

CANCER GENETICS, INC  
Form 424B5  
November 09, 2015

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**Filed Pursuant to Rule 424(b)(5)  
Registration No. 333-196374**

**PROSPECTUS SUPPLEMENT  
To Prospectus dated June 5, 2014**

3,000,000 Shares  
Common Stock  
Warrants to Purchase up to  
3,000,000 shares of Common Stock

## **CANCER GENETICS, INC.**

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This is an offering of 3,000,000 shares of the common stock of Cancer Genetics, Inc. and warrants to purchase up to 3,000,000 shares of common stock of Cancer Genetics, Inc. (and the shares of common stock that are issuable from time to time upon exercise of the warrants). The warrants will have an exercise price of \$5.00 per share. The warrants will be exercisable upon issuance and will expire five years from the date of issuance.

Our common stock trades on the NASDAQ Capital Market under the symbol "CGIX." The last reported trading price of our stock on November 5, 2015 was \$4.61 per share. There is no public trading market for the warrants, and we do not expect a market to develop. In addition, we do not intend to apply for a listing of the warrants on the NASDAQ Capital Market, any other national securities exchange, or any nationally recognized trading system.

**Investing in our common stock and warrants involves a high degree of risk. See "Risk Factors" beginning on page S-13 of this prospectus supplement and page 3 of the accompanying prospectus.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.**

	<b>Combined Per Share and Warrant</b>	<b>Total</b>
Price to the public	\$ 4.00	\$ 12,000,000
Underwriting discounts and commissions(1)	\$ 0.26	\$ 780,000
Proceeds to Cancer Genetics (before expenses)	\$ 3.74	\$ 11,220,000

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(1)

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Does not include a non-accountable expense allowance equal to 1.0% of the gross proceeds of the offering payable to the underwriters. The underwriters will also be reimbursed for certain expenses incurred in this offering. See "Underwriting" for further information regarding compensation payable to the underwriters.

We have granted the underwriters an option for a period of 45 days from the date of this prospectus supplement to purchase 450,000 additional shares of common stock and/or warrants to purchase up to 450,000 additional shares of common stock on the same terms and conditions set forth above.

The underwriters expect to deliver the shares and warrants on or about November 12, 2015.

*Joint Book-Running Managers*

**Joseph Gunnar &  
Co.**

**Feltl and  
Company**

*Co-Manager*

**Axiom Capital Management, Inc.**

November 6, 2015

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**ABOUT THIS PROSPECTUS SUPPLEMENT**

In this prospectus supplement, "Cancer Genetics," "we," "us," "our" or "ours" refer to Cancer Genetics, Inc. and its consolidated subsidiaries.

This prospectus supplement and the accompanying prospectus relate to the offering of shares of our common stock and warrants to purchase shares of our common stock. Before buying any of the shares of common stock and warrants to purchase shares of our common stock offered hereby, we urge you to carefully read this prospectus supplement and the accompanying prospectus, together with the information incorporated herein by reference as described under the headings "Where You Can Find More Information" and "Incorporation of Documents by Reference." These documents contain important information that you should consider when making your investment decision. This prospectus supplement contains information about the common stock and warrants offered hereby and may add, update or change information in the accompanying prospectus.

You should rely only on the information that we have provided or incorporated by reference in this prospectus supplement and the accompanying prospectus. Neither we nor the underwriters (or any of our or their respective affiliates) have authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it.

We and the underwriters are not making offers to sell or solicitations to buy our securities in any jurisdiction in which an offer or solicitation is not authorized or in which the person making that offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make an offer or solicitation. You should assume that the information in this prospectus supplement and the accompanying prospectus or any related free writing prospectus is accurate only as of the date on the front of the document and that any information that we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus supplement, the accompanying prospectus or any related free writing prospectus, or any sale of a security.

This document is in two parts. The first part is this prospectus supplement, which adds to and updates information contained in the accompanying prospectus. The second part, the prospectus, provides more general information, some of which may not apply to this offering. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement and the information contained in the accompanying prospectus, you should rely on the information in this prospectus supplement.

This prospectus supplement and the accompanying prospectus contain summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been or will be filed as exhibits to the registration statement of which this prospectus is a part or as exhibits to documents incorporated by reference herein, and you may obtain copies of those documents as described below under the headings "Where You Can Find More Information" and "Incorporation of Documents by Reference."

**Trademarks and Trade Names**

This prospectus supplement contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus supplement, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

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**PROSPECTUS SUPPLEMENT SUMMARY**

*The following summary of our business highlights some of the information contained elsewhere in or incorporated by reference into this prospectus supplement. Because this is only a summary, however, it does not contain all of the information that may be important to you. You should carefully read this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference, which are described under "Where You Can Find More Information" and "Incorporation of Documents by Reference" in this prospectus supplement. You should also carefully consider the matters discussed in the section titled "Risk Factors" in this prospectus supplement and in the accompanying prospectus and in other periodic reports incorporated by reference herein.*

**Overview**

We are an oncology diagnostics company focused on developing, commercializing and providing DNA-based tests and services to improve the personalization of cancer treatment and to better inform biopharmaceutical companies of genomic factors influencing subject responses to therapeutics. Our vision is to become the oncology diagnostics partner for companies and clinicians by participating in the entire care continuum from bench to bedside. We believe the diagnostic industry is undergoing a metamorphosis in its approach to oncology testing, embracing individualized medicine 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' DNA profiles in order to identify 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 DNA-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' DNA as we attempt to reach the next milestone in personalized medicine.

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 genomic 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 fighting against cancer. Our molecular diagnostic 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 genetic level.

Our business is based on demand for DNA-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 genomic-based testing since these methods produce higher value and more accurate cancer diagnostic information than traditional analytical methods. Our proprietary and focused tests aim to provide actionable information that can guide patient management decisions, potentially resulting in decreased costs for cancer centers and hospitals 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

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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 genomic testing, increasing trial efficiency, subject safety and trial success rates. Our services are also sought by researchers and research groups seeking to identify genomic based 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 technologies across each of these businesses to deliver results-oriented information 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-institutional variability. Our suite of clinical and biopharma services aim to remove subjectivity from diagnoses and additionally provide information on 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 is only possible through the use of DNA-based molecular diagnostics.

The following table lists our market strategy by customer category:

Customer Category	Types of Customers	Nature of Services
Clinical Services	Hospitals	Clinical services provide information on diagnosis, prognosis and theragnosis of cancers to guide patient management.
	Cancer Centers	
	Clinics	
Biopharma Services	Biopharma and Biotech companies performing clinical trials	Biopharma services provide companies customized solutions for patient stratification and treatment selection through an extensive suite of DNA-based testing services.
Discovery Services	Biopharma and Biotech companies	Discovery services provide the tools and testing methods for companies and researchers seeking to identify new DNA-based biomarkers for disease.
	Researchers	

In 2014, we generated approximately 55% of our revenue from Biopharma Services, approximately 43% from Clinical Services and approximately 2% from Discovery Services, a new line of service launched in 2014. In 2013, we generated approximately 55% of our revenue from Clinical Services, approximately 40% from Biopharma Services and approximately 5% from government grants. During 2014 we had no government grants.

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. The non-proprietary testing services we offer are focused in part on specific oncology categories where we are developing our proprietary tests. We believe that there is significant synergy in developing and marketing a complete set of tests and services that are disease focused and delivering those tests and services in a comprehensive manner to help with treatment decisions. The insight that we develop in delivering 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.



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**Clinical Services**

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. 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.

Our comprehensive oncology-focused testing services for cancer are utilized in the diagnosis, prognosis and predicting treatment outcomes (theranosis) of cancer patients and are growing rapidly as clinicians demand more precise and more comprehensive diagnostic evaluation of their patients. We utilize highly skilled scientists, pathologists and hematologists in our laboratory, with 35% of individuals holding advanced degrees. These individuals assist our customers in integrating and technically assessing the testing results for their patients.

We believe that we can be successful by offering cancer professionals a fully-integrated menu of oncology-focused proprietary tests and customizable laboratory services. We believe that our proprietary tests provide superior diagnostic and prognostic values than other currently available tests and services. 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.



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We currently offer a range of proprietary and non-proprietary services in the following areas:

<b>Testing Category</b>	<b>Nature of Test</b>
<b>Proprietary Microarray based testing (MatBA-CLL, MatBA-SLL, MatBA-DLBCL, MatBA-MCL and UroGenRA-Kidney)</b>	Our proprietary microarray tests for the detection of chromosomal abnormalities observed in Chronic Lymphocytic Leukemia (CLL), Small Lymphocytic Lymphoma (SLL), Diffuse Large B-Cell Lymphoma (DLBCL), Mantle Cell Lymphoma (MCL) and kidney cancer.
<b>Proprietary Next Generation Sequencing testing (Focus::CLL , Focus::Myeloma , Focus::Lymphoma)</b>	Our proprietary NGS tests for the diagnosis and prognosis of genomic alterations in CLL, Myeloma, and B-Cell Non-Hodgkin's Lymphomas.
<b>Molecular Testing</b>	Using quantitative methods, such as polymerase chain reaction, sequencing and mutation analysis, to analyze DNA and RNA to follow progression of disease and response to therapy at the genetic level.
<b>Cytogenetics Testing</b>	A series of methods that analyze human chromosomes in order to identify malignancy.
<b>FISH Testing</b>	Analysis of abnormalities at the chromosomal and gene levels using analyte specific reagents and FED-cleared probes performed on whole specimen or separated purified plasma cells.
<b>Histology Testing</b>	Microscopic examination of stained tissue sections using various special staining techniques.
<b>Cytology Testing</b>	Non-gynecological fluid preparation for microscopic evaluations by a pathologist.
<b>IHC Testing</b>	Analysis of the distribution of tumor antigens in specific cell and tissue types.

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. In addition, we intend to continue to focus on partnering with community hospitals, where nearly 85% of all cancers are initially diagnosed, through our program called Expand Dx, which was specifically designed to meet the needs of community hospitals. We believe our proprietary tests and services will enable community hospitals to optimize and expand their oncology services to better serve their cancer patients and reduce costs associated with cancer care.

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 hematopathologists and laboratory directors prepare these Summation Reports based on the clinical information and diagnosis provided by our laboratory professionals. All 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.

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Our principle clinical services leverage and utilize our proprietary tests and testing methods, which include the categories below:

***NGS Panels***

Next-Generation Sequencing performs massively parallel sequencing (over 100 reads of a selected segment of DNA in one test run) of DNA from cancer cells effectively permitting a highly sensitive analysis of not only the sequence of the genome in cancer cells to reveal mutations and other aberrations associated with a cancer, but also other genomic rearrangements previously unknown to occur in the cancer genome. Translation of these findings for clinical implementation can also be achieved with a high degree of sensitivity using deep sequencing at specific nucleotide sequences and can be translated where applicable into FISH or microarray-based assays depending on the aberrations that need to be detected, to develop more specific tests. Deep sequencing is a technique by which a selected segment of nucleotides is sequenced repeatedly in order to reveal potentially rare genetic changes that may not be discoverable by traditional sequencing methods.

***CGH Microarrays***

Oligonucleotide-based CGH microarrays are a multiplex technology that allows the attachment of thousands of microscopic spots of DNA onto a surface. The DNA sequences on the microarray can hybridize to multiple genetic aberrations in cancerous tissue and can yield diagnostic and prognostic information of importance to the treatment of the patient from a small amount of patient sample. We believe microarrays provide a powerful approach to distinguishing cancer types and differentiate those more or less likely to recur, progress or respond to specific treatments based upon comprehensive sequence analysis and the ability of one microarray to interrogate multiple cancer subtypes in parallel. Because thousands of individual DNA sequences are being tested by the microarray, analysis involves bioinformatics-based algorithms. Considering the current clinical and societal demand for minimally invasive procedures, we believe the diagnostic and prognostic applications of microarrays are highly desirable.

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

***DNA Probes***

FISH-based DNA probes are fluorescently labeled sequences of DNA complementary to a genomic region of interest, which when hybridized to chromosomes, give rise to signals revealing with high sensitivity the presence or absence of a specific genomic abnormality. One probe identifies one specific genomic region. To create higher levels of specificity, multiple probes may be required to identify multiple genomic aberrations in the same cancer cell. Depending on the color scheme and custom design of each FISH-based DNA probe, genomic gain/loss and rearrangements can be detected in cancer specimens of multiple tissue types. Our proprietary FHACT (FISH-based HPV-associated Cancer Test) probe panel for detection and prognostication of HPV-associated cervical cancer and precancerous lesions uses a patented four-probe set to differentiate between cervical lesions likely to progress to cancer and those likely to regress without intervention.

We offer these tests and expect to offer additional proprietary tests as laboratory developed tests, or LDTs, in other areas of oncology and will seek the required certification under the Clinical

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Laboratory Improvement Amendments of 1988 ("CLIA") and state approvals, as well as any U.S. Food and Drug Administration ("FDA") clearances or approvals that may be required for these tests.

