CANCER GENETICS, INC
Form 10-K
March 10, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)
ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2015
Or
.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission file number 001-35817

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

Delaware	04-3462475
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
201 Route 17 North 2nd Floor Rutherford, NJ 07070 (201) 528-9200 (Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)	

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

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

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

Indicate by check if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No ý
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes: ¨ No: ý
Indicate by check mark if the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was

required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes: ý No: ¨

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

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

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	ý
Non-accelerated filer	¨ (do not check if a smaller reporting company)	Smaller reporting company	¨

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $91 million on June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, based on the closing price of $11.76 on that date.

Indicate the number of shares outstanding of each of the registrant's classes of common equity, as of March 1, 2016:

Class	Number of Shares
Common Stock, $.0001 par value	13,652,274

Documents incorporated by reference

Portions of the registrant's proxy statement for the 2016 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year ended December 31, 2015, are incorporated by reference in Part III of this Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “bel “estimates,” “projects,” “predicts,” “potential,” or the negative of those terms, and similar expressions and comparable terminology intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties including those set forth below 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 diagnostic tests and services for cancer patients;
- our ability to raise additional capital to meet our liquidity needs;
- our ability to clinically validate our pipeline of genomic microarray tests currently in development;
- our ability to execute on our marketing and sales strategy for our genomic tests and gain acceptance of our tests in the market;
- our ability to keep pace with rapidly advancing market and scientific developments;
- 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 obtain reimbursement from governmental and other third-party payors for our tests and services;
- competition from clinical laboratory services companies, diagnostic tests currently available or new tests that may emerge;
- our ability to maintain our clinical collaborations and enter into new collaboration agreements with highly regarded organizations in the cancer field so that, among other things, we have access to thought leaders in the field and to a robust number of samples to validate our genomic tests;
- our ability to maintain our present customer base and obtain new customers;
- potential product liability or intellectual property infringement claims;
- our dependency on third-party manufacturers to supply or manufacture our products;
- our ability to attract and retain a sufficient number of scientists, clinicians, sales personnel and other key personnel with extensive experience in 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 in emerging markets, such as India and Brazil; and
- our ability to adequately support future growth.

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PART I

Item 1. Business.

Overview

We are an emerging leader in the field of personalized medicine, enabling precision medicine in the field of oncology through our diagnostic products and services and molecular markers. We develop, commercialize and provide molecular- and biomarker-based tests and services that enable physicians to personalize the clinical management of each individual patient by providing genomic information to better diagnose, monitor and inform cancer treatment and that enable biopharmaceutical 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. We have a comprehensive, disease-focused oncology testing portfolio. Our tests and techniques target a wide range of cancers, covering eight of the top ten cancers in prevalence in the United States, with additional unique capabilities offered by our Tissue of Origin® test for identifying difficult to diagnose tumor types or poorly differentiated metastatic disease.

Our vision is to become the oncology diagnostics partner for biopharmaceutical companies and clinicians by participating in the entire care continuum from bench to bedside. We believe the diagnostics industry is undergoing a rapid evolution in its approach to oncology testing, embracing precision medicine and individualized testing as a means to drive higher standards of patient treatment and disease management. Similarly, biopharmaceutical companies are increasingly engaging companies such as ours to provide information on clinical trial participants' molecular profiles in order to identify biomarker and genomic variations that may be responsible for differing responses to pharmaceuticals, and particularly to oncology drugs, thereby increasing the efficiency of trials while lowering related costs. We believe tailored therapeutics can revolutionize oncology medicine through molecular- and biomarker-based testing services, enabling physicians and researchers to target the factors that make each patient and disease unique. We have created a unique position in the industry by providing targeted somatic analysis of tumor sample cells alongside germline analysis of an individual's non-cancerous cells' molecular profile as we attempt to reach the next milestone in personalized medicine. Individuals are born with germline mutations, and somatic mutations arise in tissues over the course of a lifetime.

Cancer is genetically-driven and constitutes a heterogeneous class of diseases characterized by uncontrollable cell growth. Many cancers are becoming increasingly understood at a molecular level and it is possible to attribute specific cancers to identifiable genetic changes in unhealthy cells. Cancer cells contain modified genetic material compared to normal human cells. Common genetic abnormalities correlated to cancer include gains or losses of genetic material on specific chromosomal regions (loci) or changes in specific genes (mutations) that ultimately result in detrimental cellular changes followed by cancerous or pre-cancerous conditions. Understanding the differences in these molecular changes helps 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 level is not only useful for diagnostic purposes, but we also believe it can play an important role in prognosis and disease management. We believe technology that can apply predictive information has the potential to dramatically improve treatment outcomes for patients living with cancer. Our molecular- and biomarker-based tests for cancer aim to remove subjectivity from the diagnostic phase, and add prognostic information, thus enabling personalized treatments based on cancer analysis at its most basic level.

Our business is based on demand for molecular- and biomarker-based diagnostic services from three main sectors, including cancer centers and hospitals, biotechnology and biopharmaceutical companies, and the research community. Clinicians and oncologists in cancer centers and hospitals seek testing since these methods often produce higher value and more accurate cancer diagnostic information than traditional analytical methods. Our proprietary and disease-focused tests aim to provide actionable information that can guide patient management decisions, potentially

resulting in decreased costs for care providers and patients while streamlining therapy selection. Our services are also sought by biotechnology and biopharmaceutical companies engaged in designing and running clinical trials to determine the value and efficacy of oncology treatments and therapeutics. 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 may increase trial efficiency, subject safety and trial success rates. Our services are also sought by researchers and research groups seeking to identify biomarkers and develop methods for diagnostic technologies and tests for disease. We aggressively pursue the strategy of trying to demonstrate increased value and efficacy with payors who are trying to contain costs and academic collaborators seeking to develop new insights and cures.

Our market strategy is organized to align with the three aforementioned industry segments. We utilize relatively the same technologies across each of these businesses to deliver results-oriented information which we believe is or will become important to cancer treatment and patient management. Our tests address the limitations of traditional cancer diagnostic approaches, including reliance on human inspection of specimens and interpretation of clinical measurements, and inter-

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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. 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
Clinical Services	• Hospitals • Cancer Centers • Clinics	Clinical services provide information on diagnosis, prognosis and predicting treatment outcomes (theranosis) of cancers to guide patient management.
Biopharma Services	• Biopharma and Biotech companies performing clinical trials	Biopharma services provide companies with customized solutions for patient stratification and treatment selection through an extensive suite of molecular- and biomarker-based testing services, customized assay development and trial design consultation.
Discovery Services	• Biopharma and Biotech companies • Researchers and Academic Institutions	Discovery services provide the tools and testing methods for companies and researchers seeking to identify new molecular-based biomarkers for disease.

In 2015, we generated approximately 64% of our revenue from Biopharma Services, approximately 31% from Clinical Services and approximately 5% from Discovery Services. In 2014, we generated approximately 43% of our revenue from Clinical Services, approximately 55% from Biopharma Services and approximately 2% from Discovery Services, a new line of service launched in 2014.

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 CLIA-certified and CAP-accredited laboratories in Rutherford, NJ, Los Angeles, CA, and Raleigh, NC, as well as our laboratories in Hyderabad, India and Shanghai, China.

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 2012, the World Health Organization attributed 8.2 million deaths worldwide to cancer-related causes. In 2014, the World Health Organization projected that over the next two decades this number will rise to 13 million deaths per year. 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 incidence and deaths caused by the major cancer categories are staggering. The following table published by The American Cancer Society shows estimated new cases and deaths in 2015 in the United States for the major cancers:

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Cancer Type	Estimated New Cases For 2015	Estimated Deaths For 2015
Breast.....	234,190	40,290
Cervical.....	12,900	4,100
Colorectal.....	132,700	59,700
Endometrial.....	54,870	10,170
Kidney.....	61,560	14,080
Leukemia.....	54,270	24,450
Lung.....	221,200	158,040
Melanoma.....	73,870	9,940
Multiple Myeloma.....	26,850	11,240
Non-Hodgkin's Lymphomas.....	71,850	19,790
Ovarian.....	21,290	14,180
Pancreatic.....	48,960	40,560
Prostate.....	220,800	27,540

United States Clinical Trials Market Overview

The United States is currently the world leader in biopharmaceutical research and development and manufacturing. In 2013 it is estimated that over $50 billion dollars was spent in pharmaceutical research and development, increasing 20% from spending in 2005. The average cost to develop a drug can be as high as $1.2 billion and the approval process from development to market may be as long as 15 years. Since 1980, approximately 83% of life expectancy increases in cancer patients are due to new treatments and oncology medications.

While oncology drugs have the potential to be among the most personalized therapeutics, oncology clinical trials continue to have some of the poorest approval rates. The application of pharmacogenomics to oncology clinical trials enables researchers to better predict differences in drug response, efficacy and toxicity among trial participants, as well as to optimize treatment regimens based on these differences. According to IMS Health, it is estimated that by 2020, half of all pharmaceutical sales in the United States will be from specialty drugs, a category of drugs including oncology treatments tailored to patients’ genomic profiles. A study by Grand Market Research places the oncology market at 34% of revenue for molecular diagnostics services in 2013, with the pharmacogenomics market following closely at 26.3%. Pharmacogenomics is the study of genetic analysis based on a patient's response to a particular therapy or drug. We believe a growing demand for personalized medicine as a diagnostic tool is a growth driver of this market.

India Clinical Oncology and Biopharma Market Overview

India has a growing market for molecular diagnostics and oncology services. According to a 2010 study published in the Asian Pacific Journal of Cancer Prevention, each year, approximately 1 million new cases of cancer are diagnosed in India. In those cancer types for which we provide diagnostic and prognostic proprietary tests and services, incidences are also predicted to rise steadily over the next decade even while the population is expected to experience a decrease in population growth rate. Gynecological cancers account for approximately 30% of the total cancer incidence among women in India. Furthermore, over 80% of cancers in India are first detected in advanced or terminal stages, indicating an important opportunity in this market for DNA-based oncology diagnostic tools that can provide early-stage information to guide treatment resulting in greater survival rates.

It is estimated by the India Brand Equity Foundation that the Indian biopharma and biotech markets are expected to experience over a 20% increase in compound annual growth rate by 2017 due to favorable business conditions and increasing government expenditures in these sectors. The biopharmaceutical services segment accounted for the

largest share of sector growth in 2013 and 2014, accounting for approximately 64% of total revenues, and experienced the highest growth rate in this period, with an approximately 17% compound annual growth rate. Over the next decade, growth in this industry is anticipated to come largely from India's strong position in biosimilars and molecular diagnostics, as well as from personalized medicine. The Indian government has been increasing spending on the biotech and biopharma sectors through 5-year budget allocation plans aimed at research and development as well as health care.

In the fourth quarter of 2015 we entered into an agreement with a hospital network in India to validate FHACT® in the Indian

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rural population, enabling our proprietary test to be used as an accurate screening tool for cervical cancer and HPV-associated cancer risk in the Indian population. In the first quarter of 2014 we launched FHACT® in collaboration with Kamineni Hospitals in Hyderabad, India for the detection and management of cervical cancer. This was the first broad-scale adoption of FHACT® in India. The launch culminates a collaboration that was begun in July 2013 to assess the value and clinical utility of FHACT® in India.

China Clinical Oncology and Biopharma Market Overview

Cancer is one of the leading public health problems in both urban and rural China. The disease is among the leading causes of death in the Chinese population, 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. The Chinese biopharma 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 biopharma 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 13thfive-year plan. Our Shanghai laboratory performs clinical trials services for biopharma companies in China, where governmental regulations prevent human samples from being exported from the country.

Our Strategy

Our strategy is to serve a diverse group of market participants - biotechnology and pharmaceutical companies, cancer centers and community hospitals, and research centers both public and private - that all require biomarker-based assessment of cancer and biomarker-based information to understand and manage the patient, their cancer and customized therapy choices. We believe that our integrated approach to testing combined with our ability to rapidly translate research insights about the genetics and molecular mechanisms of cancer into the clinical setting will improve patient treatment 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 genomic 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 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, we intend to:

- Leverage our specialized, disease-focused genomic knowledge, insights and proprietary portfolio to secure additional collaborations or partnerships with leading biopharmaceutical companies and clinical research organizations. Oncology drugs have the potential to be among the most personalized of therapeutics, and yet oncology trials have one of the worst approval success rates. In an effort to improve the outcome of these trials, and more rapidly advance targeted therapeutics, the biotechnology and pharmaceutical community is increasingly looking to companies like us that have both proprietary disease insights and comprehensive testing services as they move toward biomarker-based therapeutics. We believe our comprehensive, disease-focused testing portfolio, which covers 8 of the 10 most prevalent solid and hematological cancers positions us to help the biopharmaceutical community with clinical trials and companion diagnostic development in areas of our core expertise.

- Leverage our expanded clinical sales force and our relationship with ICON to expand our customer base. Through our acquisition of Response Genetics in the fourth quarter of 2015, we increased the size of our sales force and our geographic presence, particularly in the Western and Southeastern United States. We believe that our joint clinical sales force is among the largest oncology-focused clinical sales groups in the molecular diagnostics field. Leveraging our expanded clinical sales group, we plan to continue to focus on partnering with community hospitals, where according to the National Cancer Database approximately 85% of cancer patients in the United States are initially diagnosed, by targeting our sales and marketing efforts on this important customer segment though our branded Expand Dx™ program. Furthermore in mid-2015, we entered into a strategic alliance with the laboratory services group

of ICON plc, a global CRO, which we plan to leverage to expand our biopharma customer base.

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

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- 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. We also continue to seek to identify cost efficiencies as we integrate our operations with those of Gentris and Response Genetics.

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

Our Service Offerings

Our business is based on demand for molecular- and biomarker-based characterization of cancers from three main sectors: cancer centers and hospitals, biotechnology and biopharmaceutical companies, and the research community. Clinicians and oncologists in cancer centers and hospitals seek molecular-based testing since these methods often produce higher value and more accurate cancer diagnostic information than traditional analytical methods. Our proprietary and disease-focused tests aim to provide actionable information that can guide patient management decisions, potentially resulting in decreased costs for care providers and patients while streamlining therapy selection. Our services are also sought by biotechnology and biopharmaceutical companies engaged in designing and running clinical trials for their value and efficacy in oncology treatments and therapeutics. We believe trial participants' likelihood of experiencing either favorable or adverse responses to the trial treatment can be determined by biomarker testing, increasing trial efficiency, participant safety and trial success rates. 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. We aggressively pursue the strategy of trying to demonstrate increased value and efficacy with payors who are trying to contain costs and academic collaborators seeking to develop new insights and cures.

Our market strategy is organized to align with the three aforementioned industry segments. We utilize relatively the same proprietary tests, non-proprietary test and technologies across each of these businesses to deliver results-oriented information important to cancer treatment and patient management.

Clinical Services

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. Our proprietary tests target cancers that are difficult to prognose and predict treatment outcomes through currently available mainstream techniques. We utilize an expansive range of non-proprietary test and technologies to provide a comprehensive profile for each patient we serve. Clinical testing is available through anatomic pathology, flow cytometry, karotype, FISH and molecular diagnostics (including next generation sequencing and gene expression panels).

Our comprehensive oncology-focused testing services for cancer are utilized in the diagnosis, prognosis and prediction of treatment outcomes (theranosis) of cancer patients and are growing rapidly as clinicians demand more precise and more comprehensive diagnostic 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 32% of individuals holding advanced degrees. These individuals assist our customers in integrating and technically assessing the testing results for their patients.

We believe that our proprietary tests provide superior diagnostic and prognostic values than other currently available tests and services. For example, prior to the introduction of MatBA®, the assessment of the gain or loss on only four chromosomal regions and potentially one gene mutation was available to clinicians when testing for and stratifying a CLL patient. MatBA® improves on this by identifying information on five additional chromosomal regions, providing more valuable diagnostic data and critical information about the risk of progression and overall prognosis of the patient. For particular cases, patient results indicating a “favorable outcome” that would have been reported to the clinician was determined by MatBA® to be inaccurate, leading to a change in the prognosis and consequently decision-making by the clinician regarding the management of these 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.

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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/SLL, DLBCL, MCL, MDS, myeloproliferative neoplasms (MPN), colorectal, lung and breast cancers.

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

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

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

Biopharma Services

Biopharma services include laboratory and testing services performed for biopharmaceutical companies engaged in clinical trials. Our biopharma services focus on providing pharmaceutical companies with oncology specific and non-oncology genetic testing services for phase I-III trials along with ancillary services including biorepository and trials logistics, design and customized assay development support. These services include DNA and RNA extraction and purification, genotyping, gene expression and biomarker analyses, custom assay design and biorepository sample storage solutions. We also seek to apply our expertise in LDTs to assist in developing and commercializing drug-specific companion diagnostics.

Industry research has shown many promising drugs have produced disappointing results in clinical trials. For example, a study by Princess Margaret Hospital in Toronto estimated that 85% of the phase III trials testing new therapies for solid tumors studied over a five-year period failed to meet their primary endpoint. Given such a high failure rate of oncology drugs, combined with constrained budgets for biopharmaceutical 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 have the potential to be among the most personalized of therapeutics, and yet oncology clinical trials continue to have some of the poorest approval rates. In an effort to improve the outcome of these trials, and more rapidly advanced targeted therapeutics, the biotechnology and pharmaceutical

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community is increasingly looking to companies that have both proprietary disease insights and comprehensive testing services as they move toward biomarker-based therapeutics.

In June 2015, the United States National Institutes of Health reported over 74,000 clinical trials were currently being conducted in the United States, and over 14,000 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 biopharmaceutical 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 biopharmaceutical companies. In 2015, 51 new drugs were approved by the FDA. This is the highest number of FDA approvals since 1950, and nearly a third 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 biopharmaceutical 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 biopharmaceutical 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 biopharmaceutical 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 biopharmaceutical 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 Gilead Sciences Inc. to provide clinical trial services and molecular profiling of CLL patients, and we performed the biomarker-based testing for Gilead’s FDA-approved Zydelig® (idelalisib) for relapsed CLL, FL and SLL. We believe our clinical trial services may allow Gilead and others to improve patient responder

selection, thereby potentially increasing the likelihood our customer's product is approved by FDA. 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 biopharmaceutical 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.

Discovery Services

Our discovery services provide the tools and testing methods for companies and researchers seeking to identify new molecular- and biomarker-based indicators for disease. Discovery services we offer include validation of biomarkers for diseases including

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cancers, from which tests for diagnosis or prognosis may be established. We also provide consulting, guidance and preparation of samples and clinical trial design. We believe the ability to analyze variations in biomarkers and interpret these changes into meaningful predictors of disease or indicators of diagnosis is essential to discovering new molecular markers for cancer and targets for therapies.

Our Disease-Focused Testing Portfolio

Our disease-focused testing portfolio includes our portfolio of proprietary tests, along with a comprehensive range of non-proprietary oncology-focused tests and laboratory services. We have a comprehensive oncology testing portfolio, spanning eight of the ten most prevalent solid and hematological cancers, including the FDA-cleared test for tumors of unknown origin, our 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 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, and 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.

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.

Mature B-cell Neoplasm Array - MatBA®

MatBA® is the first targeted oligonucleotide-based microarray we developed for the analysis of genomic alterations to determine prognosis and theranosis in mature B-cell neoplasms. MatBA® incorporates a common architecture of specific genomic regions that can be applied across the seven major mature B-cell neoplasms. We currently offer the following applications of MatBA®: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL), Diffuse Large B-Cell Lymphoma (DLBCL), Mantle Cell Lymphoma (MCL) and Follicular Lymphoma (FL).

MatBA® is designed to detect genomic copy number changes in mature B-cell neoplasms either solely or in a unique combination, thus assisting the clinician in the management of a patient's disease. The test relies on the comparative genomic hybridization of fluorescently differentially-labeled normal DNA and DNA extracted from the cancer specimen (array-CGH). We have optimized the utility of the MatBA® array-CGH so that it can be routinely applied to the study of a range of specimen types including blood and bone marrow and FFPE biopsy specimens, which are often the only specimen available for analysis of FL, DLBCL and MCL. MatBA® was custom-designed to represent 80 regions of the human genome which have diagnostic and/or prognostic value in one or more of the mature B-cell neoplasm subtypes as identified through our research and analysis efforts. Unlike other technologies such as FISH, array-CGH using MatBA® simultaneously permits the detection of genomic gains and losses at multiple locations on a chromosome (loci) that characterize the mature B-cell neoplasm subtypes. MatBA® is designed to improve prognostication by determining each patient's unique genetic profile, allowing doctors to more accurately select the best treatment options.

Focus::NGS™

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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 and which may be missed by other, less sensitive methodologies. We currently offer Focus::CLL™ and Focus::Myeloid™ in the United States for the characterization of hematological cancers.

Our proprietary Focus::CLL™ panel is the only test that assesses 7 genes in a single test, providing clinically relevant data for prognosis, disease management and treatment selection. The panel is available both for routine clinical patient diagnosis and management, as well as for patient stratification in clinical trials for CLL or SLL. CLL is often a slow-moving cancer, and many patients can survive for years after a diagnosis; however, chronic leukemias are difficult to treat and some forms of CLL grow faster, requiring that the patient undergo treatment fairly immediately. The American Cancer Society predicts that in 2016 there will be nearly 19,000 new cases of CLL and approximately 4,600 deaths, mostly among individuals over 40 years of age.

Our proprietary Focus::Myeloid™ panel is designed to target 54 genes, and we believe it will provide important prognostic information for myelodysplastic syndromes (MDS) and acute myeloid leukemia (AML), as well as diagnostic and prognostic information for myeloproliferative neoplasms (MPN). MDS are a group of bone marrow disorders in which the bone marrow does not produce enough healthy blood cells. Approximately 30% of patients diagnosed with MDS will progress to AML, which is a cancer of the myeloid line of blood cells characterized by rapid growth of abnormal white blood cells which interferes with the normal production of other blood cells. MPNs consist of a group of diseases where there is an overproduction of different types of blood cells. The form of MPN is defined by the type of cell that is overproduced. MPNs also have a high possibility of progressing to AML depending on the mutations responsible for the MPN. AML is the most common acute leukemia in adults and its incidence increases with age. AML is expected to account for approximately 20,800 new leukemia cases in 2015, and its prevalence is expected to increase as the population ages.

Solid Tissue Cancers

Tissue of Origin® (TOO®)

Through our acquisition of substantially all the assets of Response Genetics, Inc. in the fourth quarter of 2015, we acquired the FDA-cleared and Medicare-approved Tissue of Origin® (TOO®) test. 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. 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. TOO® assesses 2,000 genes, covering 15 of the most common tumor types and 90% of all solid tumors. These tumors include thyroid, breast, non-small cell lung, pancreas, gastric, colorectal, liver, bladder, kidney, non-Hodgkin’s lymphoma, melanoma, ovarian, sarcoma, testicular germ cell and prostate. TOO® is FDA-cleared, Medicare-approved, and provides extensive analytical and clinical validation for statistically significant improvement in accuracy over other methods. Our TOO® test increases diagnostic accuracy and confidence in site-specific treatment decisions. Our TOO® test leads to a change in patient treatment based on results 65% of the time it is used.

Other

Through our acquisition of substantially all the assets of Response Genetics, Inc. in the fourth quarter of 2015, we also acquired a clinically actionable and validated portfolio of tests for solid tumors. The tests include a variety of methodologies--from IHC and FISH to gene-expression, microarrays as well as next-generation sequencing (NGS). This portfolio includes proprietary tests for non-small cell lung cancer, colorectal cancer, gastric and gastroesophageal

cancer, melanoma, thyroid cancer, breast cancer and glioma.

HPV-Associated Cancers

FHACT® HPV-Associated Cancer Test

We have developed a 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. We have obtained CE marking for FHACT®, which allows us to market the test in the European Economic Area (which includes the 27 Member States of the EU plus Norway, Liechtenstein and Iceland). We anticipate that we will need to conduct additional developmental activities for this test and to submit it for regulatory clearance or approval by FDA or other

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regulatory agencies prior to commercialization outside of our reference laboratories in each of the markets where we plan to introduce it.

We currently offer an application of FHACT® as an LDT for cervical cancer. 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.

FHACT® is designed to determine copy number changes of four particular genomic regions by 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.

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 both the United States and India. 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 biomarker discovery studies.
India	Clinical Sales	- Develop relationships with oncologists, corporate hospitals and reference labs, as well as with physicians in local clinics. - Engage the population of oncology patients in India, where a majority of oncology drugs are paid for out-of-pocket.
	Biopharma & Discovery Sales	- Work with academic and research institutions for validation of our tests in the Indian population. - Collaborate with scientific development teams at biopharma companies and government agencies on studies involving tests and services.
China	Biopharma Sales	- Leverage US-based companies conducting clinical trials with a component of those trials occurring in China.

Our sales force professionals have backgrounds in hematology, pathology, and laboratory services, and many years of experience in clinical oncology sales, esoteric laboratory sales from leading biopharmaceutical, pharmaceutical or specialty reference laboratory companies. We currently have a team of 12 sales professionals in the United States and 6 in India. We support our sales force with clinical specialists who bring deep domain knowledge in the design and use of our tests and services.

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

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

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Our Laboratory Facilities

Rutherford, New Jersey, United States

Our Rutherford location is a 17,900 square foot facility and also serves as our corporate headquarters. We offer our clinical services, biopharma services and discovery services out of our Rutherford location. This location has been accredited by the College of American Pathologists, or CAP, which is an approved accreditation entity under CLIA, to perform high complexity testing. CLIA certification and accreditation are required before any laboratory may perform clinical testing on human samples for the purpose of diagnosis, prevention, treatment of disease or assessment of health.

Our Rutherford location is licensed by the appropriate state departments of health and able to receive and test patient samples from all 50 states, as well as from oversees locations. Additionally, our Rutherford laboratory is self-certified under the US-EU and US-Swiss Safe Harbor Frameworks governing use of personal information received on patients or clinical trial participants from the European Union. Our Rutherford laboratory also holds the requisite licenses from the New Jersey State Department of Health to operate and perform clinical testing on patient samples. In addition, certain states, such as New York, require out-of-state laboratories to obtain licenses in order to accept patient specimens from such states. Our Rutherford location holds clinical laboratory licenses from the New York Department of Health, Florida Department of Health, Maryland Department of Health, Pennsylvania Department of Health, and California Department of Health for all of our clinical departments.

Los Angeles, California, United States

Our Los Angeles location is an approximately 27,000 square foot facility. We offer clinical services and biopharma services out of our Los Angeles location. We provide proprietary tests and panels for lung, colon, gastric, and melanoma cancers, as well as our FDA-cleared Tissue of Origin® Test, or TOO®, from our Los Angeles location. This location is CLIA-certified, GLP-compliant and CAP accredited. Our Los Angeles laboratory also holds the requisite licenses from the California State Department of Health to operate and perform clinical testing on patient samples. Our Los Angeles location holds clinical laboratory licenses from the New York Department of Health, Florida Department of Health, Maryland Department of Health, Pennsylvania Department of Health, and Rhode Island Department of Health for all of our clinical departments.

Morrisville, North Carolina, United States

We offer our biopharma services, including biopharmaceutical trials testing services, pharmacogenomics testing, and sample storage and biorepository services from our 25,000 square foot facility located in Research Triangle Park, Morrisville, North Carolina. Our facility in Morrisville is CLIA-certified and subject to Good Laboratory Practices ("GLP") requirements, and has received accreditation by CAP for its industry-leading biorepository capabilities. We do not believe that our Morrisville laboratory requires individual state licensure since it is not performing clinical testing on patient samples and is only involved in clinical trials testing. Our Morrisville laboratory is also self-certified under US-European and US-Swiss Safe Harbor frameworks.

