

CANCER GENETICS, INC  
Form 10-K  
March 28, 2014  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 10-K**

(Mark One)

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

**For the fiscal year ended December 31, 2013**

**Or**

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

**For the transition period from                      to**

**Commission file number 001-35817**

**CANCER GENETICS, INC.**

**(Exact name of registrant as specified in its charter)**

**Delaware**  
**(State or other jurisdiction of**

**04-3462475**  
**(I.R.S. Employer**

**incorporation or organization)**

**Identification No.)**

**201 Route 17 North 2<sup>nd</sup> Floor**

**Rutherford, NJ 07070**

**(201) 528-9200**

**(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)**

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

| <b>Title of each class</b>  | <b>Name of each exchange on which registered</b> |
|---|--|
| <b>Common Stock, \$0.0001 par value per share</b>                       | <b>NASDAQ Capital Market</b>                     |
| <b>Securities registered pursuant to Section 12(g) of the Act: None</b> |  |

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements

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incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (do not check if a smaller reporting company) Smaller reporting company   
Indicate by check mark if the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes:  No:

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was \$25.3 million on June 28, 2013, the last business day of the registrant's most recently completed second fiscal quarter, based on the closing price of \$9.96 on that date.

Indicate the number of shares outstanding of each of the registrant's classes of common equity, as of March 17, 2014:

| Class                           | Number of Shares |
|---------------------------------|------------------|
| Common Stock, \$.0001 par value | 9,275,586        |

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**FORWARD-LOOKING STATEMENTS**

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

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

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

our ability to clinically validate our pipeline of genomic microarray tests currently in development;

our ability to execute on our marketing and sales strategy for our genomic tests and gain acceptance of our tests in the market;

our ability to keep pace with rapidly advancing market and scientific developments;

our ability to satisfy U.S. (including FDA) and international regulatory requirements with respect to our tests and services, many of which are new and still evolving;

our ability to obtain reimbursement from governmental and other third-party payors for our tests and services;

competition from clinical laboratory services companies, 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;

our ability to maintain our present customer base and obtain new customers;

potential product liability or intellectual property infringement claims;

our dependency on third-party manufacturers to supply or manufacture our products;

our ability to attract and retain a sufficient number of scientists, clinicians, sales personnel and other key personnel with extensive experience in oncology, who are in short supply;

our ability to obtain or maintain patents or other appropriate protection for the intellectual property in our proprietary tests and services;

our dependency on the intellectual property licensed to us or possessed by third parties;

our ability to expand internationally and launch our tests in emerging markets, such as India and Brazil; and

our ability to adequately support future growth.

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We are 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. These tests are described in more detail in the section entitled **Item 1- Business**. 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<sup>®</sup>-CLL, our first proprietary microarray test for chronic lymphocytic leukemia (CLL). In January 2012, we received CLIA approval for MatB<sup>®</sup>ASLL, our proprietary microarray for risk stratification in small lymphocytic lymphoma (SLL), and we are currently offering MatB<sup>®</sup>ASLL in our laboratory. In 2013, we received CLIA approval for MatBA<sup>®</sup>-DLBCL, our proprietary microarray for diagnosis, prognosis and patient monitoring in diffuse large-B-cell lymphoma (DLBCL), MatB<sup>®</sup>AMCL, our proprietary microarray for diagnosis, prognosis and patient monitoring in mantle cell lymphoma (MCL) and UroGenRA<sup>®</sup>-Kidney, our proprietary microarray for patient management and treatment protocols in kidney cancer (UroGenRA<sup>®</sup>-Kidney), as well as 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 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. Additionally, we have research collaborations with Memorial Sloan-Kettering Cancer Center and the Cleveland Clinic to further demonstrate UroGenRA<sup>®</sup>-Kidney's value to renal cancer patients and further validate the test in the clinical setting.

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<sup>®</sup>) for clinical use.



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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.

We currently offer our proprietary tests 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 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 Onē<sup>TM</sup> program, integrating 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 intend to continue offering our proprietary tests in the United States as laboratory-developed tests ( LDTs ) offered in our laboratory and internationally as CE-marked in vitro diagnostic medical devices. In addition, as part of our long-term strategy, we may seek Food and Drug Administration ( FDA ) clearance or approval to expand the commercial use of our tests to other laboratories and testing sites. 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 our proprietary tests outside of our clinical laboratory. Our sales 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. 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.

## **Market Overview**

### ***Cancer Market Overview***

Despite many advances in the treatment of cancer, it remains one of the greatest areas of unmet medical need. In 2012, the World Health Organization attributed 8.2 million deaths worldwide to cancer-related causes. The

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World Health Organization projects that by 2030 this number will rise to 11 million deaths per year. Within the United States, the North Carolina Central Cancer Registry projects cancer to surpass cardiovascular disease as the leading cause of death by 2015. The incidence and deaths caused by the major cancers are staggering. The following table published by The American Cancer Society shows estimated new cases and deaths in 2013 in the United States for the major cancers:

| <b>Cancer Type</b>       | <b>Estimated New Cases For 2013</b> | <b>Estimated Deaths For 2013</b> |
|--------------------------|-------------------------------------|----------------------------------|
| Bladder*                 | 72,570                              | 15,210                           |
| Breast                   | 234,580                             | 40,030                           |
| Cervical*                | 12,340                              | 4,030                            |
| Colorectal               | 142,820                             | 50,830                           |
| Endometrial*             | 49,560                              | 8,190                            |
| Kidney*                  | 65,150                              | 13,680                           |
| Leukemia*                | 48,610                              | 23,720                           |
| Lung                     | 228,190                             | 159,480                          |
| Melanoma                 | 76,690                              | 9,480                            |
| Multiple Myeloma         | 22,350                              | 10,710                           |
| Non-Hodgkin s Lymphomas* | 69,740                              | 19,020                           |
| Ovarian*                 | 22,240                              | 14,030                           |
| Pancreatic               | 45,220                              | 38,460                           |
| Prostate*                | 238,590                             | 29,720                           |
| Thyroid                  | 60,220                              | 1,850                            |

\* Areas where we currently have active development programs.

In addition to the human toll, the financial cost of cancer is overwhelming. An independent study published in 2010 and conducted jointly by the American Cancer Society and LIVESTRONG ranked cancer as the most economically devastating cause of death in the world estimated to be as high as \$895 billion globally in 2008. According to the National Institutes of Health, the direct cost of cancer care in the United States was approximately \$125 billion in 2010.

***Cancer is a Genetically Driven Disease***

Cancer constitutes a heterogeneous class of diseases characterized by uncontrollable cell growth, and results from a combination of both environmental and hereditary risk factors. It has only been in recent years that technology has progressed far enough to enable researchers to understand many cancers at a molecular level and attribute specific cancers to genetic bases.

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. For example, multiple gains or losses on various chromosomes and movement of genetic material among chromosomes (chromosomal translocations), collectively called copy number variation, have been often observed in various lymphomas and leukemias. Such genetic alterations can be caused by multiple factors, including genetic predisposition, environmental or lifestyle factors or viral infections, such as with HPV-associated cancers. 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 also plays an important role in prognosis and disease management. We believe technology that can apply this predictive information has the potential to dramatically improve treatment outcomes for patients suffering from cancer.

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Cancer is difficult to diagnose and manage due to its heterogeneity at morphologic, genetic and clinical levels. Traditional methods of diagnosis, routinely used as the initial step in cancer detection, involve a pathologist examining a thin slice of potentially cancerous tissue under a microscope or smear of blood or bone marrow. A relatively new tissue sample must be used along with chemical staining techniques to view the biopsy. Through visual inspection, the pathologist determines whether the biopsy contains normal or cancerous cells; those that are deemed cancerous are graded on a level of aggressiveness. After the diagnosis, a clinical workup is performed according to established guidelines for the specific cancer type. From there, the physician determines the stage of progression of the cancer based on a series of clinical measures (i.e., size, grade, metastasis rates, symptoms and patient history) and decides on a treatment plan (i.e., surgery, watchful waiting, chemotherapy, radiation, stem cell transplant).

When deciding treatment and management options for the particular cancer, the physician uses a combination of clinical and pathological features (i.e., the tumor's assigned grade and stage) which depend heavily upon human interpretation and can suffer from inter-institutional variability. Due to the relatively subjective nature of this diagnostic process, the qualitative results of the analysis may not correlate well to the molecular structure and individual nature of the patient's cancer. This subjectivity creates risk of misclassification that can ultimately prove dangerous, resulting in over-treatment for some patients and under-treatment for others. For example, a patient with a mild form of cancer may be mistakenly assigned to highly aggressive treatment. Side effects associated with such misaligned treatment can result in detrimental side effects or risks more significant than those posed by the original tumor. In addition, it is now well established that patients respond differently to the same medication, and multiple studies have linked the differences in patients' response to various cancer drugs to differences at the genetic level. As such, the level of personalized treatment required to optimize a patient's treatment regimen is only possible through the use of biomarker analysis and molecular diagnostics.

With the trend in medical practice for less invasive procedures, overall less specimen material is routinely available for diagnostic purposes and often the specimen type available for genetic analysis is restricted to that used for morphologic analysis (formalin-fixed paraffin-embedded material). Several adaptations of current procedures are being undertaken to improve diagnostic procedures for these cancer types to allow maximum sensitivity and specificity. For solid tissue specimens, the formalin-fixed paraffin-embedded (FFPE) diagnostic material is often the only tissue available for study and recent technologies, including MatBA<sup>®</sup>-SLL and MatBA<sup>®</sup>-DLBCL, have had to accommodate such limitations previously not encountered. Another trend in medical practice is the increased use of fine needle aspiration or core biopsy for diagnostic purposes, often requiring image guidance. Morphologic analysis of such specimens is challenging especially where the architecture of the specimen has been damaged. Genome-based analysis of such specimens is one method by which diagnostic results can be obtained.

***Use of Genomic-Based Analysis in Cancer Diagnosis and Treatment***

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. To date, genomic-based testing has produced higher value and more accurate cancer diagnostic information than traditional analytical methods. These tests create a data set that can both define the cancer subtype and help determine the best course of treatment by detecting mutations, gene fusions and DNA copy number changes, all of which are possible causes of or precursors to malignant growth. As a result of the ability to produce such genomic data and increased adoption of molecular testing, we believe that genomic-based analysis is becoming the fastest growing segment within oncology testing.

An important method of measuring changes in the genomic profile of cancer cells is copy number variation. This method measures the gain or loss of DNA within specific regions of chromosomes. Three primary techniques for quantifying copy number variations include the following:

*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 the presence

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or absence of a specific genomic abnormality with high sensitivity. 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.

*Oligonucleotide-based microarrays* are a multiplex technology that allow the attachment of thousands of microscopic spots of DNA onto a surface. The DNA sequences on the microarray can read multiple genetic aberrations in more than one cancer type following hybridization with DNA from a specific cancer sample and can yield diagnostic and prognostic information of importance to the treatment of the patient. We believe microarrays provide a powerful approach to distinguishing cancer types and 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 types in parallel. Because of the large number of DNA sequences being tested by the microarray, analysis involves bioinformatics-based algorithms. Considering the current clinical and societal demand for minimally invasive procedures, the diagnostic and prognostic applications of microarrays are highly desirable.

*Next-Generation Sequencing* performs massively parallel sequencing of human cancers 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. Deep sequencing is a technique by which a segment of nucleotides is sequenced repeatedly in order to reveal potentially rare genetic changes that may not be discoverable by traditional sequencing methods.

To date, molecular and genetic detection methods have been successfully utilized to provide diagnostic, prognostic and theranostic information for several cancers, including breast and colon. The discovery of breast cancer genes *BRCA-1*, *BRCA-2* and *TP53* and colon cancer genes *AXIN2* and *APC* have highlighted cancer's underlying genetic component. With the prognostic nature of next generation genomic tests, physicians and researchers have begun to optimize patient treatment, increase survival rates and reduce healthcare costs in these cancer categories. For example, within the past year, mutations in genes *KRAS* and *BRAF* have been found to associate with response to therapy in metastatic colon cancer and malignant melanoma, respectively. Meanwhile, there are no equivalent prognostic tests for many other forms of cancer, including lymphomas, leukemias and urogenital and HPV-associated cancers.

## **Our Strategy**

We seek to provide the cancer professional and cancer patient a fully integrated offering of high-value, proprietary tests and customized services in cancers where there are no equivalent prognostic tests, including lymphomas, leukemias, and urogenital and HPV-associated cancers. We believe that our integrated approach combined with our ability to rapidly translate research insights about the genetics and molecular mechanisms of cancer into the clinical setting will improve patient treatment and management and will become a key component in the standard of care for personalized cancer treatment.

Our approach is to develop and commercialize proprietary genomic tests and services to enable us to provide a full service solution to improve the diagnosis, prognosis and treatment of hematological, urogenital and HPV-associated

cancers. To achieve this, we intend to:

*Continue investing in our portfolio by developing and commercializing additional proprietary genomic tests and services. We intend to continue the development of additional proprietary diagnostic and prognostic tests and services to provide information that is essential to personalized cancer treatment. To date, we have launched for use in our CLIA-accredited facility the following proprietary genomic-based tests, MatBA<sup>®</sup>- CLL, MatBA<sup>®</sup>-*



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SLL, MatBA<sup>®</sup>-DLBCL, UroGenRA -Kidney and MatBA<sup>®</sup>-MCL. We are also developing a number of other microarray-based tests, including additional MatBA<sup>®</sup>-based tests for additional hematological malignancies, as well as UroGenRA and UGenRA microarray platforms for urogenital cancers.

To facilitate the development of additional tests and further demonstrate the clinical value of our existing tests, we will develop and expand our collaborations with leading universities and research centers. We have established research collaborations and joint research initiatives with key thought leaders and clinical research facilities, including Mayo, the National Cancer Institute, Memorial Sloan-Kettering Cancer Center, the University of Iowa Cancer Center and Cleveland Clinic. Our collaborations enable us to validate the effectiveness and utility of our proprietary tests and service offerings in a clinical setting and provide us access to clinically well characterized and highly annotated patient data. These data accelerate our validation process and facilitate the testing and refinement of our microarray algorithms.

*Continue our focus on translational oncology and drive innovation and cost efficiency in diagnostics by developing next generation sequencing offerings through our joint venture with Mayo Clinic.* Translational oncology refers to our focus on bringing novel research insights that characterize cancer at the genomic level directly and rapidly into the clinical setting with the overall goal of improving value to patients in the treatment and management of disease. We believe next generation sequencing will enable significant growth and efficiencies. We will leverage our joint venture with Mayo to advance diagnostic technology. The joint venture, OncoSpire, was formed in May 2013 and is based in Rochester, MN. The joint venture will initially pursue the development of next generation sequencing panels for lung cancer, multiple myeloma and follicular lymphoma. We actively integrate the dual disciplines of clinical diagnosis and fundamental research to foster a unique, interdisciplinary approach.

*Increase our focus on providing biopharmaceutical companies and clinical research organizations with our proprietary and non-proprietary genomic tests and services through our SelectOne offering.* Oncology drugs have the potential to be among the most personalized of therapeutics, and yet oncology trials have one of the worst approval rates, hovering under 7%. 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. Our SelectOne offering was created specifically to help the biopharmaceutical community with clinical trials and companion diagnostic development in areas of our core expertise. In our core areas of disease focus, hematologic malignancies, urogenital cancers and HPV-associated cancers, there are over 4500 active trials in the United States according to [clinicaltrials.gov](http://clinicaltrials.gov). Based on recent contract growth in this service offering at CGI, we expect to increase our sales and marketing focus in this business as well as seeking additional collaborations and partnerships with the biopharmaceutical community.

*Enhance our efforts to partner with community hospitals.* According to the American Hospital Association, there are over 4,000 community hospitals in the United States. Community hospitals represent a large target market for our genomic tests and services because approximately 85% of cancer patients in the United States are initially diagnosed in such hospitals as reported to the National Cancer Database. We intend to continue to focus on partnering with such hospitals by targeting our sales and marketing efforts on this important customer segment. Our branded Expand Dx program is a suite of diagnostic and consultative services offered on a collaborative basis. Expand Dx is intended to expand and optimize the oncology diagnostics services and personalization of cancer treatment provided by community hospitals so that such hospitals can optimize and expand their oncology services to better serve their cancer patients.

*Increase our geographic coverage by expanding our scalable sales and marketing capabilities.* We currently have a specialized team of sales professionals with backgrounds in hematology, pathology, and laboratory services. We

intend to expand our sales force in order to provide geographic coverage throughout the United States. Additionally, we intend to expand internationally, particularly in emerging markets, by seeking additional leading local partners such as Roche Servicios, S.A. in Central Americas and Caribbean, DASA, S. A. in Brazil and Kamineni Life Sciences in India, to market and sell our tests and services.

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*Continue to reduce the costs associated with the development, manufacture, and interpretation of our proprietary genomic tests and services.* We intend to work closely with select key suppliers and partners to reduce the costs associated with key material components of our microarrays and DNA probes. We have successfully migrated key components of our probe manufacturing to India in 2013, which reduced the labor costs involved and increased manufacturing yield and flexibility. We will continue to assess how geographic advantage with help us improve our cost structure.

*Continue to work with healthcare providers and payers to demonstrate the value of our testing in providing cost efficient and accountable care.* We have initiated dialogue with key payers, cost management organizations and insurance providers to demonstrate the value and effectiveness of our approach in genomic assessment of complex tumor systems.

## **Our Competitive Advantages**

We believe that our competitive advantages are as follows:

*Our proprietary and clinically relevant genetic tests are the first to address several complex cancers that are difficult to prognose and where it is difficult to predict treatment outcomes using currently available technologies.* Two of our marketed tests are the first to address several underserved, complex cancers. MatBA<sup>®</sup>-CLL is, to our knowledge based on our informal communications with New York State Department of Health personnel, the only microarray that has been approved by the New York State Department of Health for diagnostic treatment and management of CLL. FHACT, our HPV-associated cancer test, is the first multi-region DNA probe to identify and stage HPV-associated cancers, which includes cervical, anal and oropharyngeal cancers.

*We have collaborative relationships with Mayo and other leading research centers, medical centers and oncology groups.* Our collaborations with leading cancer centers provide us with a number of benefits, including valuable access to patient samples. In particular, we entered into an agreement with Mayo whereby we formed a joint venture with Mayo, which will focus on developing oncology diagnostic services and tests utilizing next-generation sequencing. With respect to marketing, we can leverage the brand name recognition of our collaborators when selling to our customers. With regard to research, our collaborations provide us with the fundamental science and research that underpin the development of our diagnostic tests. Additionally, these collaborations provide us with insight to maximize the utility of our tests in the clinical setting.

*Our tests provide more information than existing tests to enable a more personalized treatment plan.* Our tests are designed to provide an earlier, more accurate and more complete diagnosis, which potentially leads to better treatment and lower healthcare costs. For example, MatBA<sup>®</sup>-CLL evaluates a set of five biomarkers not previously assessed in CLL and also allows a more accurate interpretation of the loss at chromosome 13q as a sole abnormality than previously possible.

*Our tests are designed for a wide range of sample types and sample preparation methods and we have the ability to test on FFPE tissue samples which accelerates the time required to validate, develop and patent new tests.* We can currently process specimen types that include blood, bone marrow and tissue, including fresh, frozen and FFPE tissue samples. The ability to interrogate a wide variety of sample types increases clinical adoption of our tests and allows the health care provider to quickly and efficiently integrate our tests into its established workflow. This integration with existing oncology and pathology workflow and tissue analysis methods is integral to ensuring near term adoption. For several reasons, we have designed our tests for FFPE tissue samples. For decades, archival FFPE has routinely been used to preserve cancer samples and offers a wealth of information and collaboration potential in comparison with fresh or freshly prepared samples. Our use of FFPE has three important consequences. First, it

significantly increases the datasets of samples that can be used to validate our products, leading to more robust and reliable diagnostic tools. Second, it permits utilization of FFPE in a clinical setting, where often it is the only specimen available for study. This is of particular importance to

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tumors diagnosed using minimally invasive technologies where often very small biopsy material is available for diagnostic and prognostic studies. Third, it affords enrichment, or more specific targeting within, the sample to be analyzed, increasing the probability with which genomic aberrations will be detected for any given specimen.

*Our genomic tests are not platform dependent.* The biology and algorithms behind our tests are adaptable to multiple instrumentation platforms, allowing us to incorporate our tests into a variety of existing clinical laboratory infrastructures without additional capital investment. We have currently optimized our tests for the Agilent platform. However, we believe that we can migrate to other similar platforms, including next gen sequencing, without significant modification.

*We offer consultative, oncology-centered laboratory and clinical trial services.* Our specimens are tested and interpreted by highly qualified oncology-focused laboratory professionals, many of whom hold MDs and PhDs. Because our clinical staff is highly specialized in oncology, we are better positioned to consult with our oncologist customers to help them derive maximum value from the diagnostic and prognostic data generated by our tests.

## **Our Proprietary Genomic Tests and Services**

We currently develop and produce two types of DNA-based genomic tests: microarrays and probes. Both are directed at identifying specific genetic aberrations in cancer cells that serve as markers for diagnosis, prognosis and prediction of treatment outcomes (called theragnosis). In addition, we formed a joint venture with that will focus on developing oncology diagnostic services and tests utilizing next-generation sequencing.

We offer both microarrays and probes because each serves a unique diagnostic or prognostic function. FISH-based tests, or probes, offer great sensitivity while microarrays provide a more comprehensive analysis of the cancer genome. While we expect both platforms to be utilized in cancer diagnostics for the foreseeable future, we believe microarrays will become a significant factor in our growth as they offer a broader range of genomic information, are of a higher resolution and lend themselves to automation. Beyond microarrays, we believe that next generation sequencing will rapidly become a powerful tool for the personalized diagnosis and management of cancer.

FDA clearance or approval is not currently required to offer these tests in our laboratory once they have been clinically and analytically validated and approved by the appropriate regulatory bodies. We seek licenses and approvals for our laboratory facility and for our LDTs from the appropriate regulatory authorities, such as the CMS, which oversees CLIA, and various state regulatory bodies, including the New York State Department of Health. At the federal level, certain proprietary tests must be part of proficiency testing programs approved under CLIA in order for us to be able to bill government payor program beneficiaries, such as Medicare patients, for such tests. In addition, certain states, such as New York, require us to obtain approval of our proprietary tests in order for us to collect patient specimens from such state.

Through our subsidiary, Cancer Genetics Italia, S.r.l. ( CGI Italia ), based in Milan, Italy, we have obtained CE marking for 32 of our DNA probes, which entitles us to market these probes in the European Economic Area (which includes the 27 Member States of the EU plus Norway, Liechtenstein and Iceland). We anticipate that we will need to conduct additional developmental activities for each of these tests and to submit these tests for regulatory clearance or approval by FDA or other regulatory agencies prior to commercialization outside of our reference laboratory in each of the markets where we plan to introduce them.

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The following diagram portrays our proprietary programs:

**Hematological Cancer Arrays: Our MatBA® Arrays.**

MatBA® is the first targeted oligonucleotide-based microarray we developed for the analysis of genomic alterations in mature B-cell neoplasms to determine prognosis and theranosis. MatBA® incorporates a common architecture of specific genomic regions that can be applied across the seven major mature B-cell neoplasms. Mature B-cell neoplasms account for approximately 7% of all cancers diagnosed in the United States annually (approximately 119,760 expected in 2014) and for approximately 6% of all estimated cancer-related deaths (approximately 35,860 expected in 2014). They are the fifth most common malignancy in both males and females, and the incidence is rising.

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

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MatBA<sup>®</sup> is designed to detect genomic copy number changes in mature B-cell neoplasms either solely or in a unique combination, thus assisting the clinician in the management of a patient's disease. The test relies on the comparative genomic hybridization of fluorescently differentially-labeled normal DNA and DNA extracted from the cancer specimen (array-CGH). Array-CGH utilizes minimal biopsy material and uses DNA as the analyte (the component whose properties are being measured), which is more stable, as compared to RNA used in other array detection methodologies. Both are important considerations for the ever increasing demand for less invasive procedures for diagnostic and prognostic purposes. Additionally, we have optimized the utility of the MatBA<sup>®</sup> array-CGH so that it can be routinely applied to the study of a range of specimen types including blood and bone marrow and FFPE biopsy specimens, which are often the only specimen available for analysis of FL, DLBCL and MCL. With the exception of CLL, biopsy/surgical procedures are rarely performed for B-cell neoplasms prior to the initiation of treatment, thus limiting the amount of tissue available for testing prior to deciding on the initial treatment regimen.

MatBA<sup>®</sup> was custom-designed to represent 80 regions of the human genome which have diagnostic and/or prognostic value in one or more of the mature B-cell neoplasm subtypes as identified through our research and analysis efforts. Unlike other technologies such as FISH, array-CGH using MatBA<sup>®</sup> simultaneously permits the detection of genomic gains and losses at multiple locations on a chromosome (loci) that characterize the mature B-cell neoplasm subtypes. For each subtype of B-cell neoplasm, cohorts of specimens with full clinical annotation are evaluated using MatBA<sup>®</sup> to identify novel associations between single and weighted combinations of genomic gains/losses and clinically relevant endpoints, including time to first treatment, treatment response, progression-free survival and overall survival, and to validate previously known associations. It is these associations, we believe, that provide valuable assistance to clinicians in risk stratification and guiding treatment plans for patients with these cancers.

***MatBA<sup>®</sup> Microarrays offered as LDTs***

We offer the first application of MatBA<sup>®</sup> for prognostication in one subtype of mature B-cell neoplasm, CLL, where about half of patients experience indolent disease, or slow progression, and the remaining half, a relatively aggressive progression. MatBA<sup>®</sup>-CLL provides important genetic-based information to guide clinical management of this disease. The test results are reported out in a unique format that allows ease of interpretation by the hematologist or oncologist. MatBA<sup>®</sup>-CLL is included in the tests we can provide under our New York laboratory and CLIA licenses, effective April 2011. New York is one of only a few states that separately reviews LDTs for clinical and analytical validity. To date there are only a few companies that have commercially available oncology microarrays and, to our knowledge based on our informal communications with New York State Department of Health, MatBA<sup>®</sup>-CLL was the first oncology microarray approved for commercial use by the New York State Department of Health.