**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 support. These services include DNA and RNA extraction and purification, genotyping, gene expression analyses and biorepository sample storage solutions.

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 potentially 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 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. Genomic 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 2014, 41 new drugs were approved by the FDA. This is the highest number of FDA approvals since 1996, and 20% of these drugs were personalized medicines, highlighting the potential value of incorporating genomic information into 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.

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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 laboratory's 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 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. 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 DNA-based biomarkers for disease. In 2014, we added discovery services as a new revenue category and this category accounted for approximately 2% of our total revenue for the year ended December 31, 2014. Discovery services we offer include validation of biomarkers for diseases including 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 DNA and interpret these changes into meaningful predictors of disease or indicators of diagnosis is essential to discovering new biomarkers for cancer and targets for therapies.

**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.

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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 overseas 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.

***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.

**Recent Developments**

***Response Genetics Acquisition***

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 \$13.4 million, comprised of \$7.0 million, in cash, and 788,584 shares of the Company's common stock, with the common stock being valued at \$6.4 million.

We believe this acquisition will enhance our business for the following reasons:

*Enable us to have a West Coast facility by adding Response Genetics' Los Angeles, California-based laboratory. We assumed the lease of Response Genetics' approximately 27,000 square foot, CLIA-certified and CAP-accredited laboratory located in Los Angeles, California, which has performed clinical oncology diagnostic testing for over 3,000 unique physicians, laboratories and hospital sites across the United States.*

*Expand the size and geographic presence of our clinical sales force. Through this acquisition, we added 9 salespeople and increased our geographic presence, particularly in the Western and Southeastern United States. We expect that our joint clinical sales force will have national reach*

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and be among the largest oncology-focused clinical sales groups in the molecular diagnostics field.

*Acquire Response Genetics' Tissue of Origin® (TOO®) test, which we believe is the only FDA-cleared and Medicare-reimbursed test for identifying the primary site of otherwise unclassifiable malignant tumors.* TOO® is a gene expression-based microarray that targets over 2,000 genetic sites to classify the originating tissue type of cancerous cells. TOO® will represent our first test with FDA clearance.

*Gain expertise in solid tumor cancer types and expand our portfolio of proprietary genomic tests and services.* Response Genetics is a leader in solid tumor molecular diagnostics, particularly in lung cancer, colorectal cancer and melanoma, with these tests assisting clinical decision-making based on a patient's genomic information. Solid tumors account for eight of the ten most common cancer types in the United States, impacting nearly 1.2 million patient lives annually. The acquisition provides us with the immediate opportunity to offer our existing customers an expanded test menu in solid tumors as well as the TOO® test. We expect to start marketing the combined entity's comprehensive portfolio of tests and services immediately.

*Expand our biopharma customer base and our biopharma service offering.* Through this acquisition, we expanded our biopharma customer base and contracts, including the multi-year ALCHEMIST Trial contract with the National Cancer Institute, or NCI, focused on biomarker-based treatment for lung cancer, which was awarded to Response Genetics in 2014. Further, this acquisition provides us with an opportunity to capitalize on our expanded portfolio of oncology diagnostics by upselling to our and Response Genetics' existing biopharma customers.

*Expand our collaborative relationships with leading research centers and research and development of next-generation sequencing panels.* Through the acquisition, we acquired the rights to offer and market a lung cancer next-generation sequencing panel developed by leading genomic scientists and clinicians at Knight Laboratories at Oregon Health & Science University.

**Third Quarter Preliminary Results**

We are currently finalizing our financial results for the three months ended September 30, 2015. While complete financial information and operating data as of and for such period are not available, based on the information and data currently available, our management preliminarily estimates that for the three months ended September 30, 2015 our revenue was \$4.0 million, compared to revenue of \$4.2 million for the three months ended June 30, 2015 and \$3.2 million for the three months ended September 30, 2014. In addition, our management preliminarily estimates that for the three months ended September 30, 2015 our operating loss and net loss was \$5.6 million and \$5.2 million, respectively, compared to an operating loss and net loss of \$4.4 million and \$5.0 million, respectively, for the three months ended June 30, 2015 and \$4.9 million and \$4.8 million, respectively, for the three months ended September 30, 2014. The Company had cash, cash equivalents and short-term investments of approximately \$19.9 million at September 30, 2015.

Cancer Genetics' preliminary results of operations and financial data included in this prospectus has been prepared by, and are the responsibility of, the Company's management. RSM US LLP (formerly McGladrey LLP) has not audited, reviewed, compiled or performed any procedures with respect to the foregoing preliminary results of operations and financial data. Accordingly, RSM US LLP (formerly McGladrey LLP) does not express an opinion or any other form of assurance with respect thereto.

We are currently obtaining and finalizing the financial results of Response Genetics for purposes of preparing condensed pro forma financial information in our quarterly report. While complete financial information and operating data as of and for such period are not available, based on the information and data currently available, our management preliminarily estimates that for the three

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months ended September 30, 2015 Response Genetics' revenue was \$2.7 million. In addition, our management preliminarily estimates that for the three months ended September 30, 2015 Response Genetics' net loss was \$5.8 million. We did not acquire any of the Response Genetics cash or accounts receivable associated with their clinical business.

Response Genetics' preliminary results of operations and financial data included in this prospectus has been prepared by, and are the responsibility of, the Company's management. BDO USA LLP has not audited, reviewed, compiled or performed any procedures with respect to the foregoing preliminary results of operations and financial data. Accordingly, BDO USA, LLP does not express an opinion or any other form of assurance with respect thereto.

All of these estimates are preliminary and may change. There can be no assurance that Response Genetics' final results for this quarter will not differ from these estimates, including as a result of quarter-end closing procedures or review adjustments, and such changes could be material. In addition, these preliminary results of operations and financial data for the three months ended September 30, 2015 are not necessarily indicative of the results to be achieved for the remainder of 2015 or any future period.

The Response Genetics numbers above are derived from the historical numbers of Response Genetics. Over time the operations of Response Genetics will be integrated into the operations of Cancer Genetics. 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, Cancer Genetics does not have enough information to prepare a reliable estimate of any possible changes.

Response Genetics filed for Chapter 11 bankruptcy on August 9, 2015. GAAP requires specific adjustments when an entity is in bankruptcy. These adjustments can affect the measurement of assets and liabilities from the discharge of bankruptcy, potential recognition of gain or loss resulting and classification of assets and liabilities to be discharged in the bankruptcy process. Cancer Genetics has also not made any adjustments to the Response Genetics financial information to reflect the bankruptcy of Response Genetics in the preliminary financial information for the period ended September 30, 2015.

As of the date of this filing, Cancer Genetics has not completed the detailed valuation studies necessary to finalize the required estimates of the fair value of the Response Genetics' assets acquired and liabilities assumed and the related allocations of the purchase price, nor has Cancer Genetics identified the adjustments necessary, to conform Response Genetics' accounting policies to those of Cancer Genetics.

**Corporate 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, or 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., or 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.

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](http://www.cancergenetics.com). The information on our website is not part of, and is not incorporated by reference into, this prospectus supplement and the accompanying prospectus.

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**THE OFFERING**

<b>Common stock offered by us</b>	3,000,000 shares
<b>Warrants offered by us</b>	Warrants to purchase up to 3,000,000 shares of common stock. Each warrant will have an exercise price of \$5.00 per share, will be exercisable upon issuance and will expire five years from the date of issuance.
<b>Common stock to be outstanding following this offering</b>	12,844,360 shares, or 15,844,360 shares if the warrants offered in this offering are exercised in full (assuming no exercise of the underwriters' option to purchase additional shares and/or warrants)
<b>Over-allotment Option</b>	We have granted the underwriters a 45-day option to purchase an additional 450,000 shares of common stock and/or warrants to purchase up to 450,000 additional shares of our common stock.
<b>Risk Factors</b>	Investing in our common stock and warrants involves a high degree of risk. See "Risk Factors" beginning on page S-13.
<b>Use of Proceeds</b>	We intend to use the net proceeds received by us in this offering to fund contributions to our JV with Mayo, expansion of our sales and marketing capabilities, further research and development activities, expansion of business, strategic transactions and for working capital and other general corporate purposes. See "Use of Proceeds" on page S-55.
<b>NASDAQ Capital Market symbol</b>	CGIX

Certain of our officers and directors have indicated an interest in purchasing up to an aggregate of approximately \$420,000 in shares of our common stock and warrants in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, less or no shares and warrants to any of these potential investors and any of these potential investors could determine to purchase more, less or no shares and warrants in this offering.

The total number of shares of common stock to be outstanding immediately after this offering assumes no exercise of the underwriters' option to purchase additional shares and/or warrants and is based on 9,844,360 shares of common stock issued and outstanding as of June 30, 2015, which does not include the following:

1,932,411 shares issuable upon the exercise of outstanding stock options, as of June 30, 2015, with a weighted-average exercise price of \$10.55 per share;

1,116,940 shares issuable upon the exercise of outstanding warrants, as of June 30, 2015, with a weighted-average exercise price of \$13.53 per share;

1,008,951 shares available for future issuance under the 2011 Equity Incentive Plan, or the 2011 Plan, and the 2008 Stock Option Plan, or 2008 Plan; and

788,584 shares of common stock issued on October 9, 2015 in connection with the closing of the Response Genetics acquisition.





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Unless otherwise stated, all information in this prospectus supplement:

excludes shares issuable upon the exercise of warrants sold in this offering;

assumes no exercise of outstanding options to purchase common stock and no issuance of shares available for future issuance under our equity compensation plans;

assumes no exercise of the underwriters' option to purchase additional shares and/or warrants; and

reflects all currency in U.S. dollars.

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**RISK FACTORS**

*An investment in the shares of our common stock and warrants involves a number of risks. Before deciding whether to purchase the shares of common stock and warrants, you should give careful consideration to the risks discussed below and elsewhere in this prospectus supplement, including those set forth under the heading "Special Note Regarding Forward-Looking Statements" on page S-53 of this prospectus supplement, and in our filings with the Securities and Exchange Commission (SEC) that we have incorporated by reference in this prospectus supplement and the accompanying prospectus. Additional risks and uncertainties not currently known to us or that we currently believe to be immaterial may also impair our business operations.*

*Any of the risks discussed below or elsewhere in this prospectus supplement or in our SEC filings incorporated by reference in this prospectus supplement and the accompanying prospectus, and other risks we have not anticipated or discussed, could have a material impact on our business, consolidated financial condition, results of operations or liquidity. In that case, the market price for our common stock could decline and you may lose all or part of your investment.*

**Risks Related to this Offering and our Common Stock and Warrants**

**Management will have broad discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively.**

We currently intend to use the net proceeds received by us in this offering to fund contributions to our JV with Mayo, expansion of our sales and marketing capabilities, further research and development activities, expansion of business, strategic transactions and for working capital and other general corporate purposes. However, our management will have broad discretion as to the application of the net proceeds from this offering and could use them for purposes other than those contemplated at the time of the offering. Our management may use the net proceeds for corporate purposes that may not improve our financial condition or market value.

**You will experience immediate and substantial dilution in the book value per share of the common stock you purchase.**

Because the price per share of our common stock being offered will be higher than the book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. See the section titled "Dilution" below for a more detailed discussion of the dilution you will incur if you purchase common stock and warrants in this offering. In addition, we have a significant number of options and restricted stock outstanding. If the holders of these securities exercise them or become vested in them, as applicable, you may incur further dilution.

**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. Prior to that date, our common stock had been quoted on the OTCQB, and prior to our initial public offering in April 2013, there was no trading activity in our common stock. Although the NASDAQ listing improved the liquidity of our common stock, such listing has been of limited duration and no assurance can be given that recent levels of trading activity will continue. 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.

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**There is no public market for the warrants to purchase shares of our common stock being offered in this offering.**

There is no public trading market for the warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the warrants on any national securities exchange or other nationally recognized trading system, including The NASDAQ Capital Market. Without an active market, the liquidity of the warrants will be limited.

**Due to the speculative nature of warrants, there is no guarantee that it will ever be profitable for investors in the offering to exercise their warrants.**

The warrants offered hereby do not confer any rights of share ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire our common stock at a fixed price for a limited period of time. Investors in this offering may exercise their right to acquire the shares of common stock underlying their warrants at any time after the date of issuance by paying an exercise price of \$5.00 per share (which is equal to 125% of the public offering price of the shares being offered pursuant to this prospectus), prior to their expiration on the date that is five years from the date of issuance, after which date any unexercised warrants will expire and have no further value. See "Description of the Securities We are Offering." There can be no assurance that the market price of our common stock will ever equal or exceed the exercise price of the warrants, and, consequently, whether it will ever be profitable for investors to exercise their warrants.