Hyderabad, India and Shanghai, China

We also have two laboratories operating outside of the United States: one in Hyderabad, India and one in Shanghai, China. Our 10,000 square foot Hyderabad facility services government entities, academic institutions, and health and cancer centers. It is a Department of Scientific and Industrial Research ("DSIR") recognized laboratory and is ISO9001-2008 and National Accreditation Board for Testing and Calibration Laboratories ("NABL") certified. Our

2,700 square foot Shanghai facility is both CLIA-certified and subject to GLPs, and provides biopharma services to companies performing clinical trials in China.

Research and Development Expenses

We incurred research and development expenses of $5.5 million, which represented 30% of our net revenue, for the year ended December 31, 2015; $4.6 million, which represented 45% of our net revenue for the year ended December 31, 2014; and $2.2 million, which represented 33% of our net revenue, for the year ended December 31, 2013. Research and development expenses represented 22% of our total operating expenses for the year ended December 31, 2015, 22% of our total operating expenses for the year ended December 31, 2014, and 22% of our total operating expenses for the year ended December 31, 2013. Major components of the research and development expenses included direct personnel costs, laboratory equipment and consumables and overhead expenses.

Research and Development Collaborations

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

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

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 MatBA®-CLL and search for additional DNA-based biomarkers of CLL
Memorial Sloan-Kettering Cancer Center, New York	Dr. Julie Teruya-Feldstein	Clinical validation of MatBA®
	Dr. Raju S.K. Chaganti	Validation of a CGH microarray-based assay
	Dr. Jonathan Coleman	Evaluation of FISH-based CGH-array tests
	Dr. Jeremy Durack	Evaluation of FISH-based and CHG-array tests
National Cancer Institute, Maryland	Dr. Nicolas Wentzensen	Evaluation of FISH-based tests
Kamineni Hospital, Hyderabad, India	Dr. Annie Hassan	Evaluation of FHACT®
University of Iowa Cancer Center, Iowa	Dr. Sergei Syrbu	Evaluation methods to improve the diagnosis, prognosis and management of DLBCL
Columbia University, New York	Dr. Azra Raza Dr. Siddhartha Mukherjee	Identification of genomic biomarkers
Beth Israel Deaconess Medical Center, New York	Dr. Rajan Dewar	Analysis of genomic biomarkers
Keck Medicine of University of Southern California, California	Dr. Imran Siddiqi	Identification and evaluation of genomic biomarkers
University of Southern California, California, & HTG Molecular, Arizona	Dr. Pamela Ward	MicroRNA whole transcription assay validation
University of Southern California, California, & HTG Molecular, Arizona	Dr. Heinz-Josef Lenz and Dr. Yu Sunakawa	Gene expression analysis for immuno-oncology panel
Groupe Hospitalier Pitié Salpétriere, Paris		Analyze the variability of genomic alterations
Huntsman Cancer Center Institute, University of Utah, Utah		Examine and validate genomic biomarkers
Moffitt Cancer Center, Florida		Examine a number of genetic variants
University of Alabama, Alabama		Investigate biomarkers
University of Virginia School of Medicine, Virginia, & HTG Molecular, Arizona		Evaluation of genomic signatures of immuno-oncology biomarkers

Scientific and Clinical Advisory Boards

We have two advisory boards to counsel our scientific and clinical direction. Our Scientific Advisory Board is comprised of preeminent scientists and physicians from the fields of cancer biology, cancer pathology, cancer medicine and molecular genetics. We have scientists and clinicians from leading cancer centers, including Memorial Sloan-Kettering Cancer Center, Mt. Sinai and the Institute for Cancer Genetics at Columbia University. These distinguished scientists and clinicians help oversee and review the scientific innovation, integrity and clinical relevancy of our program. The board of directors appoints members to the Scientific Advisory Board. Our Clinical Advisory Board is comprised of preeminent clinicians and scientists focused on clinical implementation of our proprietary tests and services and mapping those tests and services to patient needs.

Competition

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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.

With respect to our clinical services and our biopharma services, we also face competition from companies that offer products or have conducted research to profile genes, gene expression or protein biomarkers in various cancers. In particular, Quest Diagnostics market arrays which are competitive to our MatBA®-CLL and MatBA®-SLL arrays, and both Foundation Medicine and LabCorp offer NGS based tests and panels for oncology. Personalized genetic diagnostics is a new area of science, and we cannot predict what tests others will develop that may compete with or provide results superior to the results we are able to achieve with the tests we develop. Our competitors include public companies such as: NeoGenomics, Inc., Quest Diagnostics, Abbott Laboratories, Inc., Johnson & Johnson, Roche Molecular Systems, Inc., bioTheranostics, Inc. (part of the bioMérieux S.A.), Genomic Health, Inc., LabCorp, Inc., Clarient, Inc. (acquired by GE), Myriad Genetics, Inc., Qiagen N.V., Genoptics Inc. (acquired by Novartis Pharmaceuticals), Caris Life Sciences (acquired by Miraca), Rosetta Genomics Ltd., and Foundation Medicine, Inc., and many private companies. We expect that pharmaceutical and biopharmaceutical companies will increasingly focus attention and resources on the personalized diagnostic sector as the potential and prevalence increases of molecularly targeted oncology therapies approved by FDA along with companion diagnostics. For example, FDA has recently approved two such agents- Xalkori crizotinib from Pfizer Inc. along with its companion anaplastic lymphoma kinase FISH test from Abbott Laboratories, Inc. and Zelboraf vemurafenib from Genentech USA Incorporated and Daiichi-Sankyo Inc. along with its companion B-RAF kinase V600 mutation test from Roche Molecular Systems, Inc. These two recent FDA approvals are only the second and third instances ever of simultaneous approvals of a drug and companion diagnostic, the first being the 1998 approval of Genentech, Inc.’s Herceptin trastuzumab for HER2 positive breast cancer along with the HercepTest from partner Dako A/S. Our competitors may invent and commercialize technology platforms or tests that compete with ours.

Additionally, projects related to the molecular mechanisms driving cancer development have received increased government funding, both in the United States and internationally. 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 and Manufacturers

We maintain control, validation and quality assurance over our NGS panels, DNA microarrays and probes. Our microarrays are designed in our facility by our scientists and technicians using state of the art genomic mapping and analysis software. The specifications are sent to Agilent for final manufacturing. Agilent manufactures our microarrays under strict quality control and compliance with ISO 9001 and ISO 13485 at its Santa Clara, California facility. Agilent also has another manufacturing facility in Europe that can be made available for microarray printing. Upon manufacturing our custom, proprietary microarrays, Agilent ships them back to our Rutherford facility for testing and acceptance.

The DNA component of our DNA FISH probes is produced under strict adherence to regulatory procedures in our Rutherford facility and also at a third party facility depending on demand and workflow. The DNA is shipped for final

manufacture to our partner in India. In February 2012 we entered in to an agreement with Kamineni Life Sciences to supply outsourced manufacturing for the production of our DNA FISH probes. The manufacturing operations became fully operational in India in the fourth quarter of 2012 and several batches of DNA FISH probes have been successfully manufactured. We control overall quality and process management and the final quality assurance in a manner that is CE compliant and adheres to our Quality Management System.

We also currently rely on contracted manufacturers and collaborative partners to produce materials necessary for our Tissue of Origin® test. We plan to continue to rely on these manufacturers and collaborative partners to manufacture these materials, including those materials required for use in our FDA-cleared TOO® test.

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, trademark applications, trade secrets, industry know-how, as well as various contractual arrangements, in order to protect the proprietary aspects of our technology.

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Our patent portfolio consists of 49 issued U.S. patents, several pending U.S. applications, and 175 foreign patents. We have a disease-focused portfolio of patents. Our key patents include:

- Hematological cancers. We have two U.S. patents (U.S. Patent Nos. 8,580,713 and 8,557,747), as well as patents in the EU, India and Canada 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 and foreign application 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. These patents and foreign application also cover the use of computer-assisted means to facilitate and expedite that detection process. The MatBA® microarray patents issued from the first of our family of applications in the microarray space. The term of these patents runs through 2030.

- Solid Tumors. We have 13 U.S. patents, including (U.S. Patent Nos. 7,049,059, 7,560,543, 7,732,144, 8,586,311, 8,026,062, 6,956,111, 6,905,821, 7,005,278, 6,686,155, 7,138,507, as well as numerous foreign patents, including patents in Australia, Canada, China and Japan. These patents relate to certain aspects of the gene expression technology used in our solid tumor tests. The solid tumor markers covered by these patents include thymidylate synthase (TS), dihydropyrimidine dehydrogenase (DPD), excision repair gene CC1 (ERCC1), glutathione-s transferase pi (GST-p), epidermal growth factor receptor (EGFR) and HER2/neu gene, though our patents are not directed to all aspects of expression of such markers. 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) and one EU patent. These patents 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. We also have two patent applications for methods and tools for the diagnosis of female gynecological cancers and precancers (US Patent Application No. 61/581,350) and methods and tools for the diagnosis and prognosis of urogenital cancers (US Patent Application No. 61/765,678).

- HPV-Associated Cancers. We have three U.S. patents (U.S. Patent Nos. 9,157,129, 8,865,882 and 8,883,414) and an EU patent. These patents 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 U.S. registered trademarks, including a federal registration for "CGI" as well as four U.S. trademark applications and one foreign trademark registration for certain of our proprietary tests and services. Our strategic use of distinctive trademarks has garnered increased name recognition and brand awareness for our tests and services within the industry.

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

In addition to our proprietary intellectual property, we exclusively license from University of Southern California, or USC, the use of extraction methodologies and related technologies used in our solid tumor tests, which have been patented in the United States and a number of other jurisdictions, including Australia, Austria, Belgium, Canada, China, Denmark, France, Germany,

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Hong Kong, Ireland, Israel, Italy, Luxembourg, Mexico, The Netherlands, Norway, Russia, South Korea, Spain, Sweden, Switzerland and the United Kingdom. Currently, this exclusive license includes seven United States patents claiming methods related to this technology. Our USC licensed patents are scheduled to expire between December 2019 and December 2020.

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

Operations and Production Facilities

We work with electronic medical records providers to facilitate seamless communication between our clinical laboratories and the oncologist or pathologist at the test ordering site. Currently, we have the ability to integrate with electronic medical record systems, as we have already done with MDL, an electronic medical record provider. 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, XiFin, as well as with its electronic medical records partners such as MDL. 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 HIPAA compliant manner. The reports are generated in industry standard PDF formats which allows for high definition color images to be reproduced clearly. This portal has been fully operational at our facilities since 2011.

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

Quality Assurance

We are committed to providing reliable and accurate diagnostic services to our customers. Accurate specimen identification, timely communication of diagnoses, and prompt correction of errors, is critical. We monitor and improve our performance through a variety of methods, including performance improvement indicators, proficiency testing (CAP and New York State), external audits and satisfaction surveys. All quality concerns and incidents are subject to root cause analysis and our procedures are put through annual evaluation to ensure that we are providing the

best services possible to our patients and customers. Protection of patient results from misuse and improper access is imperative and thus electronic and paper results are guarded via password- protection and identification cards.

We have established a comprehensive Quality Assurance and Management Program for our laboratories designed to drive accurate and timely test results and to ensure the consistent high quality of our testing services. The Quality Assurance and Management Program documents the quality assurance/performance improvement plans and policies and the laboratory quality assurance and quality control procedures that are necessary to ensure that we offer the highest quality of diagnostic testing services. This program is designed to satisfy all the requirements necessary for local and state licensures applicable to our business, including requirements from the New Jersey Health Department, the California Department of Health and the New York Department of Health Clinical Laboratory Evaluation Program, and accreditation for clinical diagnostic laboratories by CAP. We follow the policies and procedures for patient and employee safety, hazardous waste disposal and fire codes stated in the general laboratory procedure manual. We believe that all pertinent regulations of CLIA, Occupational Safety and Health Administration (“OSHA”), Environmental Protection Agency and FDA are satisfied by following the established guidelines

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and procedures of our Quality Assurance and Management Program.

In addition to the compulsory proficiency programs and external inspections required by CMS and other regulatory agencies, we have developed a variety of internal systems and procedures to emphasize, monitor and continuously improve the quality of our operations. We maintain internal quality controls by routinely processing specimens with known diagnoses in parallel with patient specimens. We also have an extensive, internally administered program of specimen proficiency testing, in which our laboratory staff are blinded to the results.

We participate in numerous externally administered quality surveillance programs and our laboratories are accredited by CAP. The CAP accreditation program involves both unannounced on-site inspections of our laboratories and our participation in CAP's ongoing proficiency testing program. CAP is an independent, non- governmental organization of board-certified pathologists that accredits laboratories nationwide on a voluntary basis and that has been recognized by CMS as an accreditation organization to inspect laboratories to determine adherence to the CLIA standards. Successful participation in CAP's proficiency testing program satisfies the CLIA requirement for participation in proficiency testing programs administered by an external source.

Each of our facilities maintains its own quality assurance processes, which are coordinated across sites to maintain consistency in standard operating procedures, employee training and safety manuals.

Third-Party Payor Reimbursement

Depending on the billing arrangement and applicable law, we are reimbursed for clinical services by: third-party payors that provide coverage to the patient, such as an insurance company, managed care organization or a governmental payor program; physicians or other authorized parties (such as hospitals or independent laboratories) that order testing service or otherwise refer the services to us; or the patient. For the year ended December 31, 2015, we derived approximately 12% of our total revenue from private insurance, including managed care organizations and other health care insurance providers, 10% from Medicare, and 9% from other health care facilities, including hospitals.

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

We are reimbursed for three categories of tests: (1) genetic and molecular testing; (2) anatomic pathology and IHC and (3) general immunology and flow cytometry. Reimbursement under the Medicare program for the diagnostic services that we offer is based on either the Medicare Physician Fee Schedule or Medicare Clinical Laboratory Fee Schedule (CLFS), each of which in turn is subject to geographic adjustments and is updated annually. Medical services provided to Medicare beneficiaries that require a degree of physician supervision or other involvement, such as pathology tests, are generally reimbursed under the Medicare Physician Fee Schedule, whereas clinical diagnostic laboratory tests are generally reimbursed under the Clinical Laboratory Fee Schedule. Most of the services that we provide are for genetic and molecular testing, which are reimbursed as clinical diagnostic laboratory tests.

Medicare fee schedule amounts for clinical diagnostic laboratory tests are established for each billing code, or CPT code. In addition, for its laboratory fee schedule, Medicare also sets a cap on the amount that it will pay for any individual test. This cap, usually referred to as the National Limitation Amount, is set at a percentage of the median of all the contractor fee schedule amounts for each billing code. In the past, Congress has lowered the percentage of the

median used to calculate the National Limitation Amount in order to achieve budget savings. Currently, the National Limitation Amount ceiling is set at 74% of the median for established tests and 100% of the median for certain new tests that were not previously reimbursed. In billing Medicare for clinical laboratory services, we are required to accept, as payment in full, the lowest of our actual charge, the fee schedule amount for the state or local geographical area or the National Limitation Amount. There is currently no copayment or deductible required for tests paid under the CLFS, although Congress periodically has considered implementing such a requirement.

In addition, Congress routinely lowers or eliminates the update factor that would otherwise apply to the applicable clinical laboratory fee schedule (CLFS) payment. For example, under the health care reform legislation, passed in 2010, payments under the CLFS are reduced by 1.75% through 2015 and, in addition, a productivity adjustment, further reducing payment rates is also 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%.

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Further, in 2014, Congress passed the Protecting Access to Medicare Act or PAMA which also makes significant changes in the way the Medicare will pay for laboratory services. Under PAMA, laboratories were required to report the amount that they are paid by third party payors for each test beginning in January 2016. CMS will use this data to calculate a weighted median for each test. That new price is supposed to become effective on January 1, 2017, although any resulting reductions will be phased in over time. This data reporting process will be repeated every three years for most tests, although Advanced Diagnostic Laboratory Tests (ADLTs) will have to be reported every year. 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. Although CMS was also required to issue a Final Rule implementing PAMA by June 30, 2015, it failed to do so. It did issue a Proposed Rule, however, on October 1, 2015. As a result of this delay, many of the statutory deadlines will likely not be met. It is not known at this time how the implementation of PAMA will affect our reimbursement.

Certain of our tests are paid under the Physician Fee Schedule, rather than the CLFS. Tests paid for under the PFS are based on “relative value units” established for each service. These RVUs are then multiplied by a conversion factor to arrive at a monetary amount. Each year, CMS calculates 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 is applied, this SGR formula often would require a decrease in reimbursement unless Congress acts to overturn this result. As a result, Congress consistently passes legislation to prevent implementation of significant cuts that would otherwise be effective. For 2014, CMS had projected the reimbursement cut resulting from the SGR formula would be approximately 20 percent, unless Congress acted to prevent the reduction. On December 18, 2013, Congress passed legislation that enacted a 0.5 percent increase in the conversion factor, which was effective until March 31, 2014. On April 1, 2014, President Obama signed the Protecting Access to Medicare Act of 2014, or PAMA. PAMA extended the 0.5 percent increase through March 31, 2015 and made other changes to laboratory reimbursement discussed below.

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

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. These requirements are complex and time- consuming and, depending on what they require, may affect our ability to collect for our services.

Our reimbursement rates from private third-party payors can vary based on whether we are considered to be an “in-network” provider, a participating provider, a covered provider or an “out-of-network” provider. These definitions can vary from insurance company to insurance company, but we are generally considered an “out of network” or non-

participating provider in the vast majority of our cases. It is not unusual for a company that offers highly specialized or unique testing to be an “out of network” provider. An “in-network” provider usually has a contracted arrangement with the insurance company or benefits provider. This contract governs, among other things, service-level agreements and reimbursement rates. In certain instances an insurance company may negotiate an “in-network” rate for our testing rather than pay the typical “out-of-network” rate. An “in-network” provider usually has rates that are lower per test than those that are “out-of-network”, and that rate is based on the laboratory fee schedule. The discount rate varies based on the insurance company, the testing type and the often times the specifics of the patient’s insurance plan.

We have contracts with commercial insurance carriers that provide access to certain out our tests to approximately 35 million lives. When a test is covered as part of these contracts it is paid at the rate stated in the contract. The Company also has agreements with preferred provider agreements that cover approximately 130 million lives. 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.

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In addition, as part of the Middle Class Tax Relief and Job Creation Act of 2012 (“MCTRJCA”), signed into law by the President 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.

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 Final Physician Fee Schedule Rule, which was issued in November 2012, CMS stated that it had determined it would pay for the new codes as clinical laboratory tests, which are payable on the Clinical Laboratory Fee Schedule (CLFS). CMS also stated that it planned to “gapfill” the new codes; that is, it will ask the contractors to determine a reasonable price for the new codes. This process was completed in 2013, and these tests are now paid for under the new "gapfilled" rates.

Among the new codes that were created by CPT were 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 recently stated that it will not issue a categorical determination for all MAAA tests, but will consider each individual test that is classified by the CPT as a MAAA on its own merits. 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 when PAMA is fully implemented, many of these MAAA codes will be considered and reimbursed as ADLTs. For 2015, less than 5% of our revenue is derived from tests that may be considered MAAAs.

As of January 1, 2014 we are utilizing the “Not Otherwise Classified” (NOC) codes when billing for some of our MAAA tests. The reimbursement policies for the NOC codes vary from payor to payor with regard to specific tests and many of the payors have followed suit. This extends our revenue cycle for these particular tests, where the normal timeframe for reimbursement of a claim is approximately 45-90 days. These tests can take upwards of a year 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 are moving forward with plans to obtain billing codes for our tests. A specific code for our tests, however, does not assure an adequate coverage policy or reimbursement rate. Please see the section entitled “Legislative and Regulatory Changes Impacting Clinical Laboratory Tests” for further discussion of certain legislative and regulatory changes to these billing codes and the impact on our business.

On October 30, 2015, CMS issued its Final Physician Fee Schedule 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. At this time, we are still assessing the potential impact of these changes.

Coverage and Reimbursement for Our Proprietary Tests

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

The current landscape with payors is generally as follows:

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

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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.

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 and the Physician Fee Schedule. The payment amounts under the Medicare fee schedules are important not only for our reimbursement under Medicare, but also because the schedule often is 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.

Under the statutory formula for clinical laboratory fee schedule amounts, increases are made annually based on the Consumer Price Index for All Urban Consumers as of June 30 for the previous twelve-month period. From 2004 through 2008, Congress eliminated the Consumer Price Index for All Urban Consumers 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 Consumer Price Index for All Urban Consumers. Accordingly, the update for 2009 was reduced to 4.5% and negative 1.9% for 2010. In March 2010, the President 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 Consumer Price Index update in payments for clinical laboratory tests. In 2011, the productivity adjustment was -1.2%. In addition, the ACA includes a separate 1.75% reduction in the CPI 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 requires CMS to reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which in turn will serve as a base for 2014 and subsequent years. Based on the changes required by ACA and MCTRJCA, payment for clinical laboratory services will be 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 2013 Physician Fee Schedule Final Rule (the “Final Rule”). In the Final 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 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 will replace 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.” This automatic cut results 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 2024.

For the years ended December 31, 2015 and December 31, 2014, approximately 10% and 11%, 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 2013 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 CPTs 88300, 88302, 88304, and 88305. In particular, the 2013 Final Rule implemented a cut of approximately 33% in the global

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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 2013 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. We do not yet know what impact, if any, these changes will have on the Company's operations.

In the Proposed Physician Fee Schedule Rule for 2014, issued on July 8, 2013, CMS made two proposals that could affect laboratory reimbursement. First, CMS made a proposal to change how it calculates 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 Final Physician Rule for 2014, 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.

In addition, in the 2014 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. 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 CMS's authority to implement its plan to adjust payments based on technological advances. CMS has since stated it will not implement this proposal.

In PAMA, Congress also changed the way the Medicare will pay for clinical laboratory services. Under PAMA, laboratories will be required to report the amount that they are paid by third party payors for each test beginning in January 2016. CMS will use this data to calculate a weighted median for each test. That new price will become effective on January 1, 2017, although any resulting reductions will be phased in over time. This data reporting process will be repeated every three years for most tests, although Advanced Diagnostic Laboratory Tests ("ADLTs") will have to report every year. 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. It is not known at this time how these changes will affect our reimbursement. As noted above, because of CMS's delay in issuing a Final Rule implementing these requirements, it is unlikely that all of the statutory deadlines will be met.

In addition, CMS made several other changes in the 2014 Final Rule that could impact our business. First, CMS implemented a policy that will bundle 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. In addition, CMS also has developed new codes applicable to billing for Immunohistochemistry procedures, which are a common staining procedure used in pathology. Those codes will reduce the reimbursement that we will receive when we provide these services. Finally, CMS has also implemented a set of edits under its National Correct Coding Initiative, which will only pay 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 the clinical laboratory fee schedule, 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.

Finally, some of our Medicare claims may be subject to policies issued by Palmetto GBA, the current Medicare Administrative Contractor for North Carolina, South Carolina, Virginia and West Virginia. The Medicare contractor has recently issued a Local Coverage Decision 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,

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effective May 1, 2012, Palmetto implemented its new Molecular Diagnostic Services Program, under which, among other things, laboratories must use newly-assigned billing codes specific to the test. These new billing codes 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. Other Medicare contractors are also following the policies adopted by Palmetto.

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 bill 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").

In addition to CLIA requirements, 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.

As to state laws, our clinical operations at our Rutherford and Los Angeles laboratories are required to meet certain state laboratory licensing and other requirements, which in some areas are more stringent than CLIA. Our laboratories are required hold the required licenses and accreditations obtained from the applicable state agencies in which we operate. State clinical laboratory laws generally require that laboratories and/or laboratory personnel meet certain qualifications. State clinical laboratory laws also generally require laboratories to specify certain quality assurance metrics and to maintain certain records. Several states, including Rhode Island, Florida, Maryland, New York and Pennsylvania, require that clinical laboratories hold licenses to test specimens from patients residing in those states, even though the laboratory is not located in such state. From time to time, other states may require out of state laboratories to obtain licensure in order to accept specimens from the state. If we identify any other state with such requirements or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements. In addition, the New York

Department of Health separately approves certain LDTs offered in New York State. The Company has obtained the requisite approvals for its LDTs.

Our Rutherford laboratory is licensed and in good standing under the State Departments of Health standards for New Jersey, New York, Pennsylvania, California, Florida and Maryland . Our Los Angeles laboratory is licensed and in good standing in California, New York, Pennsylvania, Rhode Island, Florida and Maryland. If we are found to be out of compliance with applicable state statutory or regulatory standards we may be subject to suspension, restriction or revocation of our laboratory license or assessed civil money penalties. 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.

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

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to perform diagnostic testing. Such devices must undergo pre-market review by FDA prior to commercialization unless the device is of a type exempted from such review by statute or pursuant to FDA's exercise of enforcement discretion. FDA, to date, has not exercised its authority to actively regulate the development and use of LDTs such as ours as medical devices and therefore we do not believe that our LDTs currently require pre-market clearance or approval.

Section 1143 of the Food and Drug Administration Safety and Innovation Act, signed by the President on July 9, 2012, requires FDA to notify Congress at least 60 days prior to issuing a draft or final guidance regulating LDTS and provide details of the anticipated action. On July 31, 2014, FDA notified Congress pursuant to the FDASIA that it intended to issue draft Guidances that would regulate LDTs. On October 3, 2014, the FDA issued two separate draft guidances: "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" ("The Framework Draft Guidance") and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests" (the "Notification Draft Guidance."). In the Framework Draft Guidance, FDA states that after the Guidances are finalized, it will no longer exercise enforcement discretion with respect to most LDTs and will, instead, regulate them in a risk-based manner consistent with the existing classification of medical devices. Thus, the FDA plans to begin to enforce its medical device requirements, including premarket submission requirements, on LDTs that have historically been marketed without FDA premarket review and oversight. Comments on the Draft Guidances were due on February 2 and those comments are now being considered by the FDA. It is not known when the FDA may issue final Guidances or what form those Guidances may take.

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

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. Class I devices are those for which reasonable assurance of the safety and effectiveness can be provided by adherence to FDA's general regulatory controls for medical devices, which include compliance with the applicable portions of FDA's Quality System Regulations, facility registration and product listing, reporting of adverse medical events and appropriate, truthful and non-misleading labeling, advertising and promotional materials, or general controls. Many Class I devices are exempt from pre-market regulation, however, some Class I devices require pre-market clearance by FDA through the 510(k) pre-market notification process described below.

