individually and in their official capacities, from any and all Claims which it has had in the past, now has, or might now have, through the date of your execution of this Release, in any way resulting from, arising out of or connected with your employment by the Company or its termination. By acceptance of or reliance on this release of Claims by Releasor, the Company promises that neither it nor any of the other Released affiliated with the Company will take any action that is designed, specifically as to you or with respect to a class of similarly situated former employees, to reduce or abrogate, or may reasonably be expected to result in an abridgement or elimination of, any rights of indemnification or contribution available to Releasor, as described above, or under any such policy or policies of directors and officers liability insurance, unless any such abridgement- or elimination of rights also is generally applicable to all then- current officers and employees of the Company.

Excluded from the scope of this Release is (i) any claim by Releasor for payment of wages (including salary, bonus, severance, and unused PTO) or reimbursement of expenses or under the terms of any of the Company's employee qualified and non-qualified benefit plans (including without limitation the Company's employee pension plan, profit sharing plan, stock option plan or stock ownership plan); (ii) any claim or right of Releasor under any policy or policies of directors and officers liability insurance maintained by the Company as in effect from time to time; and (iii) any right of or for indemnification or contribution pursuant to contract and/or the Articles of Incorporation or By-Laws (or other charter documents) of the Company that Releasor has or hereafter may acquire if any claim is asserted or proceedings are brought against Releasor including, without limitation, if by any governmental or regulatory agency, or by any customer, creditor, employee or shareholder of the Company, or by any self-regulatory organization, stock exchange or the like, arising out of or related or allegedly related to the undersigned individual being or having been an officer or employee of the Company or to any of his actions, inactions or activities as an officer or employee of the Company. Also excluded from this release are any Claims which cannot be waived by law. By signing this Release you are waiving, however, your right to any monetary recovery should any governmental agency or entity, such as the EEOC or the DOL, pursue any claims on your behalf. Releasor acknowledges that he is knowingly and voluntarily waiving and releasing any rights he may have under the ADEA, as amended.

The undersigned individual further acknowledges that he/she has been advised by this

writing that: (a) his/her waiver and release in this Release does not apply to any rights or claims that may arise after the execution date of this Release; (b) that he/she has the right to consult with an attorney prior to executing this Release; (c) he/she has up to the entirety of until twenty-one (21) days after the date he/she received this Release executed by the Company in which to consider this Release (although if the undersigned individual does execute this Release before the end of such twenty-one (21) days, he will also sign the Consideration Period waiver below); (d) /heshe has seven (7) days following his execution of this Release to revoke this Agreement by so notifying the Company; and (e) this Release shall not be effective until the date upon which the this seven (7) day revocation period has expired unexercised (the "Effective Date"), which shall be the eighth day after this Release is executed by the undersigned individual. Upon the lapse of said seven (7) day period without revocation, this Release will have effect retroactively to the date it was signed by the Company.

This Release does not constitute an admission by the Company or by the undersigned individual of any wrongful action or violation of any federal, state, or local statute, or common law rights, including those relating to the provisions of any law or statute concerning employment actions, or of any other possible or claimed violation of law or rights. This Release is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Release may not be modified or amended except in a writing signed by both the undersigned individual and a duly authorized officer of the Company. This Release will bind the heirs, personal representatives, successors and assigns of both the undersigned individual and the Company, and inure to the benefit of both the undersigned individual and the Company and their respective heirs, successors and assigns. If any provision of this Release is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Release and the provision in question will be modified by the court so as to be rendered enforceable. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the state of New Jersey as applied to contracts made and to be performed entirely within New Jersey.

Cancer Genetics, Inc. **Dr. Ralf Brandt**

By: _____ _____

CONSIDERATION PERIOD WAIVER

I, Dr. Ralf Brandt understand that I have the right to take at least 21 days to consider whether to sign this Release, which I received on _____ __, ____. If I elect to sign this Release before 21 days have passed, I understand I am to sign and date below this paragraph to confirm that I knowingly and voluntarily agree to waive the 21-day consideration period.