**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.

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

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

As of June 30, 2015, we had outstanding options to purchase an aggregate of 1,932,411 shares of our common stock at a weighted-average exercise price of \$10.55 per share and warrants to purchase an aggregate of 1,116,940 shares of our common stock at a weighted-average exercise price of \$13.53 per share. As a result of this offering, we will have outstanding warrants to purchase an aggregate of 4,116,940 shares of our common stock at a weighted-average exercise price of \$7.20 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 31.6% of our outstanding common stock, based on the number of shares outstanding on June 30, 2015. After giving effect to this offering (including giving effect to anticipated purchases by certain directors and officers of the Company in this offering) and the recent acquisition of Response, our directors and executive officers, together with their affiliates, will, in the aggregate, beneficially own approximately 24.9% of our outstanding common stock. 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.

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**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.

**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

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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.

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.



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**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.

#### **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 \$9.3 million for the six months ended June 30, 2015 and \$16.6 million, \$12.4 million and \$6.7 million for fiscal years ended December 31, 2014, 2013 and 2012, respectively. From our inception in April 1999 through June 30, 2015, we had an accumulated deficit of \$87.2 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

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years ended December 31, 2014 and 2013, respectively. From its inception in September 1999 through June 30, 2015, Response Genetics had an accumulated deficit of \$87.8 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 the combined company's operations, to develop, validate and commercialize new tests and technologies, to expand our operations and repay indebtedness. At June 30, 2015, we had cash and cash equivalents of \$23.7 million. Net cash used in operating activities was \$7.4 million for the six months ended June 30, 2015 and \$12.3 million for the year ended December 31, 2014. We also need capital to fund our capital contributions of up to \$4.0 million to our joint venture with Mayo, which payments are subject to achievement of operational milestones and are expected to be paid over the next 30 months 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 June 30, 2015, the aggregate principal amount due under our New Credit Facility was approximately \$6 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. The interest rate of the Term Note is the Wall Street Journal prime plus 2% with a floor of 5.25% 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 plus 1.5% and matures on May 7, 2017.

On July 15, 2015, we entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement with Cantor Fitzgerald & Co., as sales agent, pursuant to which we may offer and sell, from time to time, through Cantor Fitzgerald shares of our common stock, par value \$0.0001 per share for an aggregate offering price of up to \$20,000,000. We are not obligated to sell any shares under the Sales Agreement. Subject to the terms and conditions of the Sales Agreement, Cantor Fitzgerald 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 our instructions, including any price, time or size limits specified by us.

Since July 15, 2015, we have issued 2,800 shares of our common stock for aggregate net proceeds of approximately \$34,000 pursuant to such Sales Agreement. As of November 5, 2015, shares of common stock having an aggregate offering price of up to \$19.9 million remain available for issuance under the Sales Agreement. In July 2015, we announced that we had suspended sales under the Sales Agreement. Furthermore, under the terms of our lock up agreement with the underwriters of this offering, we may not resume selling our common stock under the Sales Agreement until 90 days after this offering is consummated. See "Underwriting."

We believe that our current cash, together with the anticipated net proceeds from this offering, will support our operations for at least the next 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

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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" in our quarterly report on Form 10-Q for the period ended June 30, 2015, which is incorporated by reference herein.

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

increase our sales and marketing efforts to drive market adoption and address competitive developments;

fund development, validation and marketing efforts of current and future tests;

comply with current and evolving regulatory requirements;

further expand our clinical laboratory operations;

expand our technologies into other types of cancer;

acquire, license or invest in technologies;

acquire or invest in complementary businesses or assets; and

finance capital expenditures and general and administrative expenses.

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

our ability to achieve revenue growth;

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 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;

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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 in 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 NGS panels, microarrays and FHACT probe;

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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 and Discovery 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.

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 and Discovery 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

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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 genomic-based 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 theragnosis 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;

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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 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 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.

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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 potential benefits could harm the business and operating results of the combined company.**

We expect that the acquisition of the Response Genetics businesses will result in potential benefits for the combined company, including the expansion of the number and geographic coverage of our marketing team, the expansion of our menu of genetic 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.**

Acquisitions may entail numerous risks for us, including:

- competing claims for capital resources;
- ability to retain and grow relationships with Response Genetics' 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 could have a material adverse effect on our business, financial condition and operating results.

**If the market for the combined company's tests and services does not experience significant growth or if the combined company's tests and services do not achieve broad acceptance, the combined company's operations will suffer.**

We cannot accurately predict the future growth rate or the size of the market for the combined company's 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 the combined company's tests and services, and the tests and services offered by competitors;
- customers' perceptions regarding the benefits of the combined company's tests and services;



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customers' satisfaction with our tests and services; and

marketing efforts and publicity regarding our tests and services.

**If the combined company is unable to manage growth in its business, its prospects may be limited and its future results of operations may be adversely affected.**

The combined company intends to expand its research and development activities, its sales and marketing programs and other activities as needed to meet future demand. Any significant expansion may strain the combined company's managerial, financial and other resources. If the combined company is unable to manage its growth, its business, operating results and financial condition could be adversely affected. The combined company will need to improve continually its 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.

**If the Response Genetics tests that we acquired do not continue to perform as expected, or if we cannot continue to improve those tests to keep pace with rapid advances in technology, medicine and science, our operating results, reputation and business could 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 the tests or services we acquired from Response Genetics to perform as expected could significantly impair the reputation and the public image of the tests and services of the combined company as a whole, and we may be subject to legal claims arising from any defects or errors. Further, in recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer and 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. The tests we acquired from Response Genetics could become obsolete unless we continually innovate to incorporate the latest science of and expand them to demonstrate benefit in patients treated with new therapies. If we cannot adequately update our tests to incorporate the latest advances in genetic information and 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.

**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 no experience with acquiring other companies and limited experience with 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

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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 diagnostic services and tests utilizing next generation sequencing. We have made \$2.0 million in capital contributions to that joint venture through September 30, 2015. The agreement requires additional capital contributions by us of up to \$4.0 million, subject to the joint venture achieving certain operational milestones, which are expected to occur over the next 30 months. 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,

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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 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,

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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 cancer diagnostic tests and are unable to gain acceptance in the market, we may be unable to generate sufficient revenue to sustain our business.**

We are an early-stage company and have engaged in only limited sales and marketing activities for the diagnostic tests and services offered in our clinical laboratory. To date, we have received very limited revenue from sales of our tests.

Although we believe that our diagnostic 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 will need to establish a market for our diagnostic tests and build that market 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 diagnostic 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 June 30, 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;

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place us at a disadvantage compared to competitors that may have proportionately less debt; and

increase our cost of borrowing.

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

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

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

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

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

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

We also face competition from companies that currently offer or are developing products to profile genes, gene expression or protein biomarkers in various cancers. 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

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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), Clariant, 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.**

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 2014, 2013 and 2012 accounted for 56%, 69% and 58% respectively, of our clinical testing volumes, with 38%, 36% and 46% respectively, of the volume coming from community hospitals. 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. During 2012 there were three sites which each accounted for more than 10% of our revenue: a Biopharma client accounted for approximately 13%, a university teaching center accounted for approximately 11% and a community hospital accounted for approximately 10% of our revenue.

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**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, 2014, our research and development expenses were \$4.6 million, which was 45% of our 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. For the year ended December 31, 2012, our research and development expenses were \$2.1 million, which was 49% of our revenue and our sales and marketing expenses were \$1.4 million, which was 33% 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.



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

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

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

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

Our activities currently require the controlled use of potentially harmful biological materials and hazardous materials and chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject to, on an ongoing basis, federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant and could have a material adverse effect on our financial condition, results of operations and cash flows. In the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines.

**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.

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

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

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

In the ordinary course of our business, we and our third-party billing and collections provider collect and store sensitive data, including legally protected health information, 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

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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.

**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

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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 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.

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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 clinical laboratory fee schedule 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 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 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. On September 25, 2015, CMS issued a proposed rule that sets out how CMS proposes to implement PAMA. If PAMA results in a significant reduction in the prices for our tests, it could have a significant impact on our revenues.

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. In April 2015, however, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, was signed into law, which repealed and replaced the statutory formula for Medicare payment adjustments to physicians. MACRA provides a permanent end to the annual interim legislative updates that had previously been necessary to delay or prevent significant reductions to payments under the Medicare Physician Fee Schedule. MACRA extended existing payment rates through June 30, 2015, with a 0.5% update for July 1, 2015 through December 31, 2015, and for each calendar year through 2019, after which there will be a 0% annual update each year through 2025. In addition, MACRA requires the establishment of the Merit-Based Incentive Payment System ("MIPS"), beginning in 2019, under which physicians may receive performance-based payment incentives or payment reductions based on their performance with respect to clinical quality, resource use, clinical improvement activities and meaningful use of electronic health records. MACRA also requires the Centers for Medicare & Medicaid Services, or CMS, beginning in 2019, to provide incentive payments for physicians and other eligible professionals that participate in alternative payment models, such as accountable care organizations, that emphasize quality and value over the traditional volume-based fee-for-service model. 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

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Rule for 2013, CMS announced that it has decided to keep the new molecular codes on the Clinical Laboratory Fee Schedule (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 has proposed "crosswalking" these codes to an unrelated test, resulting in a significant cut in their reimbursement. If CMS finalizes these rates, it could eventually adversely affect our reimbursement in this area. 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 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.

**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, 2014, we derived approximately 16% of our total revenue from private insurance, including managed care organizations and other health care insurance providers, 11% from Medicare and 16% from other health care facilities billed directly. For the year ended December 31, 2014, Response Genetics derived approximately 38% of its revenue from the Medicare program. Medicare and other third-party payors may withdraw their coverage policies or cancel their contracts with us at any time, review and adjust the rate of reimbursement or stop paying for our tests altogether, which would reduce our total revenues.

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

In addition, we are currently considered a "non-contracting provider" by a number of private third-party payors because we have not entered into a specific contract to provide our specialized diagnostic services to their insured patients at specified rates of reimbursement. If we were to become a contracting provider in the future, the amount of overall reimbursement we receive is likely to decrease because we will be reimbursed less money per test performed at a contracted rate than at a non-contracted rate, which could have a negative impact on our revenues. Further, we typically are

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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

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

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

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

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

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

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



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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.

**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

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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.

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 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 genetic-based 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 genetic-based tests, we may be required to conduct additional clinical testing prior to submitting a

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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

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health services" with whom the physician or a member of the physician's immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies;

HIPAA, which established federal crimes for knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services;

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

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attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, and/or exclusion from participation in Medicare, Medi-Cal or other state or federal health care programs, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

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

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

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

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**Intellectual Property Risks Related to Our Business**

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

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

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

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

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

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

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**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



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

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

**Risks Relating to our International Operations**

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

Our business strategy incorporates international expansion, including our recent acquisitions which have provided us with facilities in 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;



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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 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.



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**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.

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

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

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

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

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**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein contain forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements represent our management's judgment regarding future events. In many cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "plan," "expect," "anticipate," "estimate," "predict," "intend," "potential" or "continue" or the negative of these terms or other words of similar import, although some forward-looking statements are expressed differently. All statements other than statements of historical fact included in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein regarding our financial position, business strategy and plans or objectives for future operations are forward-looking statements. We cannot guarantee the accuracy of forward-looking statements, and you should be aware that results and events could differ materially and adversely from those described in the forward-looking statements due to a number of factors, including:

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

our ability to achieve profitability by increasing sales of our laboratory tests and services and to continually develop and commercialize novel and innovative genomic-based diagnostic tests and services for cancer patients;

our ability to raise additional capital to meet our liquidity needs;

our ability to integrate Response Genetics' operations with our own operations, to realize anticipated efficiencies and cost-savings, and to realize anticipated benefits of the Response Genetics acquisition;

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, genomic-based 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;



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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;

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our ability to manage significant fluctuations in our quarterly operating results, which may occur as a result of the timing, size and duration of our contracts with biopharmaceutical companies and clinical research organizations;

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.

You should also consider carefully the statements set forth in the section titled "Risk Factors" or elsewhere in this prospectus supplement, the accompanying prospectus and the documents incorporated or deemed incorporated herein or therein by reference, which address various factors that could cause results or events to differ from those described in the forward-looking statements. All subsequent written and oral forward-looking statements attributable to us or to persons acting on our behalf are expressly qualified in their entirety by the applicable cautionary statements. We have no plans to update these forward-looking statements.

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**USE OF PROCEEDS**

We estimate that the net proceeds received by us from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us and excluding the proceeds, if any, from the exercise of the warrants issued pursuant to this offering, will be approximately \$10.5 million, or approximately \$12.2 million, if the underwriters exercise their option to purchase additional shares and warrants in full.