Class II devices are subject to FDA's general controls, and any other special controls as deemed necessary by FDA to provide reasonable assurance of the safety and effectiveness of the devices. Pre-market review and clearance by FDA for Class II devices are generally accomplished through the 510(k) pre-market notification procedure. Pre- market notification submissions are subject to user fees, unless a specific exemption applies. To obtain 510(k) clearance for a medical device (or for certain modifications to devices that have received 510(k) clearance), a manufacturer must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or to a pre-amendment device that was in commercial distribution before May 28, 1976 (a "predicate device") for which FDA has not yet called for the submission of a pre-market approval ("PMA") application. In making a determination that the device is substantially equivalent to a predicate device, FDA compares the proposed device to the predicate device or predicate devices and assesses whether the subject device is comparable to the

predicate device or predicate devices with respect to intended use, technology, design and other features which could affect the safety and effectiveness. If FDA determines that the subject device is substantially equivalent to the predicate device or predicate devices, the subject device may be cleared for marketing. FDA's 510(k) clearance pathway generally takes from three to twelve months from the date the application is completed, but can take significantly longer. Moreover, in January 2011, FDA announced twenty-five specific action items it intended to take to improve transparency and predictability of the 510(k) program. We anticipate that the changes may also result in additional requirements with which manufacturers will need to comply in order to obtain or maintain 510(k) clearance for their devices. These additional requirements could increase the costs or time for manufacturers' seeking marketing clearances through the 510(k) process. Moreover, the 510(k) process could result in a not-substantially equivalent determination, in which case the device would be regulated as a Class III device, discussed below, or could be eligible for de novo classification available for novel low and moderate risk devices. In the de novo process, FDA can classify a device into Class I or Class II based on a risk- based determination without the submission of a 510(k) or within 30 days after receipt of a not-substantially equivalent determination. In 2013, several assays and diagnostic tests received pre-market approval through the de novo process.

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Class III devices are those devices which are deemed by FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device. Reasonable assurance of the safety and effectiveness of Class III devices cannot be assured solely by the general controls and the other requirements described above. These devices are required to undergo the pre-market approval ("PMA") process in which the manufacturer must demonstrate reasonable assurance of the safety and effectiveness of the device to FDA's satisfaction. A PMA application must provide extensive preclinical and clinical trial data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. Premarket approval applications (and supplemental pre-market approval applications) are subject to significantly higher user fees than are 510(k) pre-market notifications. After approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process. The PMA process, including the gathering of clinical and nonclinical data and the submission to and review by FDA, can take several years.

A clinical trial may be required in support of a 510(k) submission and generally is required for a PMA application. These trials generally require an effective Investigational Device Exemption from FDA for a specified number of patients, unless the product is exempt from Investigational Device Exemption requirements or deemed a non-significant risk device eligible for more abbreviated Investigational Device Exemption requirements. The Investigational Device Exemption application must be supported by appropriate data, such as animal and laboratory testing results. Clinical trials may begin 30 days after the submission of the Investigational Device Exemption application unless FDA or the appropriate institutional review boards at the clinical trial sites place the trial on clinical hold.

Under the Guidances, LDTs would also be subject to significant post-market requirements as well. After a device is placed on the market, regardless of the classification or pre-market pathway, it remains subject to significant regulatory requirements. Even if regulatory approval or clearance of a medical device is granted, FDA may impose limitations or restrictions on the uses and indications for which the device may be labeled and promoted. Medical devices may be marketed only for the uses and indications for which they are cleared or approved.

Device manufacturers must also establish registration and device listings with FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the Quality Systems Regulations, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by FDA. FDA also may inspect foreign facilities that export products to the United States.

Failure to comply with applicable regulatory requirements can result in enforcement action by FDA, which may include any of the following sanctions: warning letters, fines, injunctions, civil or criminal penalties, recall or seizure of current or future products, operating restrictions, partial suspension or total shutdown of production, denial of 510(k) clearance or PMA applications for new products, or challenges to existing 510(k) clearances or PMA applications.

We are monitoring developments and anticipate that our products (CGH-Microarrays and FISH Probes) will be able to comply with requirements that are ultimately imposed by the FDA. In the meantime, we maintain our CLIA accreditation, which permits the use of LDTs for diagnostics purposes.

We believe that our LDTs and, should we reach that point, our in vitro diagnostic test kits, would likely be regulated as either Class II or Class III devices should FDA decide to proceed in the way that it has outlined in the Guidances. It is also possible under those circumstances that some may fall into one Class and some into the other. Accordingly, some level of premarket review-either a 510(k), PMA or de novo approval-would likely be required for each test.

While the data requirements are typically greater for Class III devices, the data required for Class II devices has increased, and it is likely that some amount of clinical data (retrospective or prospective or both) would be required for either type of submission. FDA continues to review the adequacy of its 510(k) process. It is difficult to predict what changes may result, but it should be assumed that any changes will increase, not decrease, the regulatory requirements.

In addition to the Draft Guidances discussed above, the FDA has taken other actions that could have an impact on our business. In 2013, FDA issued Final Guidance for industry regarding appropriate labeling and distribution practices for in vitro diagnostic products intended for research or investigational use only. FDA's guidance cautions that labeling or distribution practices that conflict with research or investigational use (e.g., use in clinical diagnostic applications) could subject products shipped with research or investigational use labeling to all applicable requirements of the FDCA as well as enforcement action. As a result of FDA's recent guidance, 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.

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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. If it were determined that our tests qualified as Diagnostic Devices then we might be required to file for either a 510(k) or a PMA, depending on the nature of the particular test.

Post-market Regulation

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

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

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

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

Federal, State and Foreign Fraud and Abuse Laws

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-

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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 $5,500 to $11,000 for each false claim.

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 offence. 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 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 bill submission, an assessment of up to three times the amount claimed and possible exclusion from participation in federal governmental payor programs. Bills 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 bill is obligated to refund such amounts. 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.

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

Corporate Practice of Medicine

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

Other Regulatory Requirements

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

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

Segment and Geographical Information

We operate in one reportable business segment and derive revenue from multiple countries, with 95%, 97%, and 97% coming from the United States in fiscal year 2015, 2014 and 2013, respectively.

Employees

As of December 31, 2015, we had a total of 223 full-time and 14 part-time employees, with 33 employees in sales and marketing, 156 employees in research and development and laboratory operations and 48 employees in general and administrative. None of our employees are represented by a labor union, and we consider our employee relations to be good.

Corporate and Available Information

We were incorporated in the State of Delaware on April 8, 1999. On July 16, 2014 we purchased substantially all of the assets of Gentris Corporation ("Gentris"), a laboratory specializing in pharmacogenomics profiling for therapeutic development, companion diagnostics and clinical trials. On August 18, 2014 we entered into two agreements by which we acquired BioServe Biotechnologies (India) Pvt. Ltd. (“BioServe”), a premier genomics services provider serving both the research and clinical markets in India, and as a result of the acquisition, BioServe became a subsidiary of ours. On October 9, 2015, Cancer Genetics acquired substantially all the assets and assumed certain liabilities of Response Genetics, Inc. ("Response Genetics") in connection with Response Genetics' filing of a chapter 11 petition for bankruptcy in the Delaware Bankruptcy Court for approximately $12.9 million, comprised of $7.5 million, in cash, and 788,584 shares of the Company's common stock, with the common stock being valued at $5.4 million.

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®,

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Item 1A. Risk Factors.

Risks Relating to Our Financial Condition and Capital Requirements

We are an early stage company with 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 $20.2 million, $16.6 million and $12.4 million for fiscal years ended December 31, 2015, 2014 and 2013, respectively. From our inception in April 1999 through December 31, 2015, we had an accumulated deficit of $98.2 million. Response Genetics incurred losses of $8.9 million, $13.7 million, and $8.0 million for the first six months of fiscal 2015, and for the fiscal years ended December 31, 2014 and 2013, respectively. From its inception in September 1999 through October 9, 2015, Response Genetics had an accumulated deficit of $93.7 million. We expect losses for the combined company to continue principally as a result of ongoing research and development expenses and increased 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.

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

We may need to raise additional financing to fund our operations, to develop, validate and commercialize new tests and technologies, to expand our operations and repay indebtedness. At December 31, 2015, we had cash and cash equivalents of $19.5 million. Net cash used in operating activities was $13.6 million and $12.3 million for the years ended December 31, 2015 and 2014, respectively. We also need capital to fund our capital contributions of up to $4 million to our joint venture with Mayo, which payments are subject to achievement of operational milestones, and to satisfy indebtedness to our New Credit Facility with Silicon Valley Bank. Our New Credit Facility with Silicon Valley Bank consists of the Term Note and Line of Credit. As of December 31, 2015, the aggregate principal amount due under our New Credit Facility was approximately $6.0 million. The Term Note requires interest only payments through April 30, 2016 and beginning May 1, 2016, monthly principal payments of approximately $167,000 will be required plus interest through maturity on April 1, 2019. Pursuant to the amendment dated January 28, 2016, we are restricted from using the Line of Credit until $13 million of additional equity is raised.

We believe that our current cash will support operations for the next 15 to 24 months. 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.

Additional financing, which is not in place at this time, 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 strategic partnership coupled with an investment in us or a combination of forms. We may be unable to raise sufficient additional financing on

terms that are acceptable to us, if at all. Our failure to raise additional capital and in sufficient amounts when needed may significantly impact our ability to expand 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;

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- 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;
- the costs for funding the operations of Response Genetics, which we recently acquired, and our ability to successfully integrate those operations with and into our own;
- 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;
- 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 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 NGS panels, microarrays and FHACT probe;
- 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 international expansion; and
- our ability to secure financing and the amount thereof.

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

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

Risks Relating to Our Business and Strategy

If we are unable to increase sales of our laboratory 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 laboratory testing services. We have only recently begun offering our proprietary NGS panels and microarrays through our CLIA-certified, CAP-accredited and state

licensed laboratory. We also only recently launched FHACT for use as a diagnostic tool for cervical cancer in non-U.S. markets. We are in varying stages of research and development for other diagnostic tests that we may offer.

We also have only recently begun to provide our Biopharma Services. Biopharma Services are services and tests provided to biopharmaceutical 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 biopharmaceutical 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.

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

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 biopharmaceutical 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 pathologists and oncologists decide not to order our diagnostic tests and/or biopharmaceutical companies and clinical research organizations decide not to use our diagnostic tests and 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 biopharmaceutical 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, biopharmaceutical 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.

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 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, biopharmaceutical 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 biopharmaceutical companies to more rapidly advance targeted therapeutics. While we have validated all of the tests that we currently offer, we believe that we will need to finance and successfully complete additional and more powerful studies, and then effectively disseminate the results of those studies, to drive widespread adoption of our tests and thereby increase our revenues.

The commercial success of our Clinical Services business could be compromised if third-party payors, including 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 managed care organizations and government payors, such as Medicare and Medicaid, pay a substantial portion of the test price. Coverage and reimbursement by a third-party payor may depend on a number of factors, including a payor's

determination that tests using our technologies are:

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

Uncertainty surrounds third-party payor coverage and reimbursement of any test incorporating new technology, including tests developed using our microarrays and NGS panels. Technology assessments of new medical tests and devices conducted by

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research centers and other entities may be disseminated to interested parties for informational purposes. Third-party payors and health care providers may use such technology assessments as grounds to deny coverage for a test or procedure.

Because each payor generally determines for its own enrollees or insured patients whether to cover or otherwise establish a policy to reimburse our diagnostic tests, seeking payor approvals is a time-consuming and costly process. We cannot be certain that coverage for our tests will be provided in the future by additional third-party payors or that existing contracts, agreements or policy decisions or reimbursement levels will remain in place or be fulfilled under existing terms and provisions. If we cannot obtain coverage and reimbursement from private and governmental payors such as Medicare and Medicaid for our current tests, or new tests or test enhancements that we may develop in the future, our ability to generate revenues from our clinical services could be limited, which may have a material adverse effect on our financial condition, results of operations and cash flow. Further, we have experienced in the past, and will likely experience in the future, delays and temporary interruptions in the receipt of payments from third-party payors due to missing documentation and other issues, which could cause delay in collecting our revenue.

Our 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.

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

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

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

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

Failure of the Response Genetics acquisition to achieve anticipated revenue levels and other potential benefits could harm the business and operating results of the combined company.

We expect that the acquisition of the Response Genetics business will result in increased revenue and other potential benefits for the combined company, including the expansion of the number and geographic coverage or our marketing team, the expansion of our menu of tests offered to cover 8 of the 10 most common solid tumor types, the expansion of the geographic coverage of our laboratories and introductions to additional potential biopharmaceutical partners for our testing services. No assurance can be given that we will achieve any or all of these potential benefits. Even if we are able to achieve any of these potential benefits, we cannot predict with certainty when the benefits will occur, or to the extent to which they actually will be achieved. For example, the benefits from the acquisition may be offset by costs incurred in integrating the businesses or in obtaining or attempting to obtain regulatory or court approvals for the acquisition. The failure to achieve anticipated benefits could harm the business, financial condition and operating results of the combined company.

Any acquisition exposes a company to additional risks.

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Acquisitions may entail numerous risks for us, including:

- competing claims for capital resources;
- ability to retain and grow relationships with the acquired company's key customers;
- difficulties in assimilating acquired operations, technologies or products; and
- diversion of management's attention from our core business.

Our management has limited experience in purchasing and integrating new businesses. Our failure to successfully complete the integration of Response Genetics or any other new acquisition could have a material adverse effect on our business, financial condition and operating results.

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.

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 expand 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.

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 entered into a joint venture in May 2013 with Mayo Foundation for Education and Research. We have limited 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.

Our agreement with Mayo may not proceed successfully.

In November 2011, we entered into an affiliation agreement with the Mayo Foundation for Medical Education and Research, subsequently amended. Under the agreement, we formed a joint venture in May 2013 to focus on developing oncology

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diagnostic services and tests utilizing next generation sequencing. We have made $2.0 million in capital contributions to that joint venture through December 31, 2015. The agreement requires additional capital contributions by us of up to $4.0 million, subject to the joint venture achieving certain operational milestones. The operation of the joint venture may also divert management time from operating our business. No assurances can be given that we will be able to fully fund our obligations under the joint venture agreement, or that, even if funded, the joint venture will ever achieve the research, development and commercial objectives currently contemplated by the parties, such as the discovery and commercialization of new diagnostic tests utilizing next-generation sequencing. If the development efforts of the joint venture do not result in commercially successful tests or services, it will have an adverse effect on our business, financial condition and results of operations.

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

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

Recent announcements from the Federal Food and Drug Administration may impose additional regulatory obligations and costs upon our business.

On October 3, 2014 the FDA issued two draft guidance documents regarding its intent to modify its policy of enforcement discretion and increase oversight over LDTs. The two draft guidance documents are entitled “Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)” (the “Framework Guidance”) and “FDA Notification and Medical Device Reporting for Laboratory Developed Test (LDTs)" (the "Notification Guidance”). According to the Framework Guidance, FDA plans to modify its policy of enforcement discretion with respect to LDTs using a phased-in, risk-based approach consistent with the existing classification of medical devices. Thus, the FDA plans to begin to enforce its medical device requirements, including premarket submission requirements, to many LDTs that have historically been marketed without FDA premarket review and oversight. The FDA states its intention in the Framework Guidance to publish general LDT classification guidance within 18 months of the date on which the Framework Guidance is finalized. According to the Framework Guidance, devices that are already in use at the time FDA initiates enforcement of the premarket review requirements will be permitted to remain in use-pending FDA's review and consideration of the premarket submission-so long as a premarket submission is timely made. For the highest risk LDTs, the Framework Guidance provides that enforcement of the premarket submission requirements will begin 12 months after the guidance is finalized. For lower risk LDTs, enforcement will be phased in over the following four to nine years. Under this new risk based approach, it is possible that some level of pre-market review may be required for our LDTs-either a 510(k) or PMA-which may require us to generate additional clinical data. While the FDA has proposed that

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devices that are already in use at the time FDA initiates enforcement of the premarket review requirements will be permitted to remain in use-pending FDA's review and consideration of the premarket submission-so long as a premarket submission is timely made, we may nevertheless be required to cease commercial sales of our products and conduct additional clinical testing prior to making submissions to the FDA to obtain premarket clearance or approval.

The draft guidance documents are subject to public comment. The final date for comments was February 2, 2015. We cannot tell at this time what additional costs and regulatory burdens, any final FDA guidance or FDA enforcement of its regulations may have on our business or operations.

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

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.

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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.

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 biopharmaceutical companies and clinical research organizations. To achieve our marketing and sales goals, we will need to substantially expand our sales and commercial infrastructure, with which to date we have had little experience. 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 December 31, 2015, we had indebtedness for borrowed money due on April 1, 2019 in the aggregate principal amount of $6.0 million under our New Credit Facility with Silicon Valley Bank. We are required to comply with certain financial covenants and restricts us from, among other things, paying cash dividends, incurring debt and entering into certain transactions without the prior consent of the lenders. 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 such financial covenants and negative covenants. 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, Morrisville, North Carolina, Hyderabad, India and Los Angeles, California. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including fire, flooding and power outages, which may render it difficult or impossible for us to perform our tests or provide laboratory services for some period of time. The inability to perform our tests or the backlog of tests that could develop if any of our facilities is inoperable for even a short period of time may result in the loss of customers or harm to our reputation or relationships with collaborators, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facilities and the equipment we use to perform our research and development work could be costly and time-consuming to repair or replace.

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

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

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

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

We also face competition from companies that currently offer or are developing products to profile genes, gene expression or protein biomarkers in various cancers. Personalized genetic diagnostics is a new area of science, and we cannot predict what tests others will develop that may compete with or provide results superior to the results we are able to achieve with the tests we develop. Our competitors include public companies such as NeoGenomics, Inc., Quest Diagnostics, Abbott Laboratories, Inc., Johnson & Johnson, Roche Molecular Systems, Inc., bioTheranostics, Inc. (part of bioMérieux SA), Genomic Health, Inc., Myriad Genetics Inc., and Foundation Medicine, Inc., and many private companies. We expect that pharmaceutical and biopharmaceutical 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. For example, FDA has recently approved two such agents-Xalkori crizotinib from Pfizer Inc. along with its companion anaplastic lymphoma kinase FISH test from Abbott Laboratories, Inc. and Zelboraf vemurafenib from Genentech USA Incorporated and Daiichi-Sankyo Inc. along with its companion B-RAF kinase V600 mutation test from Roche Molecular Systems, Inc. These two recent FDA approvals are only the second and third instances of simultaneous approvals of a drug and companion diagnostic, the first being the 1998 approval of Genentech, Inc.'s Herceptin trastuzumab for HER2 positive breast cancer along with the HercepTest from partner Dako A/S.

With respect to our clinical laboratory sciences business we face competition from companies such as Genoptix, Inc. (a Novartis AG Company), Clarient, Inc. (a division of GE Healthcare, a unit of General Electric Company), Bio-Reference Laboratories, Inc., and Genzyme Genetics (a LabCorp Specialty Testing Group).

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.

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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 biopharmaceutical 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 biopharmaceutical company in which the patient is being enrolled. The top five test ordering sites during 2015, 2014 and 2013 accounted for 49%, 56% and 69% respectively, of our clinical testing volumes, with 18%, 38% and 36% respectively, of the volume coming from community hospitals. During the year ended December 31, 2015, one Biopharma client accounted for approximately 19% of our revenue. During the year ended December 31, 2014, two Biopharma clients accounted for approximately 23% and 12%, respectively, of our revenue. During the year ended December 31, 2013 there was one Biopharma client that accounted for approximately 40% of our revenue.

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, 2015, our research and development expenses were $5.5 million, which was 30% of our revenue and our sales and marketing expenses were $5.3 million, which was 29% of revenue. For the year ended December 31, 2014, our research and development expenses were $4.6 million, which was 45% of our net revenue and our sales and marketing expenses were $4.0 million, which was 39% of revenue. For the year ended December 31, 2013, our research and development expenses were $2.2 million, which was 33% of our revenue, and our sales and marketing expenses were $1.8 million, which was 28% of revenue. We expect our expenses to continue to increase, in absolute dollars, for the foreseeable future as we seek to expand the clinical utility of our diagnostic tests, drive adoption of and reimbursement for our diagnostic tests and develop new tests. As a result, we will need to generate significant revenues in order to achieve sustained profitability.

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

Under standard clinical practice in the United States, tumor biopsies removed from patients are chemically preserved, embedded in paraffin wax and stored. Our clinical development relies on our ability to access these archived tumor biopsy samples, as well as information pertaining to their associated clinical outcomes. Other companies often compete with us for access. Additionally, the process of negotiating access to archived samples is lengthy, because it typically involves numerous parties and approvals to resolve complex issues such as usage rights, institutional review board approval, privacy rights, publication rights, intellectual property ownership and research parameters.

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

We currently rely on a single third-party to produce our microarrays and any problems experienced by this vendor could result in a delay or interruption in the supply of our microarrays to us until the problem is cured by such vendor

or until we locate and qualify an alternative source of supply.

The design of our microarrays is currently optimized on a family of instruments referred to as the Agilent Microarray Platform, which is currently produced solely by Agilent Technologies Inc. (“Agilent”). We currently purchase these components from Agilent under purchase orders and do not have a long-term contract with Agilent. If Agilent were to delay or stop producing our microarrays, or if the prices Agilent charges us were to increase significantly, we would need to identify another supplier and optimize our microarrays on a new technology platform. We could experience delays in manufacturing the microarrays while finding another acceptable supplier, which could impact our results of operations. The changes could also result in increased costs associated with migrating to the new technology platform and in increased manufacturing costs. Further, any prolonged disruption in Agilent's operations could have a significant negative impact on the supply of our microarrays.

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

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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.

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

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

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

We depend on information technology and telecommunications systems for significant aspects of our operations. In addition, our third-party billing and collections provider depends upon telecommunications and data systems provided by outside vendors and information we provide on a regular basis. These information technology and

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

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

In the ordinary course of our business, we and our third-party billing and collections provider collect and store sensitive data, including legally protected health information, personally identifiable information, intellectual property, and proprietary business information owned or controlled by ourselves or our customers, payors, and biopharmaceutical 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”), their implementing regulations, and similar state laws. Unauthorized access, loss, or dissemination could also disrupt our operations, including our ability to conduct our analyses, provide test results, bill payors or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process, and prepare company financial information, provide information about our products and other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business, and damage our reputation, any of which could adversely affect our business.

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

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

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

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

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

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Regulatory Risks Relating to Our Business

Health care policy changes, including recently enacted legislation reforming the U.S. health care system, may have a material adverse effect on our financial condition, results of operations and cash flows.

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

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

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

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

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

Further, in 2014, Congress passed the Protecting Access to Medicare Act or PAMA which also makes significant changes in the way the Medicare will pay for laboratory services. Under PAMA, laboratories were required to report the amount that they are paid by third party payors for each test beginning in January 2016. CMS will use this data to calculate a weighted median for each test. That new price is supposed to effective on January 1, 2017, although any resulting reductions will be phased in over time. This data reporting process will be repeated every three years for most tests, although certain advanced diagnostic tests will have to report every year. It is possible that some of our tests may qualify as Advanced Diagnostic Laboratory Tests, which will require us to submit pricing annually. In addition, under PAMA, we will also be required to obtain new codes from CMS or any entity it designates, for our tests that do not currently have codes. Although CMS was also required to issue a Final Rule implementing PAMA by June 30, 2016, it failed to do so. It did issue a Proposed Rule, however, on October 1, 2015. As a result of this delay, many of the statutory deadlines will likely not be met. 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.

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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 SGR formula and implements a new physician payment system that is designed to reward the quality of care. In addition, it extends the current Medicare Physician Fee Schedule rates through June 2015, and then increases them by 0.5%t for the remainder of 2015. Beginning on January 1, 2016, the rates will be increased annually by 0.5%, through 2019. For 2020 through 2025 payments will be frozen, although payment will be adjusted to account for performance on certain quality metrics under the Merit-Based Incentive Payment Systems (“MIPS”) or to reflect physician participation in alternative payment models (“APMs”). For 2026 and subsequent years, qualified APM participants receive an annual 0.75% update on Medicare physician payment rates, while those not participating receive a 0.25% annual payment update, plus any applicable MIPS-based payment adjustments. At this time, it is too early to determine how these changes may impact our business beyond 2015. It is unclear what impact, if any, MACRA will have on our business and operating results, but any resulting decrease in payment may result in reduced demand for our services, which could adversely impact our revenues and results of operations.

On October 30, 2015, CMS issued its Final Physician Fee Schedule Rule for 2016, which set out policies that will be 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. At this time, we are still assessing the potential impact of these changes.

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

For the year ended December 31, 2015, we derived approximately 12% of our total revenue from private insurance, including managed care organizations and other health care insurance providers, 10% from Medicare and 9% from other health care facilities billed directly. Medicare and other third-party payors may withdraw their coverage policies or cancel their contracts with us at any time, review and adjust the rate of reimbursement or stop paying for our tests altogether, which would reduce our total revenues.

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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. Recently, 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. Other states may have similar requirements or may adopt similar requirements in the future. Finally, we may be subject to regulation in foreign jurisdictions as we seek to expand international distribution of our tests.

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

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

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

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

Moreover, FDA guidance and policy pertaining to diagnostic testing is continuing to evolve and is subject to ongoing review and revision. A significant change in any of the laws, regulations or policies may require us to change our business model in order to maintain regulatory compliance. At various times since 2006, FDA has issued guidance documents or announced draft guidance regarding initiatives that may require varying levels of FDA oversight of our tests. For example, in June 2010, FDA announced a public meeting to discuss the agency's oversight of LDTs prompted by the increased complexity of LDTs and their increasingly important role in clinical decision-making and disease management, particularly in the context of personalized medicine. FDA indicated that it was considering a risk-based application of oversight to LDTs and that, following public input and discussion, it might issue separate draft guidance on the regulation of LDTs, which ultimately could require that we seek and obtain either pre-market clearance or approval of LDTs, depending upon the risk-based approach FDA adopts. The public 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 states that after the Guidances are finalized, it will no longer exercise enforcement discretion with respect to LDTs and will, instead, regulate them in a risk-based manner consistent with the existing classification of medical devices. Thus, the FDA plans to begin to enforce its medical device

requirements, including premarket submission requirements, on LDTs that have historically been marketed without FDA premarket review and oversight. Comments on the Draft Guidances were due on February 2 and those comments are now being considered by the FDA. It is not known when the FDA may issue final Guidances or what form those Guidances may take.

The Framework Draft Guidance states that within six months after the Guidances are finalized, all laboratories will be required to give notice to the FDA and provide basic information concerning the nature of the LDTs offered. The FDA will then begin a phased review of the LDTs available, based on the risk associated with the test. For the highest risk LDTs, which the FDA classifies as Class III devices, the Framework Draft Guidance states that the FDA will begin to require premarket review within 12 months after the Guidance is finalized. Other high risk LDTs will be reviewed over the next four years and then lower risk tests, which will be classified as Class II, will be reviewed in the following four to nine years. The Framework Draft Guidance states that FDA expects to issue a separate Guidance describing the criteria for its risk-based classification 18-24 months after the Guidances are finalized. At this time, we cannot predict how our tests would be classified.

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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 and when the Guidances are finalized, and the FDA begins to actively enforce its premarket submission regulations with respect to LDTs, we will be required to obtain premarket clearance for our tests under Section 510(k) of the FDCA or approval of a PMA, unless an exemption applies. The premarket review process may require that we conduct clinical trials in support of a 510(k) submission or PMA application. These trials generally require an effective Investigational Device Exemption, or IDE, from FDA for a specified number of patients, unless the product is exempt from IDE requirements or deemed a non-significant risk device eligible for more abbreviated IDE requirements. The IDE application must be supported by appropriate data, such as animal and laboratory testing results. Clinical trials may begin 30 days after the submission of the IDE application unless FDA or the appropriate institutional review boards at the clinical trial sites place the trial on clinical hold.