Dr. Ralf Brandt

EXHIBIT C

CANCER GENETICS, INC.
Confidentiality, Proprietary Information and Inventions Agreement

I (the "Employee") recognize that Cancer Genetics, Inc., a Delaware corporation (the "Company"), is engaged in the business of designing, developing, manufacturing and marketing genetic tests for global cancer diagnosis, prognosis and prediction; developing and marketing proprietary nucleic acid and molecular-based diagnostic kits, including next generation sequencing panels, probes, liquid biopsies and microarrays; and operating a diagnostic laboratory that is used to process proprietary lab tests developed by the Company and conventional cancer testing services (the "Business"). Any company with which the Company enters into, or seeks or considers entering into, a business relationship in furtherance of the Business is referred to as a "Business Partner."

I understand that as part of my performance of duties as an employee of the Company (the "Employment"), I will have access to confidential or proprietary information of the Company and the Business Partners, and I may make new contributions and inventions of value to the Company. I further understand that my Employment creates in me a duty of trust and confidentiality to the Company with respect to any information: (1) related, applicable or useful to the business of the Company, including the Company's anticipated research and development or such activities of its Business Partners; (2) resulting from tasks performed by me for the Company; (3) resulting from the use of equipment, supplies or facilities owned, leased or contracted for by the Company; or (4) related, applicable or useful to the business of any partner, client or customer of the Company, which may be made known to me or learned by me during the period of my Employment.

For purposes of this Agreement, the following definitions apply: "Proprietary Information" shall mean information relating to the Business or the business of any Business Partner and generally unavailable to the public that has been created, discovered, developed or otherwise has become known to the Company or in which property rights have been assigned or otherwise conveyed to the Company or a Business Partner, which information has economic value or potential economic value to the business in which the Company is or will be engaged. Proprietary Information shall include, but not be limited to, trade secrets, processes, formulas, writings, data, know-how, negative know-how, improvements, discoveries, developments, designs, inventions, techniques, technical data, patent applications, customer and supplier lists, financial information, business plans or projections and any modifications or enhancements to any of the above. Proprietary Information does not include, and the restrictions upon use and disclosure of Proprietary Information shall not apply to, information that: (1) is now in the public domain or subsequently enters the public domain through no breach of this Agreement, or (2) I lawfully receive from any third party without restriction as to use or confidentiality as shown by written or other tangible evidence, or (3) is independently developed by me, or for me by others.

"Inventions" shall mean all Business-related discoveries, developments, designs, improvements, inventions, formulas, software programs, processes, techniques, know-how,

negative know-how, writings, graphics and other data, whether or not patentable or

registrable under patent, copyright or similar statutes, that are related to or useful in the business or future business of the Company or its Business Partners or result from use of premises or other property owned, leased or contracted for by the Company. Without limiting the generality of the foregoing, Inventions shall also include anything related to the Business that derives actual or potential economic value from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use.

As part of the consideration for my Engagement or continued Engagement, as the case may be, and the compensation received by me from the Company from time to time, I hereby agree as follows:

1. Proprietary Information and Inventions. All Proprietary Information and Inventions related to the Business shall be the sole property of the Company and its assigns, and the Company or its Business Partners, as the case may be, and their assigns shall be the sole owner of all patents, trademarks, service marks, copyrights and other rights (collectively referred to herein as "Rights") pertaining to Proprietary Information and Inventions. I hereby assign to the Company, any rights I may have or acquire in Proprietary Information or Inventions or Rights pertaining to the Proprietary Information or Inventions which Rights arise in the course of my Engagement. I further agree as to all Proprietary Information or Inventions to which Rights arise in the course of my Engagement to assist the Company or any person designated by it in every proper way (but at the Company's expense) to obtain and from time to time enforce Rights relating to said Proprietary Information or Inventions in any and all countries. I will execute all documents for use in applying for, obtaining and enforcing such Rights in such Proprietary Information or Inventions as the Company may desire, together with any assignments thereof to the Company or persons designated by it. My obligation to assist the Company or any person designated by it in obtaining and enforcing Rights relating to Proprietary Information or Inventions shall continue beyond the cessation of my Engagement ("Cessation of my Engagement"). I hereby acknowledge that all original works of authorship that are made by me (solely or jointly with others) within the scope of my Engagement and which are protectable by copyright are "works for hire" as that term is defined in the United States Copyright Act (17 USCA, Section 101).