We intend to use the net proceeds of the offering as follows:

\$4.0 million to fund our anticipated contributions to our joint venture with Mayo over the next 30 months; and

the balance for general corporate purposes including integration of our recent acquisition and sales and marketing to support new product launches.

Pending the use of the net proceeds of this offering, we intend to invest the funds in short-term, investment grade, interest-bearing securities.

The amount and timing of actual expenditures for the purposes set forth above may vary based on several factors, and our management will retain broad discretion as to the ultimate allocation of the proceeds.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through at least the next 24 months. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

Table of Contents**MARKET PRICE FOR OUR COMMON STOCK**

Prior to our initial public offering on April 4, 2013, no public trades occurred in our common stock. From our initial public offering until August 13, 2013, our common stock was quoted on the OTCQB under the symbol "CGIX," and since August 14, 2013, our common stock has been listed on The NASDAQ Capital Market under the symbol "CGIX." The following table sets forth, for the periods indicated, the reported high and low bid quotations per share for our common stock based on information provided by the OTC Market Group, Inc. and our high and low sales prices on The NASDAQ Capital Market. Such OTCQB over-the-counter market quotations reflect inter-dealer prices, without markup, markdown or commissions and, particularly because our common stock is traded infrequently, may not necessarily represent actual transactions or a liquid trading market.

	High	Low
<b>Fiscal 2013</b>		
Second Quarter (beginning April 5, 2013, first trading day after our initial public offering)	\$ 17.00	\$ 7.00
Third Quarter	\$ 23.25	\$ 8.58
Fourth Quarter	\$ 22.59	\$ 11.00
<b>Fiscal 2014</b>		
First Quarter	\$ 20.95	\$ 13.31
Second Quarter	\$ 16.88	\$ 8.48
Third Quarter	\$ 11.50	\$ 8.25
Fourth Quarter	\$ 9.08	\$ 4.83
<b>Fiscal 2015</b>		
First Quarter	\$ 9.76	\$ 6.55
Second Quarter	\$ 12.22	\$ 7.57
Third Quarter	\$ 12.75	\$ 7.57
Fourth Quarter (through November 5, 2015)	\$ 8.51	\$ 4.60

On November 5, 2015, the closing sales price of our common stock on The NASDAQ Capital Market was \$4.61 per share. As of November 5, 2015, we had 68 stockholders of record.

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**DIVIDEND POLICY**

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. Furthermore, our loan agreement with Silicon Valley Bank prohibits us from paying cash dividends on our common stock. For further discussion, see the section entitled "Risk Factors Risks Relating to Our Business and Strategy We have indebtedness with restrictive covenants that limit our ability to obtain additional debt financing and that requires us to 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." 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.

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Table of Contents**CAPITALIZATION**

The following table sets forth our capitalization as of June 30, 2015:

on an actual basis;

on a pro forma basis to give effect to our acquisition of substantially all the assets and assumption of certain liabilities of Response Genetics on October 9, 2015; and

on a pro forma, as adjusted basis to give effect to our receipt of net proceeds of approximately \$10.5 million from the sale of 3,000,000 shares of the common stock and accompanying warrants to purchase up to 3,000,000 shares of common stock we are offering at a combined public offering price of \$4.00 per share and warrant after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

This capitalization table should be read in conjunction with management's discussion and analysis of results of operations and our consolidated financial statements and related notes included in our 2014 Form 10-K and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2015.

	<b>As of June 30, 2015</b>		
	<b>Actual</b>	<b>(unaudited)</b>	
		<b>Pro Forma</b>	<b>Pro Forma, as adjusted</b>
Cash and cash equivalents	\$ 23,744,173	\$ 16,244,173	\$ 26,794,173
Restricted cash	\$ 300,000	\$ 300,000	300,000
Bank term note	6,000,000	6,000,000	6,000,000
Preferred stock, authorized 9,764,000 shares, \$0.0001 par value, none issued			
Common stock, authorized 100,000,000 shares, \$0.0001 par value, 9,844,360 shares issued and outstanding at June 30, 2015, actual; 10,632,944 shares issued and outstanding, pro forma; and 13,632,944 shares issued and outstanding pro forma, as adjusted	984	1,063	1,363
Additional paid-in capital	113,996,507	120,396,428	130,946,128
Accumulated deficit	(87,225,649)	(87,725,649)	(87,725,649)
Total stockholders' equity (deficit)	\$ 26,771,842	\$ 32,671,842	\$ 43,221,842
Total capitalization	\$ 32,771,842	\$ 38,671,842	\$ 49,221,842

The total number of shares of common stock to be outstanding immediately after this offering assumes no exercise of the underwriters' option to purchase additional shares and warrants and no exercise of the 3,000,000 warrants being issued in the offering and is based on 9,844,360 shares of common stock issued and outstanding as of June 30, 2015, which does not include the following:

1,932,411 shares issuable upon the exercise of outstanding stock options, as of June 30, 2015, with a weighted-average exercise price of \$10.55 per share;

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1,116,940 shares issuable upon the exercise of outstanding warrants, as of June 30, 2015, with a weighted-average exercise price of \$13.53 per share; and

1,008,951 shares available for future issuance under the 2011 Plan and the 2008 Plan.

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Table of Contents**DILUTION**

If you invest in our common stock and warrants in this offering, your ownership interest will be diluted to the extent of the difference between the combined public offering price per share and accompanying warrant and our pro forma net tangible book value per share after this offering. We calculate net tangible book value per share by dividing our net tangible book value, which is tangible assets less total liabilities, by the number of outstanding shares of our common stock.

Our net tangible book value as of June 30, 2015 was approximately \$23.0 million, or \$2.34 per share. After giving effect to our acquisition of substantially all the assets and assumption of certain liabilities of Response Genetics, our pro forma net tangible book value as of June 30, 2015 was \$17.4 million, or \$1.64 per share. After giving effect to the sale by us of 3,000,000 shares of common stock and warrants to purchase up to 3,000,000 shares of common stock offered by this prospectus supplement at the combined public offering price of \$4.00 per share and accompanying warrant and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2015 would have been approximately \$28.0 million, or \$2.05 per share. This represents an immediate increase in as adjusted net tangible book value of \$0.41 per share to existing stockholders and an immediate dilution of \$1.95 per share to new investors purchasing our common stock in this offering. The following table illustrates the per share dilution to investor purchasing shares and warrants in this offering:

Combined public offering price per share of common stock and warrant	\$ 4.00
Historical net tangible book value per share as of June 30, 2015	\$ 2.34
Pro forma decrease in net tangible book value as of June 30, 2015 attributable to the Response acquisition	\$ (0.70)
Pro forma net tangible book value per share as of June 15, 2015 before giving effect to this offering	\$ 1.64
Increase in pro forma net tangible book value per share after this offering	\$ 0.41
As adjusted pro forma net tangible book value per share as of June 30, 2015, after giving effect to this offering	\$ 2.05
Dilution per share to new investors in this offering	\$ 1.95

The information above assumes that the underwriters do not exercise their option to purchase additional shares and warrants. If the underwriters exercise their option to purchase additional shares and/or warrants in full, our as adjusted pro forma net tangible book value per share at June 30, 2015 after giving effect to this offering would have been \$2.11 per share, and the dilution in as adjusted net tangible book value per share to investors in this offering would have been \$1.89 per share.

The above table is based on 9,844,360 shares of our common stock issued and outstanding as of June 30, 2015, which assumes no exercise of the underwriters' option to purchase additional shares and no exercise of the 3,000,000 warrants being issued in the offering and does not include the following:

1,932,411 shares issuable upon the exercise of outstanding stock options, as of June 30, 2015, with a weighted-average exercise price of \$10.55 per share;

1,116,940 shares issuable upon the exercise of outstanding warrants, as of June 30, 2015, with a weighted-average exercise price of \$13.53 per share; and

1,008,951 shares available for future issuance under the 2011 Plan and the 2008 Plan.



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**MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS**

The following discussion is a general summary of the material U.S. federal income tax consequences applicable to Non-U.S. Holders of the purchase, ownership and disposition of shares of our common stock in this offering as of the date hereof.

For purposes of this discussion, a "Non-U.S. Holder" of common stock means a holder that, for U.S. federal income tax purposes, is not a U.S. person. The term "U.S. person" means:

an individual citizen or resident of the United States,

a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States or any State thereof or the District of Columbia,

an estate the income of which is subject to U.S. federal income taxation regardless of its source, or

a trust, if it (1) is subject to the primary supervision of a court within the United States and one or more United States persons (within the meaning of Section 7701(a)(30) of the U.S. Internal Revenue Code of 1986, as amended (the "Code")) have the authority to control all substantial decisions of the trust, or (2) has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a United States person.

This summary is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This summary does not consider specific facts and circumstances that may be relevant to a particular Non-U.S. Holder's tax position and does not consider the state, local or non-U.S. tax consequences of an investment in common stock. It also does not consider Non-U.S. Holders subject to special tax treatment under U.S. federal income tax laws (including partnerships or other pass-through entities (or investors therein), banks and insurance companies, regulated investment companies, real estate investment trusts, dealers in securities, holders of our common stock held as part of a "straddle," "hedge," "conversion transaction" or other risk-reduction transaction, controlled foreign corporations, passive foreign investment companies, companies that accumulate earnings to avoid U.S. federal income tax, foreign tax-exempt organizations, "expatriated entities," companies subject to the "stapled stock" rules, former U.S. citizens or residents and persons who hold or receive the shares of common stock as compensation). This summary is based on provisions of the Code, applicable U.S. Treasury Regulations, administrative pronouncements of the U.S. Internal Revenue Service ("IRS") and judicial decisions, all as in effect on the date hereof, and all of which are subject to change, possibly on a retroactive basis, and different interpretations.

**This summary is included herein as general information only. We urge each prospective Non-U.S. Holder to consult their tax advisor concerning the particular U.S. federal, state, local and non-U.S. income, estate and other tax consequences of the purchase, ownership and disposition of our common stock.**

**U.S. Trade or Business Income**

For purposes of this discussion, dividend income, and gain on the sale or other taxable disposition of our shares, will be considered to be "U.S. trade or business income" if such dividend income or gain is (1) effectively connected with the conduct by a Non-U.S. Holder of a trade or business within the United States; and (2) in the case of a Non-U.S. Holder that is eligible for the benefits of an income tax treaty with the United States, attributable to a "permanent establishment" or "fixed base" maintained by the Non-U.S. Holder in the United States. U.S. trade or business income is not subject to U.S. federal withholding tax (provided the Non-U.S. Holder complies with applicable certification

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and disclosure requirements); instead, U.S. trade or business income is subject to U.S. federal income tax on a net income basis at regular U.S. federal income tax rates generally in the same manner as if the recipient were a U.S. person. Any U.S. trade or business income received by a Non-U.S. Holder that is treated as a corporation also may be subject to a "branch profits tax" at a 30% rate, or such lower rate as provided under an applicable income tax treaty.

**Dividends**

Distributions of cash or property (other than certain stock distributions) that we pay with respect to our common stock (or certain redemptions that are treated as distributions with respect to our shares) will be taxable as dividends for U.S. federal income tax purposes to the extent paid out of our current or accumulated earnings and profits as determined for U.S. federal income tax purposes. Subject to the discussions below regarding backup withholding and the Foreign Account Tax Compliance Act, a Non-U.S. Holder generally will be subject to withholding of U.S. federal income tax at a rate of 30% of the gross amount of our distributions treated as dividends or such lower rate as may be specified by an applicable income tax treaty. To obtain a reduced rate of U.S. federal withholding tax under an applicable income tax treaty, a Non-U.S. Holder will be required to provide a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E, as applicable (or appropriate substitute or successor form) certifying its entitlement to benefits under the tax treaty. A Non-U.S. Holder of our common stock that is eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for refund with the IRS. Each Non-U.S. Holder is encouraged to consult its tax advisor regarding its possible entitlement to benefits under an income tax treaty.

The U.S. federal withholding tax does not apply to dividends that are U.S. trade or business income, as described above, of a Non-U.S. Holder who provides a properly executed IRS Form W-8ECI (or appropriate substitute or successor form), certifying that the dividends are subject to tax as income effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

**Sale, Exchange or Other Disposition of Common Stock**

Subject to the discussions below regarding backup withholding and the Foreign Account Tax Compliance Act, a Non-U.S. Holder generally will not be subject to U.S. federal income tax or withholding tax in respect of any gain recognized on a sale, exchange or other taxable disposition of shares of our common stock unless:

the gain is U.S. trade or business income, as described above under "U.S. Trade or Business Income,"

the Non-U.S. Holder is an individual, is present in the United States for 183 or more days in the taxable year of the sale or other disposition but is not treated as a resident of the United States for that year, and certain other conditions are met, or

we are or have been during a specified testing period a "United States real property holding corporation" ("USRPHC") for U.S. federal income tax purposes.