Approximately 15,720 new cases of CLL are expected to be diagnosed in the United States this year, and importantly, over time these cases undergo evolution, requiring risk stratification and guidance on patient management issues at multiple points during the course of the disease. Prior to the introduction of MatBA<sup>®</sup>, clinicians relied on the assessment of the gain or loss on only four chromosomal regions and potentially one gene mutation when testing for and stratifying a CLL patient. MatBA<sup>®</sup> improves on this by identifying information on five additional chromosomal regions, providing more valuable diagnostic data and critical information about the risk of progression and overall prognosis of the patient. In particular, because MatBA<sup>®</sup> has greater resolution than that available with prior tests, we can interrogate two different regions or loci on the 13q chromosome. Loss of one specific locus or loss of both loci are in some circumstances believed to have differing prognostic value, hence the importance of being able to evaluate both loci. Also, loss of 13q as a sole abnormality is associated with a lower risk of progression and overall favorable outcome. With the increased capacity of MatBA<sup>®</sup> to assess abnormalities in multiple regions of the genome not usually assessed by other technologies, our studies have indicated that up to 23% of cases that would have shown 13q loss as a sole abnormality when assessed by FISH technologies do in fact have additional abnormalities. For these cases, the favorable outcome that would have been reported to the clinician was not accurate, leading to a change in

the prognosis and consequently decision-



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making by the clinician regarding the management of these patients. We believe this type of genomic assessment of the patient's cancer also saves the health care system thousands of dollars per year per patient as a result of improved patient management and more targeted therapeutic intervention. In addition we have identified novel biomarkers using MatBA<sup>®</sup> that are associated with a poor outcome in CLL. These include gains at 2p, 3q and 8q and a loss at 8p. Additional prognostic regions have been identified and are undergoing validation. These will be reported, further driving the value of more comprehensive genomic assessment of the patient's cancer.

We performed validation of these important new biomarkers in 317 CLL specimens in conjunction with Dr. Kanti Rai at Long Island Jewish / North Shore Hospital. We presented this data at the 2011 International Workshop on Chronic Lymphocytic Leukemias and the American Society of Hematology's 2011 Annual Meeting and Exposition. In 2011, we also presented a poster on the key methods involved in enabling the usage of DNA from FFPE material involved in certain sub-types of MatBA<sup>®</sup> at the Association for Molecular Pathology. In the poster, results from over 360 samples were reviewed and demonstrated highly accurate aberration detection as confirmed using Quantitative Polymerase Chain Reaction, an industry standard in molecular diagnostic measurement.

We validated MatBA<sup>®</sup>-SLL for risk stratification in SLL. In January 2012, MatBA<sup>®</sup>-SLL was approved under CLIA and accordingly may now be offered as an LDT by our laboratory. This adaptation of MatBA<sup>®</sup> for SLL has allowed us to develop a robust mechanism to analyze DNA that is derived from FFPE biopsy material and has been a critical development that we believe will accelerate the development of our microarrays for other solid tumors or cancers that present themselves as a mass.

We validated MatBA<sup>®</sup>-DLBCL for diagnosis, prognosis and clinical management of DLBCL patients. In January 2013, this assay received approval by CLIA and New-York State for clinical use, and accordingly may now be offered as an LDT by our reference laboratory. This application of MatBA<sup>®</sup> for DLBCL allowed us to offer what we believe to be the only CLIA and New-York State approved microarray for the genomic assessment of DLBCL. In addition, the microarray will be included in the DLBCL CompleteSM Program offered by us, which includes a suite of esoteric tests used in the diagnosis, prognosis and monitoring of DLBCL patients.

We validated MatBA<sup>®</sup>-MCL for diagnosis and treatment selection of mantle cell lymphoma (MCL). In May 2013, this microarray received approval by CLIA for clinical use and may now be offered as an LDT by our laboratory.

### ***MatBA<sup>®</sup> Microarray in Development***

We are now undergoing similar development of MatBA<sup>®</sup> as a prognostic tool in another main subtypes of mature B-cell lymphomas, namely FL. FL is characterized by a slow progression that in up to approximately 60% of cases transforms to DLBCL, an aggressive lymphoma. Prognostic and theranostic biomarkers of therapeutic options are required for this disease. We have identified several additional loci which we believe are relevant to the prognosis of FL, which cannot be assessed by currently available FISH tests alone. We are currently validating this extension of MatBA<sup>®</sup>. We believe MatBA<sup>®</sup> will provide increased management insight for patients with this type of lymphoma based on a more complete genomic assessment of the lymphoma.

### **Urogenital cancer arrays: UroGenRA , UGenRA**

There is a unmet clinical and patient need for improved diagnosis, prognosis and theranosis, including more detailed and staging information, in urogenital cancers, where biopsy materials are increasingly scarce. The cumulative number of annual new reported cases for kidney, prostate and bladder cancers is estimated at 374,610 for 2014 according to the American Cancer Society. Gynecologic neoplasms contribute substantially to female mortality and morbidity in the United States and are an area where nearly 95,000 new cases are expected to be diagnosed this year.

Although generally characterized by early stage detections, these cancers still represent a major health risk, a significant variability in patient outcome, which can be better managed through genomic assessment of the tumor(s), and a substantial medical cost burden to the public with the high rates of incidence and ongoing patient management needs.

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Developing sophisticated, state-of-the-art molecular tests that enable more accurate diagnosis and/or prognosis of these cancers will not only benefit the patients by offering more appropriate treatments, but also effectively reduce the unnecessary medical cost associated with surgery, long-term follow-up surveillance, or therapy after the treatment.

The UroGenRA microarray, which is being validated in collaboration with Memorial Sloan-Kettering Cancer Center, will provide diagnostic and prognostic analysis for kidney, bladder and prostate cancer. Our first UroGenRA assay to launch was the kidney cancer-targeting UroGenRA -Kidney in May 2013, validated in collaboration with Drs. Eric Klein and Magi Galluzzi at the Cleveland Clinic. We are also developing extensions of UroGenRA for bladder and prostate cancers. UroGenRA will provide diagnostic, prognostic and theranostic information for the primary gynecological cancers, cervical, ovarian and endometrial.

***UroGenRA for Kidney, Prostate and Bladder Cancers***

UroGenRA is a proprietary CGH-based array which will serve as a platform for the diagnosis, prognosis and theranosis of kidney, prostate and bladder cancers. It was designed to detect gains and losses that frequently occur in genetic material in these three cancer types and has the potential to differentially diagnose and/or stratify patients to assist and guide clinical management. It represents 101 regions of the human genome potentially with diagnostic, prognostic and/or theranostic value in one or more of these types of cancers.

***UroGenRA -Kidney*** For kidney cancer, UroGenRA is specifically designed to classify renal tumors into the four main subtypes (clear cell, papillary, chromophobe and oncocytoma), which is critical to patient management and treatment protocols. This allows the clinician, especially in cases where there is limited biopsy material, to (i) diagnose renal cancer and accurately classify it into the correct subtype, (ii) provide rationale for selection among surgical and non-surgical intervention or ablation, (iii) stratify patients based on prognostic information for the advancement of renal cancer into local or regional cancer which then guides decisions on surgical intervention, and (iv) guide drug trial decisions in those with metastatic disease or unclassified renal cancers.

We developed a study with two leading academic cancer centers for which we obtained and used a group of 200 specimens comprising four kidney cancer subtypes to further develop and validate the algorithm of copy number variation known to be associated with these tumors that gives the best ability to differentiate among these four subtypes. These copy number changes are already known to minimally include loss in six regions of chromosomes among these four types and gain in three other regions and we were able to define additional and specific regional copy number variations. The derived proprietary renal cancer diagnostic algorithm or decision tree based on UroGenRA copy number alterations was validated for diagnostic potential in the IRB-approved study of over 50 image-guided needle biopsies and compared with the sensitivity and specificity obtained by our proprietary FISH-based assay, FReCaD .

UroGenRA -Kidney is now available as a LDT. At the current time, validation of the clinical utility of UroGenRA is further advanced for kidney cancers than for prostate and bladder cancers, because we are able to leverage research and insights used in the clinical validation of FReCaD in our development activity for the UroGenRA indication for kidney cancer.

***UroGenRA -Prostate*** For prostate cancer, UroGenRA has the potential to use prostate core/needle biopsy to assess genomic variability of the cancer and help in the identification of biomarkers for assessment of the risk of recurrence, to assess treatment options for intermediate risk patients, and to explore the genomic aberrations of circulating tumor cells. In the case of recurrence, gain or loss in a limited number of regions represented on UroGenRA is considered informative. Application of the UroGenRA to circulating tumor cell genome scanning would require a modified version of the regions represented on UroGenRA , but we believe it could be implemented considering the plasticity of

the array platform. UroGenRA -Prostate is in the commercial development stage.

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***UroGenRA -Bladder*** Newly diagnosed bladder cancers are defined by the fact or extent of invasion of the muscle. For non-muscle invasive bladder cancers, there is clinical need to identify the high proportion of patients in which the cancer will recur. The need in muscle-invasive tumors is to identify those patients most likely to benefit from treatment, considering that the survival benefit of peri-operative chemotherapy for such patients is only 5-10%. Genomic copy number alterations likely to be involved in the response of tumor cells to such therapy have been incorporated in UroGenRA for this specific application, and we are currently attempting to validate this microarray for this use. UroGenRA -Bladder is in the clinical development stage.

***UGenRA for Endometrial, Ovarian and Cervical Cancers***

UGenRA was designed as a platform to detect gains and losses of genomic material in 83 regions of the chromosome associated with responses to particular therapies in patients with endometrial, ovarian and cervical cancers. We are committed to the development of UGenRA as a diagnostic tool that will assist in the screening, diagnosis and/or prognosis of these cancers. The use of UGenRA can be easily integrated into current clinical management protocols because it requires only small amounts of genetic material to test and can be performed on FFPE specimens.

***UGenRA -Endometrial*** Endometrial cancer is the fourth most common cancer in women in the United States representing approximately 6% of all newly diagnosed cancers in women in 2011. In this disease, endometrial hyperplasia is a precursor lesion of endometrioid endometrial carcinoma and since about 50% of women with atypical hyperplasia also have concurrent endometrioid endometrial carcinoma, it is important to identify those precursor lesions more likely to progress to cancer. UGenRA offers the opportunity to identify such specimens and potentially guide clinical management. Five regions of the chromosome interrogated by UGenRA have already been implicated to harbor gains and losses that, if detected in hyperplastic lesions, have a high likelihood of progression to cancer. We are in the process of clinically validating the use of UGenRA for these purposes, along with any novel regions that may be identified in the planned studies. Another potential application in endometrial cancer is to stratify those tumors likely to recur, permitting the identification of patients most likely to benefit from therapy. UGenRA Endometrial is in the clinical development stage.

***UGenRA -Ovarian*** There are approximately 22,000 cases of ovarian cancer diagnosed in the United States each year and approximately 14,000 women die from ovarian cancer each year in the United States. Risk-stratification of stage III/IV ovarian cancer patients after cytoreductive surgery (involving removal of only part of a malignant tumor) for a certain type of chemotherapy is a potential application for UGenRA, and the design of UGenRA currently contains the sites of genomic gain/loss with such prognostic value. We believe we can validate these regions using the publicly available data copy number information from the Center for Applied Genomes for over 300 ovarian cancers with known response and overall outcome. This is a powerful resource for validation and would serve to confirm our test in a different cohort of patients than those used in the preliminary validations performed at our laboratory. UGenRA Ovarian is in the clinical development stage.

***UGenRA -Cervical*** There are approximately 12,300 cases of cervical cancer diagnosed and approximately 4,000 deaths from cervical cancer each year in the United States. With respect to cervical cancer, current clinical tests are unable to distinguish regressive cervical lesions from progressive lesions. Hence low-risk patients are treated the same way as high-risk patients, which increases health care costs. There is a great need for molecular-based diagnostic assays to address these questions, so that physicians can plan appropriate treatment strategies. We have designed UGenRA -Cervical to distinguish among lesions which have a high likelihood of progression into cervical cancer versus those that do not have the genomic abnormalities related to progression to cervical cancer. UGenRA Cervical is in the commercial development stage.

**Proprietary FISH-based DNA Probes**

***FHACT HPV-Associated Cancer Test***

We have developed a proprietary, 4-color FISH-based DNA probe designed to identify the gain of the three most important chromosomal regions that have been implicated in cancers associated with HPV: cervical, anal and

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oropharyngeal. According to the National Cancer Institute, about 55 million PAP smear tests to detect HPV are performed in the United States each year. It is estimated that approximately 2 million patients have abnormal PAP smear test results and are referred for biopsy/colposcopy as a result of such tests. However, only 0.6%, or approximately 12,000, of these patients will develop cancer. It is believed that early detection of HPV-associated cancers could eliminate unnecessary biopsies/colposcopies and thereby reduce health care costs.

FHACT is designed to determine copy number changes of four particular genomic regions by FISH. These regions of DNA give specific information about the progression from HPV infection to cervical cancer, in particular the stage and subtype of disease. FHACT is designed to enable earlier detection of abnormal cells and can identify the additional biomarkers that allow for the prediction of cancer progression. FHACT is designed to leverage the same PAP smear sample taken from the patient during routine screening, thus reducing the burden on the patient while delivering greater genomic-based information to the clinician. We in-license a biomarker from the National Cancer Institute that is used in our FHACT probe.

In conjunction with the National Cancer Institute, we completed a blinded study to evaluate the effectiveness of FHACT for both anal and cervical cancers associated with the HPV virus that involved over 1,000 specimens. We also completed a blinded study of over 300 cervical specimens and the data has been provided to National Cancer Institute. This has been used for validation of the assay and development of automatic analysis for the FHACT probe. Upon review, National Cancer Institute will provide the remaining samples. We have yet to begin work with anal samples. We continue further clinical validations in collaborations that have been established with the University of Iowa and with Kamineni Hospital in Hyderabad, India to further strengthen the claims and data for use of FHACT as a staging and prognostic tool for cervical cancer in both the United States and in emerging markets. The sensitivity of FHACT was presented as a poster at the 27th International Pappillomavirus Conference in Berlin, Germany in September 2011. The publication demonstrated that by using FHACT over 90.9% sensitivity can be achieved as a screening tool for cervical intraepithelial neoplasia of 2nd degree or higher (known as CIN2+), which is a critical milestone in the development of cervical cancer.

In 2012, we made FHACT available outside the United States as a diagnostic tool in certain emerging market countries, including India. This initial launch is applicable for detection and staging of cervical cancer, which is the third most common cancer among women worldwide, with one-fifth of the cases originating in India. The World Health Organization projects that cervical cancer deaths will rise to 320,000 in 2015 and 435,000 in 2030. In many emerging economies, cervical cancer is the most common cancer that affects women, and 80% of deaths from cervical cancer occur in these developing countries. We have accomplished our goal of making FHACT available in the United States by the end of 2013.

We continue to validate FHACT for anal and oropharyngeal cancers using specimens from the National Cancer Institute and are actively seeking collaborations to further validate the clinical utility of FHACT for anal and head and neck cancers.

Research for FHACT has been to date funded through a \$763,958 grant awarded in 2009 from the National Cancer Institute. In October 2010, we were awarded a grant in lieu of a federal income tax credit under the Qualifying Therapeutic Discovery Project Program for approximately \$244,500 to help in the further validation and commercialization of FHACT.

## **FISH-based DNA Probes**

We also develop FISH-based DNA probes for sale outside the United States. Our portfolio includes 32 CE-marked probes for hematopoietic neoplasms and solid tumors.

Our strategy is to sell conventional probes into emerging markets through Cancer Genetics Italia and local or regional partners. We have entered into an agreement with Labomics S.A., based near Brussels, Belgium, which



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will provide us with the manufacturing support, storage facilities, and fulfillment management of our FISH-based DNA probes to better serve European and global demand. We have moved these manufacturing operations to Kamineni Life Sciences in India.

We plan for all of our probes to conform to the requirements of the European In Vitro Diagnostic Medical Devices Directive (98/79/EC IVDD). This entitles them to bear the CE marking, which enables us to market them in the European Economic Area and provides for clinical acceptance in other countries where the CE mark is valued.

## **Laboratory Services**

We provide our complete suite of oncology-focused laboratory services to hospitals, cancer centers, oncologists and pathologists from our 17,936 square foot state-of-the-art, laboratory in Rutherford, New Jersey. At the federal level, clinical laboratories, such as ours, must be accredited under CLIA in order for us to perform testing on human specimens. Our laboratory is accredited by the College of American Pathology ( CAP ) which is one of six approved accreditation methods under CLIA. Our clinical laboratory is located in New Jersey and we hold the requisite licenses from the New Jersey State Department of Health to operate our laboratory. 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. In addition to New Jersey, we hold clinical laboratory licenses from the New York Department of Health, Florida Department of Health, Maryland Department of Health, and Pennsylvania Department of Health for all of our clinical departments. We are also qualified to accept specimens from all states in the United States, as well as from overseas locations.

Historically we have generated most of our revenue through our laboratory services. In 2013, we generated approximately 92% of our revenue from laboratory services, approximately 5% from government grants and approximately 3% from sales of our DNA probes. In 2012, we generated approximately 85% of our revenue from laboratory services, approximately 13% from government grants and approximately 2% from sales of our DNA probes, which are currently only sold outside the United States.

Our comprehensive oncology-focused testing services for hematological, solid tumor urogenital cancers are utilized in the diagnosis, prognosis and 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, including 15 individuals with doctorate degrees. These individuals assist our customers in integrating and technically assessing the testing results for their patients.

The non-proprietary testing services that we offer are focused 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 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<sup>®</sup>) for clinical use.

We currently offer a range of services in the following areas:

**Proprietary Microarray based testing (MatBA<sup>®</sup>-CLL, MatBA<sup>®</sup>-SLL, MatBA<sup>®</sup>-DLBCL, MatBA<sup>®</sup>-MCL and UroGenRA - Kidney):** our proprietary microarray tests for the detection of chromosomal abnormalities observed in Chronic Lymphocytic Leukemia, and Small Lymphocytic

Lymphoma Diffuse Large B-cell Lymphoma, Mantle Cell Lymphoma and kidney cancer;

**Molecular testing:** using quantitative methods, such as polymerase chain reaction, sequencing and mutahine analysis, to analyze DNA and RNA to follow progression of disease and response to therapy at the genetic level;

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**Cytogenetics testing:** a series of methods that analyze human chromosomes in order to identify malignancy;

**FISH testing:** analysis of abnormalities at the chromosomal and gene levels using analyte specific reagents and FDA-cleared probes performed on whole specimen or magnehell separated purified plasma cells;

**Flow cytometry testing:** Immuno phenotype analysis of specific markers inside cells including specific cytosolic surface proteins, and on cell surfaces;

**Histology testing:** microscopic examination of stained tissue sections using various special staining techniques;

**Cytology testing:** non-gynecological fluid preparation for microscopic evaluations by a pathologist; and

**IHC testing:** analysis of the distribution of tumor antigens in specific cell and tissue types.

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.

We expect to offer additional proprietary tests as LDTs in other areas of oncology and will seek the required CLIA and state approvals for these tests.

***Clinical Trials Services (Select One®)***

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 under development, 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 success rates by helping clinicians identify patients that are most likely to benefit from a therapy based on their individual genetic profile.

We launched our clinical trials services offering, which we have branded as Select One®, to help increase the efficiency and economic viability of clinical trials for biopharmaceutical companies and clinical research organizations. Our clinical trials services leverage our knowledge of clinical oncology and molecular diagnostics and our laboratory's fully integrated capabilities. Our clinical trial services are aimed at developing customizable tests and techniques utilizing our proprietary microarrays 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 chronic lymphocytic leukemia (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.

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### **Test Development Process**

Our proprietary microarrays and DNA probes have been, and continue to be, developed in conjunction with leading academic and clinical research centers to ensure that the needs of the clinical community are being met with the latest research on genomic alterations that cause, lead to, or are related to the development of cancer. We undergo a thorough research and validation process to ensure we are providing diagnostic and prognostic information that is clinically relevant and accurate. In our experience the time-frame for this process from design through development and market launch can be between 18 to 40 months based on complexity of the disease, the specific clinical claims being pursued and the availability of high quality samples with strong clinical correlations. We monitor and review the process in four stages as detailed below:

**Stage 1, Research and Discovery.** We conduct extensive research of peer-reviewed publications and other disease-specific literature and public information databases. We gather the public information regarding genomic abnormalities as hallmarks and references for particular cancers and clinical correlations. Within a cancer type, the observed gains, losses or other aberrations and rearrangements of genetic material are recorded and noted when reported to have diagnostic or prognostic potential. During this process, which is technology and platform agnostic, we extensively cross-analyze our findings in the literature with published data sets across a variety of technologies. Finally, we assess the merits of these findings internally with our research and development teams and with our scientific advisory board, when applicable, so that we can assure robust genomic coverage as we proceed into clinical development.

**Stage 2, Clinical Development.** We design a targeted array or probe panel based on the information gathered from the literature and database searches and review. A team of our scientists then seeks to refute the evidence compiled in the literature search process, serving as a system of checks and balances. Once that process is complete, we design an array based on its application within a particular cancer. For example, the kidney array is designed to subtype among the four main types of kidney cancers at various stages in the treatment of the patient. Within one array, we may be assessing three to four different subtypes of a cancer and for different applications, ranging from differential diagnosis to prognosis to prediction of therapeutic response. During this stage we select and refine the targeted regions and their potential suitability for analysis on the microarray.

**Stage 3, Commercial Development.** This process involves validating the performance characteristics of the microarray, as well as developing protocols for the use of the array or the DNA probe for the intended specimen. This quality assurance process notes reproducibility, accuracy, sensitivity, and specificity, and potential compliance to ranges of normalcy and reportability. We also compare data obtained for specimens and cell lines across different technology platforms to ensure accuracy of our processes. In this process, we confirm and validate the genomic biomarkers in independent clinically relevant datasets. During this process we also begin to develop the decision trees and algorithms, which are core to our intellectual property that guide the diagnostic and prognostic value of the microarray or other DNA probe. Once the initial decision tree and algorithm for the microarray and its use have begun development, we conduct trials which help to validate the design and usage of the tests. For this validation process, we partner with leading cancer institutions and regional cancer centers.

**Stage 4, Market Entry and Launch.** After commercial development is completed and prior to launch, we take several steps to prepare for marketing our tests as LDTs. We create standard operating procedures and quality assurance and quality control measures to ensure repeatability and high standards of quality. We train our staff on the interpretation and use of the data. Licenses and approvals for our laboratory to use LDTs are obtained from the appropriate regulatory authorities, such as the Centers for Medicare and Medicaid Services ( CMS ), which oversees CLIA, and different state regulatory bodies. Before we CE mark our tests we also need to assess the conformity of our tests with the essential requirements of the European In Vitro Diagnostic Medical Devices Directive. As part of our long-term strategy, we plan to seek FDA clearance or approval to expand the commercial use of

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our tests to other laboratories and testing sites in the United States. We will also need to complete additional activities to submit each of these tests for regulatory clearance or approval prior to commercialization in each of the international markets where we plan to introduce them.

### **Research and Development Expenses**

We incurred research and development expenses of \$2.2 million, which represented 33% of our net revenue, for the year ended December 31, 2013; \$2.1 million, which represented 49% of our net revenue, for the year ended December 31, 2012; and \$2.1 million, which represented 69% of our net revenue, for the year ended December 31, 2011. Research and development expenses represented 22% of our total operating expenses for the year ended December 31, 2013, 26% of our total operating expenses for the year ended December 31, 2012, and 26% for the year ended December 31, 2011. Major components of the research and development expenses included direct personnel costs, laboratory equipment and consumables and overhead expenses.

### **Sales and Marketing**

Our sales and marketing efforts consist of (i) a direct sales force in the United States focused on developing direct channels to hospitals, cancer centers, pathologists and oncologists; and (ii) a channel approach outside the United States, specifically in the emerging markets, that is focused on partnering with leading distributors, medical facilities or medical service operators to develop and serve such regional oncology markets. We also sell our clinical trial services to biopharmaceutical companies and research organizations.

We currently have a dedicated and direct sales force consisting of six sales professionals focused on the eastern and midwestern United States with backgrounds in hematology, pathology, and laboratory services. Our sales professionals have an average of 20 years of experience in clinical oncology sales, esoteric laboratory sales from leading biopharmaceutical, pharmaceutical or specialty reference laboratory companies, including Laboratory Corporation of America Holdings, US LABS, Inc., Celgene Corporation and Genzyme, a Sanofi company, among others. We plan on growing this specialized, oncology-focused sales force and supporting it with clinical specialists who bring deep domain knowledge in the design and use of the microarrays that we plan on offering in the United States as LDTs.

Our sales and marketing efforts are based on a three part go-to-market strategy:

Collaborate with leading research universities and institutions that enable the validation of our new tests;

Work with community hospitals and community-based cancer centers that need a reliable and collaborative partner for genomic-based cancer testing; and

Build relationships with individual thought leaders in oncology, hematology and pathology to provide services that provide value to their patients.

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

***Expand Dx Program***

According to American Hospital Association's 2012 data, there are approximately 5,000 community hospitals registered in the United States, 1,068 of which are for profit. These hospitals are under pressure to create profitable cancer testing centers. However, community hospitals face numerous barriers, including rising costs of diagnostic technologies and treatments, complexity of new test validations and laboratory licensing requirements,



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difficulty in hiring, training and retaining qualified personnel and challenges in integrating new information technology systems. In particular, they generally do not have a dedicated pathologist or hematopathologist, and are not able to perform tests that provide an understanding of the genetic features of the tumor. Without this information, cancer specialists at these institutions are unable to plan an adequate course of treatment, which then limits the community hospital's ability to adequately service their cancer patients. While nearly 85% of cancer patients in the United States are initially diagnosed in community hospitals, over half of these cancer patients are referred out to specialized cancer centers because community hospitals currently lack state-of-the-art oncology and pathology testing capabilities.

Our Expand Dx program for community hospitals is a suite of diagnostic and consultative services offered on a collaborative basis to expand and optimize the oncology diagnostics services and personalized cancer treatment provided by community hospitals so that such hospitals can retain their cancer patients. Our Expand Dx program focuses on enhancing the quality and increasing the efficiency of the community hospital's oncology diagnostic process, including billing, turn around time for diagnostic tests, diagnostic procedures and training and assistance in the use of additional biomarkers for their routine cancer testing. We believe that through our Expand Dx solution, community hospitals and laboratories can get cost-effective access to leading-edge diagnostic tests and specialized testing capabilities of our clinical reference laboratory. Our Expand Dx solution provides the community hospitals with the necessary skills and services needed for comprehensive management of patients and their treatment while allowing laboratories to focus on efficient delivery of individual tests rather than comprehensive interpretation of specialized cases. Our focus on oncology allows the Expand Dx customers to intervene earlier and more comprehensively with their patients, thereby improving testing and treatment revenue.

Our sales force works with our laboratory directors as a team to market our Expand Dx solution to community hospitals, geographically focused on the eastern and mid-western United States.

## ***Emerging Markets***

We are initially targeting certain emerging markets, including India, Brazil, Turkey and Mexico, as an area of expansion of sales of our proprietary tests and probes. We sell in these countries through regional partners that have the ability to service both the cancer laboratories and doctors in that country. In February 2012, we entered an exclusive distribution agreement with Kamineni Life Sciences Pvt. Ltd for sale of our probes in India. In 2012, we launched FHACT in India and other emerging markets as a tool to provide specific information about the progression from HPV infection to cervical cancer. Cervical cancer is the third most common cancer among women worldwide, with more than 85% of cervical cancers and related deaths occurring in developing countries. Deaths from cervical cancer in India account for 27% of all deaths from cancer globally.