The process for submitting a 510(k) premarket notification and receiving FDA clearance usually takes from three to twelve months, but it can take significantly longer and clearance is never guaranteed. The process for submitting and obtaining FDA approval of a PMA is much more costly, lengthy and uncertain. It generally takes from one to three years or even longer and approval is not guaranteed. PMA approval typically requires extensive clinical data and can be significantly longer, more expensive and more uncertain than the 510(k) clearance process. Despite the time, effort and expense expended, there can be no assurance that a particular test ultimately will be cleared or approved by the FDA through either the 510(k) clearance process or the PMA process on a timely basis, or at all.

Under the Guidances, we could also for the first time be subject to enforcement of other regulatory requirements applicable to medical devices. For example, our currently-marketed LDTs would be subject to the above pre-market requirements, as well as significant post-market requirements. After a device is placed on the market, regardless of the classification or pre-market pathway, it remains subject to significant regulatory requirements. Even if regulatory approval or clearance of a medical device is granted, FDA may impose limitations or restrictions on the uses and indications for which the device may be labeled and promoted. Medical devices may be marketed only for the uses and indications for which they are cleared or approved.

Device manufacturers must also comply with the FDA's registration and device listing requirements. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the Quality Systems Regulation, which covers the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by FDA. FDA also may inspect foreign facilities that export products to the United States.

Failure to comply with applicable regulatory requirements can result in enforcement action by FDA, which may include any of the following sanctions: warning letters, fines, injunctions, civil or criminal penalties, recall or seizure of current or future products, operating restrictions, partial suspension or total shutdown of production, denial of 510(k) clearance or PMA applications for new products, or challenges to or withdrawal of existing 510(k) clearances or PMA applications. 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.

We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our tests, whether through additional 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 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.

The requirement of pre-market review could negatively affect our business until such review is completed and clearance or approval to market is obtained. FDA could require that we stop selling our tests pending pre-market clearance or approval. If FDA allows our tests to remain on the market but there is uncertainty about our tests, if they are labeled investigational by FDA or if labeling claims FDA allows us to make are very limited, orders or reimbursement may decline. The regulatory approval

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process may involve, among other things, successfully completing additional clinical trials and making a 510(k) submission, or filing a PMA application with FDA. If FDA requires pre-market review, our tests may not be cleared or approved on a timely basis, if at all. We may also decide voluntarily to pursue FDA pre-market review of our tests if we determine that doing so would be appropriate.

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

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

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

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

- the federal Anti-kickback Statute, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, in return for or to induce either the referral of an individual for, or the purchase order or recommendation of, any item or services for which payment may be made under a federal health care program such as the Medicare and Medicaid programs;
- the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of "designated health services" with whom the physician or a

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

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

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

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

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

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

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

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The privacy regulations cover the use and disclosure of Protected Health Information by health care providers. It also sets forth certain rights that an individual has with respect to his or her Protected Health Information maintained by a health care provider, including the right to access or amend certain records containing Protected Health Information or to request restrictions on the use or disclosure of Protected Health Information. We have implemented policies, procedures and standards in an effort to comply appropriately with the final HIPAA security regulations, which establish requirements for safeguarding the confidentiality, integrity and availability of Protected Health Information, which is electronically transmitted or electronically stored. The HIPAA privacy and security regulations establish a uniform federal "floor" and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing Protected Health Information. As a result, we are required to comply with both HIPAA privacy regulations and varying state privacy and security laws. Moreover, HITECH, among other things, established certain health information security breach notification requirements. Under HIPAA, a covered entity must notify any individual "without unreasonable delay and in no case later than 60 calendar days after discovery of the breach" if their unsecured Protected Health Information is subject to an unauthorized access, use or disclosure. If a breach affects 500 patients or more, it must be reported to HHS and local media without unreasonable delay, and HHS will post the name of the breaching entity on its public website. If a breach affects fewer than 500 individuals, the covered entity must log it and notify HHS at least annually.

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

Intellectual Property Risks Related to Our Business

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

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

fees. Such royalties and fees are a component of cost of product revenues and will impact the margins on our tests.

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

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

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otherwise arise with respect to the intellectual property developed with the use of a collaborator's samples, we may be limited in our ability to capitalize on the market potential of these inventions.

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

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

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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 collaborators, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States. In addition, interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our current or future collaborators.

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

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

Filing, prosecuting and defending patents on our technologies in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. For example, many foreign countries

have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our technologies in jurisdictions where we do not have any issued patents and our patent claims or other intellectual rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not

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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 India and China, and the possibility of establishing and maintaining clinician marketing and education capabilities in other locations outside of the United States and expanding our relationships with distributors and manufacturers. Doing business internationally involves a number of risks, including:

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

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

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

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

With the completion of the Gentris acquisition, a portion of our assets and operations are located in China and we are subject to regulatory, economic, political and other uncertainties in China.

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

There can be no assurance that China's economic, political or legal systems will not develop in a way that becomes detrimental to our business, results of operations and financial condition. Our activities may be materially and adversely affected by changes

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in China's economic and social conditions and by changes in the policies of the government, such as measures to control inflation, changes in the rates or method of taxation and the imposition of additional restrictions on currency conversion.

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

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

With the completion of the BioServe acquisition a portion of our assets and operations are located in India and we are subject to regulatory, economic, political and other uncertainties in India.

In August 2014 we acquired BioServe a leading genomic service and next-generation sequencing company founded in 2002 serving both the research and clinical markets and based in Hyderabad, India. In the past, the Indian economy has experienced many of the problems that commonly confront the economies of developing countries, including high inflation, erratic gross domestic product growth and shortages of foreign exchange. The Indian government has exercised, and continues to exercise, significant influence over many aspects of the Indian economy through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries, and Indian government actions concerning the economy could have a material adverse effect on private sector entities like us.

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

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

Some of our contract manufacturers and distributors are located outside of the United States, which may subject us to increased complexity and costs.

We rely on manufacturing facilities located outside the United States for our FHACT probes, particularly in India. We also utilize distributors to sell FHACT probes outside the United States. Our FHACT probe manufacturing and international sales may be subject to certain risks, including:

- difficulty in obtaining, maintaining or enforcing intellectual property rights in some countries;
- local business and cultural factors that differ from our normal standards and practices;

- foreign currency exchange fluctuations;
- different regulatory requirements;
- impediments to the flow of foreign exchange capital payments and receipts due to exchange controls instituted by certain foreign governments and the fact that local currencies of some countries are not freely convertible;
- geopolitical and economic instability and military conflicts;
- difficulties in managing international distributors;
- burdens of complying with a variety of foreign laws and treaties and changes in local laws and regulations, including tax and transfer pricing laws;
- difficulty in enforcing agreements, judgments and arbitration awards in foreign jurisdictions; and
- adverse economic conditions in any jurisdiction.

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.

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

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

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

Risks Relating to Our Common Stock

There has been a limited trading market for our common stock.

We received approval to list our common stock on The NASDAQ Capital Market in August 2013. No assurance can be given that an active trading market will be sustained. A lack of an active market may impair the ability of our stockholders to sell shares at the time they wish to sell them or at a price that they consider reasonable. The lack of an active market may also reduce the fair market value of our shares. An inactive market may also impair our ability to raise capital by selling shares of capital stock and may impair our ability to acquire other companies or technologies by using our common stock as consideration.

The price of our common stock may be volatile, and the market price of our common stock may decrease.

Our stock price per share may vary from time to time. Even if an active market for our stock continues, our stock price nevertheless may be volatile. Market prices for securities of early-stage life sciences companies have historically been particularly volatile. The factors that may cause the market price of our common stock to fluctuate include, but are not limited to:

- progress, or lack of progress, in developing and commercializing our proprietary tests;
- favorable or unfavorable decisions about our tests or services from government regulators, insurance companies or other third-party payors;
- our ability to recruit and retain qualified regulatory and research and development personnel;
- changes in investors' and securities analysts' perception of the business risks and conditions of our business;

- changes in our relationship with key collaborators;
- changes in the market valuation or earnings of our competitors or companies viewed as similar to us;
- changes in key personnel;
- depth of the trading market in our common stock;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the granting or exercise of employee stock options or other equity awards;
- realization of any of the risks described under this section titled “Risk Factors”; and
- general market and economic conditions.

In addition, the equity markets have experienced significant price and volume fluctuations that have affected the market prices for the securities of newly public companies for a number of reasons, including reasons that may be unrelated to our business or operating performance. These broad market fluctuations may result in a material decline in the market price of our common

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stock and you may not be able to sell your shares at prices you deem acceptable. In the past, following periods of volatility in the equity markets, securities class action lawsuits have been instituted against public companies. Such litigation, if instituted against us, could result in substantial cost and the diversion of management attention.

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

As of December 31, 2015, we had outstanding options to purchase an aggregate of 1,960,929 shares of our common stock at a weighted average exercise price of $10.55 per share and warrants to purchase an aggregate of 4,431,925 shares of our common stock at a weighted average exercise price of $6.78 per share. The exercise of such outstanding options and warrants will result in dilution of the value of our shares.

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

Securities research analysts, including those affiliated with our underwriters, 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 25.2% of our outstanding common stock, based on the number of shares outstanding on December 31, 2015. 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 an “emerging growth company,” and any decision on our part to comply only with certain reduced disclosure requirements applicable to “emerging growth companies” could make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and, for as long as we continue to be an “emerging growth company,” we intend to take advantage of exemptions from various reporting requirements applicable to other public companies but not to “emerging growth companies,” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as discussed below, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.0 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial

public offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; and (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We have irrevocably chosen to "opt out" of the extended transition periods available under the JOBS Act for complying with new or revised accounting standards. We intend to take advantage of certain exemptions from various reporting requirements including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved, and if we do take advantage of these exemptions, we cannot predict if investors will find our common stock less attractive as a result. If some investors find our common stock less attractive as a result of any choices to take advantage of these reduced disclosure obligations, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

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

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. In addition, after we are no longer an “emerging growth company,” 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 comply 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:

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

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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.

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of December 31, 2015, 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, 10,000 square feet of laboratory space in Hyderabad, India, 2,700 square feet of laboratory space in Shanghai, China and approximately 27,000 square feet of laboratory space in Los Angeles, California. We have escalating lease agreements for both our New Jersey and North Carolina spaces which expire February 2018 and May 2020 respectively. We also have a lease agreement for our California space which expires on June 30, 2016. We currently are negotiating an extension of our California lease.

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Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

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

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

	High	Low
4th Quarter 2015	$8.51	$2.75
3rd Quarter 2015	$12.75	$7.57
2nd Quarter 2015	$12.22	$7.57
1st Quarter 2015	$9.76	$6.55
4th Quarter 2014	$8.95	$4.83
3rd Quarter 2014	$11.35	$8.36
2nd Quarter 2014	$16.55	$8.54
1st Quarter 2014	$20.00	$13.50

Holders

As of December 31, 2015, we had approximately 105 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. 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.

Stock Performance Graph

This graph is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference into any of our filings under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The following graph shows the total stockholder return of an investment of $100 in cash on April 5, 2013 (the first day of trading on our common stock), through December 31, 2015 for (i) our common stock, (ii) the NASDAQ Composite Index (U.S.), and (iii) NASDAQ Biotechnology Index. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends; however, no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

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Equity Compensation Plan Information

The following table provides information as of December 31, 2015 regarding shares of our common stock that may be issued under our existing equity compensation plans, including our 2008 Stock Option Plan (the "2008 Plan") and our 2011 Equity Incentive Plan (the "2011 Plan") as well as shares issued outside of these plans.

	Equity Compensation Plan Information			
Plan Category	(a) Number of securities to be issued upon exercise of outstanding options and rights(1)	(b) Weighted Average exercise price of outstanding options and rights	(c) Number of securities remaining available for future issuance under equity compensation plan (excluding securities referenced in column (a))	
Equity compensation plans approved by security holders (2)	1,924,929	$10.56	964,253	(3)
Equity compensation plans not approved by security holders (4)	36,000	$10.00	—	
Total	1,960,929	$10.55	964,253	

(1)Does not include any restricted stock as such shares are already reflected in our outstanding shares.
(2)Consists of the 2008 Plan and the 2011 Plan.
(3)Includes securities available for future issuance under the 2008 Plan and the 2011 Plan.
(4)These options were issued to one of our current board members in connection with consulting services.

Item 6. Selected Financial Data.

The selected financial data set forth below as of December 31, 2015 and 2014, and for each of the years ended December 31, 2015, 2014, and 2013 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 for the years ended December 31,

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2012 and 2011, and as of December 31, 2013, 2012 and 2011 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,				
	2015	2014	2013	2012	2011
	(in thousands, expect per share data)				
Consolidated Statements of Operations Data:					
Revenue	$18,040	$10,199	$6,610	$4,302	$3,019
Cost of revenues	14,098	8,453	4,925	3,929	3,117
Gross profit (loss)	3,942	1,746	1,685	373	(98)
Operating expenses:					
Research and development	5,483	4,622	2,190	2,112	2,074
General and administrative	14,567	12,369	6,115	4,503	4,439
Sales and marketing	5,269	3,964	1,842	1,399	1,574
Total operating expenses	25,319	20,955	10,147	8,014	8,087
Loss from operations	(21,377)	(19,209)	(8,462)	(7,641)	(8,185)
Other income (expense):					
Interest expense	(344)	(473)	(2,388)	(4,701)	(1,314)
Interest income	49	74	30	—	—
Change in fair value of warrant liability	35	417	4,633	7,538	(10,388)
Change in fair value of acquisition note payable	269	198	—	—	—
Loss on debt and warrant restructuring	—	—	—	(1,862)	—
Debt conversion costs	—	—	(6,850)	—	—
Total other income (expense)	9	216	(4,575)	975	(11,702)
Loss before income taxes	(21,368)	(18,993)	(13,037)	(6,666)	(19,887)
Income tax (benefit)	(1,184)	(2,350)	(664)	—	—
Net (loss)	$(20,184)	$(16,643)	$(12,373)	$(6,666)	$(19,887)
Basic net (loss) per share	$(1.96)	$(1.76)	$(2.65)	$(4.97)	$(15.61)
Diluted net (loss) per share	$(1.96)	$(1.80)	$(3.64)	$(10.55)	$(15.61)
Basic weighted average shares outstanding	10,298	9,449	4,665	1,342	1,274
Diluted weighted average shares outstanding	10,299	9,462	4,676	1,346	1,274

	Year Ended December 31,				
	2015	2014	2013	2012	2011
Consolidated Balance Sheet Data:	(in thousands)				
Cash and cash equivalents	$19,459	$25,554	$49,460	$820	$2,417
Working capital (deficit)	18,333	27,389	43,272	(9,612)	(1,078)
Total assets	48,884	47,105	55,157	8,952	7,031
Debt, excluding current portion	4,642	6,000	—	8,441	10,350

Accumulated deficit	(98,151)	(77,967)	(61,325)	(48,935)	(42,269)
Total stockholders' equity (deficit)	$33,017	$34,554	$45,463	$(23,981)	$(19,065)

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

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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 and BioServe Biotechnologies (India) Private Limited, 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 Form10-K. This MD&A may contain forward-looking statements that involve risks and uncertainties. For a discussion on forward-looking statements, see the information set forth in the Introductory Note to this Annual Report under the caption “Forward Looking Statements”, which information is incorporated herein by reference.

Overview

We are an emerging leader in the field of personalized medicine, enabling precision medicine in the field of oncology through our diagnostic products and services and molecular markers. We develop, commercialize and provide molecular- and biomarker-based tests and services that enable physicians to personalize the clinical management of each individual patient by providing genomic information to better diagnose, monitor and inform cancer treatment and that enable biopharmaceutical 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. We have a comprehensive, disease-focused oncology testing portfolio. Our tests and techniques target a wide range of cancers, covering eight of the top ten cancers in prevalence in the United States, with additional unique capabilities offered by our Tissue of Origin® test for identifying difficult to diagnose tumor types or poorly differentiated metastatic disease.

Our vision is to become the oncology diagnostics partner for biopharmaceutical companies and clinicians by participating in the entire care continuum from bench to bedside. We believe the diagnostics industry is undergoing a rapid evolution in its approach to oncology testing, embracing precision medicine and individualized testing as a means to drive higher standards of patient treatment and disease management. Similarly, biopharmaceutical companies are increasingly engaging companies such as ours to provide information on clinical trial participants' molecular profiles in order to identify biomarker and genomic variations that may be responsible for differing responses to pharmaceuticals, and particularly to oncology drugs, thereby increasing the efficiency of trials while lowering related costs. We believe tailored therapeutics can revolutionize oncology medicine through molecular- and biomarker-based testing services, enabling physicians and researchers to target the factors that make each patient and disease unique. We have created a unique position in the industry by providing targeted somatic analysis of tumor sample cells alongside germline analysis of an individual's non-cancerous cells' molecular profile as we attempt to reach the next milestone in personalized medicine. Individuals are born with germline mutations, and somatic mutations arise in tissues over the course of a lifetime.

Our services are performed at our state-of-the-art laboratories located in New Jersey, North Carolina, California, Shanghai (China), and Hyderabad, India. Our laboratories comply with the highest regulatory standards as appropriate for the services they deliver including CLIA, CAP, NY State, California State and NABL (India). We have two advisory boards to counsel our scientific and clinical direction. Our Scientific Advisory Board is comprised of preeminent scientists and physicians from the fields of cancer biology, cancer pathology, cancer medicine and molecular genetics. Our Clinical Advisory Board is comprised of clinicians and scientists focused on clinical implementation of our proprietary tests and services and mapping those tests and services to patient needs. 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.

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, 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.

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The insight that we develop in delivering the non-proprietary services are often leveraged in the development of our proprietary programs and now increasingly in the validation of our proprietary programs, such as MatBA and Focus::NGS.

We expect to continue to incur significant losses for the near future. We incurred losses of $20.2 million, $16.6 million and $12.4 million for fiscal years ended December 31, 2015, 2014 and 2013, respectively. As of December 31, 2015, we had an accumulated deficit of $98.2 million.

Acquisitions

On July 16, 2014, we purchased substantially all of the assets of Gentris Corporation, a Delaware corporation ("Gentris"), with its principal place of business in North Carolina, for aggregate consideration of approximately $4.8 million.

On August 18, 2014, we acquired BioServe Biotechnologies (India) Private Limited, an Indian corporation ("BioServe") for an aggregate purchase price of approximately $1.1 million.

On October 9, 2015, we acquired substantially all of the assets of Response Genetics, Inc. ("Response Genetics") with its principal place of business in California, for aggregate consideration of approximately $12.9 million.

Key Factors Affecting our Results of Operations and Financial Condition

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

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

Revenues

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

We have historically derived a significant portion of our revenue from a limited number of test ordering sites, although the test ordering sites that generate a significant portion of our revenue have changed from period to period. Test ordering sites account for all of our Clinical Services revenue along with a portion of the Biopharma Services revenue. Our test ordering sites are hospitals, cancer centers, reference laboratories, physician offices and 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.

The top five test ordering clients during 2015 and 2014 accounted for 49% and 56%, respectively, of our testing volumes, with 18% and 38%, respectively, of the test volume coming from community hospitals. During the year ended December 31, 2015, one Biopharma client accounted for approximately 19% of our revenue. During the year ended December 31, 2014 there were two Biopharma clients that accounted for approximately 23% and 12%, respectively, of our revenue. The loss of our largest client would materially adversely affect our results of operations, however the loss of any other test ordering client would not materially adversely affect our results of operations.

We receive revenue for our Clinical Services from Medicare, other insurance carriers and other healthcare facilities. Some of our customers choose, generally at the beginning of our relationship, to pay for laboratory services directly as opposed to having patients (or their insurers) pay for those services and providing us with the patients' insurance information. A hospital may elect to be a direct bill customer and pay our bills directly, or may provide us with patient information so that their patients pay our bills, in which case we generally expect payment from their private insurance carrier or Medicare. In a few instances,

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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, 2015, Medicare accounted for approximately 10% of our total revenue, other insurance accounted for approximately 12% of our total revenue and other healthcare facilities accounted for 9% of our total revenue. On average, we generate less revenue per test from other healthcare facilities billed directly, than from other insurance payors.

Cost of Revenues

Our cost of revenues consists principally of internal personnel costs, including 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. We completed two acquisitions in 2014; Gentris in North Carolina and BioServe in India. In 2015, we acquired substantially all of the assets of Response Genetics in California. With these three acquisitions, we have made significant process with integrating our resources and services in an effort to reduce costs. We will continue to assess how geographic advantage can help us improve our cost structure.

Operating Expenses

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

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

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

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

Seasonality

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

Results of Operations

Years Ended December 31, 2015 and 2014

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

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	Year Ended December 31,		Change	
	2015	2014	$	%
(dollars in thousands)				
Revenue	$18,040	$10,199	$7,841	77 %
Cost of revenues	14,098	8,453	5,645	67 %
Research and development expenses	5,483	4,622	861	19 %
General and administrative expenses	14,567	12,369	2,198	18 %
Sales and marketing expenses	5,269	3,964	1,305	33 %
Total operating loss	$(21,377)	$(19,209)	$(2,168)	11 %
Interest income (expense)	(295)	(399)	104	-26 %
Change in fair value of warrant liability	35	417	(382)	-92 %
Change in fair value of acquisition note payable	269	198	71	36 %
Loss before income taxes	(21,368)	(18,993)	(2,375)	13 %
Income tax benefit (expense)	1,184	2,350	(1,166)	-50 %
Net loss	$(20,184)	$(16,643)	$(3,541)	21 %

Revenue

The breakdown of our revenue is as follows:

	Year Ended December 31,						Change		
	2015			2014					
(dollars in thousands)	$	%		$	%		$	%	
Biopharma Services	11,564	64	%	5,606	55	%	5,958	106	%
Clinical Services	5,651	31	%	4,432	43	%	1,219	28	%
Discovery Services	825	5	%	161	2	%	664	412	%
Total Revenue	18,040	100	%	10,199	100	%	7,841	77	%

Revenue increased 77%, or $7.8 million, to $18.0 million for the year ended December 31, 2015, from $10.2 million for the year ended December 31, 2014, principally due to the acquisitions of Gentris, BioServe and Response Genetics, whose revenue accounted for $5.5 million of the increase. The increase of $2.4 million was driven by additional clinical trial studies performed by our New Jersey location. Our average revenue (excluding probe revenue) per test decreased to $532 per test for the year ended December 31, 2015 from $550 per test for the year ended December 31, 2014, principally due to lower revenue per test at the newly acquired West Coast location. Overall test volumes increased by 68% from 11,912 tests for the year ended December 31, 2014 to 19,996 tests for the year ended December 31, 2015.

Revenue from Biopharma Services increased 106%, or $6.0 million, to $11.6 million for the year ended December 31, 2015, from $5.6 million for the year ended December 31, 2014, principally due to the acquisition of Gentris whose revenue accounted for a $3.1 million increase; additional clinical trial studies performed at our New Jersey location which accounted for $2.4 million of the increase; and the acquisition of Response Genetics, which accounted for $0.5 million of the increase. Revenue from Clinical Services customers increased 28%, or $1.2 million, to $5.7 million for the year ended December 31, 2015, from $4.4 million for the year ended December 31, 2014, principally due to the acquisition of Response Genetics, which accounted for $1.2 million of the increase. Revenue from Discovery Services, our new line of business in 2014, increased $0.7 million, to $0.8 million for the year ended December 31, 2015, representing 5% of total revenue.

Cost of Revenues

Cost of revenues increased 67%, or $5.6 million, to $14.1 million for the year ended December 31, 2015, from $8.5 million for the year ended December 31, 2014, principally due to the following: costs of revenue from the acquired businesses of $4.8 million, lab supplies expenses increased by $0.4 million or 27% as a result of higher test volumes, and compensation costs increased by $0.2 million or 9% as a result of us securing the expertise needed to continue to deliver high quality test results. Overall the cost of revenue as a percentage of revenue decreased in comparison to 2014 as a result of us implementing cost transformation programs to reduce shipping, consulting and direct labor costs.

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Operating Expenses

Research and Development Expenses. Research and development expenses increased 19%, or $0.9 million, to $5.5 million for the year ended December 31, 2015, from $4.6 million for the year ended December 31, 2014, principally due to the following: compensation increased by $0.4 million or 24% due to key additions to the R&D team; supplies costs increased by $0.3 million or 45% as a result of us accelerating the development of proprietary tests; costs associated with the acquired businesses of $0.2 million; and collaboration costs increased by $0.2 million or 65% as we teamed up with other research labs to capitalize on R&D efforts. These increases were partially offset by a decrease in our share of the loss from Oncospire, our joint venture with Mayo Clinic, of $0.2 million or 25%.

General and Administrative Expenses. General and administrative expenses increased 18%, or $2.2 million to $14.6 million for the year ended December 31, 2015, from $12.4 million for the year ended December 31, 2014, principally due to the following: $0.9 million of costs from the acquisition of Response Genetics; costs from the acquired businesses of $2.2 million; increased compensation costs of $0.2 million or 8% as a result of increased headcount; and increased bad debt allowance of $0.2 million or 92% as a result of establishing a reserve for potential uncollectible amounts in our Clinical Services businesses. These increases were partially off-set by a decrease in stock-based compensation of $0.9 million or 32%; a reduction in Delaware corporate taxes of $0.1 million or 41%; a reduction of Medical Billing third-party expenses of $0.1 million or 17% as a result of bringing part of the function in-house; a reduction of $0.1 million in recruiting fees or 35% as a result of stabilizing our staff; and a reduction of $41,000 or 19% in printing costs as a result of our cost transformation initiatives.

Sales and Marketing Expenses. Sales and marketing expenses increased 33%, or $1.3 million, to $5.3 million for the year ended December 31, 2015, from $4.0 million for the year ended December 31, 2014, principally due to the following: costs from the acquired businesses of $1.0 million, and compensation costs increased by $0.3 million, or 11%, as a result of increased commissions resulting from increased revenue and us building and developing our team.

Interest Income and Expense

Interest expense decreased 26%, or $0.1 million, to $0.3 million for the year ended December 31, 2015, from $0.4 million for the year ended December 31, 2014, principally due to the decrease in amortization of loan guarantee and financing fees, offset by the higher interest rate related to debt that was refinanced in May 2015.

Change in Fair Value of Warrant Liability

The change in the fair market value of our warrant liability resulted in $35,000 in non-cash income for the year ended December 31, 2015, as compared to non-cash income of $0.4 million for the year ended December 31, 2014. The fair market value of these common stock warrants decreased as a consequence of a decrease in our stock price and the expiration 15,000 warrants in 2015.

Change in Fair Value of Acquisition Note Payable

The change in fair value of the acquisition note payable resulted in $0.3 million in non-cash income for the year ended December 31, 2015, as compared to $0.2 million for the year ended December 31, 2014. The fair value of the note, representing part of the purchase price for BioServe, decreased as a consequence of a decrease in our stock price.

Income Taxes

In November 2015, we received $1.2 million from sales of state NOL's and research and development tax credits. During the year ended December 31, 2014, we received two payments totaling $2.4 million from sales of state NOL’s.