Gain described in the first bullet above will be subject to U.S. federal income tax in the manner described under "U.S. Trade or Business Income." Gain described in the second bullet above will be subject to a flat 30% tax (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S. source capital losses (even though the Non-U.S. Holder is not considered a

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resident of the United States), provided that the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

In general, a corporation is a USRPHC if the fair market value of its "U.S. real property interests" equals or exceeds 50% of the sum of the fair market value of its worldwide (domestic and foreign) real property interests and its other assets used or held for use in a trade or business. For this purpose, real property interests generally include land, improvements and associated personal property. We believe that we have not been, and we are not and do not anticipate becoming, a USRPHC for U.S. federal income tax purposes. If we are or become a USRPHC, a Non-U.S. Holder, nevertheless, will not be subject to U.S. federal income or withholding tax in respect of any gain on a sale or other disposition of our common stock so long as shares of our common stock are "regularly traded on an established securities market" as defined under applicable U.S. Treasury Regulations and such Non-U.S. Holder owned, actually and constructively, 5% or less of our shares at all times during the shorter of the five-year period ending on the date of disposition or such Non-U.S. Holder's holding period for our shares; if the foregoing exception does not apply, then if we are or were to become a USRPHC a purchaser may be required to withhold 10% of the proceeds payable to a Non-U.S. Holder from a sale of our common stock and such Non-U.S. Holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Prospective investors should be aware that no assurance can be given that our shares will be regularly traded when a Non-U.S. Holder sells its shares of our common stock.

**U.S. Federal Estate Tax**

Individual Non-U.S. Holders and entities the property of which is potentially includible in an individual's gross estate for U.S. federal estate tax purposes (for example, a trust funded by an individual and with respect to which the individual has retained certain interests or powers), should note that, unless an applicable tax treaty provides otherwise, shares of our common stock will be treated as U.S. situs property subject to U.S. federal estate tax.

**Foreign Account Tax Compliance Act**

The Foreign Account Tax Compliance Act ("FATCA") generally imposes withholding taxes on certain payments made to non-U.S. financial institutions and certain other non-U.S. entities (including financial intermediaries) unless various U.S. information reporting, diligence requirements and certain other requirements have been satisfied. Specifically, a 30% withholding tax may be imposed on dividends on, or gross proceeds from the sale or other disposition of our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence, reporting and withholding obligations, (ii) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence, reporting and withholding requirements in (i) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Various requirements and exceptions are provided under FATCA and additional requirements and exceptions may be provided in subsequent guidance. Further, the United States has entered into (and may enter into more) intergovernmental agreements ("IGAs") with foreign governments relating to the implementation of, and information sharing under, FATCA and such IGAs and/or the laws implementing them may alter one or more of the FATCA requirements.

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FATCA withholding generally applies to all payments of dividends on our common stock, and will apply to payments of gross proceeds from the disposition of our common stock made on or after January 1, 2017. A Non-U.S. Holder that is not subject to FATCA withholding generally may certify its exempt status by furnishing a properly executed Form W-8BEN or Form W-8BEN-E (or appropriate substitute or successor form), as applicable.

Prospective investors are urged to consult with their tax advisors regarding the possible implications of FATCA on their investment in our common stock.

**Information Reporting and Backup Withholding**

We must annually report to the IRS and to each Non-U.S. Holder any dividends paid on our common stock, regardless of whether any tax was actually withheld. Copies of these information returns also may be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides. Under certain circumstances, the Code imposes a backup withholding obligation on certain reportable payments. Dividends paid to a Non-U.S. Holder of our common stock generally will be exempt from backup withholding if the Non-U.S. Holder provides a properly executed IRS Form W-8BEN, W-8BEN-E or W-8ECI (or appropriate substitute or successor form) or otherwise establishes an exemption.

The payment of the proceeds from the disposition of our common stock to or through the U.S. office of any broker, U.S. or foreign, will be subject to information reporting and possible backup withholding unless the owner certifies (usually on IRS Form W-8BEN or W-8BEN-E, as applicable) as to its non-U.S. status under penalties of perjury or otherwise establishes an exemption, provided that the broker does not have actual knowledge or reason to know that the holder is a U.S. person or that the conditions of any other exemption are not, in fact, satisfied. The payment of the proceeds from the disposition of our common stock to or through a non-U.S. office of a non-U.S. broker will not be subject to information reporting or backup withholding unless the non-U.S. broker has certain types of relationships with the United States (which we refer to as a United States related person). In the case of the payment of the proceeds from the disposition of our common stock to or through a non-U.S. office of a broker that is either a U.S. person or a United States related person, the U.S. Treasury Regulations require information reporting (but not the backup withholding) on the payment unless the broker has documentary evidence in its files that the owner is a Non-U.S. Holder and the broker has no knowledge to the contrary. Non-U.S. Holders should consult their tax advisors on the application of information reporting and backup withholding to them in their particular circumstances (including upon their disposition of our common stock).

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a Non-U.S. Holder will be credited against the Non-U.S. Holder's U.S. federal income tax liability, if any, with any excess withholding refunded to such holder, provided that the required information is timely furnished to the IRS.

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**DESCRIPTION OF THE SECURITIES WE ARE OFFERING**

In this offering, we are offering 3,000,000 shares of our common stock together with warrants to purchase up to an aggregate of 3,000,000 shares of our common stock at the combined public offering price of \$4.00 per share and accompanying warrant. This prospectus also includes the offering of the shares of common stock issuable upon exercise of the offered warrants.

**Common Stock**

The material terms and provisions of our common stock are described under the caption "Description of Common Stock" beginning on page 5 of the accompanying prospectus.

**Warrants**

The following is a brief summary of certain terms and conditions of the warrants and is subject in all respects to the provisions contained in the warrants.

*Form.* The warrants will be issued as individual warrant agreements to the investors. You should review a copy of the form of warrant, which is filed as an exhibit to our Current Report on Form 8-K filed on November 6, 2015 and is incorporated by reference herein, for a complete description of the terms and conditions applicable to the warrants.

*Exercisability.* The warrants are exercisable at any time after their original issuance, expected to be November 12, 2015, and at any time up to the date that is five years after their original issuance. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is effective and available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. If a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is not effective or available, the holder may, in its sole discretion, elect to exercise the warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant.

*Exercise Limitation.* A holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates and any other persons acting as a group within such holder) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon at least 61 days' prior notice from the holder to us.

*Exercise Price.* The exercise price per whole share of common stock purchasable upon exercise of the warrants is \$5.00 per share of common stock. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

*Transferability.* Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

*Exchange Listing.* We do not plan on applying to list the warrants on The NASDAQ Capital Market, any other national securities exchange or any other nationally recognized trading system.

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*Fundamental Transactions.* In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction.

*Rights as a Stockholder.* Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

Table of Contents**UNDERWRITING**

Joseph Gunnar & Co., LLC and Feltl and Company, Inc. are acting as representatives of the underwriters and joint book-running managers of this offering. Under the terms of an underwriting agreement, which have entered into with the representatives, each of the underwriters named below has severally agreed to purchase from us the respective number of shares of common stock and warrants shown opposite its name below:

<b>Underwriters</b>	<b>Number of Shares</b>	<b>Number of Warrants</b>
Joseph Gunnar & Co., LLC	1,425,000	1,425,000
Feltl and Company, Inc.	1,425,000	1,425,000
Axiom Capital Management, Inc.	150,000	150,000
Total	3,000,000	3,000,000

The underwriting agreement provides that the underwriters' obligation to purchase shares of common stock and warrants depends on the satisfaction of the conditions contained in the underwriting agreement including:

the obligation to purchase all of the shares of common stock and warrants offered hereby (other than those shares of common stock covered by their option to purchase additional shares and warrants as described below), if any of the shares and warrants are purchased;

the representations and warranties made by us to the underwriters are true;

there is no material change in our business or the financial markets; and

we deliver customary closing documents to the underwriters.

Certain of our officers and directors have indicated an interest in purchasing up to an aggregate of approximately \$420,000 in shares of our common stock and warrants in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, less or no shares and warrants to any of these potential investors and any of these potential investors could determine to purchase more, less or no shares and warrants in this offering.

**Commissions and Expenses**

The following table summarizes the underwriting discounts and commissions we will pay to the underwriters. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares and/or warrants. The underwriting fee is the difference between the initial price to the public and the amount the underwriters pay to us for the shares.

	<b>No Exercise</b>	<b>Full Exercise</b>
Combined per Share and Warrant	\$ 0.26	\$ 0.26
Total	\$ 780,000	\$ 897,000

The representatives have advised us that the underwriters propose to offer the shares of common stock and warrants directly to the public at the public offering price on the cover of this prospectus supplement and to selected dealers, which may include the underwriters, at such offering price less a selling concession not in excess of \$0.16 per share. After the offering, the representatives may change the offering price and other selling terms.

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The expenses of the offering that are payable by us are estimated to be approximately \$550,000 (excluding underwriting discounts and commissions). We also have agreed to pay a non-accountable expense allowance to the underwriters equal to 1.0% of the gross proceeds received in this offering as well as a 0.05% allowance for legal fees, up to \$60,000; however, an allowance shall not be paid in connection with the over-allotment option if the over-allotment option is exercised and will be offset by the \$15,000 set forth below. We have paid an expense deposit of \$15,000 to the underwriters, which will be applied against accountable expenses that will be paid.

**Option to Purchase Additional Shares**

We have granted the underwriters an option exercisable for 45 days after the date of this prospectus supplement to purchase, from time to time, in whole or in part, up to an aggregate of 450,000 shares and/or warrants to purchase 450,000 additional shares from us at the public offering price less underwriting discounts and commissions. To the extent that this option is exercised, each underwriter will be obligated, subject to certain conditions, to purchase its pro rata portion of these additional shares based on the underwriter's percentage underwriting commitment in the offering as indicated in the table at the beginning of this Underwriting Section.

**Lock-Up Agreements**

We and all of our directors and executive officers have agreed that, for a period of 90 days after the date of this prospectus supplement subject to certain limited exceptions as described below, we and they will not directly or indirectly, without the prior written consent of Joseph Gunnar & Co., LLC and Feltl and Company, Inc., (1) offer for sale, sell, pledge, or otherwise transfer or dispose of (or enter into any transaction or device that is designed to, or could be expected to, result in the disposition by any person at any time in the future of) any shares of common stock (including, without limitation, shares of common stock that may be deemed to be beneficially owned by us or them in accordance with the rules and regulations of the SEC and shares of common stock that may be issued upon exercise of any options or warrants) or securities convertible into or exercisable or exchangeable for common stock (other than the stock and shares issued pursuant to employee benefit plans, qualified stock option plans, or other employee compensation plans existing on the date of this prospectus supplement), or sell or grant options, rights or warrants with respect to any shares of common stock or securities convertible into or exchangeable for common stock (other than the grant of options pursuant to option plans existing on the date of this prospectus supplement), (2) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of shares of common stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common stock or other securities, in cash or otherwise, (3) make any demand for or exercise any right or file or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any shares of common stock or securities convertible, exercisable or exchangeable into common stock or any of our other securities, or (4) publicly disclose the intention to do any of the foregoing.

The representatives of the underwriters in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release common stock and other securities from lock-up agreements, the representatives of the underwriters will consider, among other factors, the holder's reasons for requesting the release, the number of shares of common stock and other securities for which the release is being requested and market conditions at the time.

**Indemnification**

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.



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**Stabilization, Short Positions and Penalty Bids**

The representatives may engage in stabilizing transactions, short sales and purchases to cover positions created by short sales, and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, in accordance with Regulation M under the Exchange Act:

Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.

A short position involves a sale by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase in the offering, which creates the syndicate short position. This short position may be either a covered short position or a naked short position. In a covered short position, the number of shares involved in the sales made by the underwriters in excess of the number of shares they are obligated to purchase is not greater than the number of shares that they may purchase by exercising their option to purchase additional shares. In a naked short position, the number of shares involved is greater than the number of shares in their option to purchase additional shares. The underwriters may close out any short position by either exercising their option to purchase additional shares and/or purchasing shares in the open market. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through their option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.

Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions.

Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of the common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on The NASDAQ Capital Market or otherwise and, if commenced, may be discontinued at any time.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

**Passive Market Making**

In connection with the offering, underwriters and selling group members may engage in passive market making transactions in the common stock on the NASDAQ Global Market in accordance with Rule 103 of Regulation M under the Securities Exchange Act of 1934 during the period before the commencement of offers or sales of common stock and extending through the completion of distribution. A passive market maker must display its bids at a price not in excess of the highest independent bid of the security. However, if all independent bids are lowered below the passive market maker's bid that bid must be lowered when specified purchase limits are exceeded.

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**Listing on The NASDAQ Capital Market**

Our common stock is listed on The NASDAQ Capital Market under the symbol "CGIX". The warrants are not listed on The NASDAQ Capital Market and we do not intend to apply for a listing of the warrants on The NASDAQ Capital Market, any other national securities exchange, or any nationally recognized trading system.