2. Confidentiality. At all times, both during my Engagement and after the Cessation of my Engagement, whether the cessation is voluntary or involuntary, for any reason or no reason, or by disability, I will keep in strictest confidence and trust all Proprietary Information, and I will not disclose or use or permit the use or disclosure of any Proprietary Information or Rights pertaining to Proprietary Information, or anything related thereto, without the prior written consent of the Company, except as may be necessary in the ordinary course of performing my duties for the Company. I recognize that the Company has received and in the future will receive from third parties (including Business Partners) their confidential or proprietary information subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. I agree that I owe the Company and such third parties (including Business Partners), during my Engagement and thereafter, a duty to hold all such confidential or proprietary information in the strictest confidence, and I will not disclose or use or permit

the use or disclosure of any such confidential or proprietary information without the prior

written consent of the Company, except as may be necessary in the ordinary course of performing my duties for the Company consistent with the Company's agreement with such third party.

3. Noncompetition and Nonsolicitation.

(a) During my Engagement and for (i) a period equal to the remainder of the contract term, if the Cessation of my Engagement occurs during the initial two (2)-year term of my Employment Agreement with Company, as measured from the Commencement Date, or (ii) for a period of six (6) months, after the date of Cessation, whichever is greater, I will not, either directly or indirectly, either alone or in concert with others, solicit or encourage any employee of or consultant to the Company or any Business Partner to leave the Company or Business Partner or engage directly or indirectly in competition with the Company or Business Partner in the Business.

(b) Employee acknowledges that (i) the restrictions contained in this section are reasonable and necessary to protect the legitimate business interests of the Company, (ii) that the term of this obligation is reasonable in scope, and (iii) that this obligation is a material term, without which the Company would be unwilling to enter into an employer-employee relationship with the Employee.

(c) In the event of any such breach or threatened breach, Employee acknowledges that, in addition to all other remedies available at law and equity, the Company shall be entitled to seek equitable relief (including a temporary restraining order, a preliminary injunction and/or a permanent injunction), and an equitable accounting of all earnings, profits or other benefits arising from such breach and will be entitled to receive such other damages, direct or consequential, as may be appropriate.

4. Delivery of Company Property and Work Product. In the event of the Cessation of my Engagement, I will deliver to the Company all biological and chemical materials, devices, records, sketches, reports, memoranda, notes, proposals, lists, correspondence, equipment, documents, photographs, photostats, negatives, undeveloped film, drawings, specifications, tape recordings or other electronic recordings, programs, data, marketing material and other materials or property of any nature belonging to the Company or its clients or customers, and I will not take with me, or allow a third party to take, any of the foregoing or any reproduction of any of the foregoing.

5. No Conflict. I represent to the best of my knowledge that my performance of all the terms of this Agreement and the performance of my duties for the Company does not and will not breach any agreement to keep in confidence proprietary information acquired by me in confidence or in trust prior to my Engagement. I have not entered into, and I agree that I will not enter into, any agreement, either written or oral, in conflict herewith.

6. No Use of Confidential Information. I represent to the best of my knowledge that I have not brought and will not bring with me to the Company or use in my Engagement any materials or documents of a former employer, or any person or entity for which I have acted as an independent contractor or consultant, that are not generally available to the public, unless I have obtained written authorization from any such former employer, person or firm for their possession and use. I understand and agree that, in my service to the

Company, I am not to breach any obligation of confidentiality that I have to former

employers or other persons.