Roche Servicios, S.A., an affiliate of the Swiss drug maker Roche based in Costa Rica, selected us as their exclusive service provider for biomarker based cancer testing services. As part of our relationship with Roche Servicios, we will perform a variety of molecular, cytogenetic and immunohistochemistry based testing services to aid Roche Servicios, S.A. in delivering genetic testing results to hospitals and clinicians based in 14 different locations covering Central America and the Caribbean. Our testing will focus on assessing the biomarkers that are related to a variety of solid tumors and blood borne cancers which are the most prevalent cancers in those regions and which also correspond to therapeutics and treatments that are offered by Roche and Genentech.

## **Key Research and Development Collaborations**

We formally and informally collaborate with leading oncology centers and community-based hospitals to develop our proprietary diagnostic tests, and we work closely with leading cancer researchers at these institutions to develop

proprietary tests tailored to their needs and specifications. Additionally, many of these centers have obtained Specialized Programs of Research Excellence status, as designated by the National Cancer Institute. Our collaborations with these centers give us access to large datasets of information that we use to develop our proprietary tests.

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

### ***Joint Venture with Mayo Foundation for Medical Education and Research Focused on Next-Generation Sequencing and Oncology***

On November 7, 2011, we entered into an affiliation agreement with the Mayo Foundation for Medical Education and Research, pursuant to which we agreed to form a joint venture with Mayo. We funded the joint venture with an initial \$1.0 million contribution in October 2013. The objectives of the joint venture entity will be to try to discover and validate biomarkers in lung cancer, multiple myeloma and follicular lymphoma utilizing next-generation sequencing with a possible expansion into other solid tumors, such as esophageal, head and neck and breast cancers. Additionally, the joint venture entity will engage in biomarker discovery utilizing Mayo's next-generation sequencing facility and the development of commercial products in the form of diagnostic products and services, as well as early stage therapeutic markers.

The joint venture entity is in the form of a limited liability company named OncoSpire Genomics, LLC, and is governed by a board of governors consisting of six members, with three members appointed by us and three members appointed by Mayo. Our appointees to the board of governors are Dr. Raju Chaganti, John Pappajohn, and Panna L. Sharma. It is anticipated that Mr. Sharma will need to devote administrative time to facilitate the initiation of OncoSpire Genomics, LLC. Initially, we hold fifty percent of the issued and outstanding membership interests and Mayo holds fifty percent of the issued and outstanding membership interests of the new entity. In exchange for our membership interests in the joint venture entity, in addition to the initial \$1.0 million capital contribution, we currently anticipate that we will make capital contributions of \$1.0 million in the second quarter of 2014 and \$2.0 million each on the first and second anniversaries of the closing date, respectively, with the latter two installments subject to the joint venture entity's achievement of certain operational milestones agreed upon by the board of governors of the joint venture entity (the "Milestones"). In addition, on November 14, 2011, we granted Mayo 20,000 shares of common stock and as part of the May 2013 amendment of the affiliation agreement, we granted to Mayo an additional 10,000 shares of common stock.

We also entered into a three-year joint development intellectual property agreement with Mayo and the joint venture entity, pursuant to which we and Mayo will grant each other non-exclusive, non-transferable licenses to use certain intellectual property required for the performance of statements of work to be issued under such agreement. Also pursuant to the joint development agreement, we, Mayo and the joint venture entity will agree that unless otherwise specified in the applicable statement of work any intellectual property created by the joint venture entity shall be the property of the joint venture entity; however, the joint venture entity will grant us and Mayo licenses to commercialize such intellectual property in the form of diagnostic products and diagnostic lab services, respectively, at prices to be determined by the board of governors of the joint venture entity. The joint development agreement further provides that the prior written consent of Mayo is required before we or the joint venture entity can commercialize products or services that contain Mayo's pre-existing property and that our prior written consent is required before Mayo or the joint venture entity can commercialize products or services that contain our pre-existing property.

The board of governors will be advised by a six-member scientific review committee, which will also be composed of three members selected by us and three members selected by Mayo. The affiliation agreement may be terminated by mutual consent of the parties or by the non-breaching party upon a material breach of the affiliation agreement that remains uncured for a period of 90 days.

### ***North Shore-Long Island Jewish Health System***

In 2007, we started working with Drs. Kanti Rai and Nicholas Chiorazzi at the Feinstein Institute for Medical Research at the North Shore-Long Island Jewish Health System. Drs. Rai and Chiorazzi are leading clinicians

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and scientists in the study of chronic lymphocytic leukemia ( CLL ) and have provided over 300 clinical specimens and associated clinical and laboratory data for panels of CLL specimens that were used for clinical validation of MatBA®-CLL. We analyzed these samples at our clinical laboratory and published the resulting data jointly with Drs. Rai and Chiorazzi. We will use the same samples for additional collaborative studies involving the search for additional genomic-based biomarkers of CLL. This collaboration is not governed by a formal written agreement.

### ***Memorial Sloan-Kettering Cancer Center***

We have multiple research collaborations with Memorial Sloan-Kettering Cancer Center including

In March 2008, we entered into a Biological Material Transfer Agreement with Memorial Sloan-Kettering Cancer Center, pursuant to which Dr. Victor Reuter at Memorial Sloan-Kettering Cancer Center provided us with slides of cells of over 140 renal tumor *ex vivo* core biopsies. These samples were used for validation of our FReCaD assay to evaluate the ability of the FISH-based assay to classify renal cortical neoplasms. In this study, we calculated the sensitivity and specificity of the core biopsy relative to that obtained by routine pathology of the core biopsy and the specimen proper. These studies are currently being written for joint publication.

In October 2009, we entered into a Biological Material Transfer Agreement with Dr. Julie Teruya-Feldstein at Memorial Sloan-Kettering Cancer Center, whereby Dr. Teruya-Feldstein provided us with 1,000 lymphoma specimens of varying histologies and with known clinical outcomes for clinical validations of MatBA® in all subtypes of mature B cell neoplasms. Dr. Teruya-Feldstein has provided cores of FFPE tumor material spear-heading and providing justification for the use of this tissue type in array-CGH. We evaluate the genomic gain or loss using MatBA® at our clinical reference laboratory and we are in the process of analyzing these specimens for clinical correlations. We will jointly publish the results of this collaboration with Dr. Teruya-Feldstein.

In June 2009 and March 2010, we entered into separate Biological Material Transfer Agreements with Dr. Raju S.K. Chaganti of Memorial Sloan-Kettering Cancer Center. Pursuant to the June 2009 agreement, Dr. Chaganti provided us with 50 follicular lymphoma and diffuse large B-cell lymphoma specimens. We used the specimens for purposes of validating a comparative genomic hybridization microarray-based assay in the diagnosis and prognosis of mature B-cell neoplasms. Pursuant to the March 2010, agreement, Dr. Chaganti provided us with 30 DNA samples. We used the samples for purposes of validating a comparative genomic hybridization microarray-based assay in the diagnosis and prognosis of genitourinary cancers.

In January 2011, we entered into a Biological Material Transfer Agreement with Dr. Jonathan Coleman at Memorial Sloan-Kettering Cancer Center to evaluate FISH-based and array-CGH tests in the diagnosis of renal mass aspirates/core biopsies. Dr. Coleman provided us with approximately 50 needle biopsy specimens. We will use the specimens to perform assays of prostate, bladder and kidney specimens using FReCaD and UroGenRA and compare the classification with that obtained by routine pathology. Any resulting data could be prepared for joint publication.

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In January 2013, we entered in to a Biological Material Transfer Agreement with Dr. Jeremy Durack at Memorial Sloan Kettering cancer center to evaluate FISH-based and array based tests in the diagnosis of renal Oncocytoma. We will use these specimens to perform our proprietary FReCaD™ and UroGenRA™ assays and compare the classification with that obtained by routine pathology. Any resulting data could be prepared for joint publication.

### *National Cancer Institute*

In July 2009 and December 2009, we entered into Simple Letter Agreements for the Transfer of Materials with the National Cancer Institute and began our collaboration with Dr. Nicolas Wentzensen at National Cancer Institute, an Institute of the National Institutes of Health, to interrogate the potential role of identification of host

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genomic abnormalities by FISH as a screening tool for the detection of HPV-associated pre-cancerous cells and cancerous cells. Dr. Wentzensen has provided us with liquid biopsy specimens for analysis by FISH using the FHACT DNA-FISH probe. In our first project together, National Cancer Institute provided cervical liquid biopsy specimens and in later collaborations, National Cancer Institute provided anal liquid biopsy specimens. We published a poster from the data generated as part of the collaboration at the 27<sup>th</sup> International Papillomavirus conference and clinical workshop held at Berlin, Germany in September 2011.

### ***Kamineni Hospital***

In November 2010, we began collaborating with Dr. Annie Hasan at the Kamineni Hospital in Hyderabad, India, to evaluate the FHACT DNA-FISH Probe as a screening tool for the identification of pre-cancerous and cancerous cervical cells. In this collaboration, we provide the FHACT DNA-FISH Probe to Dr. Hasan's laboratory where the assay is performed on Pap smears obtained during routine health visits. We are analyzing the data from this collaboration jointly with Dr. Hasan and any resulting publications will be jointly produced. We anticipate providing Dr. Hasan with FReCaD for use as a screening tool in renal cancers to be performed on specimens obtained in Kamineni Hospital. This collaboration is not governed by a formal written agreement. Any resulting data from the collaboration could be prepared for joint publication.

### ***University of Iowa Hospitals and Clinics***

In 2011, we entered into a Material Transfer Agreement with the University of Iowa Research Foundation, whereby Dr. Aaron Bossler will provide specimens useful to our studies evaluating the FHACT assay in cervical liquid biopsy specimens with known HPV type and clinical follow-up. In this study, specimens will be sent to us for FISH-based assays and the data analyzed jointly.

In February 2013, we entered into a biological transfer agreement with Dr. Sergei Syrbu, at University of Iowa for development and validation of molecular Tests (LDT) to improve the diagnosis, prognosis and management of Diffuse large B-cell lymphoma (DLBCL). The specimens obtained will be used for further validation of our proprietary MatBA<sup>®</sup>- DLBCL array.

### ***Hackensack University Medical Center***

In May 2012, we entered into a biological material transfer agreement with Dr. Anthony Mato of the John Theurer Cancer Center at the Hackensack University Medical center. Under this agreement Dr. Mato provided us with specimens for performing MatBA<sup>®</sup>- CLL array testing. The resulting data can be prepared for joint publication.

### ***Cleveland Clinic***

In May 2012, we entered into a collaborative research agreement and non-exclusive license arrangement with Cleveland Clinic to start development around a renal cell carcinoma diagnostic focused on validating genomic biomarkers from DNA. In connection with this collaboration, we issued 2,000 shares of our common stock to Cleveland Clinic. In this relationship we worked with Drs. Eric Klein and Magi Galluzzi at the Cleveland Clinic. Drs. Klein and Galluzzi are leading clinicians and scientists in the study of renal and urogenital cancers and provided over 200 clinical specimens and associated clinical and laboratory data for the validation of our UroGenRA<sup>™</sup>-Kidney microarray. We analyzed these samples at our clinical laboratory and will have the opportunity to publish the resulting data jointly with Cleveland Clinic.

### ***Stanford University***

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Stanford University recently granted us a worldwide, non-exclusive license under U.S. Patent No. 7,622,253 and U.S. Patent No. 7,332,280 directed to a method and an assay for the classification of diffuse large B-cell



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lymphoma (DLBCL) patients based on risk stratification and a predictive model for patient survival. The method and assay covered in these patents have been developed in the lab of Dr. Ronald Levy, a pioneer researcher in the area of lymphoma. DLBCL is an aggressive form of non-Hodgkin's lymphoma with estimated 10,000 deaths annually in the United States. A current method of prognostication for DLBCL is done by using the International Prognostic Index score. However, a disadvantage to this method is that two individuals with an identical International Prognostic Index score can react differently to treatment thereby affecting their life expectancy and patient survival. The licensed technology analyzes the expression of six genes by a real-time PCR methodology in conjunction with an algorithm. This method and assay is not currently available in a clinical lab setting to our knowledge. We believe that developing and commercializing this licensed technology will allow us to provide a more accurate classification, stratification and prediction of the DLBCL patient population and also provide more personalized therapeutic options to this patient population. This assay will be added to our growing menu of tests (IHC, mutation analysis, etc.) to be offered under our Complete DLBCL program.

### ***Georgia Health Sciences University***

In August 2012, we entered into a research collaboration agreement with Drs. Vamsi Kota and Ravindra Kolhe at Georgia Health Sciences University for the development of molecular testing to facilitate diagnosis, prognosis and management of DLBCL cancer patients. The specimens provided by the investigators will be used for ABC-GCB subtype classification by immunohistochemistry to identify and further validate genomic biomarkers for DLBCL using the proprietary MatBA®- DLBCL array.

In September 2012, we entered into a biological material transfer agreement with Dr. Ravindra Kolhe at Georgia Health Sciences University for validation of the proprietary FHACT™ probe in the diagnosis and disease management of head and neck squamous cell carcinoma (HNSCC). Any data resulting from this collaboration could be prepared for joint publication.

### ***Dana Farber***

In April 2013, a research collaboration was initiated with Dr. Jennifer Brown of the Dana Farber Cancer Institute. Dr. Brown will analyze a microarray dataset of over 100 CLL specimens for clinical validation of the CLL outcome scheme. In this research collaboration, there will be shared publication of results.

## **Scientific Advisory Board**

Our Scientific Advisory Board is comprised of preeminent scientists and physicians from the fields of cancer biology, cancer pathology, cancer medicine and molecular genetics. We have scientists and clinicians from leading cancer centers, including Memorial Sloan-Kettering Cancer Center, Mt. Sinai and the Institute for Cancer Genetics at Columbia University. These distinguished scientists and clinicians help oversee and review the scientific innovation, integrity and clinical relevancy of our program. The board of directors appoints members to the Scientific Advisory Board for terms of one year.

## **Competition**

As a provider of genomic-based tests and services that provide personalized diagnostic and prognostic information for hematological, urogenital and HPV-associated cancers, we rely extensively on our ability to combine research insights with high-quality, state-of-the art clinical laboratory testing. We believe that we compete principally on the basis of:

our ability to address complex cancers that are currently difficult to prognose and challenging to predict treatment outcomes using currently available technologies;

the ability of our proprietary tests and services to provide more information than existing tests with respect to the cancers we address;

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our ability to utilize a wide variety of sample types, accelerating the time-frame for clinical validation of our tests and allowing health care providers to readily integrate our tests into their established workflow;

our ability to perform clinical studies using FFPE samples to either validate or develop novel insights for our proprietary programs;

the quality of our services and our ability to collaborate with our customers on a consultative basis;

our research and clinical collaborations with key academic and clinical study groups;

the quality of our clinical reference laboratory, which enables consistent, comprehensive and reproducible results;

the level of disease specific knowledge and customer service we provide, both to academic centers and community based health care professionals; and

our workplace environment, recognized by being named #20 nationwide by The Scientist in Best Places to Work Industry, 2011 , which increases our ability to attract both clinical and research talent.

We believe that we compete favorably with respect to these factors, although we cannot assure you that we will be able to continue to do so in the future or that new products or tests that perform better than our proprietary tests and services will be introduced. We believe that our continued success depends on our ability to:

expand and enhance our MatBA<sup>®</sup> tests to provide clinically meaningful information in additional indications;

continue to innovate and maintain scientifically advanced technology;

successfully market and sell our proprietary tests in the United States;

continue to obtain appropriate regulatory approvals in the United States and abroad;

continue to validate our pipeline of microarray tests and DNA probes;

continue to obtain positive reimbursement decisions from payors and from CMS;

continue to enter into partnerships with local distributors and/or manufacturers to expand into emerging markets, including India, Mexico and Brazil;

maintain existing and enter into new research and clinical collaborations with key academic and clinical study groups;

continue to attract and retain skilled scientific and clinical personnel;

obtain patents or other protection for our proprietary tests and services; and

obtain and maintain our clinical reference laboratory accreditations and licenses.

Our principal competition comes from existing 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. In addition, companies offering capital equipment and kits or reagents to local pathology laboratories represent another source of potential competition. These kits are used directly by the pathologist, which can facilitate adoption.

We also face competition from companies that offer products or have conducted research to profile genes, gene expression or protein biomarkers in various cancers. In particular, Quest Diagnostics market arrays which are competitive to our MatBA<sup>®</sup>-CLL and MatBA<sup>®</sup>-SLL arrays. Personalized genetic diagnostics is a new area of science, and we cannot predict what tests others will develop that may compete with or provide results superior to the results we are able to achieve with the tests we develop. Our competitors include public companies such as

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NeoGenomics, Inc., Quest Diagnostics, Abbott Laboratories, Inc., Johnson & Johnson, Roche Molecular Systems, Inc., bioTheranostics, Inc. (part of the bioMérieux S.A.), Genomic Health, Inc., Myriad Genetics, Inc., Qiagen N.V., Response Genetics, Inc., Rosetta Genomics Ltd., and Foundation Medicine, Inc., and many private companies. We expect that pharmaceutical and biopharmaceutical companies will increasingly focus attention and resources on the personalized diagnostic sector as the potential and prevalence increases of molecularly targeted oncology therapies approved by FDA along with companion diagnostics. For example, FDA has recently approved two such agents Xalkori crizotinib from Pfizer Inc. along with its companion anaplastic lymphoma kinase FISH test from Abbott Laboratories, Inc. and Zelboraf vemurafenib from Genentech USA Incorporated and Daiichi-Sankyo Inc. along with its companion B-RAF kinase V600 mutation test from Roche Molecular Systems, Inc. These two recent FDA approvals are only the second and third instances ever of simultaneous approvals of a drug and companion diagnostic, the first being the 1998 approval of Genentech, Inc.'s Herceptin trastuzumab for HER2 positive breast cancer along with the HercepTest from partner Dako A/S. Our competitors may invent and commercialize technology platforms or tests that compete with ours.

With respect to our clinical laboratory services 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).

Additionally, projects related to cancer genomics have received increased government funding, both in the United States and internationally. As more information regarding cancer genomics becomes available to the public, we anticipate that more products aimed at identifying targeted treatment options will be developed and that these products may compete with ours. In addition, competitors may develop their own versions of our tests in countries where we did not apply for patents or where our patents have not issued and compete with us in those countries, including encouraging the use of their test by physicians or patients in other countries.

## **Third-Party Suppliers and Manufacturers**

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

The DNA component of our DNA FISH probes is produced under strict adherence to regulatory procedures in our Rutherford facility and also at a third party facility depending on demand and workflow. The DNA is shipped for final manufacture to our partner in India. In February 2012 we entered into an agreement with Kamineni Life Sciences to supply outsourced manufacturing for the production of our DNA FISH probes. The manufacturing operations became fully operational in India in the fourth quarter of 2012 and several batches of DNA FISH probes have been successfully manufactured. We control overall quality and process management and the final quality assurance in a manner that is CE compliant and adheres to our Quality Management System.

## **Patents and Proprietary Technology**

Our business is dependent upon our ability to develop and protect proprietary tests that enable oncologists and pathologists at hospitals, cancer centers, and physician offices to properly diagnose and inform cancer treatment. We rely on a combination of patents, patent applications, trademarks, trademark applications, trade secrets, industry know-how, as well as various contractual arrangements, in order to protect the proprietary aspects of our technology.

Our patent portfolio consists of five issued U.S. patents and several pending U.S. and foreign applications. These patents and patent applications are related to various DNA-based probes and microarrays designed for detecting

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and correlating certain chromosomal markers associated with particular types of cancers. As of the date of this filing, we have five issued U.S. Utility Patents (U.S. Patent Nos. 7,585,964, 7,964,345, 8,557,747, 8,580,713, and 8,603,948), which cover our probe and microarray technologies.

U.S. Patent Nos. 7,585,964 and 7,964,345 cover probes and methodologies designed to detect and analyze particular chromosomal translocations (genetic lesions) associated with a wide range of cancers using a technique known as FISH and serve as the backbone for several of our other pending patent applications, which are more specifically geared towards other probes (and methodologies).

U.S. Patent Nos. 8,580,713 and 8,557,747 have recently issued in the microarray space. These two patents and foreign PCT Application No. US2010/062295 are directed to a microarray for detecting (and distinguishing) particular types of mature B cell neoplasms present in typical non-Hodgkin's lymphoma, Hodgkin's lymphoma and chronic lymphocytic leukemia. These patents and foreign application cover our trademarked MatBA<sup>®</sup> microarray and are directed to both the microarray itself as well as associated methodologies designed to detect the particular type of mature B cell neoplasm present in a patient. These patents and foreign application also cover the use of computer-assisted means to facilitate and expedite that detection process. The MatBA<sup>®</sup> patents issued from the first of our family of applications in the microarray space.

U.S. Patent No. 8,603,948 recently issued and is directed to a novel, highly sensitive, and specific probe panel which detects the type of renal cortical neoplasm present in a biopsy sample. This patent covers a probe that permits diagnosis of the predominant subtypes of renal cortical neoplasms without the use of invasive methods and provides a molecular cytogenetic method for detecting and analyzing the type of renal cortical neoplasm present in a renal biopsy sample. We recently filed U.S. Patent Application No. 14/078,726 which relates to this technology as well.

Moreover, we recently filed patent applications on a detection method and probe sets associated with HPV-associated cancers (US. Patent Application Nos. 13/227,027 and 13/474,111). We are also working on several additional patent filings directed to our other microarrays, and we filed a patent application covering UroGenRA<sup>®</sup> earlier this year (U.S. Patent Application No. 61/765,768).

In addition to patents, we hold six U.S. registered trademarks, including a federal registration to CGI<sup>®</sup> as well as five U.S. trademark applications and one foreign trademark registration for certain of our proprietary tests and services. Our strategic use of distinctive trademarks has garnered increased name recognition and brand awareness for our tests and services within the industry.

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

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

**Operations and Production Facilities**

Our research and development laboratories and our diagnostic laboratories are located in our Rutherford, New Jersey headquarters.



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We work with electronic medical records providers to facilitate seamless communication between our laboratory and the oncologist or pathologist at the test ordering site. Currently, we have the ability to integrate with electronic medical record systems, as we have already done with MDL, an electronic medical record provider. We do this integration through utilizing HL7 interfaces, which are standard in health care information technology systems. We currently employ HL7 for its integration with a revenue cycle management company, Xifin, as well as with its electronic medical records partners such as MDL. The use of the HL7 interface allows systems written in different languages and running on different platforms to be able to talk to each other through the use of an abstracted data layer. This means that we do not have to spend significant extra time, often months, designing and developing common communications protocols when integrating with other electronic health records systems or billing systems providers.

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

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

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

## **Quality Assurance**

### ***Clinical Lab Services***

We are committed to providing reliable and accurate diagnostic services to our customers. Accurate specimen identification, timely communication of diagnoses, and prompt correction of errors, is critical. We monitor and improve our performance through a variety of methods, including performance improvement indicators, proficiency testing (CAP and New York State), external audits and satisfaction surveys. All quality concerns and incidents are subject to root cause analysis and our procedures are put through annual evaluation to ensure that we are providing the best services possible to our patients and customers. Protection of patient results from misuse and improper access is imperative and thus electronic and paper results are guarded via password-protection and identification cards.

We have established a comprehensive Quality Assurance and Management Program for our laboratory designed to drive accurate and timely test results and to ensure the consistent high quality of our testing services. The Quality Assurance and Management Program documents the quality assurance/performance improvement plans and policies and the laboratory quality assurance and quality control procedures that are necessary to ensure that we offer the highest quality of diagnostic testing services. This program is designed to satisfy all the requirements necessary for local and state licensures by the New Jersey Health Department and the New York Department of Health Clinical

Laboratory Evaluation Program and accreditation for clinical diagnostic laboratories by CAP. We follow the policies and procedures for patient and employee safety, hazardous waste disposal and fire codes stated in the general laboratory procedure manual. We believe that all pertinent

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regulations of CLIA, Occupational Safety and Health Administration ( OSHA ), Environmental Protection Agency and FDA are satisfied by following the established guidelines and procedures of our Quality Assurance and Management Program.

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

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

### ***Microarrays***

We test each lot of microarrays that are manufactured for us by Agilent and maintain a log of all the hybridizations. We also have an extensive process of testing the hybridization results and comparing them to prior lots to ensure consistency and to review for potential changes. Any changes or results that are not consistent with expectations are logged and then immediately reviewed by our team, including the Vice President of Research & Development. In cases where a manufacturing problem is suspected, we immediately review the entire lot and prepare the results for review with Agilent.

### ***FISH-based DNA Probes***

We are committed to the highest level of quality in the development and manufacture of fluorescently-labeled DNA intended to compose our DNA-FISH probes. Our probes are manufactured to meet or exceed all established quality and performance specifications, and comply with relevant safety and regulatory requirements as defined in the European In Vitro Diagnostic Directive in order to qualify them for CE marking.

On behalf of our subsidiary, CGI Italia, we have created and implemented a Quality Management System applicable throughout the entire life cycle of our DNA-FISH probes. This Quality Management System maintains control over the quality of the goods manufactured by us or third parties employed by us and services provided to CGI Italia. This system addresses within other procedures the organizational structure, manufacturing process and related responsibilities, the systematic quality assurance and quality control of production, the means to monitor the performance of the quality system (internal/external audit) and the post-production vigilance.

### **Third-party Payor Reimbursement**

Revenues from our clinical laboratory tests are derived from several different sources. Depending on the billing arrangement and applicable law, parties that reimburse us for our services include:

third-party payors that provide coverage to the patient, such as an insurance company, managed care organization or a governmental payor program;

physicians or other authorized parties (such as hospitals or independent laboratories) that order the testing service or otherwise refer the services to us; or

the patient.

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For the year ended December 31, 2013, we derived approximately 21% of our total revenue from private insurance, including managed care organizations and other health care insurance providers, 13% from Medicare, 58% from direct-bill (including clinical trial) customers, including hospitals and other laboratories, and approximately 8% government grants and DNA probes.

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

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

Medicare fee schedule amounts are established for each billing code, or CPT code. In addition, for its laboratory fee schedule, Medicare also sets a cap on the amount that it will pay for any individual test. This cap, usually referred to as the National Limitation Amount, is set at a percentage of the median of all the contractor fee schedule amounts for each billing code. In the past, Congress has lowered the percentage of the median used to calculate the National Limitation Amount in order to achieve budget savings. Currently, the National Limitation Amount ceiling is set at 74% of the median for established tests and 100% of the median for certain new tests that were not previously reimbursed. In billing Medicare for clinical laboratory services, we are required to accept, as payment in full, the lowest of our actual charge, the fee schedule amount for the state or local geographical area or the National Limitation Amount.