Year Ended December 31, 2014 and 2013

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

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	Year Ended December 31,		Change	
	2014	2013	$	%
(dollars in thousands)				
Revenue	$10,199	$6,610	$3,589	54 %
Cost of revenues	8,453	4,925	3,528	72 %
Research and development expenses	4,622	2,190	2,432	111 %
General and administrative expenses	12,369	6,115	6,254	102 %
Sales and marketing expenses	3,964	1,842	2,122	115 %
Total operating loss	$(19,209)	$(8,462)	$(10,747)	127 %
Interest income (expense)	(399)	(2,358)	1,959	-83 %
Change in fair value of warrant liability	417	4,633	(4,216)	-91 %
Change in fair value of acquisition note payable	198	—	198	n/a
Debt conversion costs	—	(6,850)	6,850	100 %
Loss before income taxes	(18,993)	(13,037)	(5,956)	46 %
Income tax benefit (expense)	2,350	664	1,686	254 %
Net loss	$(16,643)	$(12,373)	$(4,270)	35 %

Revenue

The breakdown of our revenue is as follows:

	Year Ended December 31,						Change		
	2014			2013					
(dollars in thousands)	$	%		$	%		$	%	
Biopharma Services	5,606	55	%	2,650	40	%	2,956	112	%
Clinical Services	4,432	43	%	3,663	55	%	769	21	%
Discovery Services	161	2	%	—	—	%	161	n/a	
Grants	—	—	%	297	5	%	(297)	(100)	%
Total Revenue	10,199	100	%	6,610	100	%	3,589	54	%

Revenue increased 54%, or $3.6 million, to $10.2 million for the year ended December 31, 2014, from $6.6 million for the year ended December 31, 2013, principally due to the acquisitions of Gentris and BioServe, whose revenue accounted for $3.3 million of the increase. Our average revenue (excluding grant revenue and probe revenue) per test decreased to $550 per test for the year ended December 31, 2014 from $566 per test for the year ended December 31, 2013, principally due to a decrease in the average revenue per test from private insurance carriers and other non-Medicare payors. This was offset by an 11% increase in test volume from 10,771 tests for the year ended December 31, 2013, to 11,912 tests for the year ended December 31, 2014.

Revenue from Biopharma Services increased 112%, or $3.0 million, to $5.6 million for the year ended December 31, 2014, from $2.7 million for the year ended December 31, 2013, principally due to the acquisition of Gentris whose revenue accounted for a $3.1 million increase offset by an $0.2 million decrease in legacy Biopharma Services. Revenue from Clinical Services customers increased 21%, or $0.8 million, to $4.4 million for the year ended December 31, 2014, from $3.7 million for the year ended December 31, 2013, principally due to an increase in test volume. This increase in volume was partially offset by a decrease in average revenue per test. Revenue from Discovery Services, our new line of business, increased $0.2 million for the year ended December 31, 2014 representing 2% of total revenue. Revenue from Grants decreased 100%, or $0.3 million, for the year ended December 31, 2014, due to the completion of all grant activities in the year ended December 31, 2013.

Cost of Revenues

Cost of revenues increased 72%, or $3.5 million, to $8.4 million for the year ended December 31, 2014, from $4.9 million for the year ended December 31, 2013, principally due to the following: Costs of revenue from the acquired businesses of $2.2 million, lab supplies expenses increased by $0.5 million or 40% as a result of higher test volumes, shipping costs increased by $0.3 million or 130% as a result of higher test volume, outsourcing services increased by $0.2 million or 257% as a result of us

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contracting with select labs to perform some of our tests, and compensation costs increased by $0.2 million or 9% as a result of us securing the expertise needed to continue to deliver high quality test results. Overall the cost of revenue did not increase proportionately with revenue, due to the cost of revenue in 2013 being lower in proportion as a result of us performing a large number of tests for a clinical trials client in 2013 and in 2013 there was $0.3 million in grant revenues that carried minimal costs, whereas in 2014 there were no grant revenues.

Operating Expenses

Research and Development Expenses. Research and development expenses increased 111%, or $2.4 million, to $4.6 million for the year ended December 31, 2014, from $2.2 million for the year ended December 31, 2013, principally due to the following: Our share of the loss from Oncospire, our joint venture with Mayo Clinic, increased $0.9 million, as it incurred a full year of research expenses related to the pursuit of developing new clinical tests. (In 2013, the costs associated with our joint venture was $12,000). Compensation costs increased by $0.8 million or 88% as a result of us building up our R&D team, and supplies costs increased by $0.3 million or 64% as a result of us accelerating the development of our proprietary tests.

General and Administrative Expenses. General and administrative expenses increased 102%, or $6.3 million to $12.4 million for the year ended December 31, 2014, from $6.1 million for the year ended December 31, 2013, principally due to the following: Costs from the acquired businesses of $1.4 million, stock-based compensation increased by $2.5 million, costs associated with being a public company increased by $1.5 million due to higher consulting, legal and insurance expenses, compensation costs increased by $0.6 million primarily due to a severance agreement for a former officer, allowance for doubtful accounts increased by $0.2 million as we established a reserve for potential uncollectable amounts in our Clinical Services business, professional and consulting fees increased by $0.1 million, recruiting fee costs increased by $0.1 million, and travel costs increased by $0.1 million as a result of the increased travel related to the acquisitions and our expanded customer base, partially off-set by $0.6 million in IPO costs incurred in 2013, which did not recur in 2014.

Sales and Marketing Expenses. Sales and marketing expenses increased 115%, or $2.1 million, to $3.9 million for the year ended December 31, 2014, from $1.8 million for the year ended December 31, 2013, principally due to the following: Costs from the acquired businesses of $0.5 million, compensation costs increased by $1.1 million or 86% as a result of us building and developing our team, marketing costs increased by $0.2 million or 163% as a result of a concentrated effort to expand our customer base, travel costs increased by $0.1 million, and stock-based compensation increased by $0.1 million due to increases in the number of sales personnel.

Interest Income and Expense

Interest expense decreased 83%, or $2.0 million, to $0.4 million for the year ended December 31, 2014, from $2.4 million for the year ended December 31, 2013. The decrease is attributable to the conversion of $9.6 million of debt into common stock which occurred concurrently with the closing of our IPO on April 10, 2013 and the repayment of $3.5 million in indebtedness in August 2013.

Debt Conversion Costs

On April 10, 2013, we completed our IPO. In connection with the IPO, $9.6 million of debt was converted into common stock at the IPO price of $10.00 per share. In connection with the conversion of debt into common stock, we expensed the applicable remaining debt discounts of $3.5 million, financing fees of $0.4 million and a contingently recognizable beneficial conversion feature in the converted debt of $3.0 million, the total of which resulted in a $6.9 million write-off. There were no comparable costs in 2014.

Change in Fair Value of Warrant Liability

The change in the fair market value of our warrant liability resulted in $0.4 million in non-cash income for the year ended December 31, 2014, as compared to non-cash income of $4.6 million for the year ended December 31, 2013. The fair market value of these common stock warrants decreased as a consequence of a decrease in our stock price.

Income Taxes

During the year ended December 31, 2014, we received two payments totaling $2.4 million from sales of state NOL’s. During January 2013, we received $0.7 million from the sale of state NOL’s.

Liquidity and Capital Resources

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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.

During November 2015, we received $1.2 million from sales of state NOL's and research and development tax credits. During the year ended December 31, 2014, we received two payments totaling $2.4 million from sales of state NOL's. During January 2013, we received $0.7 million from the sale of state NOL's.

In general, our primary uses of cash are providing for operating expenses, working capital purposes and servicing debt. As of December 31, 2015, we have not borrowed on our line of credit, which allows for borrowings of up to $4.0 million. Our largest source of operating cash flow is cash collections from our customers.

Offerings

On April 10, 2013, we sold 690,000 shares of common stock at a public offering price of $10.00 per share and completed our initial public offering, or IPO, with net proceeds of $5.2 million. Upon the closing of the IPO, all shares of our then-outstanding Series A and Series B convertible preferred stock automatically converted into an aggregate of 1,287,325 shares of common stock. Concurrent with the IPO, certain derivative warrants with a fair value of $7.2 million were reclassified into equity due to the lapsing of anti-dilution provisions in the warrants. Also concurrent with the IPO, $9.6 million of debt converted into 963,430 shares of common stock. Refer to Notes 1, 6 and 11 in the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report.

On August 19, 2013 in our Secondary Offering, or our Secondary Offering, we sold 1,500,000 shares of common stock at a public offering price of $10.00 per share which resulted in gross proceeds of $15.0 million ($13.3 million of net proceeds after offering expenses and underwriting discounts). On September 5, 2013, we sold 105,000 additional common shares pursuant to the underwriter's partial exercise of the over-allotment option which resulted in gross proceeds of $1.1 million ($0.9 million of net proceeds after offering expenses and underwriting discounts). Upon completion of the Secondary Offering we repaid indebtedness in the aggregate principal amount of $3.5 million plus accrued interest to DAM and to one of our directors, Andrew Pecora, and an affiliated company NJCCA, all of which indebtedness was due on August 15, 2013.

On October 28, 2013 in a follow-on public offering, or our Follow-On Offering, we sold 3,286,700 shares of common stock (including the underwriter's overallotment of 428,700 shares), at a public offering price of $14.00 per share resulting in gross proceeds of $46.0 million (net proceeds of $42.3 million).

In July 2015, we sold 2,800 shares of common stock that resulted in net proceeds to the Company of $34,000 through our sales agreement with Cantor Fitzgerald & Co. See Note 19 in the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report.

On November 12, 2015, we sold 3,000,000 shares of common stock with warrants to purchase an aggregate of 3,000,000 shares of common stock at a combined public offering price of $4.00 per share and warrant resulting in gross proceeds of $12.0 million ($10.3 million of net proceeds after offering expenses and underwriting discounts). The underwriters also received 450,000 warrants pursuant to the partial exercise of the over-allotment option. The warrants have an exercise price of $5.00, became fully-exercisable at issuance and expire on November 12, 2020.

Credit Facility

On May 7, 2015, we entered into a new debt financing facility with Silicon Valley Bank ("SVB") to refinance the Company's cash collateralized loan from Wells Fargo and to provide an additional working capital line of credit. The SVB credit facility provides for a $6.0 million term note ("Term Note") and a revolving line of credit ("Line of Credit") for an amount not to exceed the lesser of (i) $4.0 million or (ii) an amount equal to 80% of eligible accounts receivable. The Term Note requires interest-only payments through April 30, 2016 and beginning May 1, 2016, monthly principal payments of approximately$167,000 will be required plus interest through maturity on April 1, 2019. The interest rate of the Term Note is the Wall Street Journal prime rate plus 2%, with a floor of 5.25% (5.50% at December 31, 2015) and an additional deferred interest payment of $180,000 will be due upon maturity. The Line of Credit requires monthly interest-only payments of the Wall Street Journal prime rate plus 1.5% (5.00% at December 31, 2015) and matures on May 7, 2017. The new loan agreement requires maintenance of certain financial ratios and grants SVB a first security interest in substantially all Company assets (other than

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our intellectual property). Pursuant to the new loan agreement, we are no longer required to maintain restricted cash accounts. At December 31, 2015, the principal balance of the Term Note was $6,000,000 and the principal balance of the Line of Credit was $0. Pursuant to the amendment dated January 28, 2016, we are restricted from using the Line of Credit until $13 million of additional equity is raised.

Cash Flows

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

	Year Ended December 31,		
	2015	2014	2013
(in thousands)			
Cash provided by (used in):			
Operating activities	$(13,599)	$(12,338)	$(8,075)
Investing activities	(2,640)	(11,373)	(1,399)
Financing activities	10,144	(195)	58,114
Net increase (decrease) in cash and cash equivalents	$(6,095)	$(23,906)	$48,640

We had cash and cash equivalents of $19.5 million at December 31, 2015, $25.6 million at December 31, 2014, and $49.5 million at December 31, 2013.

The $6.1 million decrease in cash and cash equivalents for the year ended December 31, 2015 was principally the result of the use of $13.6 million of net cash in operations, purchasing substantially all of assets of Response Genetics for $7.5 million (plus stock), and investing $1.0 million in fixed assets, offset by the $6.0 million decrease in restricted cash and the $10.3 million in net proceeds from the 2015 Offering.

The $23.9 million decrease in cash and cash equivalents for the year ended December 31, 2014 was principally the result of the use of $12.3 million of net cash in operations, restricting $6.0 million to secure a line of credit with Wells Fargo of $6.0 million, payments of $2.9 million for the acquisitions of Gentris and BioServe, payment of $1.0 million to invest in our joint venture with Mayo and the purchase of fixed assets of $1.4 million.

The $48.6 million increase in cash and cash equivalents for the year ended December 31, 2013 was principally the result of the receipt of $5.0 million in proceeds received in our IPO, the receipt of $14.2 in net proceeds from our Secondary Offering, and the receipt of $42.3 million in net proceeds from our Follow-On Offering, all of which were offset by $1.0 million paid to invest in our joint venture with Mayo, the repayment of $3.6 million in indebtedness and the use of $8.1 million of net cash in operations.

Cash Used in Operating Activities

Net cash used in operating activities was $13.6 million for the year ended December 31, 2015. We used $15.7 million in net cash to run our core operations, which included $0.2 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 $1.7 million; an increase in other current assets of $0.4 million and an increase in other assets of $0.1 million. All of these uses of cash were partially offset by a net increase in accounts payable, accrued expenses and deferred revenue of $3.1 million and the receipt of $1.2 million from the sale of state NOL carryforwards and research and development credits in November 2015.

Net cash used in operating activities was $12.3 million for the year ended December 31, 2014. We used $13.5 million in net cash to run our core operations, which included $0.1 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 $1.7 million; an increase in other current assets of $0.2 million which included prepayments for our insurance policies. All of these uses of cash were partially offset by a net increase in accounts payable, accrued expenses and deferred revenue of $0.7 million and the receipt of $2.4 million from the sale of certain state NOL carryforwards in January 2014 and December 2014.

Net cash used in operating activities was $8.1 million for the year ended December 31, 2013. We used $7.1 million in net cash to run our core operations, which included $0.6 million in cash paid for interest. We incurred additional uses of cash as follows: $0.7 million for a net decrease in accounts payable, accrued expenses and deferred revenue; $0.4 million to increase other

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current assets which included prepayments for consumables and other supplies used to run our operations as well as prepayments for our insurance policies, and; accounts receivable increased by $0.7 million. All of these uses of cash were partially offset by the receipt of $0.7 million from the sale of certain state NOL carryforwards in January 2013.

Cash Used in Investing Activities

Net cash used in investing activities was $2.6 million for the year ended December 31, 2015 and principally resulted from the purchase of substantially all assets of Response Genetics for $7.5 million, plus stock, and the purchase of fixed assets for $1.0 million, offset by the $6.0 million decrease in restricted cash resulting from refinancing our debt in May 2015.

Net cash used in investing activities was $11.4 million for the year ended December 31, 2014 and principally resulted from an increase in our restricted cash of $6.0 million related to the collateralization of our line of credit with Wells Fargo; cash paid of $2.9 million in the acquisitions of Gentris and BioServe; investment of $1.0 million in our Joint Venture with the Mayo Foundation and purchase of fixed assets of $1.4 million.

Net cash used in investing activities was $1.4 million for the year ended December 31, 2013 and principally resulted from: a $1.0 million payment to Mayo to fund our joint venture; purchases of fixed assets of $0.3 million; patent application costs of $0.1 million, and; an increase in our restricted cash related to a $0.1 million increase in the Letter of Credit related to our lease. Pursuant to the terms of our lease for our Rutherford facility, we were required to maintain a letter of credit in the amount of $0.3 million to use as a guarantee for the security deposit.

Cash Used/Provided by Financing Activities

Net cash provided by financing activities was $10.1 million for the year ended December 31, 2015 principally due to the 2015 Offering, which resulted in $10.3 million in net proceeds, offset by capital lease payments of $0.1 million and equity issuance costs of $0.1 million.

Net cash used in financing activities was $0.2 million for the year ended December 31, 2014, and primarily resulted from payments on notes payable of $0.4 million; partially off-set by proceeds received from warrant and option exercises of $0.3 million.

Net cash provided by financing activities was $58.1 million for the year ended December 31, 2013, and primarily consisted of receipt of $61.5 million in net proceeds raised in our IPO, Secondary Offering and Follow-On Offering offset by the repayment of $3.6 million in indebtedness.

Capital Resources, Acquisitions and Expenditure Requirements

We expect to continue to incur substantial operating losses in the future. It may take several years, if ever, to achieve positive operational cash flow. Until we can generate a sufficient amount of revenue to finance our cash requirements, which we may never do, we will need to continue to raise additional capital to fund our operations.

We also expect to use significant cash to fund acquisitions. On July 16, 2014, we purchased substantially all of the assets of Gentris, with its principal place of business in North Carolina for approximately $4.8 million. On August 18, 2014, we acquired BioServe, an Indian corporation, for an aggregate purchase price of approximately $1.1 million. On October 9, 2015, we acquired substantially all of the assets of Response Genetics, Inc. for aggregate consideration of approximately $12.9 million consisting of $7.5 million in cash and our common stock valued at approximately $5.4 million.

In May 2015, we entered into a line of credit with Silicon Valley Bank. Pursuant to the amendment dated January 28, 2016, the Company agreed not to draw on the line of credit until $13 million of additional equity is raised. See Note 6 in the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report.

On July 15, 2015, the Company entered into a Controlled Equity Offering[SM] Sales Agreement ("Sales Agreement") with Cantor Fitzgerald & Co., ("Cantor") as sales agent, pursuant to which the Company may offer from time to time through Cantor, shares of our common stock having an aggregate offering price of up to $20.0 million.

We believe that our current cash will support operations for the next 15 to 24 months. 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

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general and administrative, sales and marketing and research and development activities are forward-looking statements and involve risks and uncertainties.
We expect our operating expenses to increase as we continue investing in sales and marketing, research and development and other general and administrative expenses.

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 achieve revenue growth and profitability;
- the costs for funding the operations we recently acquired, including Response Genetics, and our ability to successfully integrate those operations with and into our own;
- our ability to obtain approvals for our new diagnostic tests;
- our ability to execute on our marketing and sales strategy for our genomic 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;
- 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;
- our ability to succeed with our cost control initiative;
- the timing of and the costs involved in regulatory compliance, particularly if the regulations change;
- 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;
- our ability to secure financing and the amount thereof; and
- other risks discussed in the section entitled “Risk Factors.”

We expect that our operating expenses and capital expenditures will increase in the future as we expand our business and integrate our recent acquisitions. We plan to increase our sales and marketing headcount to promote our new clinical tests and services and to expand into new geographies and to increase our research and development expenditures associated with performing work with research collaborators, to expand our pipeline and to perform work associated with our research collaborations. For example, in 2011 we entered into an affiliation agreement to form a joint venture with the Mayo Foundation for Medical Education and Research pursuant to which we made an initial $1.0 million capital contribution in October 2013 and $1.0 million in the third quarter of 2014. We currently anticipate that we will make capital contributions of $1.0 million in the second quarter of 2016 and expect to make additional capital contributions of up to $3.0 million, subject to the joint venture entity’s achievement of certain operational milestones. Until we can generate a sufficient amount of revenues to finance our cash requirements, which we may never do, we may need to raise additional capital to fund our operations.

We 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 would have a material adverse impact on our business prospects and results of operations.

Future Contractual Obligations

The following table reflects a summary of our estimates of future contractual obligations as of December 31, 2015. 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

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our variable debt that was in effect as of December 31, 2015. 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	$6,771	$1,629	$4,288	$854	$—
Capital Lease obligations, including interest, for equipment	449	143	153	129	24
Operating lease obligations relating to corporate headquarters and clinical laboratories	3,206	1,396	1,333	477	—
Total	$10,426	$3,168	$5,774	$1,460	$24

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.

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

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

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

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.

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Foreign Exchange Risk

We conduct business in foreign markets through our subsidiary in India (BioServe Biotechnologies (India) Private Limited) and in Italy through our subsidiary (Cancer Genetics Italia, S.r.l.). For the years ended December 31, 2015, 2014 and 2013 approximately 5%, 4% and 3%, respectively, of our revenues were earned outside the United States and collected in local currency. We are subject to risk for exchange rate fluctuations between such local currencies and the United States dollar and the subsequent translation of the Indian Rupee or Euro to United States dollars. We currently do not hedge currency risk. The translation adjustments for the years ended December 31, 2015, 2014 and 2013 were not significant.

Interest Rate Risk

At December 31, 2015, we had interest rate risk primarily related to borrowings of $6.0 million on the term note with Silicon Valley Bank (“Silicon Valley Line”). Borrowings under the Silicon Valley term note bear interest at the Wall Street Journal prime rate plus 2%, with a floor of 5.25% (5.50% at December 31, 2015). If interest rates increased by 1.0%, interest expense in 2016 on our current borrowings would increase by approximately $60,000.

Investment of Cash

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

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Item 8. Financial Statements and Supplementary Data

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Cancer Genetics, Inc. and Subsidiaries

Consolidated Financial Report December 31, 2015

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Report of Independent Registered Public Accounting Firm
To the Board of Directors and Stockholders
Cancer Genetics, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Cancer Genetics, Inc. and subsidiaries as of December 31, 2015 and 2014, and the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cancer Genetics, Inc. and subsidiaries as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 in conformity with U.S. generally accepted accounting principles.

/s/ RSM US LLP
New York, New York
March 10, 2016

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

	December 31, 2015	2014
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$19,459	$25,554
Accounts receivable, net of allowance for doubtful accounts of 2015 $664; 2014 $251	6,621	5,028
Other current assets	2,118	1,173
Total current assets	28,198	31,755
FIXED ASSETS, net of accumulated depreciation	6,069	4,310
OTHER ASSETS		
Restricted cash	300	6,300
Patents and other intangible assets, net of accumulated amortization	1,727	503
Investment in joint venture	341	1,048
Goodwill	12,029	3,187
Other	220	2
Total other assets	14,617	11,040
Total Assets	$48,884	$47,105
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$7,579	$3,763
Obligations under capital leases, current portion	122	59
Deferred revenue	831	544
Bank term note, current portion	1,333	—
Total current liabilities	9,865	4,366
Obligations under capital leases	276	300
Deferred rent payable and other	315	348
Line of credit	—	6,000
Warrant liability	17	52
Acquisition note payable	—	560
Deferred revenue, long-term	752	925
Bank term note	4,642	—
Total Liabilities	15,867	12,551
STOCKHOLDERS' EQUITY		
Preferred stock, authorized 9,764 shares $0.0001 par value, none issued	—	—
Common stock, authorized 100,000 shares, $0.0001 par value, 13,652 and 9,821 shares issued and outstanding as of December 31, 2015 and 2014, respectively	1	1
Additional paid-in capital	131,167	112,520
Accumulated deficit	(98,151)	(77,967)
Total Stockholders' Equity	33,017	34,554
Total Liabilities and Stockholders' Equity	$48,884	$47,105

See Notes to Consolidated Financial Statements.

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

	Years Ended December 31,		
	2015	2014	2013
Revenue	$18,040	$10,199	$6,610
Cost of revenues	14,098	8,453	4,925
Gross profit	3,942	1,746	1,685
Operating expenses:			
Research and development	5,483	4,622	2,190
General and administrative	14,567	12,369	6,115
Sales and marketing	5,269	3,964	1,842
Total operating expenses	25,319	20,955	10,147
Loss from operations	(21,377)	(19,209)	(8,462)
Other income (expense):			
Interest expense	(344)	(473)	(2,388)
Interest income	49	74	30
Change in fair value of warrant liability	35	417	4,633
Change in fair value of acquisition note payable	269	198	—
Debt conversion costs	—	—	(6,850)
Total other income (expense)	9	216	(4,575)
Loss before income taxes	(21,368)	(18,993)	(13,037)
Income tax (benefit)	(1,184)	(2,350)	(664)
Net (loss)	$(20,184)	$(16,643)	$(12,373)
Basic net (loss) per share	$(1.96)	$(1.76)	$(2.65)
Diluted net (loss) per share	$(1.96)	$(1.80)	$(3.64)
Basic weighted average shares outstanding	10,298	9,449	4,665
Diluted weighted average shares outstanding	10,299	9,462	4,676

See Notes to Consolidated Financial Statements.

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CANCER GENETICS, INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders' Equity (Deficit)
Years Ended December 31, 2015, 2014 and 2013
(in thousands)

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	Preferred Stock Series A		Preferred Stock Series B		Common Stock		Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, December 31, 2012	588	$ —	1,822	$ —	1,350	$ —	$24,970	$ (17)	$ (48,934)	$(23,981)
Stock based compensation - employees	—	—	—	—	3	—	647	—	—	647
Stock based compensation - non-employees	—	—	—	—	—	—	88	—	—	88
Vesting of common pursuant to joint venture agreement	—	—	—	—	—	—	232	—	—	232
Conversion of preferred stock into common stock	(588)	—	(1,822)	—	1,287	—	—	—	—	—
Conversion of debt into common stock	—	—	—	—	963	—	12,596	—	—	12,596
Issuance of common stock in IPO, net of offering costs	—	—	—	—	690	—	3,743	—	—	3,743
Issuance of common stock in Secondary Offering, net of offering costs	—	—	—	—	1,605	—	14,230	—	—	14,230
Issuance of common stock in Follow-On Offering, net of offering costs	—	—	—	—	3,287	1	42,302	—	—	42,303
Issuance of common stock pursuant to license agreement	—	—	—	—	2	—	20	—	—	20
Issuance of common stock pursuant to joint venture agreement	—	—	—	—	10	—	175	—	—	175
Reclassification of derivative warrants	—	—	—	—	—	—	7,170	—	—	7,170
Exercise of warrants	—	—	—	—	78	—	612	—	—	612
Exercise of options	—	—	—	—	—	—	2	—	—	2
Retirement of treasury stock	—	—	—	—	—	—	—	17	(17)	—
Net loss	—	—	—	—	—	—	—	—	(12,373)	(12,373)
Balance, December 31, 2013	—	—	—	—	9,275	1	106,787	—	(61,324)	45,464
Stock based compensation - employees	—	—	—	—	208	—	3,462	—	—	3,462
Stock based compensation - non-employees	—	—	—	—	5	—	373	—	—	373
Exercise of warrants	—	—	—	—	135	—	303	—	—	303
Exercise of options	—	—	—	—	19	—	79	—	—	79
Issuance of stock - acquisition of Gentris Corporation	—	—	—	—	148	—	1,272	—	—	1,272
Issuance of stock - acquisition of BioServe	—	—	—	—	31	—	244	—	—	244
Net loss	—	—	—	—	—	—	—	—	(16,643)	(16,643)
Balance, December 31, 2014	—	—	—	—	9,821	1	112,520	—	(77,967)	34,554
Stock based compensation—employees	—	—	—	—	35	—	2,558	—	—	2,558

Stock based compensation—non-employees	—	—	—	—	—	—	276	—	—	276
Exercise of warrants	—	—	—	—	—	—	1	—	—	1
Exercise of options	—	—	—	—	4	—	23	—	—	23
Issuance of stock - Cantor Sales Agreement	—	—	—	—	3	—	34	—	—	34
Issuance of stock - acquisition of Response Genetics	—	—	—	—	789	—	5,436	—	—	5,436
Issuance of stock with warrants in 2015 Offering	—	—	—	—	3,000	—	10,319	—	—	10,319
Net loss	—	—	—	—	—	—	—	—	(20,184)	(20,184)
Balance, December 31, 2015	—	$—	—	$—	13,652	$1	$131,167	$—	$ (98,151)	$33,017

See Notes to Consolidated Financial Statements

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

	Years Ended December 31,		
	2015	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$(20,184)	$(16,643)	$(12,373)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,503	810	311
Amortization	159	28	15
Provision for bad debts	413	215	—
Stock-based compensation	2,834	3,835	735
Stock-based research and development/general and administrative expenses	—	—	427
Change in fair value of acquisition note payable	269	(198)	—
Change in fair value of Gentris contingent consideration	(207)	—	—
Change in fair value of warrant liability	(35)	(417)	(4,633)
Amortization of loan guarantee, financing fees and debt issuance costs	8	311	1,195
Accretion of discount on debt	—	—	585
Loss in equity-method investment	707	940	12
Loss on conversion of debt to equity	—	—	6,850
Deferred initial public offering costs expensed	—	—	618
Change in working capital components:			
Accounts receivable	(1,662)	(1,657)	(717)
Other current assets	(384)	(199)	(375)
Other non-current assets	(101)	—	—
Accounts payable, accrued expenses and deferred revenue	3,114	675	(731)
Deferred rent and other	(33)	(38)	6
Net cash (used in) operating activities	(13,599)	(12,338)	(8,075)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchase of fixed assets	(1,008)	(1,374)	(257)
(Increase) decrease in restricted cash	6,000	(6,000)	(50)
Patent costs	(137)	(130)	(92)
Investment in joint venture	—	(1,000)	(1,000)
Cash used in acquisition of Gentris, net of cash received	—	(3,181)	—
Cash from acquisition of BioServe	—	312	—
Cash used in acquisition of Response Genetics	(7,495)	—	—
Net cash (used in) investing activities	(2,640)	(11,373)	(1,399)
CASH FLOWS FROM FINANCING ACTIVITIES			
Principal payments on capital lease obligations	(83)	(44)	(17)
Payment of equity issuance costs	(117)	—	—
Proceeds from public offerings of common stock, net of offering costs	10,353	—	61,517
Proceeds from warrant exercises	1	178	192
Proceeds from option exercises	23	79	2
Payment of debt issuance costs	(33)	—	—

Principal payments on notes payable	—	(408)	(3,580)
Net cash provided by (used in) financing activities	10,144	(195)	58,114
Net increase (decrease) in cash and cash equivalents	(6,095)	(23,906)	48,640
CASH AND CASH EQUIVALENTS			
Beginning	25,554	49,460	820
Ending	$19,459	$25,554	$49,460
SUPPLEMENTAL CASH FLOW DISCLOSURE			
Cash paid for interest	$240	$128	$608
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES			
Fixed assets acquired through capital lease arrangements	$—	$42	$354
Warrants issued for financing fees	—	—	47
Retirement of treasury stock	—	—	17
Conversion of notes payable and lines of credit to common stock	—	—	9,634
Value of shares issued as partial consideration to purchase Gentris and BioServe	—	1,516	—
Value of shares issued as partial consideration to purchase Response Genetics	5,436	—	—
Reclassification of derivative warrants	—	—	7,170
Cashless exercise of derivative warrants	—	125	420
Offering costs discounted	—	—	733
Net tangible assets acquired via acquisition	2,843	1,255	—
Accrued expenses reclassified as derivative warrant liability	—	—	221

See Notes to Consolidated Financial Statements.