7. Equitable Relief. I acknowledge that in the event of my violation or of the terms of this Agreement, I expressly agree that the Company shall be entitled to seek, in addition to damages and any other remedies provided by law, an injunction or other equitable remedy respecting such violation or continued violation by me.

8. Severability. If any provision of this Agreement shall be determined by any court of competent jurisdiction to be unenforceable or otherwise invalid as written, the same shall be enforced and validated to the extent permitted by law. All provisions of this Agreement are severable, and the unenforceability or invalidity of any single provision hereof shall not affect the remaining provisions.

9. Miscellaneous. This Agreement shall be governed by and construed under the laws of the State of New Jersey applied to contracts made and performed wholly within such state. No implied waiver of any provision within this Agreement shall arise in the absence of a waiver in writing, and no waiver with respect to a specific circumstance, event or occasion shall be construed as a continuing waiver as to similar circumstances, events or occasions. This Agreement, together with the employment agreement (if any) between the Company and myself, contains the sole and entire agreement and understanding between the Company and myself with respect to the subject matter hereof and supersedes and replaces any prior agreements to the extent any such agreement is inconsistent herewith. This Agreement can be amended, modified, released or changed in whole or in part only by a written agreement executed by the Company and myself. This Agreement shall be binding upon me, my heirs, executors, assigns and administrators, and it shall inure to the benefit of the Company and each of its successors or assigns. This Agreement shall be effective as of the first day of my being retained to render services to the Company, even if such date precedes the date I sign this Agreement.

10. Thorough Understanding of Agreement. I have read all of this Agreement and understand it completely, and by my signature below I represent that this Agreement is the only statement made by or on behalf of the Company upon which I have relied in signing this Agreement.

IN WITNESS WHEREOF, I have caused this Confidentiality, Proprietary Information and Inventions Agreement to be signed on the date written below.

DATED: 8/14/2017 Signed: DocuSigned by: Ralf Brandt 0A74FCAAD7724B2...

CANCER GENETICS®
Empowering Personalized Cancer Treatment

May 14, 2018

Michael McCartney
2012 Park Falls Drive
Raleigh, NC 27614
919-720-3505

mmccartney09@gmail.com

RE: Employment with Cancer Genetics, Inc.

Dear Michael,

On behalf of Cancer Genetics, Inc. ("CGI or the Company"), I would like to take the opportunity to offer you the position of Chief Commercial Officer, a full-time salaried position, effective June 11, 2018, reporting to Jay Roberts, CEO. Your employment will be under the following terms:

Salary - $9,615.39 bi-weekly (26 Pay periods per year), or $250,000.00 annualized.

Bonus - You will have the opportunity to earn additional compensation based on our bonus program with an annual target of up to 50% of your annual base pay to be paid annually. The bonus will be paid out based on the condition that the agreed upon sales goals are met at the end of the calendar year.

Equity Compensation – The Company will award you Restricted Stock Options which will begin vesting after one year of Board Approval and vest in equal monthly increments over 48 months. You will receive 100,000 in Stock Options which is commensurate with your position within the company, and subject to formal approval by the Board of Directors. You will receive another 100,000 in Stock Options if you meet your sales goals within six months of service.

Benefits - Eligibility for participation in health, dental, vision, life insurance, and disabilities coverage, as well as participation in the company 401(K) retirement plan, is the first of the month following your date of hire.

PTO and Company Holidays - You will be eligible to accrue Paid Time Off (PTO) equivalent of 18 days for full calendar year. Additional information may be found in the PTO Policy, which you will receive during your boarding process.

Cancer Genetics provides 6 Company-paid holidays and 1 Floating Holiday per quarter in 2018.