Medicare also has policies that may limit when we can bill directly for our services and when we must instead bill another provider, such as a hospital. When the testing that we perform is done on a specimen that was collected while the patient was in the hospital, as either an inpatient or outpatient, we may be required to bill the hospital for our services, rather than the Medicare program, depending on whether or not the service was ordered more than 14 days after the patient's discharge from the hospital. These requirements are complex and time-consuming and, depending on what they require, may affect our ability to collect for our services.

Our reimbursement rates can vary based on whether we are considered to be an in-network provider, a participating provider, a covered provider or an out-of-network provider. These definitions can vary from insurance company to insurance company, but we are generally considered an out of network or non-participating provider in the vast majority of our cases. It is not unusual for a company that offers highly specialized or unique testing to be an out of network provider. An in-network provider usually has a contracted arrangement with the insurance company or benefits provider. This contract governs, among other things, service-level agreements and reimbursement rates. In certain instances an insurance company may negotiate an in-network rate for our testing rather than pay the typical out-of-network rate. An in-network provider usually has rates that are lower per test than those that are out-of-network, and that rate can vary from a single digit percentage deduction discount to upwards of 25% to 30% lower than an out-of-network provider. The discount rate varies based on the insurance company, the testing type and the often times the specifics of the patient's insurance plan.



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In May 2013 we entered into an agreement with Multiplan, Inc., a leading provider of healthcare cost management solutions, which we believe will help us improve reimbursement rates and shorten our collection times. We intend to seek similar arrangements with other health cost care managers and insurance companies.

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

### **Billing Codes for Third-party Payor Reimbursement**

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

Among the new codes that were created by CPT were a specific subset of codes called Multi-analyte Assays with Algorithmic Analysis (MAAAs). These tests typically use an algorithm applied to certain specific components to arrive at a score that is used to predict a particular clinical outcome. CMS recently stated that it will not pay for some of these new codes, because it does not believe it is permitted to pay for the underlying algorithm. Instead, it will pay for only for the specific laboratory components that are performed as part of these tests. CMS also stated it has plans to seek additional information about these codes next year. It is not clear what position CMS will finally decide to take on the MAAA tests, but its decision could adversely affect future reimbursement for such tests, including those we may develop. Currently less than 10% of our revenue is derived from tests that may be considered MAAAs.

These changes in coding and reimbursement methods could have an adverse impact on our revenues going forward. However, we are currently working with our billing consultants to determine what changes will be required by the new coding changes. The elimination of the stacking codes requires us to either use the new more specific codes where applicable effective January 1, 2013, or to use other Not Otherwise Classified (NOC) codes when billing for some of our tests. The implementation of these new codes will vary from payer to payer and it is too early to assess the impact, if any, that the migration to the new codes may have on our results of operations. If CMS decides not to reimburse for the algorithm included in the MAAA tests, then we would only be able to bill Medicare for the specific genetic examinations that we perform, without the algorithms. The introduction of the new codes, in combination with the other action being considered by CMS with regard to pricing, could result in a reduction in the payment that we receive for our tests and make it more difficult to obtain coverage from Medicare or other payers. There can be no guarantees that Medicare and other payers will establish positive or adequate coverage policies or reimbursement rates. We are moving forward with plans to obtain billing codes for our tests. A specific code for our tests, however, does not assure an adequate coverage policy or reimbursement rate. Please see the section entitled Legislative and Regulatory Changes Impacting Clinical Laboratory Tests for further discussion of certain legislative and regulatory

changes to these billing codes and the impact on our business.



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### **Coverage and Reimbursement for Our Microarray Tests**

Although MatBA<sup>®</sup> is a relatively new test, some third-party payors have established coverage and reimbursement policies set for other microarray-based tests. We have been able to receive reimbursement for our tests from some payors based on their established policies, including major commercial third-party payors.

The current landscape with payors is generally as follows:

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

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

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

### **Legislative and Regulatory Changes Impacting Clinical Laboratory Tests**

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

Under the statutory formula for clinical laboratory fee schedule amounts, increases are made annually based on the Consumer Price Index for All Urban Consumers as of June 30 for the previous twelve-month period. From 2004 through 2008, Congress eliminated the Consumer Price Index for All Urban Consumers update in the Medicare Prescription Drug, Improvement and Modernization Act of 2003. In addition, for years 2009 through 2013, the Medicare Improvements for Patients and Providers Act of 2008 ( MIPPA ) mandated a 0.5% cut to the Consumer Price Index for All Urban Consumers. Accordingly, the update for 2009 was reduced to 4.5% and negative 1.9% for 2010. In March 2010, the President signed into law PPACA, which, among other things, imposed additional cuts to the Medicare reimbursement for clinical laboratories. The PPACA replaced the 0.5% cut enacted by MIPPA with a productivity adjustment that will reduce the Consumer Price Index update in payments for clinical laboratory tests. In 2011, the productivity adjustment was -1.2%. In addition, the PPACA includes a separate 1.75% reduction in the CPI update for clinical laboratories for the years 2011 through 2015. On February 22, 2012, President Obama signed the MCTRJCA, which mandated an additional change in reimbursement for clinical laboratory services payments. This legislation requires CMS to reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which in turn will serve as a base for 2014 and subsequent years. Based on the changes required by PPACA and MCTRJCA, payment for clinical laboratory services will be reduced by approximately 0.8% for 2014.

With respect to our diagnostic services for which we are reimbursed under the Medicare Physician Fee Schedule, because of the statutory formula, the Sustainable Growth Rate (SGR), the rates would have decreased for the past several years if Congress failed to intervene. In the past, when the application of the statutory formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions. On November 1, 2012, the Centers for Medicare & Medicaid Services (CMS) issued its 2013 Physician Fee Schedule Final Rule

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(the Final Rule ). In the Final Rule, CMS called for a reduction of approximately 26.5% in the 2013 conversion factor that is used to calculate physician reimbursement. However, the American Taxpayer Relief Act of 2012, which was signed into law on January 2, 2013, prevented this proposed reduction and kept the existing reimbursement rate in effect until December 31, 2013.

For 2014, CMS projected the cut would be about 24%, unless Congress acted. However, on December 18, 2013, Congress passed legislation that enacted a 0.5% update in the conversion factor, which will be effective until March 31, 2014. Currently, Congress is considering a long-term fix to the SGR, which could eliminate the need for annual Congressional action. At this time, it is impossible to know how likely Congress is to act or what the impact will be of its actions, if any, on CGI. If Congress fails to act before March 31, 2014, or if it does not enact a long-term solution to the SGR, then the resulting decrease in payment could adversely impact our revenues and results of operations.

In addition to the reductions described above, our Medicare payments under both the CLFS and the PFS are also subject to an additional 2% reduction, as a result of sequestration. This automatic cut results because the Joint Select Committee on Deficit Reduction, which was created by congress in 2011, was unable to agree on a set of deficit reduction recommendations for Congress to vote on. The reduction is scheduled to continue until 2023.

For the year ended December 31, 2013 and the year ended December 31, 2012, approximately 13% and 18%, respectively, of our total revenues are derived from Medicare generally and any changes to the physician fee schedule that result in a decrease in payment could adversely impact our revenues and results of operations.

In addition, periodically CMS also changes its payment policies related to laboratory reimbursement in ways that could have an impact on the revenues of the Company. For example, in 2013 Final Rule, CMS included a reduction of certain relative value units and geographic adjustment factors used to determine reimbursement for a number of commonly used pathology codes, including CPTs 88300, 88302, 88304, and 88305. In particular, the 2013 Final Rule implemented a cut of approximately 33% in the global billing code for 88305 and a 52% cut in the Technical Component of that code. These codes describe services that we must perform in connection with our tests and we bill for these codes in connection with the services that we provide. In the 2013 Final Rule, CMS also announced how it intended to set prices for the new molecular diagnostic tests, for which the American Medical Association had adopted over 100 new codes. In that Rule, CMS announced it intended to continue to pay for the new molecular codes on the CLFS rather than move them to the Physician Fee Schedule, as some stakeholders had urged. It would then request that the Medicare Administrative Contractors gapfill the new codes and set an appropriate price for them. That gapfilling process took place over 2013 and CMS announced the new prices for these codes in September, 2013. The median of the prices set by the contractors will become the new prices for these codes, effective January 1, 2014. We do not yet know what impact, if any, these changes will have on the Company's operations.

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

In addition, in the 2014 Proposed Rule, CMS also noted that payments for many codes paid under the Clinical Laboratory Fee Schedule have not been revised to reflect technological advances that have occurred since the CLFS was first developed in 1984. CMS therefore proposed that it would begin to review all codes on the CLFS and adjust them to reflect technological changes, a process that it expected would take about five years. CMS

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stated that it could either increase or decrease payment levels based on this review, however, it expected that most payments were likely to decrease. CMS adopted this proposal in the Final 2014 Physician Fee Rule (the 2014 Final Rule ); therefore, it is expected this review process will begin in 2014. We do not know what impact, if any, these changes may have on our business.

In addition, CMS made several other changes in the 2014 Final Rule that could impact our business. First, CMS implemented a policy that will bundle payment for the examination of 10 or more prostate biopsies for an individual patient, rather than paying separately for each individual procedure as had been done previously. This will result in a significant reduction in reimbursement on each of these procedures. In addition, CMS also has developed new codes applicable to billing for Immunohistochemistry procedures, which are a common staining procedure used in pathology. Those codes will reduce the reimbursement that we will receive when we provide these services. Finally, CMS has also implemented a set of edits under its National Correct Coding Initiative, which will only pay for a single unit of service when we perform a FISH (Fluorescent In Situ Hybridization) test. As many FISH tests require two or more probes, this change will also reduce the reimbursement received by the Company. We are still reviewing the provisions to determine the impact of these changes.

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

Finally, some of our Medicare claims may be subject to policies issued by Palmetto GBA, the current Medicare Administrative Contractor for California, Nevada, Hawaii and certain U.S. territories. The Medicare contractor has recently issued a Local Coverage Decision that affects coverage, coding and billing of many molecular diagnostic tests. Under this Local Coverage Determination, Palmetto will not cover any molecular diagnostic tests, including our tests, unless the test is expressly included in a National Coverage Determination issued by CMS or a Local Coverage Determination or coverage article issued by Palmetto. Currently, laboratory providers may submit coverage determination requests to Palmetto for consideration and apply for a unique billing code for each test (which is a separate process from the coverage determination). In the event that a non-coverage determination is issued, the laboratory must wait six months following the determination to submit a new request. In addition, effective May 1, 2012, Palmetto implemented its new Molecular Diagnostic Services Program, under which, among other things, laboratories must use newly-assigned billing codes specific to the test. These new billing codes enable Palmetto to measure utilization and apply coverage determinations. Denial of coverage by Palmetto, or reimbursement at inadequate levels, would have a material adverse impact on market acceptance of our tests.

## **Governmental Regulations**

### ***Clinical Laboratory Improvement Amendments of 1988 and State Regulation***

As a diagnostic service provider, we are required to hold certain federal, state and local licenses, certifications and permits to conduct our business. As to federal certifications, in 1988, Congress passed the Clinical Laboratory Improvement Amendments ( CLIA ) establishing quality standards for all laboratories testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The Company's laboratory is CLIA accredited. As to state laws, we are required to meet certain laboratory licensing and other requirements. Our laboratory holds the required licenses and accreditations obtained from the applicable state agencies in which we operate. For more information on state licensing requirements, see the sections entitled Description of the

Business Government Regulations *New Jersey and New York State Laboratory Licensing* and Description of the  
Business Government Regulations *Other States Laboratory Testing* .

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Under CLIA, a laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of, or assessment of health. CLIA also requires that we hold a certificate applicable to the type of work we perform and comply with certain standards. CLIA further regulates virtually all clinical laboratories by requiring they be accredited by the federal government and comply with various operational, personnel, facilities administration, quality and proficiency requirements intended to ensure that their clinical laboratory testing services are accurate, reliable and timely. CLIA compliance and accreditation is also a prerequisite to be eligible to bill for services provided to governmental payor program beneficiaries. CLIA is user-fee funded. Therefore, all costs of administering the program must be covered by the regulated facilities, including certification and survey costs.

We are subject to survey and inspection every two years to assess compliance with program standards, and may be subject to additional unannounced inspections. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. In addition, a laboratory like ours that is certified as high complexity under CLIA may obtain analyte specific reagents, which are used to develop diagnostic tests that are developed and validated for use in examinations the laboratory performs itself known as laboratory-developed tests ( LDTs ). Our laboratory is CLIA accredited and under our CLIA accreditation, we were allowed to first use MatBA<sup>®</sup>-CLL in November 2010 and MatBA<sup>®</sup>-SLL in the first quarter 2012.

In addition to CLIA requirements, we participate in the oversight program of the College of American Pathologists ( CAP ). Under CMS requirements, accreditation by CAP is sufficient to satisfy the requirements of CLIA. Therefore, because we are accredited by CAP, we are deemed to also comply with CLIA. CLIA also provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states have implemented their own more stringent laboratory regulatory schemes. State laws may require that laboratory personnel meet certain qualifications, specify certain quality controls, or prescribe record maintenance requirements.

## ***FDA***

The U.S. Food and Drug Administration ( FDA ) regulates the sale or distribution, in interstate commerce, of medical devices under the Federal Food, Drug, and Cosmetic Act ( FDCA ), including in vitro diagnostic test kits, reagents and instruments used to perform diagnostic testing. Such devices must undergo pre-market review by FDA prior to commercialization unless the device is of a type exempted from such review by statute or pursuant to FDA 's exercise of enforcement discretion. FDA, to date, has decided not to exercise its authority to actively regulate the development and use of LDTs such as ours as medical devices and therefore we do not believe that our LDTs currently require pre-market clearance or approval. It is possible, perhaps likely, that FDA will decide to more actively enforce its regulations against all LDTs in the near term, which could lead to pre-market and post-market regulatory obligations for the continued marketing of our tests.

Section 1143 of the Food and Drug Administration Safety and Innovation Act, signed by the President on July 9, 2012, requires FDA to notify Congress at least 60 days prior to issuing a draft or final guidance regulating LDTS and provide details of the anticipated action. We are monitoring developments and anticipate that our products (CGH-Microarrays and FISH Probes) will be able to comply with anticipated requirements. In the meantime, we maintain our CLIA accreditation, which permits the use of LDTs for diagnostics purposes. FDA regulations pertaining to medical devices govern, among other things, the research, design, development, pre-clinical and clinical testing, manufacture, safety, efficacy, storage, record-keeping, packaging, labeling, adverse event reporting, advertising, promotion, marketing, distribution and import and export of medical devices. Pursuant to the FDCA, medical devices are subject to varying degrees of regulatory control and are classified into one of three classes depending on the controls FDA determines necessary to reasonably assure their safety and efficacy.

Class I devices are those for which reasonable assurance of the safety and effectiveness can be provided by adherence to FDA's general regulatory controls for medical devices, which include compliance with the



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applicable portions of FDA's Quality System Regulations, facility registration and product listing, reporting of adverse medical events and appropriate, truthful and non-misleading labeling, advertising and promotional materials, or general controls. Many Class I devices are exempt from pre-market regulation, however, some Class I devices require pre-market clearance by FDA through the 510(k) pre-market notification process described below.

Class II devices are subject to FDA's general controls, and any other special controls as deemed necessary by FDA to provide reasonable assurance of the safety and effectiveness of the devices. Pre-market review and clearance by FDA for Class II devices are generally accomplished through the 510(k) pre-market notification procedure. Pre-market notification submissions are subject to user fees, unless a specific exemption applies. To obtain 510(k) clearance for a medical device (or for certain modifications to devices that have received 510(k) clearance), a manufacturer must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or to a pre-amendment device that was in commercial distribution before May 28, 1976 (a predicate device) for which FDA has not yet called for the submission of a pre-market approval (PMA) application. In making a determination that the device is substantially equivalent to a predicate device, FDA compares the proposed device to the predicate device or predicate devices and assesses whether the subject device is comparable to the predicate device or predicate devices with respect to intended use, technology, design and other features which could affect the safety and effectiveness. If FDA determines that the subject device is substantially equivalent to the predicate device or predicate devices, the subject device may be cleared for marketing. FDA's 510(k) clearance pathway generally takes from three to twelve months from the date the application is completed, but can take significantly longer. Moreover, in January 2011, FDA announced twenty-five specific action items it intended to take to improve transparency and predictability of the 510(k) program. We anticipate that the changes may also result in additional requirements with which manufacturers will need to comply in order to obtain or maintain 510(k) clearance for their devices. These additional requirements could increase the costs or time for manufacturers seeking marketing clearances through the 510(k) process. Moreover, the 510(k) process could result in a not-substantially equivalent determination, in which case the device would be regulated as a Class III device, discussed below, or could be eligible for *de novo* classification available for novel low and moderate risk devices. In the *de novo* process, FDA can classify a device into Class I or Class II based on a risk-based determination without the submission of a 510(k) or within 30 days after receipt of a not-substantially equivalent determination. In 2013, several assays and diagnostic tests received pre-market approval through the *de novo* process.

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

A clinical trial may be required in support of a 510(k) submission and generally is required for a PMA application. These trials generally require an effective Investigational Device Exemption from FDA for a specified number of patients, unless the product is exempt from Investigational Device Exemption requirements or deemed a non-significant risk device eligible for more abbreviated Investigational Device Exemption requirements. The Investigational Device Exemption application must be supported by appropriate data, such as



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animal and laboratory testing results. Clinical trials may begin 30 days after the submission of the Investigational Device Exemption application unless FDA or the appropriate institutional review boards at the clinical trial sites place the trial on clinical hold.

After a device is placed on the market, regardless of the classification or pre-market pathway, it remains subject to significant regulatory requirements. Even if regulatory approval or clearance of a medical device is granted, FDA may impose limitations or restrictions on the uses and indications for which the device may be labeled and promoted. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. In 2013, FDA issued guidance for industry regarding appropriate labeling and distribution practices for in vitro diagnostic products intended for research or investigational use only FDA's guidance cautions that labeling or distribution practices that conflict with research or investigational use (e.g., use in clinical diagnostic applications) could subject products shipped with research or investigational use labeling to all applicable requirements of the FDCA as well as enforcement action. As a result of FDA's recent guidance, component suppliers for our LDTs may no longer be willing to distribute components to our clinical laboratory. If this were to occur, we could not produce our LDTs.

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

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

We believe that our LDTs and, should we reach that point, our in vitro diagnostic test kits, would likely be regulated as either Class II or Class III devices should FDA lift its enforcement discretion for the category of LDTs in which we believe we currently fall. It is also possible under those circumstances that some may fall into one Class and some into the other. Accordingly, some level of premarket review—either a 510(k), PMA or *de novo* approval—would likely be required for each test. While the data requirements are typically greater for Class III devices, the data required for Class II devices has increased, and it is likely that some amount of clinical data (retrospective or prospective or both) would be required for either type of submission. FDA continues to review the adequacy of its 510(k) process. It is difficult to predict what changes may result, but it should be assumed that any changes will increase, not decrease, the regulatory requirements.

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

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



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**Table of Contents*****Federal, State and Foreign Fraud and Abuse Laws***

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

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

Finally, another development affecting the health care industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act's whistleblower or qui tam provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal governmental payor program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has defrauded the federal government by submitting a false claim to the federal government and permit such individuals to share in any amounts paid by the entity to the government in fines or settlement. In addition, various states have enacted false claim laws analogous to the federal False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a governmental payor program. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties ranging from \$5,500 to \$11,000 for each false claim.

Additionally, in Europe various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines, for individuals and/or companies committing a bribery offence. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the new Bribery Act 2010, which went into effect in July 2011, a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act 2010.

Under the new regime, an individual found in violation of the Bribery Act of 2010, faces imprisonment of up to 10 years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

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### ***Physician Referral Prohibitions***

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

### ***Corporate Practice of Medicine***

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

### ***New Jersey and New York State Laboratory Licensing***

Our laboratory is licensed and in good standing under both the New Jersey and the New York State Departments of Health standards. Our current licenses permit us to receive specimens obtained in those states.

New Jersey and New York state laws and regulations also establish standards for the day-to-day operations of clinical laboratories, including physical facility requirements and equipment and quality control. New York standards include proficiency testing requirements, even for a laboratory not located in New York. In addition, the New York Department of Health separately approves certain LDTs offered in New York State. The Company has obtained the requisite approvals for its LDTs. If we are found to be out of compliance with New Jersey or New York statutory or regulatory standards we may be subject to suspension, restriction or revocation of our laboratory license or assessed civil money penalties. A noncompliant laboratory may also be found guilty of a misdemeanor under New Jersey and New York laws. A finding of noncompliance, therefore, may result in harm to our business.

### ***Other States Laboratory Testing***

In addition to New York, several other states require the licensure of out-of-state laboratories that accept specimens from those states, even though we are physically located in New Jersey. We have obtained licenses in these states and believe we are in compliance with their applicable licensing laws.

From time to time, other states may require out of state laboratories to obtain licensure in order to accept specimens from the state. If we identify any other state with such requirements or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements.

### ***Other Regulatory Requirements***

Our laboratory is subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemical, biological agents and compounds,



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blood and bone marrow samples and other human tissue. Typically, we use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors are licensed or otherwise qualified to handle and dispose of such waste.

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

## **Segment and Geographical Information**

We operate in one reportable business segment and derive revenue from multiple countries, with 97%, 92% and 97% coming from the United States in fiscal year 2013, 2012, and 2011, respectively.

## **Employees**

As of December 31, 2013, we had a total of 61 full-time and 6 part-time employees, 43% of which hold graduate degrees including 15 doctorate degrees and 7 of which are engaged in full-time research and development activities. We plan to expand production, sales and marketing and our research and development programs, and we plan to hire additional staff as these initiatives are implemented. None of our employees are represented by a labor union, and we consider our employee relations to be good. Our work place environment was recognized by being #20 nationwide by The Scientist in Best Places to Work in Industry, 2011 .

We were incorporated in the State of Delaware on April 8, 1999 and our principal executive offices are located at 201 Route 17 North, 2<sup>nd</sup> 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). We include our website address in this annual report on Form 10-K only as an inactive textual reference and do not intend it to be an active link to our website. The information on our website is not incorporated by reference in this annual report on Form 10-K.

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

This report includes the following trademarks, service marks and trade names owned by us: MatBA<sup>®</sup>, UroGenRA FHaCT , UGenRA , FReCaD , Expand Dx , Summation , SelectID<sup>®</sup>, OncoCL Complete , Cervixcyte , Leuka , CGI CLL Complete<sup>®</sup>, and Empowering Personal Cancer Treatment<sup>®</sup>. These trademarks, service marks and trade names are the property of Cancer Genetics, Inc. and its affiliates.

## **Item 1A. Risk Factors.**

### **Risks Relating to Our Financial Condition and Capital Requirements**

*We are an early stage company with a history of net losses; we expect to incur net losses in the future, and we may never achieve sustained profitability.*

We have historically incurred substantial net losses. We incurred losses of \$12.4 million, \$6.7 million and \$19.9 million for fiscal years ended December 31, 2013, 2012 and 2011, respectively. From our inception in April 1999 through December 31, 2013, we had an accumulated deficit of \$61.3 million. We expect our losses to continue 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

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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 repay indebtedness, to fund our existing operations, to develop and commercialize new tests and technologies, and to expand our operations.***

We may need to raise additional financing to repay certain indebtedness and fund our current level of operations. We need capital to fund our capital contributions of up to \$5.0 million to our joint venture with Mayo and to satisfy indebtedness of approximately \$6.0 million due to Wells Fargo Bank. We believe that our current cash will support our operations for 24 months. We may also need to raise additional capital to fund our existing operations. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all, when needed. Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative, sales and marketing and research and development activities are forward-looking statements and involve risks and uncertainties.

Additional financing, which is not in place at this time, may be from the sale of equity or convertible or other debt securities in a public or private offering, from an additional credit facility or strategic partnership coupled with an investment in us or a combination of both. 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 entitled *Liquidity and Capital Resources* *Capital Resources and Expenditure Requirements* .

We may need to raise capital to repay indebtedness and 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 and marketing efforts of any future tests;

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;

fund our subsequent contributions of up to \$5.0 million to our joint venture with Mayo if our joint venture with Mayo achieves certain operational milestones; and

finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

our ability to achieve revenue growth;

our rate of progress in establishing reimbursement arrangements with domestic and international third-party payors;

the cost of expanding our laboratory operations and offerings, including our sales and marketing efforts;

our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of and reimbursement for our microarray tests and probes;

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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

the potential cost of and delays in test development as a result of any regulatory oversight applicable to our tests.

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. 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.

The credit markets and the financial services industry have experienced a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These events have generally made equity and debt financing more difficult to obtain. Accordingly, 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 recently begun offering our MatBA<sup>®</sup>-CLL, MatBA<sup>®</sup>-SLL, MatBA<sup>®</sup>-DLBCL, MatBA<sup>®</sup>-MCL and UroGenRA<sup>®</sup>-Kidney microarrays through our CLIA-accredited and state licensed laboratory. We also recently launched FFACT<sup>®</sup> 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. If we are unable to increase sales of our laboratory tests and services or to successfully develop and commercialize other diagnostic tests, we will not produce sufficient revenues to become profitable.

***Our business depends on our ability to successfully develop and 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 commercialize our existing diagnostic tests and services and to develop and commercialize new diagnostic tests. We have multiple tests in development, but

research, development and commercialization of diagnostic tests is time-consuming, uncertain and complex. Our current diagnostic test pipeline includes: UroGenRA microarray, UGenRA microarray, FReCaD Renal Cancer Test, FHACT HPV-associated Cancer Test and expansion of the MatB<sup>®</sup> microarray as a prognostic tool in FL. Tests such as these, 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.

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In addition, prior to commercializing our diagnostic tests, we must undertake time-consuming and costly development activities, sometimes 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 clinical validation data to support the effectiveness of the test.

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

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

As part of our business strategy, we may pursue 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 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



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developing oncology diagnostic services and tests utilizing next generation sequencing and made an initial \$1.0 million capital contribution to that joint venture in October 2013. The agreement also requires additional capital contributions by us of up to \$5.0 million over the next three years, with \$4.0 million of such amount subject to the joint venture achieving certain operational milestones. The operation of the joint venture may also divert management time from operating our business. No assurances can be given that we will be able to fully fund the joint venture agreement, or that, even if funded, the joint venture will ever achieve the research, development and commercial objectives currently contemplated by the parties, such as the discovery and commercialization of new diagnostic tests utilizing next-generation sequencing. If the development efforts of the joint venture do not result in commercially successful tests or services, it will have an adverse effect on our business, financial condition and results of operations.