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CANCER GENETICS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements
Note 1. Organization, Acquisitions, Description of Business, Reverse Stock Split and Charter Amendment

We are an emerging leader in the field of personalized medicine, enabling precision medicine in the field of oncology through our diagnostic products and services and molecular markers. We develop, commercialize and provide molecular- and biomarker-based tests and services that enable physicians to personalize the clinical management of each individual patient by providing genomic information to better diagnose, monitor and inform cancer treatment and that enable biopharmaceutical 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. We have a comprehensive, disease-focused oncology testing portfolio. Our tests and techniques target a wide range of cancers, covering eight of the top ten cancers in prevalence in the United States, with additional unique capabilities offered by our Tissue of Origin® test for identifying difficult to diagnose tumor types or poorly differentiated metastatic disease.

We were incorporated in the State of Delaware on April 8, 1999 and have offices and state-of-the-art laboratories located in California, New Jersey, North Carolina, Shanghai (China), and Hyderabad (India). Our laboratories comply with the highest regulatory standards as appropriate for the services they deliver including CLIA, CAP, NY State, California State and NABL (India).We have two advisory boards to counsel our scientific and clinical direction. Our Scientific Advisory Board is comprised of preeminent scientists and physicians from the fields of cancer biology, cancer pathology, cancer medicine and molecular genetics. Our Clinical Advisory Board is comprised of clinicians and scientists focused on clinical implementation of our proprietary tests and services and mapping those tests and services to patient needs. 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.

Acquisition of Gentris Corporation
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. Gentris' laboratory is located in Morrisville, North Carolina and the company has a CLIA and FDA-compliant laboratory facility in Shanghai, China. Upon closing of the acquisition transaction, Gentris Corporation was re-named Gentris, LLC and is now a wholly-owned subsidiary of Cancer Genetics, Inc. The acquisition allows us to expand our biopharma services.

The assets and liabilities of Gentris were recorded in our consolidated financial statements at their estimated fair values as of the acquisition date. The excess value of the consideration paid over the fair value of assets acquired and liabilities assumed was recorded as goodwill. Goodwill arising from the acquisition consists largely from a trained workforce in place and expected synergies with existing operations. Goodwill recorded in conjunction with the acquisition is deductible for income tax purposes. The total consideration for the Gentris acquisition is as follows (in thousands except share amounts):

	Amount
Cash paid at closing	$3,250
Issuance of 147,843 common shares	1,272
Estimated fair value of contingent consideration	293
Total purchase price	$4,815

During the year ended December 31, 2015, we recognized a gain of $207,000 due to settling the contingent consideration for $86,400.

We incurred a finder's fee of $147,500 related to the transaction.

The following table summarizes the final valuation of the assets acquired and liabilities assumed as of July 16, 2014 (in thousands):

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	Amount
Accounts receivable	$1,869
Other current assets	266
Current liabilities	(785)
Deferred revenue, long-term	(938)
Fixed assets	1,951
Goodwill	2,452
Total purchase price	$4,815

Acquisition of BioServe Biotechnologies (India) Pvt. Ltd.

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. This transaction was completed through a newly formed subsidiary, Cancer Genetics (India) Pvt. Ltd.
BioServe is a leading genomic service and next-generation sequencing company serving both the research and clinical markets based in Hyderabad, India. With the BioServe acquisition we believe we will be able to access the Indian healthcare market. The acquisition provides us with an infrastructure in India for developing lower cost manufacturing of probes and kits including probes and kits used for our proprietary FHACT test and access to one of the fastest-growing molecular and clinical diagnostic markets in the world. BioServe will continue to serve biotechnology and biopharmaceutical companies, diagnostic companies and research hospitals, including those owned or operated by the Indian government, as well as seek to expand its customer base.

The assets and liabilities of BioServe were recorded in the Company's consolidated financial statements at their estimated fair values as of the acquisition date. The excess value of the consideration paid over the fair value of assets acquired and liabilities assumed is recorded as goodwill. Goodwill arising from the acquisition consists largely from a trained workforce in place and expected synergies from new lines of business. Goodwill recorded in conjunction with the acquisition is not deductible for income tax purposes. The aggregate purchase price is as follows (in thousands except share amounts):

	Amount
Cash paid at closing	$73
Notes payable	24
Notes payable (value of 84,278 common shares)	733
Issuance of 31,370 common shares	244
Total purchase price	$1,074

The final payment for BioServe will be a cash payment equal to the value of 84,278 shares of our common stock in November 2016. This liability is subject to future adjustment based upon changes to our stock price. During the year ended December 31, 2015 and 2014, we recognized a gain of $269,000 and $198,000, respectively, due to the decrease in value of this note. The amounts used in computing the purchase price differ from the amounts in the purchase agreements due to fair value measurement conventions prescribed in accounting standards.

During 2015, the Company made revisions to the preliminary valuation of certain assets acquired which increased goodwill by approximately $193,000, reduced fixed assets by approximately $136,000, reduced other assets by approximately $38,000 and reduced other current assets by approximately $19,000.

The following table summarizes the final valuation of the assets acquired and liabilities assumed as of August 18, 2014 (in thousands):

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	Amount
Accounts receivable	$ 151
Other current assets	102
Fixed assets	489
Other assets	378
Goodwill	735
Current liabilities	(759)
Other liabilities	(22)
Total purchase price	$ 1,074

Acquisition of Response Genetics, Inc.

On October 9, 2015, we acquired substantially all the assets and assumed certain liabilities of Response Genetics, Inc. ("Response Genetics"), with its principal place of business in California, in a transaction valued at approximately $12.9 million, comprised of $7,495,193 in cash and 788,584 shares of the Company's common stock, with the common stock being valued at $5,436,104.
Response Genetics was a life sciences company engaged in the research and development of clinical diagnostic tests for cancer. Response Genetics generated revenues primarily from sales of its ResponseDX® diagnostic tests, which Response Genetics launched in 2008, and by providing clinical trial testing services to pharmaceutical companies.

The transaction is being accounted for using the acquisition method of accounting for business combinations in accordance with GAAP. 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. 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.

Goodwill arising from the acquisition consists largely from a trained workforce in place and expected synergies from new lines of business. Goodwill recorded in conjunction with the acquisition is deductible for income tax purposes. Business transactions expense of approximately $890,000 incurred in connection with the acquisition was expensed as incurred.

The final allocation of the purchase price of the fair value of the assets acquired and the liabilities assumed as of October 9, 2015 is as follows (in thousands):

	Amount
Accounts receivable	$ 344
Prepaid expenses and other current assets	561
Fixed assets	2,254
Intangible assets	1,246
Goodwill	8,842
Current liabilities	(194)
Obligations under capital lease	(122)
Total purchase price	$ 12,931

Acquisitions Pro Forma Financial Information

The following table provides certain pro forma financial information for the Company as if the acquisitions of Response Genetics, Gentris and Bioserve discussed above occurred on January 1, 2013 (in thousands except per share

amounts):

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	Unaudited Year Ended December 31,		
	2015	2014	2013
Revenue	$28,528	$34,167	$32,488
Net loss	(33,237)	(26,427)	(26,712)
Basic net loss per share	$(3.05)	$(2.56)	$(4.74)
Dilutive net loss per share	(3.05)	(2.59)	(5.55)

The pro forma numbers above are derived from historical numbers of the Company, Response Genetics, Gentris and Bioserve. Over time the operations of Response Genetics will be integrated into the operations of the Company. This integration may change how certain tests are coded and submitted to payers (including Medicare) and, consequently, may result in differences in the future in which revenues and bad debt expenses are recorded when compared with the historical methods of Response Genetics. At the current time, we do not have enough information to prepare a reliable estimate of any possible changes.

The results of operations for the year ended December 31, 2015 include the operations of Response Genetics from October 9, 2015 and twelve months of operations of Gentris and Bioserve with combined revenues of $8,771,000. The net loss of Response Genetics, Gentris and Bioserve cannot be determined, as their operations are integrated with Cancer Genetics. The results of operations for the year ended December 31, 2014 include the the operations of Gentris from July 16, 2014 and BioServe from August 18, 2014 and include combined revenues of $3,296,465.

Reverse Stock Splits

On February 8, 2013, we filed a charter amendment with the Secretary of State for the State of Delaware and effected a 1-for-2 reverse stock split of our common stock. On March 1, 2013, we filed another charter amendment with the Secretary of State for the State of Delaware and effected a 1-for-2.5 reverse stock split of our common stock. All shares and per share information referenced throughout the consolidated financial statements have been retroactively adjusted to reflect both reverse stock splits.

Public Offerings

On April 10, 2013, we sold 690,000 shares of common stock at a public offering price of $10.00 per share and completed our initial public offering (“IPO”) with gross proceeds of $6.9 million (net proceeds of $5 million). Upon the closing of the IPO, all shares of our then-outstanding Series A and Series B convertible preferred stock automatically converted into an aggregate of 1,287,325 shares of common stock. Concurrent with the IPO, certain derivative warrants with a fair value of $7.2 million were reclassified into equity due to the lapsing of anti-dilution provisions in the warrants. Also concurrent with the IPO, $9.6 million of debt converted into 963,430 shares of common stock. All references to our Series A convertible preferred stock refer collectively to the Series A and Series A-1 convertible preferred shares.

On August 19, 2013, we sold 1,500,000 shares of common stock at a public offering price of $10.00 per share resulting in gross proceeds of $15.0 million (net proceeds of $13.3 million). We used $3.5 million of the proceeds to repay certain indebtedness which was due on August 15, 2013 (see Note 6 for further discussion of the Company’s debt). On September 5, 2013, we sold 105,000 additional common shares pursuant to partial exercise of the underwriter’s over-allotment option which resulted in gross proceeds of $1.1 million (net proceeds of $947,000). All references to the sales of common stock mentioned in this paragraph are referred to as the “Secondary Offering.”

On October 28, 2013, we sold 3,286,700 shares of common stock, (including the underwriter’s overallotment of 428,700 shares), at a public offering price of $14.00 per share resulting in gross proceeds of $46.0 million (net proceeds of $42.3 million). All references to the sales of common stock mentioned in this paragraph are referred to as the “Follow-On Offering.”

On November 12, 2015, we sold 3,000,000 shares of common stock with warrants to purchase an aggregate of 3,000,000 shares of common stock at a combined public offering price of $4.00 per share and warrant resulting in gross proceeds of $12.0 million ($10.3 million of net proceeds after offering expenses and underwriting discounts). The underwriters also received 450,000 warrants pursuant to the partial exercise of the over-allotment option. The warrants have an exercise price of $5.00, became fully-exercisable at issuance and expire on November 12, 2020. All references to the sales of common stock with warrants mentioned in this paragraph are referred to as the “2015 Offering.”

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Note 2. 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.

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 our customers; (ii) grants from the National Institutes of Health and (iii) the sale of State of New Jersey net operating loss carryforwards.

Principles of consolidation: The accompanying consolidated financial statements include the accounts of Cancer Genetics, Inc. and our wholly owned subsidiaries, Cancer Genetics Italia S.r.l ("CGI Italia"), Gentris LLC (from July 16, 2014), Bioserve Biotechnologies (India) Private Limited (from August 18, 2014).

All significant intercompany account balances and transactions have been eliminated in consolidation.

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. Our restricted cash collateralizes a $300,000 letter of credit in favor of our landlord, pursuant to the terms of the lease for our Rutherford facility.

Revenue recognition: Revenue is recognized in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 605, Revenue Recognition, and ASC 954-605 Health Care Entities, Revenue Recognition which requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred and title and the risks and rewards of ownership have been transferred to the customer or services have been rendered; (3) the price is fixed or determinable; and (4) collectability is reasonably assured. In determining whether the price is fixed or determinable, we consider payment limits imposed by insurance carriers and Medicare and the amount of revenue recorded takes into account the historical percentage of revenue we have collected for each type of test for each payor category. Periodically, an adjustment is made to revenue to record differences between our anticipated cash receipts from insurance carriers and Medicare and actual receipts from such payors. For the periods presented, such adjustments were not significant. For some Clinical Service and Biopharma customers billed directly, revenue is recorded based upon the contractually agreed upon fee schedule. When assessing collectability, we consider whether we have sufficient payment history to reliably estimate a payor's individual payment patterns. For new tests where there is no evidence of payment history at

the time the tests are completed, we only recognize revenues once reimbursement experience can be established. We then recognize revenue equal to the amount of cash received. We do not bill customers for shipping and handling fees and do not collect any sales or other taxes.

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Revenues from grants to support product development are recognized when costs and expenses under the terms of the grant have been incurred and payments under the grants become contractually due.

Accounts receivable: Accounts receivable are carried at original invoice amount less an estimate for contractual adjustments 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 direct bill 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 insurance carriers where there is not an established pattern of collection, revenue is not recorded until cash is received. For receivables where insurance carriers have made payments to patients instead of directing payments to the Company, an allowance is established for a portion of such receivables. After reasonable collection efforts are exhausted, amounts deemed to be uncollectible are written off against the allowance for doubtful accounts. Since the Company only recognizes revenue to the extent it expects to collect such amounts, bad debt expense related to receivables from patient service revenue is recorded in general and administrative expense in the consolidated statement of operations. Recoveries of accounts receivable previously written off are recorded when received.

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

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

Fixed assets are reviewed for impairment whenever changes in circumstances indicate that the carrying amount of an asset may not be recoverable. These computations utilize judgments and assumptions inherent in our estimate of future cash flows to 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 and BioServe in 2014 and the purchase of Response Genetics in 2015, as described in Note 1. In accordance with ASC 350, Intangibles - Goodwill and Other, we are required to test goodwill for impairment and adjust for impairment losses, if any, at least annually and on an interim basis if an event or circumstance indicates that it is likely impairment has occurred. Our annual goodwill impairment testing date is October 1 of each year. No such losses were incurred during the years ended December 31, 2015 and 2014.

Goodwill (in thousands)	
Balance, December 31, 2013	$—
Purchased through acquisitions of Gentris and BioServe	3,187
Balance, December 31, 2014	3,187
Purchased through acquisition of Response Genetics	8,842
Balance, December 31, 2015	$12,029

Loan guarantee and financing fees: Loan guarantee fees are amortized on a straight-line basis over the term of the guarantee. Financing fees are amortized using the effective interest method over the term of the related debt.

Warrant liability: We have issued certain warrants which contain an exercise price adjustment feature in the event we issue additional equity instruments at a price lower than the exercise price of the warrant. The warrants are described herein as derivative warrants. We account for these derivative warrants as liabilities. These common stock purchase warrants do not trade in an active securities market, and as such, we estimate the fair value of these warrants using the binomial lattice valuation pricing model 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. Volatility is estimated based on an average of the historical volatilities of the common stock of four entities with characteristics similar to those of the Company. Prior to our IPO, the measurement date fair value of the underlying common shares was based upon an external valuation of our shares. (See Notes 13 and 14). Subsequent to the IPO and Secondary Offering, we used the closing price of our shares on the OTC Bulletin Board and the NASDAQ Capital Market, respectively.

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We compute the fair value of the warrant liability at each reporting period and the change in the fair value is recorded as non-cash expense or non-cash income. The key component in the value of the warrant liability is our stock price, which is subject to significant fluctuation and is not under our control. The resulting effect on our net income (loss) is therefore subject to significant fluctuation and will continue to be so until the warrants are exercised, amended or expire. Assuming all other fair value inputs remain constant, we will record non-cash expense when the stock price increases and non-cash income when the stock price decreases.

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

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, 2015 and 2014, therefore we have not recognized any tax benefit or expense in the periods presented.

ASC 740, Income Taxes, clarifies the accounting for uncertainty in income taxes recognized in the financial statements. ASC 740 provides that a tax benefit from uncertain tax positions may be recognized when it is more-likely-than-not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. Income tax positions must meet a more-likely-than-not recognition threshold to be recognized. ASC 740 also provides guidance on measurement, de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. At December 31, 2015 and 2014 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, 2015 or 2014, and we have not recognized interest and/or penalties in the consolidated statements of operations for the years ended December 31, 2015, 2014 or 2013.

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 2015, 2014 or 2013.

Other intangible assets consist of software acquired with Response Genetics, which are amortized using the straight-line method over the estimated useful lives of the assets, which range from three to five 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.

Registration payment arrangements: We account for our obligations under registration payment arrangements in accordance with ASC 825-20, Registration Payment Arrangements. ASC 825-20 requires us to record a liability if we determine a registration payment is probable and if it can reasonably be estimated. As of both December 31, 2015 and 2014, we have an accrued liability of $300,000.

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 12.

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

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more reliably measurable. Stock-based compensation awards issued to non-employees are recorded in expense and additional paid-in capital in stockholders' equity (deficit) 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, contingent consideration and note payable to VenturEast are described in Notes 14 and 15.

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 $707,000 in 2015, $940,000 in 2014 and $12,000 in 2013 (the first year of the joint venture's operations) and is included in research and development expense on the Consolidated Statement of Operations. The Company has a net receivable due from the joint venture of approximately $10,000 and $10,000 at December 31, 2015 and 2014, respectively, which is included in other assets in the Consolidated Balance Sheet. See additional information in Note 17.

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 ASU 2016-02, "Leases (Topic 842)," which provides guidance for accounting for leases. Under ASU 2016-02, the Company will be required to recognize the assets and liabilities for the rights and obligations created by leased assets. ASU 2016-02 will take effect for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company is currently evaluating the effect this standard will have on the consolidated financial statements.

In September 2015, the FASB issued ASU 2015-16, Business Combinations (Topic 805) "Simplifying the Accounting for Measurement-Period Adjustments," which eliminates the requirement for an acquirer in a business combination to account for measurement-period adjustments retrospectively. Under this ASU, acquirers must recognize measurement-period adjustments in the period in which they determine the amounts, including the effect on earnings of any amounts they would have recorded in previous periods if the accounting had been completed at the acquisition date. The amendments in this update should be applied prospectively. This guidance is effective for fiscal years beginning after December 15, 2015, with early adoption permitted for financial statements that have not been issued.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606), requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. As issued and amended, ASU 2014-9 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective and permits the use of either a full retrospective or retrospective with cumulative effect transition method. The updated standard becomes effective for the Company in the first quarter of fiscal year 2018. Early adoption is permitted in the first quarter of fiscal year 2017. The Company has not yet selected a transition method and is currently evaluating the effect that the updated standard will have on the consolidated financial statements.

During the second quarter of 2015, the Company adopted ASU 2015-03, Interest-Imputation of Interest (Subtopic 835-30) "Simplifying the Presentation of Debt Issuance Costs" and ASU 2015-15, Interest-Imputation of Interest (Subtopic 835-30) "Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements." Previously, debt issuance costs were recorded as assets on the balance sheet. ASU 2015-03 requires that debt issuance costs related to a debt liability be presented on the balance sheet as a direct deduction from the carrying amount of the debt liability, consistent with debt discounts. ASU 2015-03 does not change the recognition and measurement of debt issuance costs and requires retrospective adoption. ASU 2015-15 expands on the treatment of debt issuance costs related to line-of-credit arrangements. Under ASU 2015-15, an entity is allowed to defer and present debt issuance costs related to line-of-credit arrangements as an asset and to amortize these costs ratably over

the term of the debt, regardless of whether there is any outstanding borrowings on the line-of-credit. The Company did not have debt issuance costs in the December 31, 2014 Consolidated Balance Sheet.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40) “Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.” The objective of the guidance is to require management to explicitly assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. In connection with each annual and interim period, management will assess if there is substantial doubt about an entity's ability to continue as a going concern within one year after the issuance date of an entity’s financial statements. The new standard defines substantial doubt and provides examples of indicators thereof. The definition of

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substantial doubt incorporates a likelihood threshold of "probable" similar to the current use of that term in U.S. GAAP for loss contingencies. The new standard will be effective for all entities in the first annual period ending after December 15, 2016. Earlier application is permitted. The Company is currently assessing this standard for its impact on future reporting periods.

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):

	2015	2014	2013
Numerator:			
Net (loss) for basic earnings per share	$(20,184)	$(16,643)	$(12,373)
Less change in fair value of warrant liability	35	417	4,633
Net (loss) for diluted earnings per share	$(20,219)	$(17,060)	$(17,006)
Denominator:			
Weighted-average basic common shares outstanding	10,298	9,449	4,665
Assumed conversion of dilutive securities:			
Common stock purchase warrants	1	13	11
Potentially dilutive common shares	1	13	11
Denominator for diluted earnings per share—adjusted weighted-average shares	10,299	9,462	4,676
Basic net loss per share	$(1.96)	$(1.76)	$(2.65)
Diluted net loss per share	$(1.96)	$(1.80)	$(3.64)

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

	2015	2014	2013
Common stock purchase warrants	4,372	1,061	1,702
Stock options	1,961	1,839	874
Restricted shares of common stock	121	133	7
	6,454	3,033	2,583

Note 3. Revenue and Accounts Receivable

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

	2015	2014	2013
Biopharma Services	$11,564	$5,606	$2,650
Clinical Services	5,651	4,432	3,663
Discovery Services	825	161	—
Grants	—	—	297
	$18,040	$10,199	$6,610

The table above includes approximately $486,000 of biopharma services revenue and approximately $1,265,000 of clinical services revenue from our acquisition of Response Genetics for the period October 9, 2015 through December 31, 2015.

Accounts receivable by service type at December 31, 2015 and 2014 consists of the following (in thousands):

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	2015	2014
Biopharma Services	$3,238	$3,203
Clinical Services	3,733	1,925
Discovery Services	314	151
Allowance for doubtful accounts	(664)	(251)
	$6,621	$5,028

Allowance for Doubtful Accounts (in thousands)	
Balance, December 31, 2013	$36
Additions to allowance for doubtful accounts	215
Balance, December 31, 2014	251
Additions to allowance for doubtful accounts	413
Balance, December 31, 2015	$664

Revenue for Biopharma Services are customized solutions for patient stratification and treatment selection through an extensive suite of DNA-based testing services. Clinical Services are tests performed to provide information on diagnosis, prognosis and theranosis of cancers to guide patient management. These 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. Grants includes revenue from grants. The breakdown of our Clinical Services revenue (as a percent of total revenue) is as follows:

	2015	2014	2013
Medicare	10%	11%	13%
Other insurers	12%	16%	25%
Other healthcare facilities	9%	16%	18%
Total Clinical Services	31%	43%	56%

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

The top five test ordering clients during 2015, 2014 and 2013 accounted for 49%, 56% and 69% respectively, of our testing volumes, with 18%, 38% and 36% respectively, of the test volume coming from community hospitals. During the year ended December 31, 2015, one Biopharma client accounted for approximately 19% of our revenue. During the year ended December 31, 2014 there were two Biopharma clients that accounted for approximately 23% and 12%, respectively, of our revenue. During 2013, there was one client that accounted for approximately 40% of our revenue.

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Note 4. Other Current Assets

At December 31, 2015 and 2014, other current assets consisted of the following (in thousands):

	2015	2014
Inventory	$133	$280
Prepaid expenses	1,985	893
	$2,118	$1,173

Note 5. Lease Commitments

We lease our laboratory, research facility and administrative office space under various operating leases. We have approximately 17,900 square feet of office and laboratory space in Rutherford, New Jersey, 24,900 square feet in Morrisville, North Carolina, 27,400 square feet in Los Angeles, California, 10,000 square feet in Hyderabad, India and 2,700 square feet in Shanghai, China. We have escalating lease agreements for both our New Jersey and North Carolina spaces which expire January 2018 and May 2020, respectively. These leases require monthly rent with periodic rent increases that vary from $1 to $2 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 $300,000 security deposit for the facility be held in a stand by letter of credit in favor of the landlord (see Note 7). The California lease expires June 30, 2016.

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 $706,154 and accumulated depreciation of $311,855, as of December 31, 2015.

Minimum future lease payments under all capital and operating leases as of December 31, 2015 are as follows (in thousands):

	Capital Leases	Operating Leases	Total
December 31,			
2016	$143	$1,396	$1,539
2017	78	936	1,014
2018	75	397	472
2019	70	342	412
2020	59	135	194
Thereafter	24	—	24
Total minimum lease payments	$449	$3,206	$3,655
Less amount representing interest	51		
Present value of net minimum obligations	398		
Less current obligation under capital lease	122		
Long-term obligation under capital lease	$276		

Rent expense for the years ended December 31, 2015, 2014 and 2013 was $1,136,778, $692,324, and $550,882, respectively.