Separation Pay - In the event that your employment with the Company is terminated at the Company's option, you will be entitled to three month's separation pay based on your annual base pay, not inclusive of any bonus payout; less all applicable and customary taxes, withholdings and other normal payroll deductions. The separation amount will be paid out to you in exchange for a signed Separation Agreement. For purposes of clarification, a termination at the Company's option, at any time, due to your failure to substantially perform the duties of the position of Chief Commercial Officer, shall not entitle you to a separation payment.

Professional Development – Cancer Genetics, Inc. is dedicated to our core values of knowledge and innovation and towards building a Company that is aware and utilizes industry best practices. To ensure the Company's industry position we are committed to the professional development of our colleagues and executive management. You will be expected to monitor, measure, and manage industry best practices through professional associations and industry conferences and apply key best-practices to the CGI business and to your team's knowledge base and processes.

201 Route 17 North, 2nd Floor, Rutherford, NJ 07070
www.cancergenetics.com

CANCER GENETICS®
Empowering Personalized Cancer Treatment

Your employment with the Company is at-will and neither this letter nor any other oral or written representations may be considered a contract of employment for any specific period of time. We recognize that you retain the option, as does the Company, to end the employment relationship at any time for any lawful reason or no reason, with or without notice. Your status as an at-will employee cannot be changed or modified except in a written agreement signed by you and the Company's CEO.

Your employment is contingent upon a positive background review and employment history screening typical for a position at CGI. Upon your acceptance of this offer, you will be provided with the Company's Employment Manual and the Code of Business Conduct and Ethics. Your employment is also contingent upon the return of your signed acknowledgement of receipt of these documents, and agreement to the terms in both of these documents which are incorporated by reference herein.

On your first day, you will be completing employment forms, **please bring appropriate documentation for the completion of your new hire forms, including proof that you are presently eligible to work in the United States for I-9 purposes**.

I am genuinely excited about you joining our team, and expect that Cancer Genetics will be greatly strengthened as a result of your contributions. If you have any questions about this offer letter, please feel free to contact me.

If the above terms and statements meet with your approval, please sign this letter in the spaces provided below to reflect your acceptance.

Sincerely,

John A. Roberts
Chief Executive Officer

Offer Acceptance:

I have read this offer of employment, understand it, and accept the offer on these terms. I understand that my employment is contingent upon receiving acceptable verification of required pre-employment screening, in addition to the requirements listed above. This offer of employment expires on May 18, 2018.

5/15/18

Michael McCartney

201 Route 17 North, 2nd Floor, Rutherford, NJ 07070
www.cancergenetics.com

CANCER GENETICS

Empowering Personalized Cancer Treatment

December 14, 2018

William Finger
827 Carpenter Fletcher Road
Durham, NC 27713

RE: Employment Offer Letter

Dear Bill,

On behalf of Cancer Genetics, Inc. ("CGI or the Company"), I would like to take the opportunity to offer you the full-time position of Executive Vice President, Precision Medicine and Pharma Services effective January 2, 2018, reporting to Jay Roberts, CEO. Your employment offer will be under the following terms:

Salary - $9,615.38 bi-weekly (26 Pay periods per year), or $250,000 annualized.

Bonus - You will have the opportunity to earn additional compensation based on our bonus program with an annual target of up to 25% of your annual base. The bonus will be paid out based on the condition that the agreed upon performance goals are met.

Equity Compensation – The Company will award you Restricted Stock Options which will begin vesting after one year of Board Approval and vest in equal monthly increments over 48 months. You will receive 75,000 in Stock Options, and subject to formal approval by the Board of Directors.

Benefits - Eligibility for participation in health, dental, vision, life insurance, and disabilities coverage, as well as participation in the company 401(K) retirement plan, is the first of the month following your date of hire.

PTO and Company Holidays - You will be eligible to receive Paid Time Off (PTO) equivalent of 18 days for full calendar year. Additional information may be found in the PTO Policy, which you will receive during your boarding process.

Cancer Genetics provides 6 Company-paid holidays and 1 Floating Holiday per quarter in 2018.