***If we 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-accredited laboratory. Because we currently offer these tests and services solely for use within our laboratory, we believe we may market the tests as LDTs. 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. However, 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. FDA regulates diagnostic kits sold and distributed through interstate commerce as medical devices. 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 DNA probes or microarray 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 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 achieve 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.

***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 probes and microarrays. While we are in the process of launching several of our DNA probes outside of the United States, we have limited experience in marketing these probes and we need to develop relationships with third-party distributors in the emerging market countries where we are targeting our selling efforts.

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 publication in leading peer-reviewed journals of results from studies using our tests. The 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.

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Our ability to successfully market the diagnostic tests that we may develop will depend on numerous factors, including:

whether healthcare 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 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.

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

As of December 31, 2013, we had indebtedness for borrowed money in the aggregate principal amount of \$6.0 million due under a line of credit with Wells Fargo. Substantially all of our assets, including our intellectual property, were pledged as collateral. In March 2014, we agreed in principle to re-negotiated terms of the line of credit. We anticipate that we will enter into an extension through April 1, 2016 at a rate of interest equal to LIBOR plus 1.75%. Effective April 1, 2014, the pledge of all of our assets and intellectual property as well as the guarantee by Mr. Pappajohn will be released. Under the terms of the extension, we will be required to restrict \$6.0 million in cash as collateral. Additionally, we will be required to maintain limits on capital spending and are restricted as to the amount we may

pledge as collateral for additional borrowings from any source. 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.

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

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

***If our sole laboratory facility becomes damaged or inoperable, or we are required to vacate the 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 facility in Rutherford, New Jersey. 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 our facility 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 facility 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 our laboratory became inoperable we may not be able to license or transfer our proprietary technology to a third-party, with established state licensure and CLIA accreditation 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.

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

Our principal competition comes from the existing 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

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believe that we can introduce our diagnostic tests successfully due to their clinical utility and the desire of pathologists and oncologists to find solutions for more accurate diagnosis, prognosis and personalized treatment options for cancer patients.

We also face competition from companies that currently offer or are developing products to profile genes, gene expression or protein biomarkers in various cancers. Personalized genetic diagnostics is a new area of science, and we cannot predict what tests others will develop that may compete with or provide results superior to the results we are able to achieve with the tests we develop. Our competitors include public companies such as NeoGenomics, Inc., Quest Diagnostics, Abbott Laboratories, Inc., Johnson & Johnson, Roche Molecular Systems, Inc., bioTheranostics, Inc. (part of bioMérieux SA), Genomic Health, Inc., Myriad Genetics Inc., Response 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 2013, 2012 and 2011 accounted for 69%, 58% and 63% respectively, of our clinical testing volumes, with 36%, 46% and 29% respectively, of the volume coming from community hospitals. During the year ended December 31, 2013, there was one site which accounted for more than 10% of our revenue: a clinical trial client accounted for approximately 40% of our revenue. During the year ended

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December 31, 2012, there were three sites which each accounted for approximately 10% or more of our clinical revenue: a clinical trial client accounted for approximately 13%, a university teaching center accounting for approximately 11%, and; a community hospital



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accounted for approximately 10%. During 2011, there were two sites which accounted for more than 10% of our revenue: a community hospital accounted for approximately 18% and a community oncology practice accounted for approximately 11%. We generally do not have formal, long-term written agreements with such test ordering sites, and, as a result, we may lose these significant test ordering sites at any time.

***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, 2013, our research and development expenses were \$2.2 million, which was 33% of our net revenues, 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. For the year ended December 31, 2011, our research and development expenses were \$2.1 million, which was 69% of our revenue and our sales and marketing expenses were \$1.6 million, which was 52% 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.

***If pathologists and oncologists decide not to order our diagnostic tests, we may be unable to generate sufficient revenue to sustain our business.***

To generate demand for our molecular diagnostic tests and 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 adequate reimbursement coverage from third-party payors. We may need to hire additional commercial, scientific, technical and other personnel to support this process. If we cannot convince medical practitioners 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.

***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. In addition, as we grow, our collaborators that are research and academic institutions will begin to seek additional financial contributions from us, which may negatively affect our results of operations.

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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, 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. 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.

***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 establishing and maintaining clinician marketing and education capabilities 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 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;

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financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;

reduced protection for intellectual property rights;

natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and

failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales and distributors activities.

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

***Our dependence on distributors for foreign sales of our FISH-based DNA probes could limit or prevent us from selling our probes in foreign markets and from realizing long-term international revenue growth.***

We intend to grow our business internationally, and to do so we must enter into agreements with local distributors to sell our FISH-based DNA probes. These agreements generally contain exclusivity provisions and generally cannot be terminated without cause during the term of the agreement. We may need to attract additional distributors to expand the territories in which we sell our probes. These distributors may not commit the necessary resources to market and sell our probes to the level of our expectations, and we may be unable to locate suitable alternatives should we terminate our agreement with such distributors or if such distributors terminate their agreement with us. If current or future distributors do not perform adequately, or we are unable to locate distributors in particular geographic areas, we may not realize long-term international revenue growth.

***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 probes, particularly in India. We also utilize distributors to sell probes outside the United States. Our 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 laws;

difficulty in enforcing agreements, judgments and arbitration awards in foreign jurisdictions; and

adverse economic conditions in any jurisdiction.

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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.

***We may encounter manufacturing problems or delays that could result in lost revenue.***

We currently manufacture our proprietary DNA probes outside the United States at a third party fully compliant facility and intend to continue to manufacture our probes outside the United States. We currently have limited



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manufacturing capacity for our probes. If demand for our probes increases significantly, we will need to either expand our manufacturing capabilities or outsource to other manufacturers. If we or third party manufacturers engaged by us fail to manufacture and deliver our probes in a timely manner, our relationships with our customers could be seriously harmed. We cannot assure you that manufacturing or quality control problems will not arise as we attempt to increase the production of our probes or that we can increase our manufacturing capabilities and maintain quality control in a timely manner or at commercially reasonable costs. If we cannot manufacture our probes consistently on a timely basis because of these or other factors, it could have a significant negative impact on the supply of our DNA probes.

### ***Declining general economic or business conditions may have a negative impact on our business.***

Continuing concerns over United States health care reform legislation and energy costs, geopolitical issues, the availability and cost of credit and government stimulus programs in the United States and other countries have contributed to increased volatility and diminished expectations for the global economy. These factors, combined with low business and consumer confidence and high unemployment, precipitated an economic slowdown and recession. If the economic climate does not improve or continues to deteriorate, our business, including our access to patient samples and the addressable market for diagnostic tests that we may successfully develop, as well as the financial condition of our suppliers and our third-party payors, could be adversely affected, resulting in a negative impact on our business, financial condition and results of operations.

### ***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.

## **Regulatory Risks Relating to Our Business**

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

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

Requires each medical device manufacturer to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices, beginning in 2013. This tax may apply to some or all of our current products and products which are in development.

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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. Therefore, most of the law's provisions will go into effect in 2013 and 2014. Congress has also proposed a number of legislative initiatives, including possible repeal of the PPACA. At this time, it remains unclear whether there will be any changes made to the PPACA, whether to certain provisions or its entirety.

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 up to 2% per fiscal year, starting in 2013. 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, CMS projects laboratory services for 2013 will be reduced by approximately 3%.

Certain of our laboratory services are paid under the Medicare Physician Fee Schedule and, under the current statutory formula, the rates for these services are updated annually. For the past several years, the application of the statutory formula would have resulted in substantial payment reductions if Congress failed to intervene. In the past, Congress passed interim legislation to prevent the decreases. On November 1, 2012, the Centers for Medicare & Medicaid Services (CMS) issued the Final Rule. In the Final Rule, CMS called for a reduction of approximately 26.5% in the 2013 conversion factor that is used to calculate physician reimbursement. However, the American Taxpayer Relief Act of 2012, which was signed into law on January 2, 2013, prevents this proposed cut and keeps the current reimbursement rate in effect until December 31, 2013. If Congress fails to act in future years to offset similar proposed reductions, the resulting decrease in payment could adversely impact our revenues and results of operations.

In addition, many of the Current Procedure Terminology (CPT) procedure codes that we use to bill our tests were recently revised by the AMA, effective January 1, 2013. In the Final Rule, 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 Physician Fee Schedule as some stakeholders had urged. CMS has also announced that for 2013 it will 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. In addition, it has also stated that it will not recognize certain of the new codes for Multi-analyte Assays for Algorithmic Assays (MAAAs) because it does not believe they

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qualify as clinical laboratory tests. Our reimbursement could be adversely affected by CMS action in this area. If it reduces reimbursement for the new test codes or does not pay for our new MAAA codes, then our revenues will be adversely affected. There can be no guarantees that Medicare and other payers 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.

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

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

not experimental or investigational;

medically necessary;

appropriate for the specific patient;

cost-effective;

supported by peer-reviewed publications; and

included in clinical practice guidelines.

Uncertainty surrounds third-party payor reimbursement of any test incorporating new technology, including tests developed using our DNA probes and microarrays. 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. No technology assessments have been performed on our tests to date.

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 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.

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***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, 2013, we derived approximately 21% of our total revenue from private insurance, including managed care organizations and other health care insurance providers, 13% from government payor programs, most of which was derived from Medicare and 58% from direct-bill customers, including hospitals and other laboratories. Medicare and other third-party payors may withdraw their coverage policies or cancel their contracts with us at any time, review and adjust the rate of reimbursement or stop paying for our tests altogether, which would reduce our total revenues.

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

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

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

Under current Medicare billing rules, claims for our tests performed on Medicare beneficiaries who were hospital inpatients when the tumor tissue samples were obtained and whose tests were ordered less than 14 days from discharge must be incorporated in the payment that the hospital receives for the inpatient services provided. Accordingly, we must bill individual hospitals for tests performed on Medicare beneficiaries during these timeframes in order to receive payment for our tests. Because we generally do not have a written agreement in place with these hospitals that purchase these tests, we may not be paid for our tests or may have to pursue payment from the hospital on a case-by-case basis. In addition, currently we are permitted to bill globally for certain anatomic pathology services we furnish to grandfathered hospitals, i.e. we bill 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 extended the special provision for grandfathered hospitals through July 1, 2012. Therefore, as of that date we were required to bill the grandfathered 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 California and surrounding areas, 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. 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.



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***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 accredited 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 of accreditation under CLIA to perform high complexity testing and our laboratory is accredited by the College of American Pathologists ( CAP ), one of six CLIA-approved accreditation organizations. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make periodic inspections of our clinical reference laboratory outside of the renewal process.

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

If we were to lose our CLIA 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 DNA probe and microarray 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 regulation but 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

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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. FDA has stated it is continuing to develop draft guidance in this area. Section 1143 of the Food and Drug Administration Safety and Innovation Act, signed by the U.S. President on July 9, 2012, requires 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.

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 to market or approval 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 pre-market approval 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 pre-market clinical testing prior to submitting a regulatory notification or

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

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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 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 pre-market 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 and delay commercialization. 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 healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.***

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

the federal Anti-kickback Statute, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, in return for or to induce either the referral of an individual for, or the purchase order or recommendation of, any item or services for which payment may be made under a federal health care program such as the Medicare and Medicaid programs;

the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of designated health services with whom the physician or a member of the physician's immediate family has an ownership interest or

compensation arrangement, unless a statutory or regulatory exception applies;

the federal Health Insurance Portability and Accountability Act of 1996 ( HIPAA ), which established federal crimes for knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services;

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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 which may apply to entities like us to the extent that our interactions with customers may affect their billing or coding practices; 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.

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

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

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

The privacy regulations cover the use and disclosure of Protected Health Information by health care providers. It also sets forth certain rights that an individual has with respect to his or her Protected Health Information maintained by a health care provider, including the right to access or amend certain records containing Protected Health Information or to request restrictions on the use or disclosure of Protected Health Information. We have also implemented policies, procedures and standards 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.



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Moreover, the Health Information Technology for Economic and Clinical Health Act ( HITECH ), among other things, established certain health information security breach notification requirements. A covered entity must notify any individual whose protected health information is breached.

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 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.

### **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.

***We may not be able to sell our probes or any other tests that we may develop using blocking DNA in the United States until patents held by third parties expire.***

Vysis, a division of Abbott Laboratories, Inc., possesses an exclusive license from the University of California for a family of patents in the United States ( Abbott patents ) directed broadly to the usage of blocking DNA. The Abbott patents may present a barrier to our penetrating the United States market with certain of our probe-related tests because our probes are configured to use blocking DNA. However, it is unclear whether these patents directly cover our probe-related tests. Therefore, the Abbott patents could pose a significant deterrent in marketing or selling certain of our products in the U.S. The Abbott patents are due to expire on or about 2017. Our current business plan does not involve developing U.S.-based sales for our DNA probe products; rather, we are currently focused entirely on growing

our DNA probe business in higher growth emerging markets and select European markets.

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***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.

***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.

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Most recently, on March 20, 2012, in the case *Mayo v. Prometheus*, the U.S. Supreme Court reversed the Federal Circuit's application of *Bilski* and invalidated a patent focused on a diagnostic process because the patent claim embodied a law of nature. On July 3, 2012, the USPTO issued its Interim Guidelines for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature in view of the *Prometheus* decision. It remains to be seen how these guidelines play out in the actual prosecution of diagnostic claims. Similarly, it remains to be seen lower courts will interpret the *Prometheus* decision. Some aspects of our technology involve processes that may be subject to this evolving standard, and we cannot guarantee that any of our pending process claims will be patentable as a result of such evolving standards.

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

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

In addition, on February 5, 2010, the Secretary's Advisory Committee on Genetics, Health and Society voted to approve a report entitled *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*. That report defines patent claims on genes broadly to include claims to isolated nucleic acid molecules as well as methods of detecting particular sequences or mutations. The report also contains six recommendations, including the creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale or selling a test developed under the patent for patient care purposes, or for anyone using the patent-protected genes in the pursuit of research. The report also recommended that the Secretary should explore, identify and implement mechanisms that will encourage more voluntary adherence to current guidelines that promote nonexclusive in-licensing of diagnostic genetic and genomic technologies. It is unclear whether the U.S. Department of Health and Human Services will act upon these recommendations, or if the recommendations would result in a change in law or process that could negatively impact our patent portfolio or future research and development efforts.

***We may face intellectual property infringement claims that 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.



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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.

Finally, 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.

## **Risks Relating to Our Common Stock**

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

We only recently received approval to list our common stock on The NASDAQ Capital Market. Prior to August 2013, 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.

### ***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;

termination of the lock-up agreements or other restrictions on the ability of persons who held our stock prior to our initial public offering to sell shares;

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 entitled **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 December 31, 2013, we had outstanding options to purchase an aggregate of 873,542 shares of our common stock at a weighted average exercise price of \$10.83 per share and warrants to purchase an aggregate of 1,797,114 shares of our common stock at a weighted average exercise price of \$12.26 per share. The exercise of such outstanding options and warrants will result in dilution of the value of our shares. In addition, shareholders may experience dilution if we issue common stock in the future.

***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, beneficially own approximately 30.0% of our outstanding common stock-based on the number of shares outstanding on December 31, 2013. 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.

***If we are unable to favorably assess the effectiveness of our internal control over financial reporting, or if our independent registered public accounting firm is not able to provide an unqualified attestation report on the effectiveness of our internal controls over financial reporting, investors may lose confidence in our financial reporting and our stock price could be materially adversely affected.***

As a private company, we were not subject to the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. As a result of the completion of our initial public offering in April 2013, we are now required to document

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and test our internal control over financial reporting. For the year ended December 31, 2011, our independent registered public accounting firm reported a material weakness in our internal control over financial reporting related to our monitoring of the performance of the third-party service providers we use in our revenue cycle. During 2011, we changed third-party service providers to improve our platform for future growth. After the conversion, we identified instances of delayed billings and collection efforts and procedural issues with the timely application of cash receipts. If we fail to remediate the material weaknesses identified or to remediate any significant deficiencies or material weaknesses that may be identified in the future, we may be unable to conclude that our internal control over financial reporting is effective and our independent registered public accounting firm may not be able to provide an attestation reporting on the effectiveness of our internal control over financial reporting to the extent such an attestation report would be required. On April 5, 2012, President Obama signed the JOBS Act. Under the JOBS Act, issuers that qualify as emerging growth companies under the JOBS Act will not be required to provide an auditor's attestation report on internal controls for so long as the issuer qualifies as an emerging growth company. We currently qualify as an emerging growth company under the JOBS Act and we will not provide an auditor's attestation report on internal controls. However, if we cannot favorably assess the effectiveness of our internal control over financial reporting, or if we require an attestation report from our independent registered public accounting firm and that firm is unable to provide an unqualified attestation report on the effectiveness of our internal controls over financial reporting, investor confidence and, in turn, our stock price could be materially adversely affected. For a discussion on our remediation of our material weaknesses please see Management's Discussion and Analysis-Internal Control over Financial Reporting.

***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 may choose 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 above, 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 could be an emerging growth company for up to five years, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed \$1 billion, (ii) the date that we become a large accelerated filer as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than \$1 billion in non-convertible debt during the preceding three year period. 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 will incur 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 will incur significant legal, accounting and other expenses that we did not incur as a private company. For example, in

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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.

However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies 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. We may choose to take advantage of these reporting exemptions until we no longer qualify as an emerging growth company.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to take advantage of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

After we are no longer an emerging growth company, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and the other rules and regulations of the SEC. We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs. We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

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

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

allow the authorized number of directors to be changed only by resolution of our board of directors;

authorize our board of directors to issue, without stockholder approval, preferred stock, the rights of which will be determined at the discretion of the board of directors and that, if issued, could operate as a poison pill to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our board of directors does not approve;

establish advance notice requirements for stockholder nominations to our board of directors or for stockholder proposals that can be acted on at stockholder meetings; and

limit who may call a stockholder meeting.

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

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

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

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

Our ability to utilize our federal net operating loss, carryforwards and federal tax credits are limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. The limitations apply since we have experienced an ownership change, as defined by Section 382, as a result of the Company's securities offerings. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect five percent shareholders changes by more than 50 percentage points over their lowest ownership percentage at any time during the applicable testing period (typically three years). Since we have experienced an ownership change, our NOL carryforwards and federal tax credits are subject to limitations as to our ability to utilize them to offset taxable income and related income taxes. In addition, future changes in our stock ownership, which may be outside of our control, may trigger further ownership changes which would further limit their utilization. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset United States federal taxable income and related income taxes are subject to limitations, which could potentially result in increased future tax liability to us.

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

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

## **Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

As of December 31, 2013, we had a lease for approximately 17,936 square feet of space in Rutherford, New Jersey for use as a clinical reference laboratory and corporate headquarters. This lease expires in February 2018. Based on our current operational plans, we believe that such facilities are adequate for our operations for the near future.



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**Item 3. Legal Proceedings**

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

**Item 4. Mine Safety Disclosures**

Not applicable.

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

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. The following table sets forth, for the periods indicated, the reported high and low closing 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.

|                  | <b>Fiscal Year 2013</b> |            |
|------------------|-------------------------|------------|
|                  | <b>High</b>             | <b>Low</b> |
| Second Quarter   | \$ 11.75                | \$ 8.50    |
| Third Quarter(1) | \$ 11.57                | \$ 10.10   |
| Third Quarter(2) | \$ 23.25                | \$ 8.58    |
| Fourth Quarter   | \$ 19.94                | \$ 11.13   |

(1) From July 1, 2013 through August 13, 2013.

(2) From August 14, 2013 through September 30, 2013.

**Holder**s

As of March 3, 2014, we had approximately 52 holders of our common stock. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies. The transfer agent of our common stock is Continental Stock Transfer & Trust, 17 Battery Place, 8<sup>th</sup> Floor, New York, New York, 10004.

**Dividends**

We have never declared dividends on our equity securities, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. Subject to the foregoing, the payment of cash dividends in the future, if any, will be at the discretion of our board of directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our board of directors.

**Table of Contents****Equity Compensation Plan Information**

The following table provides information as of December 31, 2013 regarding shares of our common stock that may be issued under our existing equity compensation plans, including our 2008 Stock Option Plan (the 2008 Plan ) and our 2011 Equity Incentive Plan (the 2011 Plan ) as well as shares issued outside of these plans.

|   | <b>Equity Compensation Plan Information</b>   |  |  |
|---|---|--|--|
|   | (a)<br>Number of securities<br>to be issued upon exercise<br>of<br>outstanding<br>options<br>and<br>rights(1) | (b)<br>Weighted Average<br>exercise<br>price of<br>outstanding options<br>and rights | (c)<br>Number of securities<br>remaining available for<br>future issuance under equity<br>compensation<br>plan<br>(excluding<br>securities<br>referenced in<br>column (a)) |
| Equity compensation plans approved by security holders(2)     | 825,542   | \$ 10.88   | 28,594(3)  |
| Equity compensation plans not approved by security holders(4) | 48,000  | \$ 10.00   | 0  |

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

**Item 6. Selected Financial Data.**

Not applicable.

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

As used herein, the Company, we, us, our or similar terms, refer to Cancer Genetics, Inc. and its wholly owned subsidiary, Cancer Genetics Italia, S.r.l. except as expressly indicated or unless the context otherwise requires. The following Management's Discussion and Analysis of Financial Condition and Results of Operations ( MD&A ) is intended to help facilitate an understanding of our financial condition and our historical results of operations for the periods presented. This MD&A should be read in conjunction with the accompanying audited consolidated financial statements and notes thereto included elsewhere in this annual report on Form 10-K. This MD&A may contain forward-looking statements that involve risks and uncertainties. See Forward-Looking Statements below.

## Overview

We are 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 complicated to prognose and for which it is difficult to predict treatment outcomes 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, reference laboratories and physician offices, as well as to biopharmaceutical companies and clinical research organizations for their clinical trials. To date, we have engaged in only limited sales and marketing activities and have generated most of our revenue through sales of our non-proprietary testing services to a limited number of oncologists, pathologists, community hospitals and biotechnology and pharmaceutical companies located mostly in the eastern and midwestern United States. Our non-proprietary laboratory testing services include molecular testing, sequencing, mutational analysis, flow

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cytometry testing, histology testing and cytology testing. We are currently offering our tests and laboratory services in 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 one of nine approved accreditation methods under the Clinical Laboratory Improvement Amendments of 1988 ( CLIA ), to perform high complexity testing.

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. We have commercially launched MatBA<sup>®</sup>-CLL, our first proprietary microarray test for chronic lymphocytic leukemia ( CLL ) for use in our CLIA-accredited clinical laboratory. In January 2012, we received CLIA approval for MatBA<sup>®</sup>-SLL, our proprietary microarray for risk stratification in small lymphocytic lymphoma ( SLL ), and we are currently offering MatBA<sup>®</sup>-SLL in our laboratory. In February 2013, we received CLIA approval for MatBA<sup>®</sup>-DLBCL, our proprietary microarray for diagnosis, prognosis and patient monitoring in diffuse large B cell lymphoma ( DLBCL ). In May 2013, we commercially launched UroGenRA<sup>™</sup>, our proprietary microarray for the diagnosis and prognosis of patients with kidney cancer for use in our CLIA-accredited clinical laboratory. We have also launched FHACT for cervical cancer outside the United States. In addition, we are developing a series of other proprietary genomic tests in our core oncology markets. Due to the recent introduction of these proprietary tests, the small numbers involved in our revenues, and the variability expected with the adoption of any new tests, no assurance or prediction can be given with respect to the level of revenues from our proprietary tests in the future.

The non-proprietary testing services we offer are entirely focused 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<sup>®</sup>) for clinical use.

We expect to continue to incur significant losses for the near future. We incurred losses of \$12.4 million and \$6.7 million for fiscal years ended December 31, 2013 and 2012, respectively. As of December 31, 2013, we had an accumulated deficit of \$61.3 million. Changes in fair value of some of our common stock warrants have significantly impacted our results in recent periods. In particular, changes in the fair value of some of our common stock warrants accounted for a large portion of our loss in 2011, whereas in 2012 and 2013 we recognized non-cash income as a result of the change in fair value of such warrants. Accounting rules require us to record certain of our warrants as a liability, measure the fair value of these warrants each quarter and record changes in that value in earnings. Consequently, we may be exposed to non-cash charges, or we may record non-cash income, as a result of this warrant exposure in future periods. During 2012 we borrowed additional funds and restructured certain of our outstanding debt obligations, and issued additional warrants to our debt holders. As a result of these borrowings and restructurings, we incurred a significant one-time, non-cash debt and warrant restructuring charge and increased interest expense in 2012 and may incur additional non-cash income or expense related to our outstanding warrants in future periods.

For the year ended December 31, 2013, the change in the fair value of our warrant liability resulted in \$4.6 million in non-cash income. The fair market value of certain of our outstanding common stock warrants that we are required to account for as liabilities decreased during the year ended December 31, 2013. The decrease principally resulted from a shareholder, Mr. John Pappajohn, limiting certain anti-dilution rights in his warrants to purchase shares of the Company's common stock resulting in a lower fair value of the warrant liability and non-cash income during this period.

**Key Factors Affecting our Results of Operations and Financial Condition**

Our overall long-term growth plan is predicated on our ability to develop and commercialize our proprietary tests outside of our clinical laboratory and to increase comprehensive oncology testing volumes in our laboratory. We

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launched MatBA<sup>®</sup>-CLL in the first quarter 2011 for use in our clinical laboratory, we received CLIA approval for MatBA<sup>®</sup>-SLL in January 2012, we received CLIA approval for MatBA<sup>®</sup>-DLBCL in February 2013, we commercially launched UroGenRA<sup>™</sup> in May 2013 for use in our clinical laboratory and we are developing additional proprietary tests. In order to market our tests to independent laboratories and testing facilities, we believe we will need to obtain approvals or clearances from the appropriate regulatory authorities. Without these approvals, the success of these commercialization efforts will be limited. To obtain these approvals and facilitate market adoption of our proprietary tests, we anticipate having to successfully complete additional studies with clinical samples and publish our results in peer-reviewed scientific journals. Our ability to complete such studies is dependent upon our ability to leverage our collaborative relationships with leading institutions to facilitate our research and obtain data for our quality assurance and test validation efforts.

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

***Revenues***

Our revenue in 2013 was generated principally through our clinical laboratory services, with approximately 3% of our revenue from sales of our DNA probes, which are only sold outside the United States and approximately 5% of our revenue from government research grants such as the National Cancer Institute. The clinical laboratory industry is highly competitive, and our relationship with the decision-makers at hospitals, cancer centers, physician offices, or pharmaceutical companies is a critical component of securing their business. Consequently, our ability to attract and maintain productive sales personnel that have and can grow these relationships will largely determine our ability to grow our clinical services revenue. In order to grow our clinical laboratory revenue, we must continue to pursue validation studies and work with oncology thought leaders to develop data that is helpful in supporting the need for our tests and services.