Note 6. Debt

Term Note - Silicon Valley Bank

On May 7, 2015, we entered into a new debt financing facility with Silicon Valley Bank (“SVB”) to refinance the Company’s cash collateralized loan from Wells Fargo and to provide an additional working capital line of credit. The SVB credit facility provides for a $6.0 million term note (“Term Note”) and a revolving line of credit (“Line of Credit”) for an amount not to exceed the lesser of (i) $4.0 million or (ii) an amount equal to 80% of eligible accounts receivable. The Term Note requires interest-only payments through April 30, 2016 and beginning May 1, 2016, monthly principal payments of approximately$167,000 will be required plus interest through maturity on April 1, 2019. The interest rate of the Term Note is the Wall Street

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Journal prime rate plus 2%, with a floor of 5.25% (5.50% at December 31, 2015) and an additional deferred interest payment of $180,000 will be due upon maturity. The Line of Credit requires monthly interest-only payments of the Wall Street Journal prime rate plus 1.5% (5.00% at December 31, 2015) and matures on May 7, 2017. The new loan agreement requires maintenance of certain financial ratios and grants SVB a first security interest in substantially all Company assets (other than our intellectual property). Pursuant to the new loan agreement, the Company is no longer required to maintain restricted cash accounts. At December 31, 2015, the principal balance of the Term Note was $6,000,000 and the principal balance of the Line of Credit was $0. On January 28, 2016, the Line of Credit was amended with SVB and we are no longer able to draw on the Line of Credit until we raise approximately $13 million of additional equity.

The following is a summary of long-term debt as of December 31, 2015 (in thousands):

Term Note, principal balance	$6,000
Less unamortized debt issuance costs	25
Term Note, net	5,975
Less current maturities	$1,333
Long-term portion	$4,642

Principal maturities of the Term Note as of December 31, 2015 are as follows: 2016 - $1,333,333; 2017 - $2,000,000; 2018 - $2,000,000; 2019 - $666,667.

Business Line of Credit - Wells Fargo

At December 31, 2014, we had a long-term, fully-utilized line of credit with Wells Fargo Bank, which provided for maximum borrowings of $6 million. The line of credit had a maturity date of April 1, 2016 and required monthly interest payments equal to the Daily One Month LIBOR rate plus 1.75%. The line of credit was collateralized with $6 million in restricted cash and was refinanced by the SVB Term Note in May 2015.

Conversion of Debt concurrent with IPO

On April 10, 2013, we completed our IPO and converted the following indebtedness into shares of common stock at the IPO price of $10.00 per share (in thousands):

	Converted Amount	Common Shares
December 2011 Financing Transaction	$4,500	450
2012 Convertible Debt Financing Transaction	3,000	300
December 2012 Bridge Financing Transaction	1,000	100
Business Lines of Credit (DAM)	1,000	100
Other Note Payable and accrued interest	134	13
	$9,634	963

In connection with the conversion of debt into common stock, we expensed the applicable remaining debt discounts of $3.5 million, financing fees of $419,000 and a contingently recognizable beneficial conversion feature in the converted debt of $3 million.

December 2011 Financing Transaction

The December 2011 Credit Agreement was with John Pappajohn and Andrew Pecora (indirectly through an investment company), both then members of our board of directors, and NNJCA Capital, LLC ("NNJCA"), a limited liability company of which Dr. Pecora is a member. Mr. Pappajohn originally provided $4.0 million of financing, NNJCA originally provided $1.5 million of financing and Dr. Pecora provided $500,000 of financing under the Credit Agreement. On April 10, 2013, Mr. Pappajohn converted $4.0 million and Dr. Pecora converted $500,000 into 450,000 shares of our common stock at the IPO price of $10.00 per share concurrent with our IPO. The remaining outstanding balance of $1.5 million was repaid on August 19, 2013 using a portion of the proceeds from our Secondary Offering.

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2012 Convertible Debt Financing Transaction

On April 10, 2013, the entire $3 million outstanding under a Restated Credit Agreement dated as of August 27, 2012, as amended and restated as of October 17, 2012, ($1,750,000 provided by Mr. Pappajohn and $1,250,000 provided by Mr. Mark Oman) was converted into 300,000 shares of common stock at the IPO price of $10 per share.

December 2012 Bridge Financing Transaction

On April 10, 2013, the entire $1 million outstanding under a credit agreement dated as of December 7, 2012, (all of which was provided by Mr. Pappajohn), was converted into 100,000 shares of common stock at the IPO price of $10.00 per share.

Business Line of Credit – DAM

On April 10, 2013, $1 million of indebtedness under this line with DAM Holdings, LLC was converted into 100,000 shares of common stock at the IPO price of $10 per share. The remaining outstanding balance of $2.0 million was repaid on August 19, 2013 using a portion of the proceeds from our Secondary Offering.

Other Note Payable

On April 10, 2013, a $100,000 note payable and accrued interest payable to Dr. Chaganti was converted into 13,430 shares of common stock at the IPO price of $10.00 per share.

Note 7. Letter of Credit

We maintain a $300,000 letter of credit in favor of our landlord pursuant to the terms of the lease for our Rutherford facility. At December 31, 2015 the letter of credit was fully secured by the restricted cash disclosed on our Consolidated Balance Sheet.

Note 8. Fixed Assets

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

	2015	2014
Equipment	$8,442	$5,777
Furniture and fixtures	1,083	548
Leasehold improvements	932	870
	10,457	7,195
Less accumulated depreciation	(4,388)	(2,885)
Net fixed assets	$6,069	$4,310

Note 9. Patents and Other Intangible Assets

Patents and other intangible assets consist of the following at December 31, 2015 and 2014:

	(in thousands) 2015	(in thousands) 2014	Weighted-Average Amortization Period
Patents	$724	$587	10 years

Patents - Response Genetics acquisition	800	—	7 years
Software - Response Genetics acquisition	446	—	2 years
	1,970	587	
Less accumulated amortization	(243)	(84)	
Net patent and other intangible assets	$1,727	$503	

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Future amortization expense for legally approved patents (excluding patent applications in progress) and other intangible assets, is estimated as follows (in thousands):

2016	$344
2017	290
2018	202
2019	151
2020	140
2021 and thereafter	282
Total	$1,409

Note 10. Income Taxes

The provision for income taxes for the years ended December 31, 2015, 2014 and 2013 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 (in thousands):

	For the Year Ended December 31, 2015		For the Year Ended December 31, 2014		For the Year Ended December 31, 2013	
	Amount (in thousands)	% of Pretax Loss	Amount (in thousands)	% of Pretax Loss	Amount (in thousands)	% of Pretax Loss
Income tax benefit at federal statutory rate	$(7,479)	35.0%	$(6,648)	35.0%	$(4,563)	35.0%
State tax provision, net of federal tax benefit	(878)	4.1%	(807)	4.2%	(359)	2.8%
Tax credits	(232)	1.1%	(154)	0.8%	(126)	1.0%
Stock based compensation	201	(0.9)%	207	(1.1)%	229	(1.8)%
Derivative warrants	(12)	0.1%	(146)	0.8%	(1,622)	12.4%
Investor consideration	(110)	0.5%	(69)	0.4%	—	—%
Debt and warrant conversion costs	—	—%	—	—%	3,454	(26.5)%
Change in valuation allowance	6,617	(31.0)%	5,255	(27.7)%	2,356	(18.1)%
Foreign operations	283	(1.3)%	—	—%	—	—%
Other	426	(2.1)%	12	—%	(33)	0.3%
Income tax (benefit) provision	$(1,184)	5.5%	$(2,350)	12.4%	$(664)	5.1%

During November 2015, we sold $15,990,475 of gross State of New Jersey NOL carryforwards relating to the 2013 and 2014 tax years as well as $289,978 of research and development tax credits, resulting in the receipt of $1,183,564, net of expenses. During January and December 2014, we sold $28,640,223 of gross State of New Jersey NOL carryforwards relating to tax years 2009 through 2012, resulting in the receipt of $2,350,185. During 2013, we sold $8,018,107 of gross State of New Jersey NOL carryforwards, resulting in the receipt of $663,900.

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, 2015 and 2014 (in thousands):

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	2015	2014
Deferred tax assets:		
Net operating loss carryforwards	$25,085	$20,982
Accruals and reserves	1,100	773
Non-qualified stock options	3,357	1,912
Research and development tax credits	989	758
Derivative warrant liability	26	26
Investment in joint venture	251	163
Goodwill	283	23
Fixed assets	78	—
Other	6	6
Total deferred tax assets	31,175	24,643
Less valuation allowance	(31,175)	(24,558)
Net deferred tax assets	—	85
Deferred tax liabilities:		
Fixed assets	—	(85)
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, 2015 and 2014. Therefore, we have recorded a full valuation allowance on our deferred tax assets. We have net operating loss carryforwards for federal income tax purposes of approximately $69 million as of December 31, 2015. The net operating loss carryforwards will begin to expire in 2027. Utilization of these carryforwards is subject to limitation due to ownership changes that may delay the utilization of a portion of the carryforwards.

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Note 11. Capital Stock

IPO

On April 10, 2013, we completed our IPO in which we issued and sold 690,000 shares of common stock (including the underwriter's overallotment of 90,000 shares) at a public offering price of $10.00 per share resulting in gross proceeds of $6.9 million. In connection with the offering, all outstanding shares of Series A preferred stock were converted into 376,525 shares of common stock, and all outstanding shares of Series B preferred stock were converted into 910,800 shares of common stock. Concurrent with the IPO, we issued 2,000 shares of common stock to Cleveland Clinic pursuant to our license agreement with Cleveland Clinic.

Secondary Offering

On August 19, 2013, we sold 1,500,000 shares of common stock at a public offering price of $10.00 per share resulting in gross proceeds of $15.0 million ($13.3 million of net proceeds after offering expenses and underwriting discounts).

On September 5, 2013, we sold 105,000 additional common shares pursuant to the underwriter's partial exercise of the over-allotment option which resulted in gross proceeds of $1.1 million ($947,000 of net proceeds after offering expenses and underwriting discounts).

Follow-On Offering

On October 28, 2013, we sold 3,286,700 shares of common stock, (including the underwriter's over-allotment of 428,700 shares), at a public offering price of $14.00 per share resulting in gross proceeds of $46.0 million (net proceeds of $42.3 million).

Cantor Sales Agreement

In July 2015, we sold 2,800 shares of common stock that resulted in net proceeds to the Company of $34,000 through our sales agreement with Cantor Fitzgerald & Co. See Note 19.

2015 Offering

On November 12, 2015, we sold 3,000,000 shares of common stock with warrants to purchase an aggregate of 3,000,000 shares of common stock at a combined public offering price of $4.00 per share and warrant resulting in gross proceeds of $12.0 million ($10.3 million of net proceeds after offering expenses and underwriting discounts). The underwriters also received 450,000 warrants pursuant to the partial exercise of the over-allotment option. The warrants have an exercise price of $5.00, became fully-exercisable at issuance and expire on November 12, 2020.

Preferred Stock

We are currently authorized to issue up to 9,764,000 shares of preferred stock.

Note 12. 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 and on May 14, 2015, the stockholders voted to increase the number of shares reserved by the plan to 2,000,000 and 2,650,000 shares of common stock, respectively, under several types of equity awards including stock options, stock appreciation rights, restricted stock awards and other awards defined in the 2011 Plan.

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

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

At December 31, 2015, 853,504 shares remain available for future awards under the 2011 Plan and 110,749 shares remain available for future awards under the 2008 Plan.

As of December 31, 2015, no stock appreciation rights and 275,500 shares of restricted stock had been awarded under the Stock Option Plans.

Prior to our IPO in April 2013, the Board of Directors authorized an offer to certain employee and non-employee options holders on the following terms: those holding stock options with a strike price of $25.00 or more had the opportunity to exchange their options for 60% of the number of options currently held with an exercise price equal to the IPO price, which was $10.00 per share, and those holding stock options with a strike price of $12.50 had the opportunity to exchange their options for 80% of the number of options currently held with an exercise price equal to the IPO price which was $10.00 per share. On April 5, 2013, our initial public offering became effective and 336,300 options with exercise prices ranging from $12.50 to $33.80 were exchanged for 242,070 options with an exercise price of $10.00. The options did not result in the recognition of incremental compensation cost. In addition, 53,500 options which were approved to be issued and priced at the IPO price were issued to employees with an exercise price of $10.00 per share.

A summary of employee and non-employee stock option activity for the years ended December 31, 2015, 2014 and 2013 is as follows:

	Options Outstanding		Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
	Number of Shares (in thousands)	Weighted-Average Exercise Price		
Outstanding January 1, 2013	553	$12.76	7.13	$1,142
Granted	427	14.57		
Canceled or expired	(106)	20.46		
Outstanding December 31, 2013	874	$10.83	7.75	$3,139
Granted	1,154	10.41		
Exercised	(30)	6.61		
Canceled or expired	(159)	11.45		
Outstanding December 31, 2014	1,839	$10.58	8.49	$618
Granted	312	$9.77		
Exercised	(4)	$5.37		
Canceled or expired	(186)	$9.69		
Outstanding December 31, 2015	1,961	$10.55	7.68	$—
Exercisable, December 31, 2015	958	$10.09	6.61	$—

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, 2015, 2014 and 2013, we received $23,480, $79,018 and $1,640, respectively, from the exercise of options. Also during the year ended December 31, 2014, an option holder exercised options to purchase 12,000 shares of common stock with an exercise price of $10.00 per share using the net issue exercise method whereby the option holder surrendered 11,429 shares in payment in full of the exercise price resulting in net issuance of 571 shares of common stock.

As of December 31, 2015, total unrecognized compensation cost related to non-vested stock options granted to employees was $4,782,125, which we expect to recognize over the next 3.10 years.

As of December 31, 2015, total unrecognized compensation cost related to non-vested stock options granted to non-employees was $150,000, which we expect to recognize over the next 2.01 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 for stock-based compensation expense requires us to make assumptions and judgments

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variables used in the calculation, including the fair value of our common stock (see Note 14), 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 also estimate forfeitures of unvested stock options. To the extent actual forfeitures differ from the estimates, the difference will be recorded as a cumulative adjustment in the period estimates are revised. No compensation cost is recorded for options that do not vest. We use the simplified calculation of expected life described in the SEC's Staff Accounting Bulletin No. 107, Share-Based Payment, and volatility is based on an average of the historical volatilities of the common stock of three entities with characteristics similar to those of the Company. 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. Expected forfeitures are assumed to be zero due to the plan design which has monthly vesting after an initial cliff vesting period.

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,		
	2015	2014	2013
Volatility	60.69 %	70.17 %	76.60 %
Risk free interest rate	1.63 %	1.78 %	1.79 %
Dividend yield	—	—	—
Term (years)	6.13	5.98	6.14
Weighted-average fair value of options granted during the period	$5.54	$5.29	$9.85

In 2010, we issued an aggregate of 80,000 options to non-employees with an exercise price of $25.00. As described above, on April 5, 2013, these options were exchanged for 48,000 options with an exercise price of $10.00. In October 2013, we issued 10,000 options to a non-employee with an exercise price of $15.39. In May 2014, we issued 200,000 options to a Director, with an exercise price of $15.89. See Note 18 for additional information. The following table presents the weighted-average assumptions used to estimate the fair value of options reaching their measurement date for non-employees during the periods presented:

	Year Ended December 31,		
	2015	2014	2013
Volatility	70.38 %	71.76 %	75.68 %
Risk free interest rate	2.10 %	2.44 %	1.53 %
Dividend yield	—	—	—
Term (years)	8.73	9.68	7.68

Starting in 2013, restricted stock awards have been granted to employees, directors and consultants as compensation for services. At December 31, 2015, there was $720,934 of unrecognized compensation cost related to non-vested restricted stock granted to employees; we expect to recognize the cost over 2.47 years.

The following table summarizes the activities for our non-vested restricted stock awards for the years ended December 31, 2015, 2014 and 2013:

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	Non-vested Restricted Stock Awards	
	Number of Shares (in thousands)	Weighted-Average Grant Date Fair Value
Non-vested at January 1, 2013	$—	$—
Granted	8	13.50
Vested	(3)	15.39
Non-vested at December 31, 2013	$5	$12.55
Granted	220	9.01
Vested	(80)	10.19
Forfeited/canceled	(12)	12.04
Non-vested at December 31, 2014	$133	$8.14
Granted	48	9.50
Vested	(47)	9.09
Forfeited/canceled	(13)	9.03
Non-vested at December 31, 2015	121	8.25

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 Statement of Operations during the periods presented (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Cost of revenues	$233	$149	$41
Research and development	360	473	114
General and administrative	2,106	3,058	516
Sales and marketing	135	155	64
Total stock-based compensation	$2,834	$3,835	$735

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Note 13. Warrants

We have issued certain warrants which contain an exercise price adjustment feature in the event we issue additional equity instruments at a price lower than the exercise price of the warrant. The warrants are described herein as derivative warrants. For all derivative warrants, in the event equity instruments are issued at a price lower than the exercise price of the warrant, the exercise price is adjusted to the price of the new equity instruments issued (price adjustment feature). For certain of these warrants, the number of shares underlying the warrant is also adjusted to an amount computed by dividing the proceeds of the warrant under its original terms by the revised exercise price (share adjustment feature). These warrants are initially recorded as a warrant liability at fair value with a corresponding entry to the loan guarantee fee asset, debt discount, additional paid-in capital or expense dependent upon the service provided in exchange for the warrant grant. Subsequently, any change in fair value is recognized in earnings until such time as the warrants are exercised, amended or expire. As of December 31, 2015 and 2014 all warrants with a share adjustment feature have either expired or have been exercised.

In connection with debt guarantees and extensions, we issued 1,051,506 warrants to Mr. Pappajohn, a member of our Board of Directors and stockholder, at various dates prior to 2013 (see Note 18). These warrants were initially recorded at fair value as a loan guarantee fee amortized over the period of the guarantee to interest expense.

In connection with the 2012 Convertible Debt Financing Transaction, we granted 4,118 warrants to Mr. Pappajohn and 2,941 warrants to Mr. Oman on February 22, 2013. The warrants have a ten-year term and an exercise price equal to the IPO price of $10.00 per share. Pursuant to a subsequent agreement, the warrants held by Mr. Pappajohn have an exercise price of $15.00 per share. These warrants were initially recorded at fair value as a financing fee asset and were amortized over the period of the note to interest expense. The issue date fair value of these warrants was $221,000.

In connection with the December 2012 Bridge Financing Transaction, we granted 2,353 ten-year warrants with an exercise price equal to the IPO price of $10.00 per share to Mr. Pappajohn on March 7, 2013. Mr. Pappajohn subsequently agreed that if our final IPO price was below $15.00, there would be no further adjustment to the price or number of shares covered by the warrants held by him. These warrants were initially recorded at fair value as a financing fee asset and were amortized over the period of the note to interest expense. The issue date fair value of these warrants was $47,000.

On February 11, 2013, John Pappajohn agreed to limit certain anti-dilution rights in his warrants to purchase shares of the Company’s common stock. Subject to the consummation of an IPO prior to April 13, 2013, Mr. Pappajohn agreed that if the final IPO price was below $15.00, the exercise price of the warrants held by him would adjust to $15.00 and the number of shares underlying the warrants would be adjusted as if the IPO price were $15.00 and then there would be no further adjustment to the price or number of shares covered by warrants held by him. In February 2013, certain warrant holders agreed to waive the price and share adjustment provisions of their warrants, except for the anti-dilution provisions related to stock splits, subdivisions and combinations, with respect to an aggregate of 114,030 shares of common stock underlying such warrants, effective immediately following the consummation of our IPO on April 10, 2013 at $10.00 per share.

On April 10, 2013, the Company completed the IPO at $10.00 per share. The shares of common stock issuable upon the exercise of warrants increased by 838,889 shares and the exercise prices of 1,656,860 warrants were adjusted as a result of share and exercise price adjustment features in certain warrants.

On April 29, 2013, the Company received $96,000 from shareholders who exercised warrants to purchase 24,000 shares of common stock at $4.00 per share.

On July 6, 2013, a warrant holder exercised a warrant to purchase 6,000 shares of common stock at an exercise price of $4.00 per share using the net issuance exercise method whereby 2,072 shares were surrendered as payment in full of the exercise price resulting in a net issuance of 3,928 shares.

On July 8, 2013, the Company received $96,000 from shareholders who exercised warrants to purchase 24,000 shares of common stock at $4.00 per share.

On September 10, 2013 and September 27, 2013, the Company extended the expiration date of 42,468 warrants for 17 days and 11 days respectively.

On September 30, 2013, warrant holders exercised warrants to purchase 30,034 shares of common stock at an exercise price of $10.00 per share using the net issuance exercise method whereby 14,313 shares were surrendered as payment in full of the exercise price resulting in a net issuance of 15,721 shares.

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On October 7, 2013 and October 8, 2013, warrant holders exercised warrants to purchase 33,868 shares of common stock, at exercise prices ranging from $10.00 – $14.10 per share, using the net issuance exercise method whereby 23,188 shares were surrendered as payment in full of the exercise price resulting in a net issuance of 10,680 shares. In January 2014, the Company received $950 from a warrant holder who exercised warrants to purchase 95 shares of common stock at $10.00 per share. In February 2014 a warrant holder exercised warrants to purchase 3,320 shares of common stock at an exercise price of $10.00 per share using the net issuance exercise method whereby 1,661 shares were surrendered in payment in full of the exercise price resulting in a net issuance of 1,659 shares. In March 2014 a warrant holder exercised warrants to purchase 12,500 shares of common stock at an exercise price of $10.00 per share using the net issuance exercise method whereby 7,230 shares were surrendered in payment in full of the exercise price resulting in a net issuance of 5,270 shares. In June 2014, we received $177,154 from Mr. Pappajohn who exercised warrants to purchase 44,288 shares of common stock at an exercise price of $4.00 per share.

In July 2014, warrant holders exercised warrants to purchase 130,000 shares of common stock at an exercise price of $4.00 per share using the net issuance exercise method whereby 45,894 shares were surrendered in payment in full of the exercise price resulting in a net issuance of 84,106 shares.

In October 2014, 470,833 warrants expired unexercised, of which 233,333 were warrants held by Mr. Pappajohn.

On April 1, 2015, 19,138 warrants expired unexercised.

On November 12, 2015, the Company issued 3,000,000 warrants in conjunction with the 2015 Offering and an additional 450,000 warrants pursuant to the underwriter’s partial exercise of the over-allotment option. The warrants have an exercise price of $5.00 per share and will expire November 12, 2020. See Note 11. We have evaluated the terms and conditions of warrants issued with the 2015 Offering and determined the warrants should be included in equity and are not required to be reported as a liability.

On November 12, 2015, the exercise price of 75,215 warrants were adjusted from $10.00 per common share to $4.00 per common share due to 2015 Offering and the exercise price adjustment feature in certain warrants.

On November 18, 2015, 14,665 warrants expired unexercised and the Company received $1,400 from a warrant holder who exercised warrants to purchase 350 shares of common stock at $4.00 per share.

On December 9, 2015, 120,000 warrants held by Mr. Pappajohn expired unexercised.

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The following table summarizes the warrant activity for the years ending December 31, 2015, 2014 and 2013 (in thousands, except exercise price):

Issued With / For	Exercise Price		Warrants Outstanding January 1, 2013	2013 Warrants Issued	2013 Warrants Exercised	2013 Warrants Expired	IPO Adjustments (E)	Warrants Outstanding December 31, 2013	2014 Warrants Exercised	2014 Warrants Expired	Warrants Outstanding December 31, 2014	2015 Warrants Issued	2015 Offering Adjustments (F)	2015 Warrants Exercised	2015 Warrants Expired	Warrants Outstanding December 31, 2015
Non-Derivative Warrants:																
Financing	$10.00		—	—	—	—	243	243	—	—	243	—	—	—	—	243
Financing	15.00		—	—	—	—	436	436	—	—	436	—	—	—	—	436
Debt Guarantee	4.00		228	—	(54)	—	—	174	(174)	—	—	—	—	—	—	—
Debt Guarantee	10.00		—	—	—	—	238	238	—	(238)	—	—	—	—	—	—
Debt Guarantee	15.00		—	—	—	—	586	586	—	(233)	353	—	—	—	(120)	233
Series A Pref. Stock	14.10		66	—	(30)	(36)	—	—	—	—	—	—	—	—	—	—
Consulting	10.00		—	—	—	—	29	29	—	—	29	—	—	—	(19)	10
2015 Offering	5.00		—	—	—	—	—	—	—	—	—	3,450	—	—	—	3,450
	$6.82	G	294	—	(84)	(36)	1,532	1,706	(174)	(471)	1,061	3,450	—	—	(139)	4,372
Derivative Warrants:																
Financing	4.00	B	—	—	—	—	—	—	—	—	—	—	60	—	—	60
Financing	10.00	B	—	—	—	—	60	60	—	—	60	—	(60)	—	—	—
Financing	25.00	B	60	—	—	—	(60)	—	—	—	—	—	—	—	—	—
Financing	42.50	BCD	75	—	—	—	(75)	—	—	—	—	—	—	—	—	—
Financing	42.50	AD	55	3	—	—	(58)	—	—	—	—	—	—	—	—	—
Financing	42.50	ACD	121	6	—	—	(127)	—	—	—	—	—	—	—	—	—
Debt Guarantee	10.00	A	—	—	—	—	13	13	(13)	—	—	—	—	—	—	—
Debt Guarantee	25.00	ACD	212	—	—	—	(212)	—	—	—	—	—	—	—	—	—
Debt Guarantee	25.00	AD	100	—	—	—	(100)	—	—	—	—	—	—	—	—	—
Debt Guarantee	32.45	AC	40	—	—	—	(40)	—	—	—	—	—	—	—	—	—
Debt Guarantee	42.50	ACD	38	—	—	—	(38)	—	—	—	—	—	—	—	—	—
Debt Guarantee	42.50	BCD	37	—	—	—	(37)	—	—	—	—	—	—	—	—	—
Series B Pref. Stock	4.00	B	—	—	—	—	—	—	—	—	—	—	15	—	(15)	—
Series B Pref. Stock	10.00	B	—	—	(34)	—	52	18	(3)	—	15	—	(15)	—	—	—
Series B Pref. Stock	25.00	B	52	—	—	—	(52)	—	—	—	—	—	—	—	—	—
Consulting	12.50	AD	4	—	—	—	(4)	—	—	—	—	—	—	—	—	—
Consulting	14.10	AD	10	—	—	—	(10)	—	—	—	—	—	—	—	—	—
Consulting	25.00	AD	4	—	—	—	(4)	—	—	—	—	—	—	—	—	—
	$4.00	G	808	9	(34)	—	(692)	91	(16)	—	75	—	—	—	(15)	60
	$6.78	G	1,102	9	(118)	(36)	840	1,797	(190)	(471)	1,136	3,450	—	—	(154)	4,432

A These warrants are subject to fair value accounting and contain exercise price and number of share adjustment features. See Note 14.

B These warrants are subject to fair value accounting and contain an exercise price adjustment feature. See Note 14.

C On February 11, 2013, these warrants held by John Pappajohn were amended to limit the adjustment feature(s) to $15.00 per share in an initial public offering (totaling 530,022 warrants).

D The exercise price and/or number of share adjustment features of these warrants expired and are no longer subject to fair value accounting after our initial public offering.

E

On April 10, 2013 the Company completed the IPO at $10.00 per share. The shares of common stock issuable upon the exercise of warrants outstanding as of April 10, 2013 increased by 838,889 shares and the exercise prices of 1,656,860 warrants were adjusted as a result of the share and exercise price adjustment features described above.