**Stamp Taxes**

If you purchase shares of common stock offered in this prospectus supplement, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus supplement.

**Other Relationships**

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for the issuer and its affiliates, for which they received or may in the future receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of the issuer or its affiliates. If the underwriters or their affiliates have a lending relationship with us, certain of those underwriters or their affiliates routinely hedge, and certain other of those underwriters or their affiliates may hedge, their credit exposure to us consistent with their customary risk management policies. Typically, the underwriters and their affiliates would hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the shares of common stock offered hereby. Any such credit default swaps or short positions could adversely affect future trading prices of the shares of common stock offered hereby. The underwriters and certain of their affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

**Selling Restrictions**

This prospectus supplement does not constitute an offer to sell to, or a solicitation of an offer to buy from, anyone in any country or jurisdiction (i) in which such an offer or solicitation is not authorized, (ii) in which any person making such offer or solicitation is not qualified to do so or (iii) in which any such offer or solicitation would otherwise be unlawful. No action has been taken that would, or is intended to, permit a public offer of the shares of common stock or possession or distribution of this prospectus supplement or any other offering or publicity material relating to the shares of common stock in any country or jurisdiction (other than the United States) where any such action for that purpose is required. Accordingly, each underwriter has undertaken that it will not, directly or indirectly, offer or sell any shares of common stock or have in its possession, distribute or publish any prospectus, form of application, advertisement or other document or information in any country or jurisdiction except under circumstances that will, to the best of its knowledge and belief, result in compliance with

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any applicable laws and regulations and all offers and sales of shares of common stock by it will be made on the same terms.

*European Economic Area*

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State") an offer to the public of any common stock which are the subject of the offering contemplated herein may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

to legal entities which are qualified investors as defined under the Prospectus Directive;

by the underwriters to fewer than 100, or, if the Relevant Member State has implemented the relevant provisions of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or

in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of common stock shall result in a requirement for us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State who receives any communication in respect of, or who acquires any common stock under, the offers contemplated here in this prospectus supplement will be deemed to have represented, warranted and agreed to and with each underwriter and us that:

it is a qualified investor as defined under the Prospectus Directive; and

in the case of any common stock acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, (i) the common stock acquired by it in the offering have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than qualified investors, as that term is defined in the Prospectus Directive, or in the circumstances in which the prior consent of the representatives of the underwriters has been given to the offer or resale or (ii) where common stock have been acquired by it on behalf of persons in any Relevant Member State other than qualified investors, the offer of such common stock to it is not treated under the Prospectus Directive as having been made to such persons.

For the purposes of this representation and the provision above, the expression an "offer of common stock to the public" in relation to any common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any common stock to be offered so as to enable an investor to decide to purchase or subscribe for the common stock, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in each Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

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***United Kingdom***

This prospectus supplement has only been communicated or caused to have been communicated and will only be communicated or caused to be communicated as an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act of 2000 (the "FSMA")) as received in connection with the issue or sale of the common stock in circumstances in which Section 21(1) of the FSMA does not apply to us. All applicable provisions of the FSMA will be complied with in respect to anything done in relation to the common stock in, from or otherwise involving the United Kingdom.

***Australia***

This prospectus supplement is not a formal disclosure document and has not been, nor will be, lodged with the Australian Securities and Investments Commission. It does not purport to contain all information that an investor or their professional advisers would expect to find in a prospectus or other disclosure document (as defined in the Corporations Act 2001 (Australia)) for the purposes of Part 6D.2 of the Corporations Act 2001 (Australia) or in a product disclosure statement for the purposes of Part 7.9 of the Corporations Act 2001 (Australia), in either case, in relation to the securities.

The securities are not being offered in Australia to "retail clients" as defined in sections 761G and 761GA of the Corporations Act 2001 (Australia). This offering is being made in Australia solely to "wholesale clients" for the purposes of section 761G of the Corporations Act 2001 (Australia) and, as such, no prospectus, product disclosure statement or other disclosure document in relation to the securities has been, or will be, prepared.

This prospectus supplement does not constitute an offer in Australia other than to wholesale clients. By submitting an application for our securities, you represent and warrant to us that you are a wholesale client for the purposes of section 761G of the Corporations Act 2001 (Australia). If any recipient of this prospectus is not a wholesale client, no offer of, or invitation to apply for, our securities shall be deemed to be made to such recipient and no applications for our securities will be accepted from such recipient. Any offer to a recipient in Australia, and any agreement arising from acceptance of such offer, is personal and may only be accepted by the recipient. In addition, by applying for our securities you undertake to us that, for a period of 12 months from the date of issue of the securities, you will not transfer any interest in the securities to any person in Australia other than to a wholesale client.

***Hong Kong***

Ordinance (Cap.32, Laws of Hong Kong), or (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

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***Japan***

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (the Financial Instruments and Exchange Law) and each underwriter has agreed that it will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

***Singapore***

This prospectus supplement has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 by a relevant person which is: (i) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (ii) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for 6 months after that corporation or that trust has acquired the shares under Section 275 except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (2) where no consideration is given for the transfer; or (3) by operation of law.

***Switzerland***

This document, as well as any other material relating to the shares which are the subject of the offering contemplated by this prospectus supplement, do not constitute an issue prospectus pursuant to Article 652a and/or 1156 of the Swiss Code of Obligations. The shares will not be listed on the SIX Swiss Exchange and, therefore, the documents relating to the shares, including, but not limited to, this document, do not claim to comply with the disclosure standards of the listing rules of SIX Swiss Exchange and corresponding prospectus schemes annexed to the listing rules of the SIX Swiss Exchange. The shares are being offered in Switzerland by way of a private placement, i.e., to a small number of selected investors only, without any public offer and only to investors who do not purchase the shares with the intention to distribute them to the public. The investors will be individually approached by the issuer from time to time. This document, as well as any other material relating to the shares, is personal and confidential and does not constitute an offer to any other person. This document may only be used by those investors to whom it has been handed out in connection with the offering described herein and may neither directly nor indirectly be distributed or made available to other persons without express consent of the issuer. It may not be used in connection with any other offer and shall in particular not be copied and/or distributed to the public in (or from) Switzerland.

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*Notice to Residents of Canada*

The offering of the common stock in Canada is being made on a private placement basis in reliance on exemptions from the prospectus requirements under the securities laws of each applicable Canadian province and territory where the common stock may be offered and sold, and therein may only be made with investors that are purchasing as principal and that qualify as both an "accredited investor" as such term is defined in National Instrument 45-106 *Prospectus and Registration Exemptions* and as a "permitted client" as such term is defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligation*. Any offer and sale of the common stock in any province or territory of Canada may only be made through a dealer that is properly registered under the securities legislation of the applicable province or territory wherein the common stock is offered and/or sold or, alternatively, by a dealer that qualifies under and is relying upon an exemption from the registration requirements therein.

Any resale of the common stock by an investor resident in Canada must be made in accordance with applicable Canadian securities laws, which may require resales to be made in accordance with prospectus and registration requirements, statutory exemptions from the prospectus and registration requirements or under a discretionary exemption from the prospectus and registration requirements granted by the applicable Canadian securities regulatory authority. These resale restrictions may under certain circumstances apply to resales of the common stock outside of Canada.

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the securities described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur canadien confirme par les présentes qu'il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d'achat ou tout avis) soient rédigés en anglais seulement.*

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**LEGAL MATTERS**

Lowenstein Sandler LLP, Roseland, New Jersey, will provide us with an opinion as to the validity of the shares of common stock and warrants offered by this prospectus supplement and the accompanying prospectus. Certain legal matters in connection with this offering will be passed upon for the underwriters by Littman Krooks LLP.

**EXPERTS**

The consolidated financial statements as of and for the year ended December 31, 2014, incorporated in this prospectus by reference from the Company's Annual Report on Form 10-K filed with the SEC on March 16, 2015, have been audited by RSM US LLP (formerly McGladrey LLP), an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference. Such consolidated financial statements have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

**WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly and current reports, proxy statements and other information with the SEC. We have also filed a registration statement on Form S-3, including exhibits, under the Securities Act with respect to the securities offered by this prospectus supplement and the accompanying prospectus. This prospectus supplement and the accompanying prospectus are a part of the registration statement but do not contain all of the information included in the registration statement or the exhibits. You may read and copy the registration statement and any other document that we file at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington D.C. 20549. You can call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference room. You can also find our public filings with the SEC on the Internet at a web site maintained by the SEC located at <http://www.sec.gov>.

**INCORPORATION OF DOCUMENTS BY REFERENCE**

The SEC allows us to "incorporate by reference" into this prospectus supplement and the accompanying prospectus certain information. This means that we can disclose important information to you by referring you to those documents that contain the information. The information we incorporate by reference is considered a part of this prospectus supplement and the accompanying prospectus, and later information we file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings we make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act, on or after the date of this prospectus supplement (other than information "furnished" under Items 2.02 or 7.01 (or corresponding information furnished under Item 9.01 or included as an exhibit) of any Current Report on Form 8-K or otherwise "furnished" to the SEC, unless otherwise stated) until this offering is completed:

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed on March 16, 2015;

Our Quarterly Reports on Form 10-Q for the period ended March 31, 2015, filed on May 11, 2015, for the period ended June 30, 2015, filed on August 10, 2015;

Our Current Reports on Form 8-K filed on March 12, 2015, May 12, 2015, May 15, 2015, July 7, 2015, July 16, 2015, August 11, 2015, August 21, 2015, September 23, 2015, October 16, 2015 and November 6, 2015 (other than information "furnished" under Items 2.02 or 7.01 (or corresponding information furnished under Item 9.01 or included as an exhibit));

Our Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 14, 2015 (other than the portions thereof which are furnished and not filed); and

## Edgar Filing: CANCER GENETICS, INC - Form 424B5

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Description of our common stock contained in the Registration Statement on Form 8-A, declared effective on August 12, 2013 (including any amendment or report filed with the SEC for the purpose of updating such description).

You may request a copy of these filings, at no cost, by writing to or telephoning us at the following address:

Cancer Genetics, Inc.  
201 Route 17 North, 2nd Floor  
Rutherford, NJ 07070  
(201) 528-9200  
Attention: Edward J. Sitar, Secretary

Any statement contained in this prospectus supplement or in a document incorporated or deemed to be incorporated by reference into this prospectus supplement will be deemed to be modified or superseded for purposes of this prospectus supplement to the extent that a statement contained in this prospectus supplement or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus supplement modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement.

You should rely only on information contained in, or incorporated by reference into, this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus supplement and the accompanying prospectus or incorporated by reference in this prospectus supplement and the accompanying prospectus. We are not making offers to sell the securities in any jurisdiction in which such an offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.

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PROSPECTUS

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**\$100,000,000**

## **CANCER GENETICS, INC.**

Common Stock  
Preferred Stock  
Warrants  
Units

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We may from time to time offer and sell common stock, preferred stock, warrants and units, having an aggregate offering price of up to \$100,000,000. We may offer and sell these securities separately or together in any combination. We may offer and sell these securities to or through underwriters, directly to investors or through agents. We will specify the terms of the securities, and the names of any underwriters or agents and their respective compensation, in supplements to this prospectus.

Our common stock is listed on the on The NASDAQ Capital Market and traded under the symbol "CGIX." The last reported sales price of our common stock on The NASDAQ Capital Market on May 28, 2014 was \$11.68 per share.

*Investing in our securities involves risks. See "Risk Factors" at page 3 of this prospectus.*

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

This prospectus may not be used to consummate sales of securities unless it is accompanied by a prospectus supplement.

The date of this prospectus is June 5, 2014.

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No dealer, salesperson or other person has been authorized to give any information or to make any representations other than those contained or incorporated by reference in this prospectus or any accompanying prospectus supplement in connection with the offer made by this prospectus or any accompanying prospectus supplement and, if given or made, such information or representations must not be relied upon as having been authorized by Cancer Genetics, Inc. or any such person. Neither the delivery of this prospectus or any accompanying prospectus supplement nor any sale made hereunder and thereunder shall under any circumstances create an implication that there has been no change in the affairs of Cancer Genetics, Inc. since the date hereof. This prospectus or any accompanying prospectus supplement does not constitute an offer or solicitation by anyone in any state in which such offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.

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**ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, using a "shelf" registration process. Under this shelf process, we may sell any combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of \$100,000,000. We have provided to you in this prospectus a general description of the securities we may offer. Each time we sell securities under this shelf registration process, we will provide a prospectus supplement that will contain specific information about the terms of the offering. We may also add, update or change in the prospectus supplement or any "free writing prospectus" we may authorize to be delivered to you any of the information contained in this prospectus. To the extent there is a conflict between the information contained in this prospectus and the prospectus supplement or any free writing prospectus we may authorize to be delivered to you, you should rely on the information in the prospectus supplement or free writing prospectus, as the case may be, provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference in this prospectus or any prospectus supplement the statement in the document having the later date modifies or supersedes the earlier statement. This prospectus, together with the applicable prospectus supplements and any free writing prospectus we may authorize to be delivered to you, includes all material information relating to this offering.