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 have changed 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. During the year ended December 31, 2013, there was one site which accounted for more than 10% of our revenue: a clinical trial client accounted for approximately 40% of our revenue. The loss of our largest customer would materially adversely affect our results of operations, however the loss of any other test ordering site would not materially adversely affect our results of operations. During the year ended December 31, 2012, there were three sites which each accounted for approximately 10% or more of our clinical revenue: a clinical trial client accounted for approximately 13%, a university teaching center accounting for approximately 11%, and; a community hospital accounted for approximately 10%. The top five test ordering sites during the years ended December 31, 2013 and 2012 accounted for 69% and 58%, respectively, of our clinical testing volumes, with 36% and 46%, respectively, of the volume coming from community hospitals.

We receive revenue for our clinical laboratory services from private insurance carriers and other non-Medicare payors (such as unions and self-insured plans), Medicare, direct bill customers, and grants. Direct bill customers are institutions that choose, generally at the beginning of our relationship, to pay for our laboratory services directly as opposed to having patients (or their insurers) pay for those services and providing us with the patients' insurance information. For instance, bio-pharmaceutical companies generally are direct bill customers. A hospital may elect to be a direct bill customer, and pay our bills directly, or may provide us with patient information so that their patients

pay our bills, in which case we generally look to payment from their private insurance carrier or Medicare. In a few instances, we have arrangements where a hospital may have two accounts with us, so that certain tests are direct billed to the hospital, and certain tests are billed to and paid by a patient s



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insurer. The billing arrangements generally are dictated by our customers and in accordance with state and federal law. For the year ended December 31, 2013, private insurance accounted for approximately 21% of our total revenue, Medicare accounted for approximately 13% of our total revenue, direct bill clients accounted for 58% of our total revenue and the balance of our revenue was attributable to grants and sales of our DNA probes. As we expand our portfolio of tests and services, our sales activities and our ExpandDX program, we expect the percentage of revenue from direct-bill customers may decrease over the long term. However, during 2012 we started working with a community hospital that preferred the direct bill model and a new direct bill clinical trial services customer, which resulted in a significant increase in direct bill customers as a percentage of revenue for 2012 and 2013. It is too early in our development to predict whether our experience during 2012 and 2013 indicates a reversal in the trend we had seen in prior years or simply a variation as we attempt to expand our business and introduce new community hospitals, regional laboratories or clinical trial services customers in a particular period. On average, we generate less revenue per test from direct-bill customers than from other third-party payors but we also have reduced sales cost associated with direct bill clients and significantly reduced collections risk from direct-bill customers and have not experienced any significant collection issues or expenses as a result. Typically, we negotiate discounts in the range of 5% to 20% with direct bill clients depending on the volume of business in a twelve month period.

***Cost of Revenues***

Our cost of revenues consists principally of internal personnel costs, including stock-based compensation, laboratory consumables, shipping costs, overhead and other direct expenses, such as specimen procurement and third party validation studies. We are pursuing various strategies to reduce and control our cost of revenues, including automating our processes through more efficient technology and attempting to negotiate improved terms with our suppliers. We have successfully migrated key components of our probe manufacturing to India in 2013, which reduced the labor costs involved and increased manufacturing yield and flexibility. We will continue to assess how geographic advantage with help us improve our cost structure.

***Operating Expenses***

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

*Research and Development Expenses.* We incur research and development expenses principally in connection with our efforts to develop our proprietary tests. Our primary research and development expenses consist of direct personnel costs, laboratory equipment and consumables and overhead expenses. We anticipate that research and development expenses will increase in the near-term, principally as a result of hiring additional personnel to develop and validate tests in our pipeline and to perform work associated with our research collaborations. In addition, we expect that our costs related to collaborations with research and academic institutions will increase. For example, we recently entered into a joint venture with the Mayo Foundation for Medical Education and Research. All research and development expenses are charged to operations in the periods they are incurred.

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

*General and Administrative Expenses.* General and administrative expenses consist principally of personnel-related expenses, professional fees, such as legal, accounting and business consultants, occupancy costs, bad debt

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and other general expenses. We have incurred increases in our general and administrative expenses and anticipate further increases as we expand our business operations. We further expect that general and administrative expenses will increase significantly due to increased information technology ( IT ), legal, insurance, accounting and financial reporting expenses associated with being a public company.

**Seasonality**

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

**Results of Operations****Year Ended December 31, 2013 and 2012**

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

|   | Year Ended December 31, |                | Change         |             |
|---|-------------------------|----------------|----------------|-------------|
|   | 2013                    | 2012           | \$             | %           |
| <i>(dollars in thousands)</i>             |                         |                |                |             |
| Revenue                                   | 6,610                   | 4,302          | 2,308          | 54%         |
| Cost of revenues                          | 4,925                   | 3,929          | 996            | 25%         |
| Research and development expenses         | 2,190                   | 2,112          | 78             | 4%          |
| Sales and marketing expenses              | 1,842                   | 1,399          | 443            | 32%         |
| General and administrative expenses       | 6,115                   | 4,503          | 1,612          | 36%         |
| <b>Total Operating Loss</b>               | <b>(8,462)</b>          | <b>(7,641)</b> | <b>(821)</b>   | <b>-11%</b> |
| Interest income (expense)                 | (2,358)                 | (4,701)        | 2,343          | 50%         |
| Change in fair value of warrant liability | 4,633                   | 7,538          | (2,905)        | -39%        |
| Debt conversion costs                     | (6,850)                 |                | (6,850)        | n/a         |
| Loss on debt and warrant restructuring    |                         | (1,862)        | 1,862          | n/a         |
| <b>Loss before income taxes</b>           | <b>(13,037)</b>         | <b>(6,666)</b> | <b>(6,371)</b> | <b>-96%</b> |
| Income tax benefit (expense)              | 664                     |                | 664            | n/a         |
| <b>Net Loss</b>                           | <b>(12,373)</b>         | <b>(6,666)</b> | <b>(5,707)</b> | <b>-86%</b> |

**Revenue**

Revenue increased 54%, or \$2.3 million, to \$6.6 million for the year ended December 31, 2013, from \$4.3 million for the year ended December 31, 2012, due to increases in test volume. Our average revenue (excluding grant revenue and probe revenue) per test increased to \$566 per test for the year ended December 31, 2013 from \$553 per test for the year ended December 31, 2012 principally due to an increase in the average revenue per test for clinical trial services offset by a decrease in the average revenue per test from private insurance carriers and other non-Medicare payors. Our test volume increased by 63% to 10,771 for the year ended December 31, 2013, from 6,610 for the year ended December 31, 2012 principally due to an increase in tests performed for a significant clinical trials client. Grant

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revenue decreased \$260,000 to \$297,000 from \$557,000 for the year ended December 31, 2013 from the year ended December 31, 2012 principally due to achieving the scheduled milestones for grant drawdowns.

Revenue from direct bill customers increased 141%, or \$2.2 million, to \$3.8 million for the year ended December 31, 2013, from \$1.6 million for the year ended December 31, 2012, principally due to an increase in revenue from a significant clinical trials client. Revenue from direct bill customers as a percentage of total revenue increased to 58% for the year ended December 31, 2013, from 37% for the year ended December 31, 2012. Revenue from private insurance carriers and other non-Medicare payors increased 9%, or \$118,000, to

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\$1.4 million for the year ended December 31, 2013, from \$1.3 million for the year ended December 31, 2012, principally due to a decrease in revenue per test offset by an increase in testing volume. Revenue from private insurance carriers and other non-Medicare payors as a percentage of total revenue decreased to 21% of total revenue for the year ended December 31, 2013, from 30% of total revenue for the year ended December 31, 2012. Revenue from Medicare increased 11%, or \$81,000, to \$834,000 for the year ended December 31, 2013, from \$753,000 for the year ended December 31, 2012, principally due to a higher number of Medicare reimbursed tests. Revenue from Medicare as a percentage of total revenue decreased to 13% for the year ended December 31, 2013, from 18% for the year ended December 31, 2012. Revenue from DNA probe sales by CGI Italia increased 133%, or \$121,000, to \$212,000 for the year ended December 31, 2013, from \$91,000 for the year ended December 31, 2012, principally due to an increase in sales volume.

***Cost of Revenues***

Cost of revenues increased 25%, or \$996,000, to \$4.9 million for the year ended December 31, 2013, from \$3.9 million for the year ended December 31, 2012, principally due to an increase in employee compensation-related expenses of \$650,000 resulting from a net increase in headcount and an increase in supply costs of \$244,000 as a result in increased testing volumes. However, due to scaling efficiencies associated with performing a large number of tests for a clinical trials client, costs did not increase proportionately relative to the increase in revenues.

***Operating Expenses***

*Research and Development Expenses.* Research and development expenses increased 4%, or \$78,000, to \$2.2 million for the year ended December 31, 2013, from \$2.1 million for the year ended December 31, 2012, principally as a result of an increase in supplies expense of \$237,000, and an increase in non-employee stock-based compensation related expenses of \$72,000, which were offset by a decrease of \$230,000 in employee compensation related expenses as a result of a reduction in stock-based compensation.

*Sales and Marketing Expenses.* Sales and marketing expenses increased 32%, or \$443,000, to \$1.8 million for the year ended December 31, 2013, from \$1.4 million for the year ended December 31, 2012, principally due to an increase in headcount and compensation-related costs.

*General and Administrative Expenses.* General and administrative expenses increased 36%, or \$1.6 million to \$6.1 million for the year ended December 31, 2013, from \$4.5 million for the year ended December 31, 2012, principally due to the write-off of \$618,000 of deferred IPO costs and an increase of \$568,000 in compensation and headcount-related expenses (including IPO bonuses paid in 2013 and stock-based compensation), an increase of \$216,000 in insurance costs coincident with the additional risk of a public company, and an increase of \$556,000 of professional and consulting fees as a result of being a public company. These increases were partially offset by a decrease of \$350,000 related to the cost of a legal settlement in 2012.

***Interest Income and Expense***

Interest expense decreased 50%, or \$2.3 million, to \$2.4 million for the year ended December 31, 2013, from \$4.7 million for the year ended December 31, 2012. The decrease is attributable to the conversion of \$9.6 million of debt into common stock which occurred concurrently with the closing of our IPO on April 10, 2013 and the repayment of \$3.5 million in indebtedness in August 2013.

***Debt Conversion Costs***

On April 10, 2013, we completed our IPO. In connection with the IPO, \$9.6 million of debt was converted into common stock at the IPO price of \$10.00 per share. In connection with the conversion of debt into common stock, we expensed the applicable remaining debt discounts of \$3.5 million, financing fees of \$419,000 and a contingently recognizable beneficial conversion feature in the converted debt of \$3.0 million, the total of which resulted in a \$6.9 million write-off.

**Table of Contents*****Change in Fair Value of Warrant Liability***

The change in the fair value of our warrant liability resulted in \$4.6 million in non-cash income for the year ended December 31, 2013, as compared to non-cash income of \$7.5 million for the year ended December 31, 2012. The fair market value of certain of our outstanding common stock warrants, that we are required to account for as liabilities, decreased during the year ended December 31, 2013, and principally resulted from a shareholder, Mr. John Pappajohn, limiting certain anti-dilution rights in his warrants to purchase shares of the Company's common stock, resulting in a lower fair value of the warrant liability and non-cash income during this period. Concurrent with the IPO on April 10, 2013, derivative warrants with a fair value of \$7.2 million were reclassified into equity due to the lapsing of anti-dilution provisions in the warrants. Since the re-classification, future changes in the value of these specific warrants are no longer required to be recorded in our financial statements although there are 95,130 warrants that are still subject to future revaluation.

During the year ended December 31, 2012, the fair market value of these common stock warrants decreased as a consequence of a decrease in our stock price and resulted in \$7.5 million of non-cash income during this period.

***Income Taxes***

During the year ended December 31, 2013, we received \$664,000 in cash for the sale of certain State of New Jersey NOL carryforwards.

***Year Ended December 31, 2012 and 2011***

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

|   | <b>Year Ended December 31,</b> |                 | <b>Change</b> |            |
|---|--------------------------------|-----------------|---------------|------------|
|   | <b>2012</b>                    | <b>2011</b>     | <b>\$</b>     | <b>%</b>   |
| <i>(dollars in thousands)</i>             |                                |                 |               |            |
| Revenue                                   | 4,302                          | 3,019           | 1,283         | 42%        |
| Cost of revenues                          | 3,929                          | 3,117           | 812           | 26%        |
| Research and development expenses         | 2,112                          | 2,074           | 38            | 2%         |
| General and administrative expenses       | 4,503                          | 4,439           | 64            | 1%         |
| Sales and marketing expenses              | 1,399                          | 1,574           | (175)         | -11%       |
| <b>Total Operating Loss</b>               | <b>(7,641)</b>                 | <b>(8,185)</b>  | <b>544</b>    | <b>7%</b>  |
| Interest income (expense)                 | (4,701)                        | (1,314)         | (3,387)       | 258%       |
| Change in fair value of warrant liability | 7,538                          | (10,388)        | 17,926        | 173%       |
| Loss on debt and warrant restructuring    | (1,862)                        |                 | (1,862)       |            |
| <b>Net Loss</b>                           | <b>(6,666)</b>                 | <b>(19,887)</b> | <b>13,221</b> | <b>66%</b> |

***Revenue***

Revenue increased 42%, or \$1.3 million, to \$4.3 million for the year ended December 31, 2012, from \$3.0 million for the year ended December 31, 2011, principally due to an increase in test volume partially offset by decreased revenue per test due to a heavier concentration of direct bill clients in the payor mix. Our average revenue (excluding grant

revenue and probe revenue) per test decreased by 22% to \$553 per test for the year ended December 31, 2012, from \$713 per test for the year ended December 31, 2011, principally due to an increase in test volume related to direct bill clients, which have a lower revenue per test on average. Our test volume increased by 83% to 6,610 for the year ended December 31, 2012 from 3,622 for the year ended December 31, 2011. Grant revenue increased 77%, or \$242,000 to \$557,000 for the year ended December 31, 2012, from \$315,000 for the year ended December 31, 2011 principally due to achieving the scheduled milestones for grant drawdowns. Revenue from grants, as a percentage of revenue, increased to 13% for the year ended December 31, 2012, from 10% for the year ended December 31, 2011. MatBA<sup>®</sup> revenue for the year



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ended December 31, 2012 was \$178,000 or 4% of revenue, compared to 1% for the year ended December 31, 2011. However, due to the recent introduction of this test, the small numbers involved in our revenues, and the variability expected with the adoption of any new tests, no assurance or prediction can be given with respect to the level of revenues from our proprietary tests in the future.

Revenue from direct bill customers increased 355%, or \$1.2 million, to \$1.6 million for the year ended December 31, 2012, from \$350,000 for the year ended December 31, 2011, principally due to the introduction of our clinical trial services, which, to date, generally have been sold on a direct bill model and the addition of a large community hospital customer that preferred the direct bill model during this period. Revenue from direct bill customers as a percentage of total revenue increased to 37% for the year ended December 31, 2012, from 12% for the year ended December 31, 2011. Revenue from private insurance carriers and other non-Medicare payors, decreased 15%, or \$239,000, to \$1.4 million for the year ended December 31, 2012, from \$1.6 million for the year ended December 31, 2011. Revenue from private insurance carriers and other non-Medicare payors as a percentage of total revenue decreased to 30% of total revenue for the year ended December 31, 2012, from 54% of total revenue for the year ended December 31, 2011. Revenue from Medicare increased 5%, or \$35,000, to \$753,000 for the year ended December 31, 2012, from \$718,000 for the year ended December 31, 2011. Revenue from Medicare as a percentage of total revenue decreased to 18% for the year ended December 31, 2012, from 24% for the year ended December 31, 2011. The changes in revenue from private insurance carriers, other non-Medicare payors and Medicare, were primarily due to a change in test mix. In 2012, we have experienced a significant increase in direct bill customers as described above, principally as a result of the recent introduction of our clinical trial services and our focus on selling directly to community hospitals and cancer centers. Due to the small numbers involved in our revenues to date and the variables expected with the adoption of any new service offering, it is difficult to predict whether this shift toward direct bill will continue on the same trajectory in our business, and no assurance can be given with respect to the level of revenues from our clinical trial services in the future, nor whether others such as community hospitals will continue the short term shift we saw last year towards the direct bill model. It is also difficult to predict at this early stage whether the lower revenues per test that we currently experience on average with direct bill customers will continue to be the case as we expand our services and as we mature the relationships with our direct bill customers. We note however that on our limited experience to date we have found there to be lower costs of billing, sales commissions and collections associated with direct bill customers, so that if the shift to direct bill does become a long term trend, we do not believe it will have a material negative effect on our net sales or income from continuing operations.

***Cost of Revenues***

Cost of revenues increased 26%, or \$812,000 to \$3.9 million for the year ended December 31, 2012, from \$3.1 million for the year ended December 31, 2011, principally due to clinical supply costs related to higher test volumes.

***Operating Expenses***

***Research and Development Expenses.*** Research and development expenses increased 2%, or \$38,000 to \$2.1 million for the year ended December 31, 2012, from \$2.1 million for the year ended December 31, 2011, principally as a result of increased supply expenses related to our microarray and DNA probe pipeline.

***Sales and Marketing Expenses.*** Sales and marketing expenses decreased 11%, or \$175,000 to \$1.4 million for the year ended December 31, 2012, from \$1.6 million for the year ended December 31, 2011, principally due to employee turnover.

***General and Administrative Expenses.*** General and administrative expenses increased 1%, or \$64,000 to \$4.5 million for the year ended December 31, 2012, from \$4.4 million for the year ended December 31, 2011. The net increase

principally resulted from \$350,000 in costs related to the settlement agreement with our former general counsel and a \$50,000 increase in penalties under a registration rights agreement, both of which were offset by a \$87,000 decrease in relocation expenses and a \$379,000 decrease in bad debt expense due to billing and collection problems in 2011 which did not recur in 2012.

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### ***Interest Income and Expense***

Interest expense increased 258%, or \$3.4 million to \$4.7 million, of which approximately \$1.1 million was cash interest payments for the year ended December 31, 2012, from \$1.3 million, of which approximately \$254,000 was cash interest payments, for the year ended December 31, 2011, principally due to a \$3.0 million new loan received at the end of March 2011, \$3.0 million in new loans received in December 2011, \$3.0 million in new loans received in February 2012, \$2.1 million in new loans received during the quarter ended September 30, 2012, and \$2.0 million in new loans received during the quarter ended December 31, 2012.

### ***Change in Fair Value of Warrant Liability***

The effect of the change in the fair value of our warrant liability caused a \$17.9 million variance in a comparison of our results. We recorded income of \$7.5 million for the year ended December 31, 2012 as compared to an expense of \$10.4 million for the year ended December 31, 2011. The fair market value of certain of our outstanding common stock warrants that we are required to account for as liabilities decreased in the year ended December 31, 2012, which is principally the result of a decrease in our stock price from December 31, 2011 to December 31, 2012, resulting in non-cash income during this period. Because our stock price increased from December 31, 2010 to December 31, 2011, our warrant liability increased in that period, resulting in a significant non-cash expense.

### ***Loss on Debt and Warrant Restructuring***

Loss on debt and warrant restructuring increased to \$1.9 million for the year ended December 31, 2012 from \$0 for the year ended December 31, 2011. The increase resulted from a \$1.5 million charge related to the restructuring of borrowings under the Restated Credit Agreement associated with our 2012 Convertible Debt Financing Transaction and a \$356,000 charge related to the cancelation of certain warrants under the Restated Credit Agreement.

## **Liquidity and Capital Resources**

### ***Sources of Liquidity***

Our primary sources of liquidity have been funds generated from our debt financings and equity financings. In addition, we have generated funds from the following sources: (i) the grants received in lieu of federal income tax credits under the Qualifying Therapeutic Discovery Project Program; (ii) grants from the National Institutes of Health and (iii) cash collections from our customers.

During January 2013, we received \$664,000 in cash in from sales of state NOL s.

On April 10, 2013, we sold 690,000 shares of common stock at a public offering price of \$10.00 per share and completed our initial public offering, or IPO, with net proceeds of \$5 million. Upon the closing of the IPO, all shares of our then-outstanding Series A and Series B convertible preferred stock automatically converted into an aggregate of 1,287,325 shares of common stock. Concurrent with the IPO, certain derivative warrants with a fair value of \$7.2 million were reclassified into equity due to the lapsing of anti-dilution provisions in the warrants. Also concurrent with the IPO, \$9.6 million of debt converted into 963,430 shares of common stock. Refer to Notes 1, 6 and 10 to the Consolidated Financial Statements accompanying this filing.

On April 29, 2013, the Company received \$96,000 from shareholders who exercised warrants to purchase 24,000 shares of common stock at \$4.00 per share. On July 8, 2013, the Company received \$96,000 from shareholders who exercised warrants to purchase 24,000 shares of common stock at \$4.00 per share.

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On August 19, 2013 in our Secondary Offering, or our Secondary Offering, we sold 1,500,000 shares of common stock at a public offering price of \$10.00 per share which resulted in gross proceeds of \$15.0 million (\$13.3 million of net proceeds after offering expenses and underwriting discounts). On September 5, 2013,

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we sold 105,000 additional common shares pursuant to the underwriter's partial exercise of the over-allotment option which resulted in gross proceeds of \$1.1 million (\$947,000 of net proceeds after offering expenses and underwriting discounts). Upon completion of the Secondary Offering we repaid indebtedness in the aggregate principal amount of \$3.5 million plus accrued interest to DAM and to one of our directors, Andrew Pecora, and an affiliated company NJCCA, all of which indebtedness was due on August 15, 2013.

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

During January 2014, we received \$1.8 million in cash in from sales of state NOL's.

Following our IPO, Secondary Offering, Follow-On Offering and the related debt repayments, we have the following credit facility outstanding:

*Wells Fargo Line of Credit.* As of December 31, 2013, we had indebtedness for borrowed money in the aggregate principal amount of \$6.0 million due under a line of credit with Wells Fargo. Substantially all of our assets, including our intellectual property, were pledged as collateral. In March 2014 we agreed in principle to re-negotiated terms of the line of credit. We anticipate that we will enter into an extension through April 1, 2016 at a rate of interest equal to LIBOR plus 1.75%. Effective April 1, 2014 the pledge of all of our assets and intellectual property as well as the guarantee by Mr. Pappajohn will be released. Under the terms of the extension, we will be required to restrict \$6.0 million in cash as collateral. Additionally, we will be required to maintain limits on capital spending and are restricted as to the amount we may pledge as collateral for additional borrowings from any source. 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.

In general, our primary uses of cash are providing for working capital purposes (which principally represent payroll costs, the purchase of supplies, rent expense and insurance costs) and servicing debt. Our largest source of operating cash flow is cash collections from our customers.

**Cash Flows**

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

|   | <b>Year Ended<br/>December 31,</b> |                   |               |
|---|------------------------------------|-------------------|---------------|
|   | <b>2013</b>                        | <b>2012</b>       | <b>2011</b>   |
| <i>(in thousands)</i>                                       |                                    |                   |               |
| <b>Cash provided by (used in):</b>                          |                                    |                   |               |
| Operating activities  | \$ (8,075)                         | \$ (7,578)        | \$ (5,073)    |
| Investing activities  | (1,399)                            | (347)             | (113)         |
| Financing activities  | 58,114                             | 6,328             | 5,824         |
| <b>Net increase (decrease) in cash and cash equivalents</b> | <b>\$ 48,640</b>                   | <b>\$ (1,597)</b> | <b>\$ 638</b> |

We had cash and cash equivalents of \$49.5 million at December 31, 2013, \$820,000 at December 31, 2012, and \$2.4 million at December 31, 2011.

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

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The \$1.6 million decrease in cash and cash equivalents from December 31, 2011, to December 31, 2012, was principally the result of our \$7.6 million net cash used in operations, including \$1.1 million in cash interest payments, payment of \$1.4 million in equity issuance costs, \$162,000 in purchases of fixed assets, and \$135,000 in patent cost, offset by \$7.8 million in net proceeds from borrowings under new notes payable and warrant exercises.

The \$638,000 increase in cash and cash equivalents from December 31, 2010, to December 31, 2011, principally was the result of our \$19.9 million net loss during the period, offset by non-cash equity compensation of \$1.1 million, the change in value of derivative warrants of \$10.4 million and an increase in accounts payable and accrued expenses of \$1.2 million, resulting in \$5.1 million of cash used in operations offset by \$6.0 million in net proceeds from borrowings under our line of credit and on a note payable. The \$1.8 million increase in our cash and cash equivalents from December 31, 2009, to December 31, 2010, resulted principally from our \$8.4 million net loss during the year, offset by approximately \$3.5 million in noncash expenses, principally due to the change in value of derivative warrants, and \$8.3 million in net proceeds from the issuance of the Series B preferred stock.

At December 31, 2013, we had total indebtedness of \$6.0 million, excluding capital lease obligations.

*Cash Used in Operating Activities*

Net cash used in operating activities was \$8.1 million for the year ended December 31, 2013. We used \$7.1 million in net cash to run our core operations, which included \$608,000 in cash paid for interest. We incurred additional uses of cash as follows: \$731,000 for a net decrease in accounts payable, accrued expenses and deferred revenue; \$375,000 to increase other current assets which included prepayments for consumables and other supplies used to run our operations as well as prepayments for our insurance policies, and; accounts receivable increased by \$716,000. All of these uses of cash were partially offset by the receipt of \$664,000 from the sale of certain state NOL carryforwards in January, 2013.

Net cash used in operating activities was \$7.6 million for the year ended December 31, 2012, consisting primarily of a \$6.7 million net loss during the period, which includes \$1.1 million in cash interest payments, and non-cash income from a change in fair value of warrant liability of \$7.5 million offset by non-cash debt costs of \$3.6 million, \$1.9 million of non-cash loss on debt and warrant restructuring, and \$900,000 in equity and warrant-based non-cash compensatory transactions.

Net cash used in operating activities was \$5.1 million for the year ended December 31, 2011 consisting primarily of a \$19.9 million net loss, offset by the change in the fair value of the warrant liability of \$10.4 million, depreciation of \$357,000, bad debt expense of \$373,000 due a decline in collections related to a change in our billing company, stock-based compensation of \$1.1 million, amortization of a loan guarantee fee of \$575,000, additional accretion of debt discount on newly outstanding debt of \$481,000 and an increase in accounts payable and accrued expenses due to an increase in professional fees.

*Cash Used in Investing Activities*

Net cash used in investing activities was \$1.4 million for the year ended December 31, 2013 and principally resulted from: a \$1.0 million payment to Mayo to fund our joint venture; purchases of fixed assets of \$257,000; patent application costs of \$92,000, and; an increase in our restricted cash related to a \$50,000 increase in the Letter of Credit related to our lease.