F On November 12, 2015 the Company completed the 2015 Offering and the exercise price of certain derivative warrants were adjusted to $4.00.

GWeighted average exercise prices are as of December 31, 2015.

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Note 14. Fair Value of Warrants

The following tables summarize the assumptions used in computing the fair value of derivative warrants subject to fair value accounting at the date of issue during the years ended December 31, 2015, 2014 and 2013 and at December 31, 2015, December 31, 2014, December 31, 2013, and April 5, 2013 (IPO valuation date). In computing the fair value of the warrants, if the stated exercise price of the warrants exceeded the assumed value of the Company stock at the date the fair value was being computed, the exercise price and number of shares (if applicable) underlying the warrants were adjusted to reflect an assumed trigger of the price and/or share adjustment features related to the applicable warrants. Such adjustments were only applicable to 2013 due to the relative price of the warrants and the assumed Company stock price:

Debt Guarantee	Exercised During the Year Ended December 31, 2014	IPO Date April 5, 2013
Exercise Price	$10.00	$13.56
Expected life (years)	0.60	2.42
Expected volatility	49.01%	66.37%
Risk-free interest rate	0.08%	0.32%
Expected dividend yield	0.00%	0.00%

	Exercised During the Year Ended December 31,		As of December 31, 2014	
Series B	2015	2014		
Exercise Price	$4.00	$10.00	$10.00	
Expected life (years)	0.01	1.72	0.88	
Expected volatility	12.33%	46.60%	49.95%	
Risk-free interest rate	0.07%	0.33%	0.25%	
Expected dividend yield	0.00%	0.00%	0.00%	

	As of December 31,		IPO Date	
Consulting	2015	2014	April 5, 2013	
Exercise Price	$4.00	$10.00	$10.00	
Expected life (years)	0.14	1.14	2.33	
Expected volatility	57.39%	49.25%	63.20%	
Risk-free interest rate	0.16%	0.25%	0.27%	
Expected dividend yield	0.00%	0.00%	0.00%	

	Issued During the Year Ended	As of December 31,		IPO Date	
Financing	December 31, 2013	2015	2014	April 5, 2013	
Exercise Price	$13.34	$4.00	$10.00	$13.21	
Expected life (years)	9.78	0.23	1.23	8.30	
Expected volatility	74.70%	70.82%	50.23%	73.22%	
Risk-free interest rate	1.95%	0.16%	0.25%	1.44%	
Expected dividend yield	0.00%	0.00%	0.00%	0.00%	

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The assumed ranges of Company stock prices used in computing the warrant fair value for warrants issued during the year is as follows: in 2015, $3.30—$11.76 in 2014, $6.68—$19.86; in 2013, $9.60—$20.26. In determining the fair value of warrants issued at each reporting date, the assumed Company stock price was $3.30 and $6.68 (the closing price on the NASDAQ Capital Market) at December 31, 2015 and 2014.

The following table summarizes the derivative warrant activity subject to fair value accounting for the years ended December 31, 2015, 2014 and 2013 (in thousands):

	Issued with Series B Preferred Stock	Issued For Debt Guarantee	Issued For Consulting	Issued For Financing	Total
Fair value of warrants outstanding as of January 1, 2013	$230	$5,679	$147	$6,493	$12,549
Fair value of warrants issued	—	—	—	268	268
Fair value of warrants exercised	(420)	—	—	—	(420)
Reclassification to equity in IPO	—	(2,514)	(108)	(4,548)	(7,170)
Change in fair value of warrants	307	(3,101)	(38)	(1,801)	(4,633)
Fair value of warrants outstanding as of December 31, 2013	117	64	1	412	594
Fair value of warrants exercised	(38)	(87)	—	—	(125)
Change in fair value of warrants	(71)	23	(1)	(368)	(417)
Fair value of warrants outstanding as of December 31, 2014	8	—	—	44	52
Change in fair value of warrants	(8)	—	—	(27)	(35)
Fair value of warrants outstanding as of December 31, 2015	$—	$—	$—	$17	$17

Note 15. 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):

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	2015			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrant liability	$17	—	—	$17
Notes payable	266	—	—	266
	$283	—	—	$283

	2014			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrant liability	$52	—	—	$52
Gentris contingent consideration	293	—	—	293
Notes payable	535	—	—	535
	$880	—	—	$880

The warrant liability consists of stock warrants we issued that contain an exercise price adjustment feature. In accordance with derivative accounting for warrants, we calculated the fair value of warrants and the assumptions used are described in Note 14, “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 Statement of Operations and Comprehensive Loss.

The value of the Gentris contingent consideration was determined using a discounted cash flow of the expected payments required by the purchase agreement. During the year ended December 31, 2015 we recognized a gain of $207,000 due to settling the contingent consideration for $86,400.

The ultimate payment to VenturEast 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 less a discount for credit risk. During the years ended December 31, 2015 and 2014 we recognized a gain of $269,000 and $198,000, respectively, due to the decrease in value of the note.

Realized and unrealized gains and losses related to the change in fair value of the Gentris contingent consideration are included in general and administrative expense, while realized and unrealized gains and losses related to the VenturEast note are included in other income (expense) on the Consolidated Statement of Operations and Comprehensive Loss.

A table summarizing the activity for the derivative warrant liability which is measured at fair value using Level 3 inputs is presented in Note 14. The following table summarizes the activity of the notes payable to VenturEast and Gentris contingent consideration which were measured at fair value using Level 3 inputs (in thousands):

	Note Payable to VenturEast	Gentris Contingent Consideration
Fair value at January 1, 2014	$—	$—
Fair value at issuance	733	293
Change in fair value	(198)	—
Fair value at December 31, 2014	$535	$293
Change in fair value	(269)	(207)
Settlement of liability	—	(86)
Fair value at December 31, 2015	$266	$—

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Note 16. Contingencies

In the normal course of business, the Company is involved in various claims and legal proceedings. In the opinion of management, the ultimate liability or disposition thereof is not expected to have a material adverse effect on our financial condition, results of operations or liquidity.

Note 17. 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. We currently anticipate that we will make capital contributions of $1.0 million in the second quarter of 2016. The timing of the remaining installments is subject to the JV's achievement of certain operational milestones agreed upon by the board of governors of the JV. In exchange for its membership interest, Mayo's capital contribution will take the form of cash, staff, services, hardware and software resources, laboratory space and instrumentation, the fair market value of which will be approximately equal to $6.0 million. Mayo's continued contribution will also be conditioned upon the JV's achievement of certain milestones.

The joint venture is considered a variable interest entity under ASC 810-10, but we are not the primary beneficiary as we do not have the power to direct the activities of the joint venture that most significantly impact its performance. Our evaluation of ability to impact performance is based on our equal board membership and voting rights and day to day management functions which are performed by the Mayo personnel.

Note 18. 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, 2015, warrants to purchase 440,113 shares of common stock have been exercised by Mr. Pappajohn and 353,333 warrants to purchase common stock have expired. After adjustment pursuant to the terms of the warrants in conjunction with our IPO, the number of these warrants outstanding retained by Mr. Pappajohn was 232,312 at $15.00 per share on December 31, 2015.

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 436,079 at $15.00 per share at December 31, 2015.

Effective January 6, 2014, the board of directors appointed John Pappajohn to serve as the Chairman of the Board, a position previously held by Dr. Raju S.K. Chaganti. As compensation for serving as the Chairman of the Board, the Company will pay Mr. Pappajohn $100,000 per year and granted to Mr. Pappajohn 25,000 restricted shares of the Company's common stock, and options to purchase an aggregate of 100,000 shares of the Company's common stock. The options have a term of ten years from the date on which they were granted. The restricted stock and the options each vest in two equal installments on the one year anniversary and the two year anniversary of the date on which Mr. Pappajohn became the Chairman of the Board.

On October 14, 2015 the Board of Directors granted John Pappajohn and Dr. Chaganti 2,500 restricted shares each of the Company’s common stock and options to purchase an aggregate of 10,000 shares each of the Company’s common stock as compensation for serving on the Board of Directors. The restricted stock vests on the one-year anniversary date of the grant and the stock options vest in two equal installments on the one-year anniversary and the two-year anniversary date of the grant.

In August 2010, we entered into a consulting agreement with Equity Dynamics, Inc. (“EDI”), an entity controlled by John Pappajohn, pursuant to which EDI received a monthly fee of $10,000. The consulting agreement was terminated effective March 31, 2014.

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Subsequently the Company entered into a new consulting agreement with EDI effective April 1, 2014 pursuant to which it receives a monthly fee of $10,000. We expensed $120,000 annually for the years ended December 31, 2015, 2014 and 2013 related to this agreement.

On May 19, 2006, we issued a convertible promissory note in favor of our then Chairman and founder, Dr. Chaganti, the holder, which obligated us to pay the holder the sum of $100,000, together with interest at the rate of 8.5% per annum, due April 1, 2014. Interest expense was $2,400 for the year ended December 31, 2013. On April 10, 2013 the note and accrued interest converted into 13,430 shares of common stock at the IPO price of $10.00 per share. Pursuant to a consulting and advisory agreement, Dr. Chaganti also received options to purchase a total of 36,000 shares of common stock at a price of $10.00 per share which vested over a two year period. Total non-cash stock-based compensation recognized under the consulting agreement for the year ended December 31, 2013 was $76,220. Additionally, on September 15, 2010, we entered into a three year consulting agreement with Dr. Chaganti which was subsequently renewed through December 31, 2016 pursuant to which Dr. Chaganti receives $5,000 per month for providing consulting and technical support services. Total expenses for each of the years ended December 31, 2015, 2014 and 2013 were $60,000. Pursuant to the terms of the renewed consulting agreement, Dr. Chaganti received an option to purchase 200,000 shares of our common stock at a purchase price of $15.89 per share vesting over a period of four years. Total non-cash stock-based compensation recognized under this consulting agreement for the years ended December 31, 2015, 2014 and 2013 was $239,375, $341,000 and $0, respectively. Also pursuant to the consulting agreement, Dr. Chaganti assigned to us all rights to any inventions which he may invent during the course of rendering consulting services to us. In exchange for this assignment, if the USPTO issues a patent for an invention on which Dr. Chaganti is listed as an inventor, we are required to pay Dr. Chaganti (i) a one-time payment of $50,000 and (ii)1% of any net revenues we receive from any licensed sales of the invention. In 2014 we paid Dr. Chaganti $150,000 which was recognized as an expense in fiscal 2013 when three patents were issued. Also in February 2015, we paid Dr. Chaganti $150,000 for which was recognized as an expense in 2014 when three additional patents were issued.

Andrew Pecora (indirectly through an investment company), when a member of our board of directors, and NNJCA, a limited liability company of which Dr. Pecora is a member originally provided $0.5 and $1.5 million of financing, respectively, under a Credit Agreement dated as of December 21, 2011, as amended and restated as of February 13, 2012. On April 10, 2013, NNJCA converted $0.5 million of its outstanding indebtedness into 50,000 shares of our common stock at the IPO price of $10.00 per share concurrent with our IPO. On August 19, 2013, the remaining principal under these notes were repaid to Dr. Pecora and NNJCA using a portion of the proceeds from our Secondary Offering. The loan bore an annual interest rate equal to the prime rate plus 6.25% (9.50% at August 19, 2013). We paid a pre-payment penalty due to Pecora and NNJCA of $130,000 of which $32,667 was paid upon conversion of the notes and the remaining balance paid on August 19, 2013.

On November 12, 2015, John Pappajohn, Chairman of the Board and Edward Sitar, Chief Financial Officer purchased 100,000 and 5,000, respectively, of shares of common stock with warrants to purchase 100,000 shares of common stock and 5,000 shares of common stock, respectively, in the 2015 Offering described in Note 11.

Note 19. Cantor Sales Agreement

On July 15, 2015, the Company entered into a Controlled Equity Offering^{SM} Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co., (“Cantor”) as sales agent, pursuant to which the Company may offer from time to time through Cantor, shares of our common stock having an aggregate offering price of up to $20.0 million. Subject to the terms and conditions of the Sales Agreement, Cantor will use commercially reasonable efforts consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations and the rules of The NASDAQ Capital Market to sell shares from time to time based upon the Company’s instructions, including any price, time or size limits specified by the Company. Under the Sales Agreement, Cantor may sell shares by any method

deemed to be an “at-the-market” offering as defined in Rule 415 under the U.S. Securities Act of 1933, as amended, or, with the Company’s prior consent, any other method permitted by law, including in privately negotiated transactions. The Company may instruct Cantor not to sell shares if the sales cannot be effected at or above the price designated by the Company from time to time. The Company is not obligated to make any sales of the shares under the Sales Agreement. The offering of shares pursuant to the Sales Agreement will terminate upon the earlier of (a) the sale of all of the shares subject to the Sales Agreement or (b) the termination of the Sales Agreement by Cantor or the Company, as permitted therein. Cantor will receive a commission rate of 3.0% of the aggregate gross proceeds from each sale of shares and the Company has agreed to provide Cantor with customary indemnification and contribution rights. The Company will also reimburse Cantor for certain specified expenses in connection with entering into the Sales Agreement. During 2015, the Company sold 2,800 shares of its common stock that resulted in net proceeds to the Company of approximately $34,000. In July 2015, we temporarily suspended selling shares of common stock using the Sales Agreement. Furthermore, under the terms of our lock up agreement with Joseph Gunnar and Feltl, we were prohibited from selling our common stock under the Sales Agreement until 90 days after the 2015 Offering, or February 5, 2016.

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Note 20. Subsequent Events

On January 28, 2016, the Line of Credit was amended with Silicon Valley Bank. See Note 6.

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 the Chief Executive Officer and Chief 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, 2015, the end of the period covered by this report on Form 10-K. Based on this evaluation, our President and Chief Executive Officer (principal executive officer) and our Chief Financial Officer (principal accounting and financial officer) have concluded that our disclosure controls and procedures were effective at December 31, 2015. 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 Chief Executive Officer and Chief Financial Officer, 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.

We completed the acquisition of Response Genetics on October 9, 2015. Management's assessment of and conclusion on the effectiveness of our internal control over financial reporting excludes the internal controls over the financial reporting of this acquisition. This acquisition contributed approximately 10 percent of our net sales for the year ended December 31, 2015 and accounted for approximately 28 percent of our total assets as of December 31, 2015. Registrants are permitted to exclude acquisitions from their assessment of internal controls over financial reporting during the first year if, among other circumstances and factors, there is not adequate time between the consummation date of the acquisition and the assessment date for assessing internal controls.

Our management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2015. 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).

Based on management's assessment, as of December 31, 2015, the Company's internal control over financial reporting was effective.

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Item 9B. Other Information.

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be contained in the Proxy Statement for our 2016 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, 2015 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 2016 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, 2015 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 2016 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, 2015 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 2016 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, 2015 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 2016 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, 2015 and is incorporated by reference herein.

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PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements. The financial statements filed as part of this report are listed on the Index to the Consolidated Financial Statements.

(a)(2) Financial Statement Schedules. Schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or notes thereto.

(a)(3) Exhibits. Reference is made to the Exhibit Index. The exhibits are included, or incorporated by reference, in this annual report on Form 10-K and are numbered in accordance with Item 601 of Regulation S-K.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Cancer Genetics, Inc.
(Registrant)

Date: March 10, 2016	/s/ Panna L. Sharma Panna L. Sharma President and Chief Executive Officer (Principal Executive Officer and duly authorized signatory)
Date: March 10, 2016	/s/ Edward J. Sitar Edward J. Sitar Chief Financial Officer (Principal Financial and Accounting Officer)

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SIGNATURES AND POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Panna Sharma and Edward Sitar, 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/ Panna L. Sharma Panna L. Sharma	President, Chief Executive Officer and Director (Principal Executive Officer)	March 10, 2016
/s/ Edward J. Sitar Edward J. Sitar	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 10, 2016
/s/ John Pappajohn John Pappajohn	Chairman of the Board of Directors	March 10, 2016
/s/ Geoffrey Harris Geoffrey Harris	Director	March 10, 2016
/s/ Edmund Cannon Edmund Cannon	Director	March 10, 2016
/s/ Howard McLeod Howard McLeod	Director	March 10, 2016
/s/ Michael J. Welsh Michael J. Welsh	Director	March 10, 2016
/s/ Raju S. K. Chaganti Raju S. K. Chaganti, Ph.D.	Director	March 10, 2016
/s/ Franklyn G. Prendergast Franklyn G. Prendergast, M.D., Ph.D.	Director	March 10, 2016

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INDEX TO EXHIBITS

Exhibit No.	Description
3.1	Third Amended and Restated Certificate of Incorporation of Cancer Genetics, Inc., filed as Exhibit 3.1 to quarterly report on Form 10-Q filed on May 15, 2013 and incorporated herein by reference.
3.2	Amended and Restated Bylaws of Cancer Genetics, Inc., filed as Exhibit 3.4 to Form S-1/A filed on April 30, 2012 (File No. 333-178836) and incorporated herein by reference.
4.1	Specimen Common Stock certificate of Cancer Genetics, Inc., filed as Exhibit 4.1 to Form S-1/A filed on May 16, 2012 (File No. 333-178836) and incorporated herein by reference.
4.2	Form of Short Form Cashless Exercise Warrant, filed as Exhibit 4.9 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.
4.3	Form of Medium Form Warrant, filed as Exhibit 4.10 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.
4.4	Form of Long Form Warrant, filed as Exhibit 4.11 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.
4.5	Form of Bridge Financing Warrant issued by Cancer Genetics, Inc. to John Pappajohn, NNJCA Capital, LLC, Pecora and Company and DAM Holdings, LLC, filed as Exhibit 10.36 to Form S-1/A filed on March 13, 2012 (File No. 333-178836) and incorporated herein by reference.
4.6	Form of Modified Bridge Warrant issued by Cancer Genetics, Inc. to John Pappajohn and Mark Oman, filed as Exhibit 10.50 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference.
4.7	Form of October 2012 Warrant issued by Cancer Genetics, Inc. to John Pappajohn and Mark Oman, filed as Exhibit 10.53 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference.
4.8	Asset Purchase Agreement, by and among Cancer Genetics, Inc., Gentris, LLC and Gentris Corporation, dated July 15, 2014 (incorporated by reference to Exhibit 4.1 of the Company's current report on Form 8-K filed on July 22, 2014 with the Securities and Exchange Commission).
4.9	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).
4.10	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).

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	Amended and Restated 2011 Equity Compensation Plan, dated May 22, 2014 (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed on May 22, 2014 with the Securities and Exchange Commission)
10.6	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.
10.7	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.

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Exhibit No.	Description
10.8	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.
10.9	Consulting Agreement, between Cancer Genetics, Inc. and R.S.K. Chaganti, dated September 15, 2010, filed as Exhibit 10.15 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.
10.10	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.
10.11	Employment Agreement, between Jane Houldsworth El Naggar, Ph.D. and Cancer Genetics, Inc., effective as of January 1, 2012, filed as Exhibit 10.19 to Form S-1/A filed on February 14, 2012 (File No. 333-178836) and incorporated herein by reference.
10.12	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.
10.13	Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated April 29, 2008, filed as Exhibit 10.21 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.
10.14	Security Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated April 29, 2008, filed as Exhibit 10.22 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.
10.15	First Addendum to Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated July 7, 2008, filed as Exhibit 10.23 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.
10.16	Second Addendum to Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated March 30, 2009, filed as Exhibit 10.24 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.
10.17	Third Addendum to Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated July 2, 2009, filed as Exhibit 10.25 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference
10.18	Fourth Addendum to Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated October 21, 2009, filed as Exhibit 10.26 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.
10.19	Fifth Addendum to Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated July 29, 2010, filed as Exhibit 10.27 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and

	incorporated herein by reference.
10.20	Credit Agreement, between Cancer Genetics, Inc. and DAM Holdings, LLC, dated March 23, 2011, filed as Exhibit 10.28 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.
10.21	Inter-creditor Agreement, between Cancer Genetics, Inc., John Pappajohn and DAM Holdings, LLC, dated March 23, 2011, filed as Exhibit 10.29 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.
10.22	General Business Security Agreement, between Cancer Genetics, Inc. and DAM Holdings, LLC, dated March 23, 2011, filed as Exhibit 10.30 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.
10.23	Promissory Note, issued by Cancer Genetics, Inc. to DAM Holdings, LLC, dated March 23, 2011, filed as Exhibit 10.31 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.
10.24	Sixth Addendum to Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated June 6, 2011, filed as Exhibit 10.32 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.
10.25	Amended and Restated Credit Agreement, by and among Cancer Genetics, Inc., John Pappajohn, Pecora and Company and NNJCA Capital, LLC dated February 13, 2012, filed as Exhibit 10.33 to Form S-1/A filed on March 13, 2012 (File No. 333-178836) and incorporated herein by reference.

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Exhibit No.	Description
10.26	Form of Promissory Note issued by Cancer Genetics, Inc. to John Pappajohn, filed as Exhibit 10.34 to Form S-1/A filed on March 13, 2012 (File No. 333-178836) and incorporated herein by reference.
10.27	Form of Promissory Note issued by Cancer Genetics, Inc. to NNJCA Capital, LLC and Pecora and Company, filed as Exhibit 10.35 to Form S-1/A filed on March 13, 2012 (File No. 333-178836) and incorporated herein by reference.
10.28	Inter-Creditor Agreement, between Cancer Genetics, Inc., John Pappajohn, DAM Holdings, LLC, Pecora and Company, NNJCA Capital, LLC and Equity Dynamics, Inc., dated February 13, 2012, filed as Exhibit 10.37 to Form S-1/A filed on March 13, 2012 (File No. 333-178836) and incorporated herein by reference.
10.29	Seventh Addendum to Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated February 15, 2012, filed as Exhibit 10.38 to Form S-1/A filed on March 13, 2012 (File No. 333-178836) and incorporated herein by reference.
10.30	Amendment to Credit Agreement, between Cancer Genetics, Inc. and DAM Holdings, LLC, dated March 9, 2012, filed as Exhibit 10.33 to Form S-1/A filed on March 13, 2012 (File No. 333-178836) and incorporated herein by reference.
10.31	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.
10.32	Consulting Agreement with Equity Dynamics, Inc., filed as Exhibit 10.38 to Form S-1/A filed on February 14, 2012 (File No. 333-178836) and incorporated herein by reference.
10.33	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.
10.34	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.
10.35	Letter Agreement between Cancer Genetics, Inc. and John Pappajohn, filed as Exhibit 10.47 to Form S-1/A filed on May 7, 2012 (File No. 333-178836) and incorporated herein by reference.
10.36	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.
10.37	Restated Credit Agreement, between Mark Oman and John Pappajohn and Cancer Genetics, Inc., dated October 17, 2012, filed as Exhibit 10.51 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference.
10.38	Form of Restated Promissory Note issued by Cancer Genetics, Inc. to John Pappajohn and Mark Oman, filed as Exhibit 10.52 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by

	reference.
10.39	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.
10.40	Letter Agreement between Cancer Genetics, Inc. and Pecora, filed as Exhibit 10.55 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference.
10.41	Letter Agreement between Cancer Genetics, Inc. and NNJCA Capital, LLC, filed as Exhibit 10.56 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference.
10.42	Letter Agreement between Cancer Genetics, Inc. and DAM Holdings, Inc., filed as Exhibit 10.57 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference.
10.43	Eighth Addendum to Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated October 18, 2012, filed as Exhibit 10.58 to Form S-1/A filed on November 16, 2012 (File No. 333-178836) and incorporated herein by reference.
10.44	Credit Agreement between John Pappajohn and Cancer Genetics, Inc. dated December 4, 2012, filed as Exhibit 10.59 to Form S-1/A filed on December 14, 2012 (File No. 333-178836) and incorporated herein by reference.

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Exhibit No.	Description
10.45	Promissory Note issued by Cancer Genetics, Inc. to John Pappajohn dated December 4, 2012, filed as Exhibit 10.60 to Form S-1/A filed on December 14, 2012 (File No. 333-178836) and incorporated herein by reference.
10.46	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.
10.47	Letter Agreement between Cancer Genetics, Inc. and John Pappajohn dated February 11, 2013, filed as Exhibit 10.63 to Form S-1/A filed on February 12, 2013 (File No. 333-178836) and incorporated herein by reference.
10.48	Letter Agreement between Cancer Genetics, Inc. and John Pappajohn (on behalf of his spouse) dated February 13, 2013, filed as Exhibit 10.64 to Form S-1/A filed on February 14, 2013 (File No. 333-178836) and incorporated herein by reference.
10.49	Letter Agreement between Cancer Genetics, Inc. and NNJCA Capital, LLC dated as of February 13, 2013, filed as Exhibit 10.65 to Form S-1/A filed on February 14, 2013 (File No. 333-178836) and incorporated herein by reference.
10.50	Letter Agreement between Cancer Genetics, Inc. and DAM Holdings, LLC dated February 13, 2013, filed as Exhibit 10.66 to Form S-1/A filed on February 14, 2013 (File No. 333-178836) and incorporated herein by reference.
10.51	Letter Agreement between Cancer Genetics, Inc. and R.S.K. Chaganti, dated February 13, 2013, filed as Exhibit 10.67 to Form S-1/A filed on March 4, 2013 (File No. 333-178836) and incorporated herein by reference.
10.52	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.
10.53	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.
10.54	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.
10.55	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.
10.56	Joint Development Intellectual Property Agreement, among the Company, Mayo Foundation for Medical Education and Research and OncoSpire Genomics, LLC, dated May 21, 2013, filed as Exhibit 10.75 to Form S-1/A filed on July 12, 2013 (File No. 333-189117) and incorporated herein by reference.

10.57	Letter Agreement, between Cancer Genetics, Inc. and Andrew L. Pecora, effective February 18, 2014 (incorporated by reference to Exhibit 10.66 of the Company's Annual Report on Form 10-K for the year ended December 31, 2013).
10.58	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).
10.59	Employment Agreement, between Cancer Genetics, Inc. and Edward J. Sitar, dated March 17, 2014 (incorporated by reference to Exhibit 10.69 of the Company's Annual Report on Form 10-K for the year ended December 31, 2013).
10.60	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).
10.61	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).
10.62	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).

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Exhibit No.	Description
10.63	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).
10.64	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).
10.65	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).
10.66	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).
10.67	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.
10.68	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).
10.69	Controlled Equity Offering^{SM} Sales Agreement, dated July 15, 2015, by and between Cancer Genetics, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to the Company's current report on Form 8-K filed on July 16, 2015).
10.70	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).
10.71*	Office Lease, between Response Genetics, Inc. and Health Research Association, dated September 16, 2014.
10.72*	Tenth Amendment to Office Lease, between Response Genetics, Inc. and University of Southern California, dated June 30, 2015.
10.73*	Consent and First Amendment to Loan and Security Agreement, between Cancer Genetics, Inc. and Silicon Valley Bank, dated January 28, 2016.
21.1*	Subsidiaries of Cancer Genetics, Inc.

23.1*	Consent of RSM US LLP.
24.1	Power of attorney (included on the signature page).
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 Chief 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 Chief 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, 2015, filed on March 10, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Income, (iii) the Consolidated Statements of Cash, (iv) the Consolidated Statements of Stockholders' Equity and (v) the Notes to the Consolidated Financial Statements.

* Filed herewith.
** Furnished herewith.