An investment in our securities involves certain risks that should be carefully considered by prospective investors. See "Risk Factors."

You should read this prospectus and any prospectus supplement as well as additional information described under "Incorporation of Certain Documents by Reference" and "Where You Can Find More Information" on pages 14 and 15, respectively.

**ABOUT CANCER GENETICS**

*Overview*

Cancer Genetics, Inc. ("we", "CGI", or the "Company") is an early-stage diagnostics company focused on developing and commercializing proprietary genomic tests and services to improve and personalize the diagnosis, prognosis and response to treatment (theranosis) of cancer. Our proprietary tests target cancers that are difficult to prognose and predict treatment outcomes by using currently available mainstream techniques. These cancers include hematological, urogenital and HPV-associated cancers. 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. To date, we have generated most of our revenue through sales of our non-proprietary testing services to oncologists, pathologists and community hospitals located mostly in the eastern and mid-western United States, as well as to biopharmaceutical companies and clinical research organizations for their clinical trials. In the fourth quarter of 2013, we have begun to expand our geographic reach into the western and southern United States. Our non-proprietary laboratory testing services include molecular testing, sequencing mutational analysis, flow cytometry testing, histology testing and cytology testing. We are currently offering our tests and laboratory services from our 17,936 square foot state-of-the-art laboratory located in Rutherford, New Jersey, which has been accredited by the College of American Pathologists, which is an approved accreditation method under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), to perform high complexity testing. CLIA certification and accreditation are required before any laboratory, including ours, may perform testing on human specimens for the purpose of obtaining information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health.

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. During the first quarter of 2011, we commercially launched MatBA®-CLL, our first proprietary microarray test for chronic lymphocytic leukemia ("CLL"). In January 2012, we received

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CLIA approval for MatBA®-SLL, our proprietary microarray for risk stratification in small lymphocytic lymphoma ("SLL"), and we are currently offering MatBA®-SLL in our laboratory. In 2013, we received CLIA approval for MatBA®-DLBCL and MatBA®-MCL, our proprietary microarrays for diagnosis, prognosis and patient monitoring in diffuse large-B-cell lymphoma ("DLBCL") and mantle cell lymphoma ("MCL") respectively, for UroGenRA<sup>®</sup>-Kidney, our proprietary microarray for patient management and treatment decision-making in kidney cancer, as well as for FHACT<sup>®</sup>, our proprietary FISH-based HPV-associated cancer test for screening of women with HPV-positive abnormal cervical lesions. In addition, we are developing a series of other proprietary genomic tests in our core oncology markets.

We have established collaborative relationships with key thought leaders in oncology, which enable us to develop and validate the effectiveness and utility of our tests in a clinical setting and which provide us access to clinically robust patient data. For example, we formed the joint venture "OncoSpire Genomics LLC" in 2013 with Mayo Foundation for Medical Education and Research ("Mayo") which will focus on developing oncology diagnostic services and tests utilizing next-generation sequencing. We are a 50% owner of the joint venture, contributing capital, commercial experience and other guidance, while Mayo will contribute laboratory resources, research expertise and other operational resources.

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

We currently offer our proprietary tests as laboratory-developed tests ("LDTs") in conjunction with our comprehensive panel of laboratory services in our CLIA-accredited laboratory. Our current laboratory services include:

**Proprietary Oncology Testing Services.** These services are based on our proprietary microarray tests and are currently available only in our clinical laboratory. After completing the testing, we provide our customers with a comprehensive analysis of all tests performed for a specific patient, designed to help the physician make an informed and definitive diagnosis and guide the treatment of the patient. We are now in the process of migrating and validating microarray tests to a Next Gen Sequencing-based platform.

**Esoteric Oncology Testing Services.** We offer a comprehensive suite of esoteric oncology testing services for hematological, urogenital and HPV-associated cancers, including conventional and molecular cytogenetic techniques such as Next Gen Sequencing, G-banding and FISH, mutation and sequencing analysis, flow-cytometry and immunohistochemistry ("IHC").

**Clinical Trial Services.** We also utilize our clinical laboratory to provide clinical trial services to biopharmaceutical and biotech 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 laboratory's fully integrated capabilities. We launched our Select One<sup>™</sup> program, integrating genomic 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.

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We believe that we can be successful by offering cancer professionals a fully-integrated menu of oncology-focused proprietary tests and customized laboratory services. Based on our discussions with leading researchers in the oncology field and our interactions with our collaborators, as well as information we learn through performing the non-proprietary genetic diagnostic testing services, which are focused on the specific oncology categories where we are developing our proprietary tests we provide to our customers, we believe that our proprietary tests provide superior diagnostic and prognostic values than currently available tests and services. In particular, our proprietary tests deliver a level of genomic information not provided by other currently available tests. 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.

**Cancer Genetics Corporate Information**

Our principal executive offices are located at 201 Route 17 North, 2<sup>nd</sup> Floor, Rutherford, New Jersey 07070, and our telephone number is (201) 528-9200. Our common stock is currently traded on The NASDAQ Capital Market under the symbol "CGIX." We maintain a corporate website at [www.cancer-genetics.com](http://www.cancer-genetics.com). The contents of our website are not incorporated by reference into this prospectus and should not be considered to be a part of this prospectus or relied upon in connection herewith.

Cancer Genetics, Inc. was incorporated under the laws of the State of Delaware in April 1999. Unless otherwise stated, all references to "us," "our," "Cancer Genetics," "we," the "Company" and similar designations refer to Cancer Genetics, Inc.

This prospectus and the information incorporated by reference include trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus are the property of their respective owners.

**RISK FACTORS**

*Investing in our securities involves significant risks. Before making an investment decision, you should carefully consider the risks and other information we include or incorporate by reference in this prospectus and any prospectus supplement. In particular, you should consider the risk factors under the heading "Risk Factors" included in our most recent Annual Report on Form 10-K, as may be revised or supplemented by our subsequent Quarterly Reports on Form 10-Q or Current Reports on Form 8-K, each of which are on file with the SEC and are incorporated herein by reference, and which may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future. The risks and uncertainties we have described are not the only ones facing our company. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also affect our business operations. Additional risk factors may be included in a prospectus supplement relating to a particular offering of securities. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The trading price of our securities could decline due to any of these risks, and you may lose all or part of your investment. This prospectus is qualified in its entirety by these risk factors.*

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**SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION**

This prospectus, any prospectus supplement and the documents we incorporate by reference in this prospectus contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements, other than statements of historical facts, that we include in this prospectus, any prospectus supplement, and in the documents we incorporate by reference in this prospectus, may be deemed forward-looking statements for purposes of the Securities Act and the Exchange Act. We use the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "project," "will," "would" and similar expressions to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and, accordingly, you should not place undue reliance on our forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from the forward-looking statements that we make, including the factors included in the documents we incorporate by reference in this prospectus. You should read these factors and the other cautionary statements made in the documents we incorporate by reference as being applicable to all related forward-looking statements wherever they appear in this prospectus, any prospectus supplement, and any document incorporated by reference. We caution you that we do not undertake any obligation to update forward-looking statements made by us.

**USE OF PROCEEDS**

Unless otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of the securities under this prospectus for working capital, including expanding our sales and marketing activities, research and development of our proprietary genomic-based diagnostic tests, potential regulatory submissions, potential collaborations, strategic transactions and other general corporate purposes. We will set forth in the prospectus supplement our intended use for the net proceeds received from the sale of any securities. Pending the use of the net proceeds, we may use the net proceeds to invest in investment-grade, interest-bearing securities.

**DESCRIPTIONS OF THE SECURITIES WE MAY OFFER**

The descriptions of the securities contained in this prospectus, together with the applicable prospectus supplements, summarize all the material terms and provisions of the various types of securities that we may offer. We will describe in the applicable prospectus supplement relating to any securities the particular terms of the securities offered by that prospectus supplement. If we indicate in the applicable prospectus supplement, the terms of the securities may differ from the terms we have summarized below. We will also include in the prospectus supplement information, where applicable, about material United States federal income tax considerations relating to the securities, and the securities exchange, if any, on which the securities will be listed.

We may sell from time to time, in one or more offerings:

common stock;

preferred stock;

warrants to purchase any of the securities listed above; and

units consisting of any combination of the securities listed above.

In this prospectus, we refer to the common stock, preferred stock, warrants and units collectively as "securities." The total dollar amount of all securities that we may sell will not exceed \$100,000,000.

This prospectus may not be used to consummate a sale of securities unless it is accompanied by a prospectus supplement.



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**DESCRIPTION OF COMMON STOCK**

Our third amended and restated certificate of incorporation authorizes us to issue up to 100,000,000 shares of common stock, par value \$0.0001 per share. As of March 31, 2014, there were 9,282,610 shares of common stock outstanding. All outstanding shares of our common stock are fully paid and non-assessable.

The holders of our common stock are entitled to the following rights:

***Voting Rights***

Holders of our common stock are entitled to one vote per share in the election of directors and on all other matters on which stockholders are entitled or permitted to vote. Holders of our common stock are not entitled to cumulative voting rights.

***Dividend Rights***

Subject to the terms of any outstanding series of preferred stock, the holders of our common stock are entitled to dividends in the amounts and at times as may be declared by the board of directors out of funds legally available therefor.

***Liquidation Rights***

Upon liquidation or dissolution, holders of our common stock are entitled to share ratably in all net assets available for distribution to stockholders after we have paid, or provided for payment of, all of our debts and liabilities, and after payment of any liquidation preferences to holders of our preferred stock.

***Other Matters***

Holders of our common stock have no redemption, conversion or preemptive rights. There are no sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to the rights of the holders of shares of any series of preferred stock that we may issue in the future.

**Anti-Takeover Provisions**

Our third amended and restated certificate of incorporation and bylaws contain some provisions that could make our acquisition by means of a tender or exchange offer, a proxy contest or otherwise more difficult. These provisions are summarized below.

*Potential Effects of Authorized but Unissued Shares of Common Stock and Preferred Stock.* We have shares of common stock and preferred stock available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, to facilitate corporate acquisitions or payment as a dividend on the capital stock. The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management.

*Special Meetings.* Stockholders cannot call special meetings of our stockholders. Our bylaws provide that special meetings of our stockholders may, unless otherwise prescribed by law, be called by our chairman of the board (if any), our board of directors or our chief executive officer and shall be held at such place, on such date and at such time as shall be fixed by our board of directors or the



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person calling the meeting. Business transacted at any special meeting shall be limited to matters relating to the purpose or purposes stated in the notice of the meeting.

*Undesignated Preferred Stock.* The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us. The ability to issue preferred stock may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

*Delaware Anti-Takeover Statute.* We are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder unless:

prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; and

on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, owned 15% or more of a corporation's outstanding voting securities. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 may discourage attempted acquisitions that might result in a premium over the market price for the shares of our common stock held by stockholders.

The provisions of Delaware law, our third amended and restated certificate of incorporation and our bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

**Transfer Agent**

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company. Its address is 17 Battery Place, New York, New York, 10004 and its telephone number is (212) 509-4000.

**NASDAQ Listing**

Our common stock is traded on The NASDAQ Capital Market under the symbol "CGIX."

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**DESCRIPTION OF PREFERRED STOCK**

Our third amended and restated certificate of incorporation authorizes us to issue up to 9,764,000 shares of preferred stock, par value \$0.0001 per share. At March 31, 2014, there were no shares of preferred stock outstanding.

***Terms of the Preferred Stock That We May Offer and Sell to You***

We summarize below some of the provisions that will apply to the preferred stock that we may offer to you unless the applicable prospectus supplement provides otherwise. This summary may not contain all information that is important to you. You should read the prospectus supplement, which will contain additional information and which may update or change some of the information below. Prior to the issuance of a new series of preferred stock, we will further amend our third amended and restated certificate of incorporation designating the stock of that series and the terms of that series. We will file a copy of the certificate of designation that contains the terms of each new series of preferred stock with the SEC each time we issue a new series of preferred stock. Each certificate of designation will establish the number of shares included in a designated series and fix the designation, powers, privileges, preferences and rights of the shares of each series as well as any applicable qualifications, limitations or restrictions. You should refer to the applicable certificate of designation as well as our third amended and restated certificate of incorporation before deciding to buy shares of our preferred stock as described in the applicable prospectus supplement.

Our board of directors has the authority, without further action by the stockholders, to issue preferred stock in one or more series and to fix the number of shares, dividend rights, conversion rights, voting rights, redemption rights, liquidation preferences, sinking funds, and any other rights, preferences, privileges and restrictions applicable to each such series of preferred stock.