Net cash used in investing activities was \$348,000 for the year ended December 31, 2012 due to an increase in our restricted cash related to a \$50,000 increase in the Letter of Credit related to our lease as well as \$135,000 in patent

application costs and \$162,000 in purchases of fixed assets. Pursuant to the terms of our lease for our Rutherford facility, we were required to maintain a letter of credit in the amount of \$450,000 to use as a



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guarantee for the security deposit. In February 2011, we allowed the letter of credit to expire, which as discussed below, led to a decrease in our restricted cash for fiscal 2011. On April 6, 2012, we reached an agreement with the landlord which requires us to provide a letter of credit in the amount of \$250,000 and in exchange, the landlord agreed to forebear taking action to enforce our obligation to maintain the \$450,000 letter of credit. The landlord also agreed on April 6, 2012 (amended on March 8, 2013) to reduce our security deposit requirement to a \$250,000 letter of credit upon a capital raise of at least \$16.0 million by April 30, 2013 and subsequently agreed to reduce our security deposit requirement to a \$300,000 letter of credit if we raise gross capital of at least \$5.0 million by April 30, 2013. On April 10, 2013, we closed our IPO, which satisfied this requirement, and in May 2013 we increased our letter of credit with the landlord to \$300,000.

Net cash used in investing activities was \$113,000 for the year ended December 31, 2011 due to purchases of fixed assets of \$269,000 and patent costs of \$83,000 offset by a decrease of \$238,000 in restricted cash related to a letter of credit with our landlord.

***Cash Provided by Financing Activities***

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

Net cash provided by financing activities was \$6.3 million for the year ended December 31, 2012, principally due to our receipt of \$7.1 million in net proceeds from various financing transactions and \$635,000 in net proceeds from the exercise of certain warrants. We paid \$1.4 million in equity issuance costs related to our IPO in the year ended December 31, 2012.

Net cash provided by financing activities was \$5.8 million for the year ended December 31, 2011 due to the issuance of the \$3.0 million DAM Holdings line of credit and the \$3.0 million portion of the December 2011 financing transaction which closed in 2011.

***Capital Resources and Expenditure Requirements***

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

To augment our cash position, in August and September of 2013 we sold 1,605,000 shares of common stock in our Secondary Offering at a price of \$10.00 per share for net proceeds of \$14.2 million. Upon completion of the Secondary Offering we repaid indebtedness in the aggregate principal amount of \$3.5 million plus accrued interest. In addition, on October 28, 2013, we sold 3,286,700 shares of common stock, (including the underwriter's overallotment of 428,700 shares), at a public offering price of \$14.00 per share resulting in gross proceeds of \$46.0 million (net proceeds of \$42.3 million).

On March 17, 2014, the Company announced that its Chief Financial Officer, Elizabeth Czerepak, will resign effective March 31, 2014. In connection with Ms. Czerepak's resignation, the Company and Ms. Czerepak have entered into a separation agreement (the "Separation Agreement"). The Separation Agreement provides for severance benefits of, among other things: one year's salary of \$250,000; a lump sum payment equal to \$125,000; her accrued 2013 annual bonus of \$125,000; a bonus of \$25,000 for the first quarter of 2014, and; payout of accrued paid-time-off of approximately \$25,000. The Separation Agreement also provides for the acceleration of all stock options held by

her and the expiration date on her options will be extended until December 31, 2014. The acceleration of the vesting terms of the stock options held by her will result in stock-based compensation expense of approximately \$124,000. Expenses of approximately \$525,000 incurred under the Separation Agreement will be reflected General and administrative expense in the Company's 10-Q for the quarterly period ended March 31, 2014.

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We believe our cash resources are sufficient to satisfy our liquidity requirements at our current level of operations for at least 24 months.

We expect our operating expenses, particularly those relating to sales and marketing, to increase as we use a portion of the net proceeds received from our latest offering of common stock, which was consummated on October 28, 2013, to hire additional sales and marketing personnel and increase sales and marketing activities.

Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative, sales and marketing and research and development activities are forward-looking statements and involve risks and uncertainties. Actual results could vary materially and negatively as a result of a number of factors, including:

the timing of and the costs involved in obtaining regulatory approvals and clearances for our tests;

the costs of operating and enhancing our laboratory facilities;

if our new diagnostic tests are approved, our commercialization activities;

the scope, progress and results of our research and development programs;

the scope, progress, results, costs, timing and outcomes of the clinical trials of our diagnostic tests;

our ability to manage the costs for manufacturing our microarrays and probes;

the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;

our ability to obtain adequate reimbursement from governmental and other third-party payors for our tests and services;

our ability to execute on our marketing and sales strategy for our genomic tests and gain acceptance of our tests in the market;

revenues received from sales of our tests, if approved by FDA and accepted by the market;

the costs of additional general and administrative personnel, including accounting and finance, legal and human resources, as a result of becoming a public company;

the costs of developing our anticipated internal sales, marketing and distribution capabilities;

our ability to collect revenues;

our ability to secure financing and the amount thereof; and

other risks discussed in the section entitled "Risk Factors."

We expect that our operating expenses and capital expenditures will increase in the future as we expand our business. We plan to increase our sales and marketing headcount to promote our new clinical tests and services and to expand into new geographies and to increase our research and development headcount to develop and validate the proprietary tests currently in our pipeline, to expand our pipeline and to perform work associated with our research collaborations. We also expect that our costs of collaborations with research and academic institutions will increase in the future as such institutions begin to view us as a commercial company. For example, in 2011 we entered into an affiliation agreement to form a joint venture with the Mayo Foundation for Medical Education and Research pursuant to which we made an initial \$1.0 million capital contribution in October 2013. We currently anticipate that we will make capital contributions of \$1.0 million in the second quarter of 2014 and expect to make additional capital contributions of up to \$4.0 million over the next two and a half years, of which \$4.0 million is subject to the joint venture entity's achievement of certain operational milestones. Until we can generate a sufficient amount of revenues to finance our cash requirements, which we may never do, we may need to raise additional capital to fund our operations.

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We may raise additional capital to fund our current operations, to repay certain outstanding indebtedness and to fund expansion of our business to meet our long-term business objectives through public or private equity offerings, debt financings, borrowings or strategic partnerships coupled with an investment in our company or a combination thereof. If we raise additional funds through the issuance of convertible debt securities, or other debt securities, these securities could be secured and could have rights senior to those of our common stock. In addition, any new debt incurred by the Company could impose covenants that restrict our operations. The issuance of any new equity securities will also dilute the interest of our current stockholders. Given the risks associated with our business, including our unprofitable operating history and our ability to develop additional proprietary tests, additional capital may not be available when needed on acceptable terms, or at all. If adequate funds are not available, we will need to curb our expansion plans or limit our research and development activities, which would have a material adverse impact on our business prospects and results of operations.

**Future Contractual Obligations**

The following table reflects a summary of our estimates of future contractual obligations as of December 31, 2013. The information in the table reflects future unconditional payments and is based on the terms of the relevant agreements, appropriate classification of items under U.S. GAAP as currently in effect and certain assumptions, such as the interest rate on our variable debt that was in effect as of December 31, 2013. Future events could cause actual payments to differ from these amounts.

|  | <b>Total</b> | <b>Less than<br/>1 Year</b> | <b>2-3 Years</b> | <b>4-5 Years</b> | <b>More than<br/>5 Years</b> |
|--|--------------|-----------------------------|------------------|------------------|------------------------------|
| <i>(dollars in thousands)</i>  |              |                             |                  |                  |                              |
| Principal and interest under notes payable and lines of credit                         | \$ 6,053     | \$ 6,053                    | \$               | \$               | \$                           |
| Capital Lease obligations, including interest, for equipment                           | 421          | 67                          | 118              | 118              | 118                          |
| Operating lease obligations relating to corporate headquarters and clinical laboratory | 2,400        | 613                         | 1,175            | 612              |                              |
| Total  | \$ 8,874     | \$ 6,733                    | \$ 1,293         | \$ 730           | \$ 118                       |

**Income Taxes**

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

**Off-Balance Sheet Arrangements**

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

**Critical Accounting Policies and Significant Judgment and Estimates**

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

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

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

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

Revenue recognition;

Accounts receivable and bad debts;

Stock-based compensation; and

Warrant liability.

**Item 7A. Qualitative and Quantitative Disclosures about Market Risk**

Not applicable.

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**Item 8. Financial Statements and Supplementary Data**

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Cancer Genetics, Inc. and Subsidiary

**Consolidated Financial Report December 31, 2013**

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders

Cancer Genetics, Inc. and Subsidiary

We have audited the accompanying consolidated balance sheets of Cancer Genetics, Inc. and subsidiary as of December 31, 2013 and 2012, and the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the three years ended December 31, 2013, 2012 and 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cancer Genetics, Inc. and subsidiary as of December 31, 2013 and 2012, and the results of their operations and their cash flows for each of the three years ended December 31, 2013, 2012 and 2011 in conformity with U.S. generally accepted accounting principles.

/s/ McGladrey LLP

Des Moines, Iowa

March 28, 2014

**Table of Contents****CANCER GENETICS, INC. AND SUBSIDIARY****Consolidated Balance Sheets**

|   | <b>December 31,</b>  |                     |
|---|----------------------|---------------------|
|   | <b>2013</b>          | <b>2012</b>         |
| <b>ASSETS</b>   |                      |                     |
| <b>CURRENT ASSETS</b>   |                      |                     |
| Cash and cash equivalents   | \$ 49,459,564        | \$ 819,906          |
| Accounts receivable, net of allowance for doubtful accounts of 2013 \$36,000;<br>2012 \$36,000          | 1,567,039            | 850,545             |
| Other current assets  | 864,616              | 489,278             |
| <b>Total current assets</b>   | <b>51,891,219</b>    | <b>2,159,729</b>    |
| <b>FIXED ASSETS, net of accumulated depreciation</b>  | <b>1,264,624</b>     | <b>964,923</b>      |
| <b>OTHER ASSETS</b>   |                      |                     |
| Security deposits   | 1,564                | 1,564               |
| Restricted cash   | 300,000              | 250,000             |
| Loan guarantee and financing fees, net of accumulated amortization of 2013<br>\$517,500; 2012 \$929,498 | 310,500              | 1,907,502           |
| Patents   | 401,709              | 324,764             |
| Investment in joint venture   | 987,657              |                     |
| Deferred offering costs   |                      | 3,343,289           |
|   | <b>2,001,430</b>     | <b>5,827,119</b>    |
| <b>Total Assets</b>   | <b>\$ 55,157,273</b> | <b>\$ 8,951,771</b> |
| <b>LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)</b>  |                      |                     |
| <b>CURRENT LIABILITIES</b>  |                      |                     |
| Accounts payable and accrued expenses   | \$ 2,346,240         | \$ 4,578,761        |
| Obligations under capital leases, current portion   | 51,400               | 17,158              |
| Deferred revenue  | 199,560              | 468,010             |
| Notes payable, current portion  | 22,298               | 3,836,567           |
| Line of credit  | 6,000,000            | 2,871,200           |
| <b>Total current liabilities</b>  | <b>8,619,498</b>     | <b>11,771,696</b>   |
| Obligations under capital leases  | 309,777              | 7,490               |
| Deferred rent payable   | 170,789              | 164,298             |
| Notes payable, long-term  |                      | 2,440,683           |
| Line of credit  |                      | 6,000,000           |
| Warrant liability   | 594,000              | 12,549,000          |
| <b>Total liabilities</b>  | <b>9,694,064</b>     | <b>32,933,167</b>   |

| <b>STOCKHOLDERS EQUITY (DEFICIT)</b>   |                      |                     |
|--|----------------------|---------------------|
| Series A Preferred Stock, authorized 588,000 shares \$0.0001 par value<br>(converted to common stock on April 10, 2013- Note 10), 587,691 shares issued<br>and outstanding in 2012                       |                      | 59                  |
| Series B Preferred Stock, authorized 2,000,000 shares \$0.0001 par value<br>(converted to common stock on April 10, 2013-Note 10), 1,821,600 shares<br>issued and outstanding in 2012                    |                      | 182                 |
| Common stock, authorized 100,000,000 and 24,000,000 shares, respectively,<br>\$0.0001 par value, 9,275,384 and 1,349,936 shares issued and outstanding as of<br>December 31, 2013 and 2012, respectively | 927                  | 135                 |
| Additional paid-in capital   | 106,786,862          | 24,970,255          |
| Treasury stock   |                      | (17,442)            |
| Accumulated deficit  | (61,324,580)         | (48,934,585)        |
| <b>Total Stockholders Equity (Deficit)</b>   | <b>45,463,209</b>    | <b>(23,981,396)</b> |
| <b>Total Liabilities and Stockholders Equity (Deficit)</b>   | <b>\$ 55,157,273</b> | <b>\$ 8,951,771</b> |

See Notes to Consolidated Financial Statements.

**Table of Contents****CANCER GENETICS, INC. AND SUBSIDIARY****Consolidated Statements of Operations**

|   | Years Ended December 31, |                |                 |
|---|--------------------------|----------------|-----------------|
|   | 2013                     | 2012           | 2011            |
| <b>Revenue</b>                              | <b>\$ 6,609,957</b>      | \$ 4,301,563   | \$ 3,019,407    |
| <b>Cost of revenues</b>                     | <b>4,924,626</b>         | 3,928,993      | 3,117,411       |
| <b>Gross profit (loss)</b>                  | <b>1,685,331</b>         | 372,570        | (98,004)        |
| Operating expenses:                         |                          |                |                 |
| Research and development                    | <b>2,190,204</b>         | 2,111,947      | 2,073,661       |
| General and administrative                  | <b>6,115,035</b>         | 4,502,424      | 4,439,170       |
| Sales and marketing                         | <b>1,841,675</b>         | 1,398,786      | 1,574,088       |
| <b>Total operating expenses</b>             | <b>10,146,914</b>        | 8,013,157      | 8,086,919       |
| <b>Loss from operations</b>                 | <b>(8,461,583)</b>       | (7,640,587)    | (8,184,923)     |
| Other income (expense):                     |                          |                |                 |
| Interest expense                            | <b>(2,387,733)</b>       | (4,701,028)    | (1,314,234)     |
| Interest income                             | <b>29,693</b>            |                | 117             |
| Change in fair value of warrant liability   | <b>4,633,000</b>         | 7,538,000      | (10,388,000)    |
| Loss on debt and warrant restructuring      |                          | (1,862,012)    |                 |
| Debt conversion costs                       | <b>(6,849,830)</b>       |                |                 |
| <b>Total other income (expense)</b>         | <b>(4,574,870)</b>       | 974,960        | (11,702,117)    |
| <b>Loss before income taxes</b>             | <b>(13,036,453)</b>      | (6,665,627)    | (19,887,040)    |
| Income tax (benefit) provision              | <b>(663,900)</b>         |                |                 |
| <b>Net loss</b>                             | <b>\$ (12,372,553)</b>   | \$ (6,665,627) | \$ (19,887,040) |
| Basic net loss per share                    | <b>\$ (2.65)</b>         | \$ (4.97)      | \$ (15.61)      |
| Diluted net loss per share                  | <b>\$ (3.64)</b>         | \$ (10.55)     | \$ (15.61)      |
| Basic Weighted Average Shares Outstanding   | <b>4,665,316</b>         | 1,342,174      | 1,274,153       |
| Diluted Weighted Average Shares Outstanding | <b>4,675,974</b>         | 1,346,161      | 1,274,153       |

See Notes to Consolidated Financial Statements.



**Table of Contents****CANCER GENETICS, INC. AND SUBSIDIARY****Consolidated Statements of Changes in Stockholders' Equity (Deficit)****Years Ended December 31, 2013, 2012 and 2011**

|  | Preferred Stock<br>Series A |        | Preferred Stock<br>Series B |        | Common Stock |        | Additional<br>Paid-in<br>Capital | Treasury<br>Stock | Accumulated<br>Deficit | Total  |
|--|-----------------------------|--------|-----------------------------|--------|--------------|--------|----------------------------------|-------------------|------------------------|--------|
|  | Shares                      | Amount | Shares                      | Amount | Shares       | Amount |                                  |                   |                        |        |
| <b>December 31, 2010</b>                               | 587,691                     | \$ 59  | 1,821,600                   | \$ 182 | 1,271,480    | \$ 127 | \$ (15,662,559)                  | \$ (17,442)       | \$ (22,381,918)        | \$ (6) |
| Issuance of common stock to employees                  |                             |        |                             |        |              |        | 306,307                          |                   |                        |        |
| Issuance of common stock to non-employees              |                             |        |                             |        |              |        | 636,810                          |                   |                        |        |
| Issuance of warrants                                   |                             |        |                             |        | 3,546        | 1      | 49,998                           |                   |                        |        |
| Liability reclassified                                 |                             |        |                             |        |              |        | 6,415,000                        |                   |                        | 6      |
| Issuance of common stock                               |                             |        |                             |        | 20,000       | 2      | 149,998                          |                   | (19,887,040)           | (19)   |
| <b>December 31, 2011</b>                               | 587,691                     | 59     | 1,821,600                   | 182    | 1,295,026    | 130    | 23,220,672                       | (17,442)          | (42,268,958)           | (19)   |
| Issuance of common stock to employees                  |                             |        |                             |        |              |        | 341,996                          |                   |                        |        |
| Issuance of common stock to non-employees              |                             |        |                             |        |              |        | 573,365                          |                   |                        |        |
| Extension of warrants                                  |                             |        |                             |        |              |        | 144,000                          |                   |                        |        |
| Issuance of warrants                                   |                             |        |                             |        | 54,910       | 5      | 690,222                          |                   | (6,665,627)            | (6)    |
| <b>December 31, 2012</b>                               | 587,691                     | 59     | 1,821,600                   | 182    | 1,349,936    | 135    | 24,970,255                       | (17,442)          | (48,934,585)           | (23)   |
| Issuance of common stock to employees                  |                             |        |                             |        | 2,500        |        | 646,983                          |                   |                        |        |
| Issuance of common stock to non-employees              |                             |        |                             |        |              |        | 88,162                           |                   |                        |        |
| Issuance of common stock pursuant to venture agreement |                             |        |                             |        |              |        | 231,396                          |                   |                        |        |
| Conversion of preferred stock to common stock          | (587,691)                   | (59)   | (1,821,600)                 | (182)  | 1,287,325    | 129    | 112                              |                   |                        |        |
| Conversion of debt into common stock                   |                             |        |                             |        | 963,430      | 96     | 12,595,970                       |                   |                        | 12     |
| Issuance of common stock in offering                   |                             |        |                             |        | 690,000      | 69     | 3,742,574                        |                   |                        | 3      |
| Issuance of common stock in Offering, net of costs     |                             |        |                             |        | 1,605,000    | 160    | 14,230,212                       |                   |                        | 14     |
|  |                             |        |                             |        | 3,286,700    | 329    | 42,302,267                       |                   |                        | 42     |

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t of treasury stock

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**December 31, 2013**

\$

\$

**9,275,384 \$ 927 \$ 106,786,862 \$**

**\$ (61,324,580) \$ 45**

See Notes to Consolidated Financial Statements

**Table of Contents****CANCER GENETICS, INC. AND SUBSIDIARY****Consolidated Statements of Cash Flows**

|   | <b>Years Ended December 31,</b> |                |                 |
|---|---------------------------------|----------------|-----------------|
|   | <b>2013</b>                     | <b>2012</b>    | <b>2011</b>     |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES</b>                                 |                                 |                |                 |
| Net loss  | <b>\$ (12,372,553)</b>          | \$ (6,665,627) | \$ (19,887,040) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                 |                |                 |
| Depreciation  | <b>311,247</b>                  | 338,176        | 356,603         |
| Amortization  | <b>15,229</b>                   | 15,229         | 13,048          |
| Provision (recovery) for bad debts  |                                 | (4,597)        | 372,680         |
| Equity-based consulting and compensation expenses                           | <b>646,983</b>                  | 915,361        | 1,093,117       |
| Extension of warrants   |                                 | 144,000        |                 |
| Equity-based research and development/general and administrative expenses   | <b>514,858</b>                  |                | 69,000          |
| Change in fair value of warrant liability                                   | <b>(4,633,000)</b>              | (7,538,000)    | 10,388,000      |
| Amortization of loan guarantee and financing fees                           | <b>1,194,960</b>                | 1,427,296      | 575,285         |
| Accretion of discount on debt   | <b>584,692</b>                  | 2,212,154      | 480,620         |
| Loss on debt and warrant restructuring                                      |                                 | 1,862,012      |                 |
| Loss on conversion of debt to equity  | <b>6,849,830</b>                |                |                 |
| Deferred initial public offering costs expensed                             | <b>617,706</b>                  |                |                 |
| Deferred rent   | <b>6,491</b>                    | 7,987          | 25,922          |
| Loss in equity-method investment  | <b>12,343</b>                   |                |                 |
| Change in working capital components:                                       |                                 |                |                 |
| Accounts receivable   | <b>(716,494)</b>                | (156,968)      | (355,816)       |
| Other current assets  | <b>(375,338)</b>                | (220,009)      | 551,738         |
| Accounts payable, accrued expenses and deferred revenue                     | <b>(731,471)</b>                | 85,134         | 1,243,594       |
| <b>Net cash (used in) operating activities</b>                              | <b>(8,074,517)</b>              | (7,577,852)    | (5,073,249)     |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES</b>                                 |                                 |                |                 |
| Purchase of fixed assets  | <b>(257,261)</b>                | (162,463)      | (268,632)       |
| Patent costs  | <b>(92,174)</b>                 | (135,306)      | (82,872)        |
| Investment in joint venture   | <b>(1,000,000)</b>              |                |                 |
| (Increase) decrease in restricted cash                                      | <b>(50,000)</b>                 | (50,000)       | 238,400         |
| <b>Net cash (used in) investing activities</b>                              | <b>(1,399,435)</b>              | (347,769)      | (113,104)       |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES</b>                                 |                                 |                |                 |
| Principal payments on capital lease obligations                             | <b>(17,158)</b>                 | (36,120)       | (42,708)        |
| Proceeds from public offerings of common stock, net of offering costs       | <b>61,516,994</b>               |                |                 |
| Payment of equity issuance costs  |                                 | (1,373,000)    | (182,933)       |
| Proceeds from option exercises  | <b>1,640</b>                    |                |                 |
| Proceeds from warrant exercises   | <b>192,000</b>                  | 635,227        | 49,999          |



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|   |                      |             |              |
|---|----------------------|-------------|--------------|
| Proceeds from borrowings on notes payable                   | 7,120,000            | 3,000,000   |              |
| Proceeds from borrowings on line of credit                  |                      | 3,200,000   |              |
| Payments on line of credit                                  |                      | (200,000)   |              |
| Principal payments on notes payable                         | (3,579,866)          | (17,836)    |              |
| <b>Net cash provided by financing activities</b>            | <b>58,113,610</b>    | 6,328,271   | 5,824,358    |
| <b>Net increase (decrease) in cash and cash equivalents</b> | <b>48,639,658</b>    | (1,597,350) | 638,005      |
| <b>CASH AND CASH EQUIVALENTS</b>                            |                      |             |              |
| Beginning   | 819,906              | 2,417,256   | 1,779,251    |
| Ending  | <b>\$ 49,459,564</b> | \$ 819,906  | \$ 2,417,256 |

SUPPLEMENTAL CASH FLOW DISCLOSURE

|                        |            |              |            |
|------------------------|------------|--------------|------------|
| Cash paid for interest | \$ 608,084 | \$ 1,091,377 | \$ 253,996 |
|------------------------|------------|--------------|------------|

SUPPLEMENTAL DISCLOSURE OF NONCASH  
INVESTING AND FINANCING ACTIVITIES

|   |            |           |           |
|---|------------|-----------|-----------|
| Fixed assets acquired through capital lease arrangement         | \$ 353,687 | \$        | \$ 49,600 |
| Warrants issued with debt                                       |            | 6,122,000 | 1,970,000 |
| Warrants issued for debt guarantee fee                          |            | 1,583,000 | 831,000   |
| Warrants issued for financing fees                              | 47,000     | 1,003,000 |           |
| Retirement of treasury stock                                    | 17,442     |           |           |
| Conversion of notes payable and lines of credit to common stock | 9,634,300  |           |           |
| Conversion of preferred stock to common stock                   | 241        |           |           |
| Reclassification of derivative warrants                         | 7,170,000  |           |           |
| Cashless exercise of derivative warrants                        | 420,000    |           |           |
| Warrant liability reclassified to equity                        |            |           | 6,415,000 |
| Offering costs discounted                                       | 733,250    |           |           |
| Accrued IPO costs   |            | 1,732,016 | 1,428,340 |
| Accrued expenses recorded as financing fees                     |            | 251,000   |           |
| Accrued expenses recorded as a discount on debt                 |            |           | 161,000   |
| Accrued expenses reclassified as derivative warrant liability   | 221,000    | 148,000   |           |
| Derivative warrant settled with accrued expense                 |            | 182,500   |           |

See Notes to Consolidated Financial Statements.

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**CANCER GENETICS, INC. AND SUBSIDIARY**

**Notes to Consolidated Financial Statements**

***Note 1. Organization, Description of Business, Reverse Stock Split and Charter Amendment***

We were incorporated in the State of Delaware on April 8, 1999 and have offices and a laboratory located in Rutherford, New Jersey. Our wholly owned subsidiary, Cancer Genetics Italia SRL ( CGI Italia ), manufactures DNA probes. CGI Italia had approximately \$398,000 and \$329,000 in total assets at December 31, 2013 and 2012, respectively and approximately \$212,000, \$91,000 and \$103,000 in total revenue for the years ended December 31, 2013, 2012 and 2011, respectively.

We are 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 complicated to prognose and for which it is difficult to predict treatment outcomes 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, reference laboratories and physician offices, as well as to biopharmaceutical companies and clinical research organizations for their clinical trials.

*Reverse Stock Splits*

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

*Public Offerings*

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

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

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

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***Note 2. Significant Accounting Policies***

**Basis of presentation:** We prepare our financial statements on the accrual basis of accounting in accordance with accounting principles generally accepted in the United States of America.

**Segment Reporting:** Operating segments are defined as components of an enterprise about which separate discrete information is used by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. We view our operations and manage our business in one operating segment, which is the business of developing and selling diagnostic tests.

**Liquidity:** Our primary sources of liquidity have been funds generated from our debt financings and equity financings. In addition, we have generated funds from the following sources: (i) the grants received in lieu of federal income tax credits under the Qualifying Therapeutic Discovery Project Program; (ii) grants from the National Institutes of Health and (iii) cash collections from our customers.

**Principles of consolidation:** The accompanying consolidated financial statements include the accounts of Cancer Genetics, Inc. and our wholly owned subsidiary, Cancer Genetics Italia SRL. All significant intercompany account balances and transactions have been eliminated in consolidation.