Professional Development – Cancer Genetics, Inc. is dedicated to our core values of knowledge and innovation and towards building a Company that is aware and utilizes industry best practices. To ensure the Company's industry position we are committed to the professional development of our colleagues and executive management. You will be expected to monitor, measure, and manage industry best practices through professional associations and industry conferences and apply key best-practices to the CGI business and to your team's knowledge base and processes.

Your employment with the Company is at-will and neither this letter nor any other oral or written representations may be considered a contract of employment for any specific period of time. We recognize that you retain the option, as does the Company, to end the employment relationship at any time for any lawful reason or no reason, with or without notice. Your status as an at-will employee cannot be changed or modified except in a written agreement signed by you and the Company's CEO.

201 Route 17 North, 2nd Floor, Rutherford, NJ 07070
www.cancergenetics.com

CANCER GENETICS

Empowering Personal and Cancer Treatment

Your employment is contingent upon a positive background review and employment history screening typical for a position at CGI. Upon your acceptance of this offer, you will be provided with the Company's Employment Manual and the Code of Business Conduct and Ethics. Your employment is also contingent upon the return of your signed acknowledgement of receipt of these documents, and agreement to the terms in both of these documents which are incorporated by reference herein.

On your first day, you will be completing employment forms, **please bring appropriate documentation for the completion of your new hire forms, including proof that you are presently eligible to work in the United States for I-9 purposes.**

I am genuinely excited about you joining our team, and expect that Cancer Genetics will be greatly strengthened as a result of your contributions. If you have any questions about this offer letter, please feel free to contact me.

If the above terms and statements meet with your approval, please sign this letter in the spaces provided below to reflect your acceptance.

Sincerely,

John A. Roberts
Chief Executive Officer

Offer Acceptance:

I have read this offer of employment, understand it, and accept the offer on these terms. I understand that my employment is contingent upon receiving acceptable verification of required pre-employment screening, in addition to the requirements listed above. This offer of employment expires on December 21, 2018.

William Finger 12/14/18

William Finger

201 Route 17 North, 2nd Floor, Rutherford, NJ 07070
www.cancergenetics.com

Exhibit 21.1

Subsidiaries of Cancer Genetics, Inc.

Name	State or Country of Incorporation or Organization
Gentris, LLC	Delaware
Gentris Hong Kong Limited	China
Gentris Shanghai Pharma Science & Technology Co. Ltd	China
PMFO, LLC	New Jersey
Wogolos, Ltd.	Israel
vivoPharm Pty, Ltd.	Australia
RDDT Pty, Ltd.	Australia
vivoPharm Europe, Ltd.	Germany
vivoPharm, LLC	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-191520, 333-191521, 333-196198, 333-205903 and 333-214599) and on Form S-3 (Nos. 333-196374 and 333-218229) and on Form S-1 (No. 333-215284) of Cancer Genetics, Inc. of our report dated April 15, 2019, relating to the consolidated financial statements of Cancer Genetics, Inc. and Subsidiaries appearing in the Annual Report on Form 10-K of Cancer Genetics, Inc. for the year ended December 31, 2018.

/s/ RSM US LLP

New York, New York
April 15, 2019

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John A. Roberts certify that:

1. I have reviewed this annual report on Form 10-K of Cancer Genetics, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: April 15, 2019

/s/ John A. Roberts

John A. Roberts

President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, M. Glenn Miles certify that:

1. I have reviewed this annual report on Form 10-K of Cancer Genetics, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: April 15, 2019

/s/ M. Glenn Miles

M. Glenn Miles
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Cancer Genetics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John A. Roberts, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 15, 2019

/s/ John A. Roberts

John A. Roberts

President and Chief Executive Officer
(*Principal Executive Officer)*

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Cancer Genetics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, M. Glenn Miles, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 15, 2019

/s/ M. Glenn Miles

M. Glenn Miles

Chief Financial Officer
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.