The issuance of any preferred stock could adversely affect the rights of the holders of common stock and, therefore, reduce the value of the common stock. The ability of our board of directors to issue preferred stock could discourage, delay or prevent a takeover or other corporate action.

The terms of any particular series of preferred stock will be described in the prospectus supplement relating to that particular series of preferred stock, including, where applicable:

the designation, stated value and liquidation preference of such preferred stock;

the number of shares within the series;

the offering price;

the dividend rate or rates (or method of calculation), the date or dates from which dividends shall accrue, and whether such dividends shall be cumulative or noncumulative and, if cumulative, the dates from which dividends shall commence to cumulate;

any redemption or sinking fund provisions;

the amount that shares of such series shall be entitled to receive in the event of our liquidation, dissolution or winding-up;

the terms and conditions, if any, on which shares of such series shall be convertible or exchangeable for shares of our stock of any other class or classes, or other series of the same class;

the voting rights, if any, of shares of such series; the status as to reissuance or sale of shares of such series redeemed, purchased or otherwise reacquired, or surrendered to us on conversion or exchange;



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the conditions and restrictions, if any, on the payment of dividends or on the making of other distributions on, or the purchase, redemption or other acquisition by us or any subsidiary, of the common stock or of any other class of our shares ranking junior to the shares of such series as to dividends or upon liquidation;

the conditions and restrictions, if any, on the creation of indebtedness by us or by any subsidiary, or on the issuance of any additional stock ranking on a parity with or prior to the shares of such series as to dividends or upon liquidation; and

any additional dividend, liquidation, redemption, sinking or retirement fund and other rights, preferences, privileges, limitations and restrictions of such preferred stock.

The description of the terms of a particular series of preferred stock in the applicable prospectus supplement will not be complete. You should refer to the applicable amendment to our third amended and restated certificate of incorporation for complete information regarding a series of preferred stock.

The preferred stock will, when issued against payment of the consideration payable therefor, be fully paid and nonassessable. Unless otherwise specified in the applicable prospectus supplement, each series of preferred stock will, upon issuance, rank senior to the common stock and on a parity in all respects with each other outstanding series of preferred stock. The rights of the holders of our preferred stock will be subordinate to that of our general creditors.

## DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. If we indicate in the prospectus supplement, the terms of any warrants offered under that prospectus supplement may differ from the terms described below. Specific warrant agreements will contain additional important terms and provisions and will be incorporated by reference as an exhibit to the registration statement that includes this prospectus.

### General

We may issue warrants for the purchase of common stock or preferred stock in one or more series. We may issue warrants independently or together with common stock or preferred stock, and the warrants may be attached to or separate from these securities.

We will evidence each series of warrants by warrant certificates that we will issue under a separate agreement. We may enter into a warrant agreement with a warrant agent. We will indicate the name and address of the warrant agent in the applicable prospectus supplement relating to a particular series of warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including in the case of warrants to purchase common stock or preferred stock, the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

### Additional Information

We will describe in the applicable prospectus supplement the terms of the series of warrants, including:

the offering price and aggregate number of warrants offered;



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the currency for which the warrants may be purchased;

if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;

if applicable, the date on and after which the warrants and the related securities will be separately transferable;

in the case of warrants to purchase common stock or preferred stock, the number of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;

the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;

the terms of any rights to redeem or call the warrants;

any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;

the dates on which the right to exercise the warrants will commence and expire;

the manner in which the warrant agreement and warrants may be modified;

a discussion on any material or special United States federal income tax consequences of holding or exercising the warrants;

the terms of the securities issuable upon exercise of the warrants; and

any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

**Exercise of Warrants**

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to 5 p.m., Eastern time, on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information, and paying the required amount to the warrant agent in immediately available funds, as provided in the applicable prospectus supplement. We will set forth on the reverse side of the warrant certificate and in the applicable prospectus supplement the information that the holder of the warrant will be required to deliver to the warrant agent.

Upon receipt of the required payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will issue and deliver the securities purchasable upon such exercise. If fewer than all of the warrants represented by the warrant certificate are exercised, then we will issue a new warrant certificate for the remaining amount of warrants. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender securities as all or part of the exercise price for warrants.



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**Enforceability of Rights by Holders of Warrants**

Each warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

**DESCRIPTION OF UNITS**

We may issue units comprised of one or more of the other securities described in this prospectus in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date. The applicable prospectus supplement may describe:

the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;

any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units;

the terms of the unit agreement governing the units;

United States federal income tax considerations relevant to the units; and

whether the units will be issued in fully registered global form.

This summary of certain general terms of units and any summary description of units in the applicable prospectus supplement do not purport to be complete and are qualified in their entirety by reference to all provisions of the applicable unit agreement. The forms of the unit agreements and other documents relating to a particular issue of units will be filed with the SEC each time we issue units, and you should read those documents for provisions that may be important to you.

**PLAN OF DISTRIBUTION**

We may sell the securities through underwriters or dealers, through agents, or directly to one or more purchasers. The accompanying prospectus supplement will describe the terms of the offering of the securities, including:

the name or names of any underwriters;

the purchase price of the securities being offered and the proceeds we will receive from the sale;

any over-allotment options pursuant to which underwriters may purchase additional securities from us;



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any agency fees or underwriting discounts and other items constituting agents' or underwriters' compensation;

any public offering price;

any discounts or concessions allowed or reallocated or paid to dealers; and

any securities exchange or market on which the securities may be listed.

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If underwriters are used in the sale, they will acquire the securities for their own account and may resell the securities from time to time in one or more transactions at a fixed public offering price or at varying prices determined at the time of the sale. The obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. We may offer the securities to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. Subject to certain conditions, the underwriters will be obligated to purchase all the securities offered by the prospectus supplement. We may change from time to time the public offering price and any discounts or concessions allowed or reallocated or paid to dealers. We may use underwriters with whom we have a material relationship. We will describe such relationships in the prospectus supplement naming the underwriter and the nature of any such relationship.

We may engage in "at the market" offerings of our common stock, which are offerings into an existing trading market, at other than a fixed price, on or through the facilities of a national securities exchange or to or through a market maker otherwise than on an exchange.

We may sell securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of the securities, and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, our agent will act on a best efforts basis for the period of its appointment.

We may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of common shares, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of common shares. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be identified in the applicable prospectus supplement or a post-effective amendment to this registration statement.

All securities we offer other than common stock will be new issues of securities with no established trading market. Any underwriters may make a market in these securities, but will not be obligated to do so and may discontinue any market making at any time without notice. We cannot guarantee the liquidity of the trading markets for any securities.

We may provide agents and underwriters with indemnification against civil liabilities related to this offering, including liabilities under the Securities Act, or contribution with respect to payments that the agents or underwriters may make with respect to these liabilities. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business.

Rules of the Securities and Exchange Commission may limit the ability of any underwriters to bid for or purchase securities before the distribution of the securities is completed. However, underwriters may engage in the following activities in accordance with the rules:

*Stabilizing transactions* Underwriters may make bids or purchases for the purpose of pegging, fixing or maintaining the price of the shares, so long as stabilizing bids do not exceed a specified maximum.

*Over-allotments and syndicate covering transactions* Underwriters may sell more shares of our common stock than the number of shares that they have committed to purchase in any underwritten offering. This over-allotment creates a short position for the underwriters. This short position may involve either "covered" short sales or "naked" short sales. Covered short sales are short sales made in an amount not greater than the underwriters' over-allotment option to purchase additional shares in any underwritten offering. The underwriters may close out any

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covered short position either by exercising their over-allotment option or by purchasing shares in the open market. To determine how they will close the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market, as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are short sales in excess of the over-allotment option. The underwriters must close out any naked position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that, in the open market after pricing, there may be downward pressure on the price of the shares that could adversely affect investors who purchase shares in the offering.

*Penalty bids* If underwriters purchase shares in the open market in a stabilizing transaction or syndicate covering transaction, they may reclaim a selling concession from other underwriters and selling group members who sold those shares as part of the offering.

Similar to other purchase transactions, an underwriter's purchases to cover the syndicate short sales or to stabilize the market price of our securities may have the effect of raising or maintaining the market price of our securities or preventing or mitigating a decline in the market price of our securities. As a result, the price of the securities may be higher than the price that might otherwise exist in the open market. The imposition of a penalty bid might also have an effect on the price of shares if it discourages resales of the securities.

If commenced, the underwriters may discontinue any of the activities at any time.

In compliance with guidelines of the Financial Industry Regulatory Authority, or FINRA, the maximum consideration or discount to be received by any FINRA member or independent broker dealer may not exceed 8% of the aggregate amount of the securities offered pursuant to this prospectus and any applicable prospectus supplement.

## LEGAL MATTERS

The validity of the issuance of the securities offered by this prospectus will be passed upon for us by Lowenstein Sandler LLP, Roseland, New Jersey.

## EXPERTS

The consolidated financial statements as of and for the year ended December 31, 2013, incorporated in this prospectus by reference from the Company's Annual Report on Form 10-K filed with the SEC on March 28, 2014, have been audited by McGladrey LLP, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference. Such consolidated financial statements have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

## INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The following documents previously filed by us with the SEC are incorporated in this prospectus by reference:

- (a) Our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed with the SEC on March 28, 2014.
- (b) Our Proxy Statement on Schedule 14A for our 2014 Annual Meeting of Stockholders, filed with the SEC on April 21, 2014.
- (c) Our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2014 filed with the SEC on May 15, 2014.

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- (d) Our Current Reports on Form 8-K and amendments thereto, filed with the SEC on January 6, February 21, March 19, April 4, May 15 and May 22, 2014, (excluding any information deemed furnished pursuant to Item 2.02 or Item 7.01 of any such Current Report on Form 8-K).
- (e) Description of our common stock contained in the Registration Statement on Form 8-A, declared effective on August 12, 2013 (including any amendment or report filed with the SEC for the purpose of updating such description).

All reports and other documents that we file pursuant to Section 13(a) and 13(c), 14 and 15(d) of the Exchange Act prior to the filing of a post-effective amendment which indicates that all securities offered hereunder have been sold or which deregisters all such securities then remaining unsold shall be deemed to be incorporated by reference in this prospectus and to be a part hereof from the date of filing of such reports and documents.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, copies of these filings, excluding all exhibits unless an exhibit has been specifically incorporated by reference in such filings, at no cost, upon written or oral request made to:

Cancer Genetics, Inc.  
201 Route 17 North, 2<sup>nd</sup> Floor  
Rutherford, NJ 07070  
(201) 528-9200  
Attention: Edward J. Sitar, Secretary

### **WHERE YOU CAN FIND MORE INFORMATION**

We have filed a registration statement on Form S-3 with the Securities and Exchange Commission under the Securities Act of 1933. This prospectus omits some information and exhibits included in the registration statement, copies of which may be obtained upon payment of a fee prescribed by the Commission or may be examined free of charge at the principal office of the SEC in Washington, D.C.

We are subject to the informational requirements of the Securities Exchange Act of 1934 and in accordance therewith file reports, proxy statements and other information with the SEC. The reports, proxy statements and other information filed by us with the SEC can be inspected and copied at the Public Reference Room maintained by the SEC at 100 Fifth Street, N.E., Washington, D.C. 20549. Copies of filings can be obtained from the Public Reference Room maintained by the SEC by calling the SEC at 1-800-SEC-0330. In addition, the Commission maintains a website that contains reports, proxy and informational statements and other information filed electronically with the SEC at <http://www.sec.gov>.

You may request, orally or in writing, a copy of these documents, which will be provided to you at no cost, by contacting Edward J. Sitar, Secretary, Cancer Genetics, Inc., 201 Route 17 North, 2<sup>nd</sup> Floor, Rutherford, NJ 07070, telephone (201) 528-9200.

You should rely only on the information contained in this prospectus, including information incorporated by reference as described above, or any prospectus supplement that we have specifically referred you to. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus or any prospectus supplement is accurate as of any date other than the date on the front of those documents or that any document incorporated by reference is accurate as of any date other than its filing date. You should not consider this prospectus to be an offer or solicitation relating to the securities in any jurisdiction in which such an offer or solicitation relating to the securities is not authorized. Furthermore, you should not consider this prospectus to be an offer or solicitation relating to the securities if the person making the offer or solicitation is not qualified to do so, or if it is unlawful for you to receive such an offer or solicitation.

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**3,000,000 Shares**

**Common Stock**

**Warrants to Purchase  
up to 3,000,000 Shares  
of Common Stock**

**Cancer Genetics, Inc.**

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Prospectus Supplement

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*Joint Book-Running Managers*

**Joseph Gunnar &  
Co.**

*Co-Manager*

**Feltl and  
Company**

**Axiom Capital Management, Inc.**

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