**Use of estimates and assumptions:** The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates made by management include, among others, realization of amounts billed, realization of long-lived assets, realization of intangible assets, accruals for litigation and registration payments and assumptions used to value stock options and warrants. Actual results could differ from those estimates.

**Risks and uncertainties:** We operate in an industry that is subject to intense competition, government regulation and rapid technological change. Our operations are subject to significant risk and uncertainties including financial, operational, technological, regulatory and other risks, including the potential risk of business failure.

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

**Revenue recognition:** Revenue is recognized in accordance with Financial Accounting Standards Board ( FASB ) Accounting Standards Codification ( ASC ) 605, Revenue Recognition, and ASC 954-605 Health Care Entities, Revenue Recognition which requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred and title and the risks and rewards of ownership have been transferred to the customer or services have been rendered; (3) the price is fixed or determinable; and (4) collectability is reasonably assured. In determining whether the price is fixed or determinable, we consider payment limits imposed by insurance carriers and Medicare and the amount of revenue recorded takes into account the historical percentage of revenue we have collected for each type of test for each payor category. Periodically, an adjustment is made to revenue to record differences between our anticipated cash receipts from insurance carriers and Medicare and actual receipts from such payors. For the periods presented, such adjustments were not significant. For direct bill customers (including clinical trials customers), revenue is recorded based upon the contractually agreed

upon fee schedule. When assessing collectability, we consider whether we have sufficient payment history to reliably estimate a payor's individual

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payment patterns. For new tests where there is no evidence of payment history at the time the tests are completed, we only recognize revenues once reimbursement experience can be established. We then recognize revenue equal to the amount of cash received. Sales of probes are recorded on the shipping date. We do not bill customers for shipping and handling fees and do not collect any sales or other taxes.

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

Accounts receivable: Accounts receivable are carried at original invoice amount less an estimate for contractual adjustments and doubtful receivables, the amounts of which are determined by an analysis of individual accounts. Our policy for assessing the collectability of receivables is dependent upon the major payor source of the underlying revenue. For direct bill clients, an assessment of credit worthiness is performed prior to initial engagement and is reassessed periodically. If deemed necessary, an allowance is established on receivables from direct bill clients. For insurance carriers where there is not an established pattern of collection, revenue is not recorded until cash is received. For receivables where insurance carriers have made payments to patients instead of directing payments to the Company, an allowance is established for a portion of such receivables. After reasonable collection efforts are exhausted, amounts deemed to be uncollectible are written off against the allowance for doubtful accounts. Since the Company only recognizes revenue to the extent it expects to collect such amounts, bad debt expense related to receivables from patient service revenue is recorded in general and administrative expense in the consolidated statement of operations. Recoveries of accounts receivable previously written off are recorded when received.

Deferred offering costs: Deferred offering costs represent legal, accounting and other direct costs related to our effort to raise capital through a stock offering. Costs related to our offering activities were deferred until the completion of the offerings, at which time they were reclassified to additional paid-in capital as a reduction of the offering proceeds. In connection with our IPO, \$617,706 in deferred offering costs was expensed and approximately \$2.5 million in deferred offering costs were reclassified to additional paid-in capital. In connection with our Secondary Offering, we incurred \$1.8 million in offering costs and underwriting discounts, all of which were reclassified to additional paid-in-capital upon completion of the offering. In connection with our Follow-On Offering, we incurred \$3.7 million in offering costs and underwriting discounts, all of which were reclassified to additional paid-in-capital.

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

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

Fixed assets are reviewed for impairment whenever changes in circumstances indicate that the carrying amount of an asset may not be recoverable. These computations utilize judgments and assumptions inherent in our estimate of future cash flows to determine recoverability of these assets. If our assumptions about these assets were to change as a result of events or circumstances, we may be required to record an impairment loss.

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

Warrant liability: We have issued certain warrants which contain an exercise price adjustment feature in the event we issue additional equity instruments at a price lower than the exercise price of the warrant. The warrants

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are described herein as derivative warrants. We account for these derivative warrants as liabilities. These common stock purchase warrants do not trade in an active securities market, and as such, we estimate the fair value of these warrants using the binomial lattice valuation pricing model with the assumptions as follows: The risk-free interest rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve. The expected life of the warrants is based upon the contractual life of the warrants. Volatility is estimated based on an average of the historical volatilities of the common stock of four entities with characteristics similar to those of the Company. Prior to our IPO, the measurement date fair value of the underlying common shares was based upon an external valuation of our shares. (See Notes 12 and 13). Subsequent to the IPO and Secondary Offering, we used the closing price of our shares on the OTC Bulletin Board and the NASDAQ Capital Market, respectively.

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

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

Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. We have established a full valuation allowance on our deferred tax assets as of December 31, 2013 and 2012, therefore we have not recognized any tax benefit or expense in the periods presented.

ASC 740, Income Taxes, clarifies the accounting for uncertainty in income taxes recognized in the financial statements. ASC 740 provides that a tax benefit from uncertain tax positions may be recognized when it is more-likely-than-not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. Income tax positions must meet a more-likely-than-not recognition threshold to be recognized. ASC 740 also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. See Note 9 for a discussion of uncertain tax positions.

Our policy is to recognize interest and/or penalties related to income tax matters in income tax expense. There is no accrual for interest or penalties on our consolidated balance sheets at December 31, 2013 or 2012, and we have not recognized interest and/or penalties in the consolidated statements of operations for the years ended December 31, 2013, 2012 or 2011.

**Patents:** We account for intangible assets under ASC 350-30. Patents consist of legal fees incurred and are recorded at cost and amortized over the useful lives of the assets, using the straight-line method. Certain patents are in the legal application process and therefore are not currently being amortized. We review the carrying value of patents at the end of each reporting period. Based upon our review, there were no intangible asset impairments in 2013, 2012 or 2011. Accumulated amortization of patents as of December 31, 2013 and 2012 was approximately \$56,000 and \$41,000, respectively. Future amortization expense for legally approved patents is estimated at \$26,800 per year through 2018 and approximately \$23,600, \$17,100, \$14,300, \$11,600 and \$11,600 for 2019, 2020, 2021, 2022 and 2023, respectively.



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

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**Registration payment arrangements:** We account for our obligations under registration payment arrangements in accordance with ASC 825-20, *Registration Payment Arrangements*. ASC 825-20 requires us to record a liability if we determine a registration payment is probable and if it can reasonably be estimated. As of December 31, 2013 and 2012, we have an accrued liability of \$300,000 and \$541,000, respectively, related to the issuance of Series B preferred stock and certain notes payable.

**Stock-based compensation:** Stock-based compensation is accounted for in accordance with the provisions of ASC 718, *Compensation-Stock Compensation*, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors based on estimated fair values on the grant date. We estimate the fair value of stock-based awards on the date of grant using the Black-Scholes option pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods using the straight-line method. See additional information in Note 11.

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

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

**Fair value of financial instruments:** The carrying amount of cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued expenses, approximate their estimated fair values due to the short term maturities of those financial instruments. These financial instruments are considered Level 1 measurement under the fair value hierarchy. The fair values of our notes payable, lines of credit and capital leases approximate carrying value under Level 2 of the fair value hierarchy. The fair value of warrants recorded as derivative liabilities is described in Note 13.

**Joint venture accounted for under the equity method:** The Company records its joint venture investment following the equity method of accounting, reflecting its initial investment in the joint venture and its share of the joint venture's net earnings or losses and distributions. The Company's share of the joint venture's net loss was approximately \$12,000 in 2013, the first year of the joint venture's operations and is included in Research and development expense on the Consolidated Statement of Operations. The Company has a net receivable due from the joint venture of approximately \$24,000 and \$0 in 2013 and 2012, respectively, which is included in other assets in the Consolidated Balance Sheet. See additional information in Note 16.

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

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



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Basic net loss and diluted net loss per share data were computed as follows:

|   | 2013            | 2012            | 2011            |
|---|-----------------|-----------------|-----------------|
| <b>Numerator:</b>   |                 |                 |                 |
| Net (loss) for basic earnings per share                                     | \$ (12,372,553) | \$ (6,665,627)  | \$ (19,887,040) |
| Less change in fair value of warrant liability                              | 4,633,000       | 7,538,000       |                 |
| Net (loss) for diluted earnings per share                                   | \$ (17,005,553) | \$ (14,203,627) | \$ (19,887,040) |
| <b>Denominator:</b>   |                 |                 |                 |
| Weighted-average basic common shares outstanding                            | 4,665,316       | 1,342,174       | 1,274,153       |
| <b>Assumed conversion of dilutive securities:</b>                           |                 |                 |                 |
| Common stock purchase warrants  | 10,658          | 3,987           |                 |
| Potentially dilutive common shares  | 10,658          | 3,987           |                 |
| Denominator for diluted earnings per share adjusted weighted-average shares | 4,675,974       | 1,346,161       | 1,274,153       |
| Basic net loss per share  | \$ (2.65)       | \$ (4.97)       | \$ (15.61)      |
| Diluted net loss per share  | \$ (3.64)       | \$ (10.55)      | \$ (15.61)      |

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

|  | 2013      | 2012      | 2011      |
|--|-----------|-----------|-----------|
| Common stock purchase warrants                                     | 1,701,984 | 1,102,176 | 888,739   |
| Stock options  | 873,542   | 553,340   | 559,990   |
| Restricted shares of common stock                                  | 7,500     |           |           |
| Common shares issuable upon conversion of Series A Preferred Stock |           | 352,614   | 352,614   |
| Common shares issuable upon conversion of Series B Preferred Stock |           | 364,320   | 364,320   |
|  | 2,583,026 | 2,372,450 | 2,165,663 |

**Note 3. Revenue and Accounts Receivable**

Revenue by payor type for each of the years ended December 31 is comprised of the following:

|   | <b>2013</b>         | <b>2012</b>  | <b>2011</b>  |
|---|---------------------|--------------|--------------|
| Medicare                                | <b>\$ 833,892</b>   | \$ 753,248   | \$ 717,661   |
| Direct bill (including clinical trials) | <b>3,843,010</b>    | 1,594,509    | 350,290      |
| Grants and royalty                      | <b>296,877</b>      | 556,940      | 315,195      |
| Insurance carrier and all others        | <b>1,636,178</b>    | 1,396,866    | 1,636,261    |
|   | <b>\$ 6,609,957</b> | \$ 4,301,563 | \$ 3,019,407 |

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Accounts receivable by payor type at December 31, 2013 and 2012 consists of the following:

|   | <b>2013</b>         | <b>2012</b> |
|---|---------------------|-------------|
| Medicare                                | <b>\$ 408,856</b>   | \$ 193,024  |
| Direct bill (including clinical trials) | <b>628,830</b>      | 339,763     |
| Insurance carrier and all others        | <b>565,353</b>      | 353,758     |
| Allowance for doubtful accounts         | <b>(36,000)</b>     | (36,000)    |
|   | <b>\$ 1,567,039</b> | \$ 850,545  |

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

The top five test ordering sites during 2013, 2012 and 2011 accounted for 69%, 58% and 63% respectively, of our clinical testing volumes, with 36%, 46% and 29% respectively, of the volume coming from community hospitals. During the year ended December 31, 2013, there was one site which accounted for more than 10% of our revenue: a clinical trial client accounted for approximately 40% of our revenue. During the year ended December 31, 2012, there were three sites which each accounted for approximately 10% or more of our clinical revenue: a clinical trial client accounted for approximately 13%, a university teaching center accounting for approximately 11%, and; a community hospital accounted for approximately 10%. During 2011, there were two sites which accounted for more than 10% of our revenue: a community hospital accounted for approximately 18% and a community oncology practice accounted for approximately 11%.

**Note 4. Other Current Assets**

At December 31, 2013 and 2012, other current assets consisted of the following:

|                   | <b>2013</b>       | <b>2012</b> |
|-------------------|-------------------|-------------|
| Inventory probes  | <b>\$ 198,789</b> | \$ 233,767  |
| Prepaid expenses  | <b>593,950</b>    | 255,511     |
| Grants receivable | <b>71,877</b>     |             |
|                   | <b>\$ 864,616</b> | \$ 489,278  |

**Note 5. Lease Commitments**

We lease our laboratory and research facilities and administrative office space in Rutherford, New Jersey under an escalating lease agreement that expires in February 2018. The lease requires monthly rent for 10 years with periodic rent increases that vary from \$1 to \$2 per square foot of the rented premises per year. The difference between minimum rent and straight-line rent is recorded as deferred rent payable. The terms of the lease require that a

\$300,000 security deposit for the facility be held in a stand by letter of credit held in favor of the landlord (see Note 7).

We acquired office and scientific equipment under long term leases which have been capitalized at the present value of the minimum lease payments. The equipment under these capital leases had a cost of \$403,288 and accumulated depreciation of \$26,454, as of December 31, 2013.

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Minimum future lease payments under all capital and operating leases as of December 31, 2013 are as follows:

|  | <b>Capital<br/>Leases</b> | <b>Operating<br/>Leases</b> | <b>Total</b>     |
|--|---------------------------|-----------------------------|------------------|
| December 31,                                 |                           |                             |                  |
| 2014   | \$ 66,709                 | \$ 613,121                  | \$ 679,830       |
| 2015   | 59,094                    | 609,828                     | 668,922          |
| 2016   | 59,094                    | 564,984                     | 624,078          |
| 2017   | 59,094                    | 564,984                     | 624,078          |
| 2018   | 59,094                    | 47,082                      | 106,176          |
| Thereafter                                   | 118,190                   |                             | 118,190          |
| <br>Total minimum lease payments             | <br>421,275               | <br>\$ 2,399,999            | <br>\$ 2,821,274 |
| <br>Less amount representing interest        | <br>60,098                |                             |                  |
| <br>Present value of net minimum obligations | <br>361,177               |                             |                  |
| Less current obligation under capital lease  | 51,400                    |                             |                  |
| <br>Long-term obligation under capital lease | <br>\$ 309,777            |                             |                  |

Rent expense for the years ended December 31, 2013, 2012 and 2011 was \$550,882, \$516,173, and \$517,667, respectively.

**Subsequent Event**

On January 15, 2014, a capital lease with a future obligation of \$7,615 was paid off prior to its contractual due date of May 26, 2014.

**Note 6. Notes Payable and Lines of Credit**

Below is a summary of our short-term and long-term debt obligations as of December 31, 2013 and 2012:

|                                      | <b>December 31,<br/>2013</b> | December 31,<br>2012 |
|--------------------------------------|------------------------------|----------------------|
| December 2011 Financing Transaction  | \$                           | \$ 4,000,000         |
| Secured Note Payable, short-term     | <b>22,298</b>                | 79,867               |
| Unamortized debt discount            |                              | (243,300)            |
| <br>Notes Payable, Current Portion   | <br>\$ <b>22,298</b>         | <br>\$ 3,836,567     |
| <br>Lines of Credit, Current Portion | <br>\$ <b>6,000,000</b>      | <br>\$ 3,000,000     |
| Unamortized Debt Discount            |                              | (128,800)            |



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|   |                     |              |
|---|---------------------|--------------|
| Lines of Credit, Current Portion            | \$ <b>6,000,000</b> | \$ 2,871,200 |
| December 2011 Financing Transaction         | \$                  | \$ 2,000,000 |
| 2012 Convertible Debt Financing Transaction |                     | 3,000,000    |
| December 2012 Bridge Financing Transaction  |                     | 1,000,000    |
| Other Note Payable                          |                     | 100,000      |
| Secured Note Payable                        |                     | 22,298       |
| Unamortized debt discount                   |                     | (3,681,615)  |
| Notes Payable, Long-Term                    | \$                  | \$ 2,440,683 |
| Lines of Credit, Long-Term                  | \$                  | \$ 6,000,000 |

**Table of Contents***Business Line of Credit Wells Fargo*

At December 31, 2013 and December 31, 2012, we have fully utilized a line of credit with Wells Fargo Bank which provides for maximum borrowings of \$6 million. Interest on the line of credit is due monthly equal to 1.75% above the Daily One Month LIBOR rate (2.0% at December 31, 2013). The line of credit requires the repayment of principal, and any unpaid interest, in a single payment due upon maturity. The line of credit matures April 1, 2014, is guaranteed by Mr. Pappajohn, our Chairman of the Board of Directors, and is collateralized by a first lien on all of our assets including the assignment of our approved and pending patent applications.

**Subsequent Event**

In March 2014 we agreed in principle to re-negotiated terms of the line of credit. We anticipate that we will enter into an extension through April 1, 2016 at a rate of interest equal to LIBOR plus 1.75%. Effective April 1, 2014, the pledge of all of our assets and intellectual property as well as the guarantee by Mr. Pappajohn will be released. Under the terms of the extension, we will be required to restrict \$6.0 million in cash as collateral. Additionally, will be required to maintain limits on capital spending and are restricted as to the amount we may pledge as collateral for additional borrowings from any source.

*Secured Note Payable*

On September 25, 2012, we entered into a note payable secured by lab equipment due March 25, 2014. The note requires monthly payments of principal and interest at 18% per annum. At December 31, 2013 and 2012, \$22,298 and \$102,165, respectively, was outstanding under the note.

**Subsequent Event**

On February 21, 2014, a secured note with a future obligation of \$22,298 was paid off prior to its contractual due date of March 25, 2014.

*Conversion of Debt concurrent with IPO*

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

|   | Converted Amount | Common Shares |
|---|------------------|---------------|
| December 2011 Financing Transaction         | \$ 4,500,000     | 450,000       |
| 2012 Convertible Debt Financing Transaction | 3,000,000        | 300,000       |
| December 2012 Bridge Financing Transaction  | 1,000,000        | 100,000       |
| Business Lines of Credit (DAM)              | 1,000,000        | 100,000       |
| Other Note Payable and accrued interest     | 134,300          | 13,430        |
|   | \$ 9,634,300     | 963,430       |

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

*December 2011 Financing Transaction*

At December 31, 2013 and 2012, \$0.0 and \$6.0 million, respectively, was outstanding under a Credit Agreement dated as of December 21, 2011, as amended and restated as of February 13, 2012.

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

The loan bore an annual interest rate equal to the prime rate plus 6.25% (9.50% at August 19, 2013). We accrued a fee due to Pecora and NNJCA of \$130,000 of which \$32,667 was paid upon conversion of the notes and the remaining balance paid on August 19, 2013. The loan was secured by all of our assets, including our intellectual property, subject to prior first and second liens in favor of Wells Fargo Bank and DAM Holdings, LLC ( DAM ).

*2012 Convertible Debt Financing Transaction*

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

Through April 10, 2013, the loan bore interest at the prime rate plus 6.25% (9.50% at April 10, 2013). In February 2013, because we did not consummate our IPO within 181 days of funding, the lenders received ten-year warrants to purchase an aggregate of 7,059 shares of our common stock (issued in proportion to their respective funding amounts) with an exercise price equal to the lesser of (i) \$42.50 per share or (ii) the IPO price per share, which was \$10.00. Pursuant to a subsequent agreement, described below, the warrants held by Mr. Pappajohn have an exercise price of \$15.00 per share. The warrant exercise price is subject to standard anti-dilution protection in the event of stock splits, stock dividends, stock combinations, reclassifications and the like.

*December 2012 Bridge Financing Transaction*

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

Through April 10, 2013, the loan bore interest at the prime rate plus 6.25% (9.50% at April 10, 2013). The credit agreement required Mr. Pappajohn to convert the outstanding principal balance into shares of our common stock at a conversion price equal to the lesser of \$42.50 or our IPO price and as a result all debt was converted on April 10, 2013 at the IPO price of \$10.00 per share. In March 2013, Mr. Pappajohn received ten-year warrants to purchase an aggregate of 2,353 shares of our common stock with an exercise price equal to the lesser of (i) \$42.50 per share or (ii) the IPO or merger price per share, because we did not consummate our IPO by March 7, 2013. Mr. Pappajohn subsequently agreed that if our final IPO price was below \$15.00, there would be no further adjustment to the price or number of shares covered by the warrants held by him. The warrant exercise price is subject to standard anti-dilution protection in the event of stock splits, stock dividends, stock combinations, reclassifications and the like.

*Business Line of Credit DAM*

At December 31, 2013 and 2012, \$0.0 million and \$3 million, respectively, were outstanding under a line of credit agreement with DAM.



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

Pursuant to an intercreditor agreement between Mr. Pappajohn and DAM (the Intercreditor Agreement), we were required to use the proceeds from our IPO to repay the full amount outstanding under the DAM Loan Agreement before any proceeds can be used to repay any debt outstanding under the Wells Fargo Line of Credit. On February 13, 2013, DAM agreed to convert \$1.0 million which had been due April 1, 2013 of outstanding indebtedness into shares of common stock at the IPO price per share. We had accrued a fee due to DAM of \$52,500 which was paid upon conversion of the line of credit. On March 19, 2013, the maturity date for \$2 million of the DAM debt was extended to mature on August 15, 2013. The DAM debt bore an annual interest rate of 10% payable in equal monthly installments.

*Other Note Payable*

At December 31, 2012, notes payable included a \$100,000 note payable to Dr. Chaganti, our Chairman of the Board. Accrued interest at December 31, 2012 was approximately \$34,300. The note bore interest at 8.5% per annum. On April 10, 2013, the note and accrued interest converted into 13,430 shares of common stock at the IPO price of \$10.00 per share.

*Loss on Debt and Warrant Restructuring*

As noted above, we entered into a Restated Credit Agreement with Mr. Pappajohn and Mr. Oman in October 2012 to provide for additional borrowing of \$1,000,000 and to remove the conversion price adjustment of a 20% discount to the IPO or merger price if the IPO or merger price is less than \$53.12 per share. We evaluated the application of ASC 470-50, *Modifications and Extinguishments* and ASC 470-60, *Troubled Debt Restructurings by Debtors* and concluded that the revised terms constituted a debt extinguishment, rather than a debt modification or troubled debt restructuring.

Also as noted above, we cancelled certain warrants with an exercise price adjustment of a 20% discount to the IPO or merger price if the IPO or merger price is less than \$53.13 per share and issued warrants without an exercise price adjustment to a 20% discount to the IPO or merger price if the IPO or merger price is less than \$53.13 per share as compensation. In connection with these transactions, we recognized a loss on debt and warrant restructuring during 2012 as presented below:

|   |                     |
|---|---------------------|
| Restated 2012 convertible debt financing transaction                    | <b>\$ 1,506,512</b> |
| Amend warrants granted for guarantee of business line of credit         | <b>268,000</b>      |
| Amend warrants granted for 2011 convertible debt financing transaction  | <b>545,000</b>      |
| Settle warrants granted for guarantee of business line of credit        | <b>(129,500)</b>    |
| Settle warrants granted for 2011 convertible debt financing transaction | <b>(328,000)</b>    |
| Loss on debt and warrant restructuring                                  | <b>\$ 1,862,012</b> |

***Note 7. Letter of Credit***

During 2013 we restricted an additional \$50,000 in cash and secured a \$300,000 letter of credit in favor of our landlord pursuant to the terms of the lease for our Rutherford facility. At December 31, 2013 the letter of credit was fully secured by the restricted cash disclosed on our Consolidated Balance Sheet.

**Table of Contents****Note 8. Fixed Assets**

Fixed assets are summarized by major classifications as follows:

|                               | <b>2013</b>         | <b>2012</b>  |
|-------------------------------|---------------------|--------------|
| Equipment                     | <b>\$ 2,513,066</b> | \$ 1,914,215 |
| Furniture and fixtures        | <b>461,119</b>      | 461,119      |
| Leasehold improvements        | <b>595,689</b>      | 583,592      |
|                               | <b>3,569,874</b>    | 2,958,926    |
| Less accumulated depreciation | <b>(2,305,250)</b>  | (1,994,003)  |
| Net fixed assets              | <b>\$ 1,264,624</b> | \$ 964,923   |

**Note 9. Income Taxes**

The provision for income taxes for the years ended December 31, 2013, 2012 and 2011 differs from the approximate amount of income tax benefit determined by applying the U.S. federal income tax rate to pre-tax loss, due to the following:

|  | <b>For the Year Ended<br/>December 31, 2013</b> |                                 | <b>For the Year Ended<br/>December 31, 2012</b> |                                 | <b>For the Year Ended<br/>December 31, 2011</b> |                                 |
|--|---|---------------------------------|---|---------------------------------|---|---------------------------------|
|  | <b>Amount</b>                                   | <b>% of<br/>Pretax<br/>Loss</b> | <b>Amount</b>                                   | <b>% of<br/>Pretax<br/>Loss</b> | <b>Amount</b>                                   | <b>% of<br/>Pretax<br/>Loss</b> |
| Income tax benefit at federal statutory rate           | <b>\$ (4,563,000)</b>                           | <b>35.0%</b>                    | \$ (2,333,000)                                  | 35.0%                           | \$ (6,960,000)                                  | 35.0%                           |
| State tax provision, net of federal tax benefit        | <b>(359,000)</b>                                | <b>2.8%</b>                     | (661,000)                                       | 9.5%                            | 604,000)  | 3.0%                            |
| Tax credits  | <b>(126,000)</b>                                | <b>1.0%</b>                     | (82,000)  | 1.1%                            | (57,000)  | 0.3%                            |
| Stock based compensation permanent differences         | <b>229,000</b>                                  | <b>-1.8%</b>                    | 85,000  | -1.2%                           | 43,000  | -0.2%                           |
| Derivative warrant permanent differences               | <b>(1,622,000)</b>                              | <b>12.4%</b>                    | (1,926,000)                                     | 26.0%                           | 3,636,000                                       | -18.2%                          |
| Debt and warrant conversion costs permanent difference | <b>4,118,000</b>                                | <b>-31.6%</b>                   |   |                                 |   |                                 |
| State tax benefit of State of New Jersey NOL           | <b>(664,000)</b>                                | <b>5.1%</b>                     |   |                                 |   |                                 |
| Change in valuation allowance                          | <b>2,356,000</b>                                | <b>-18.1%</b>                   | 4,858,000                                       | -70.2%                          | 5,320,000                                       | -26.8%                          |
| Change in uncertain tax positions                      | <b>0.0%</b>                                     | <b>0.0%</b>                     | 0.0%  | 0.0%                            | (1,395,000)                                     | 7.0%                            |
| Other  | <b>(33,000)</b>                                 | <b>0.3%</b>                     | 59,000  | -0.2%                           | 17,000  | -0.1%                           |
| Provision for income taxes                             | <b>\$ (664,000)</b>                             | <b>5.1%</b>                     | \$  | 0.0%                            | \$  | 0.0%                            |



Approximate deferred taxes consist of the following components as of December 31, 2013 and 2012:

|                                      | 2013              | 2012          |
|--------------------------------------|-------------------|---------------|
| Deferred tax assets:                 |                   |               |
| Net operating loss carryforwards     | \$ 17,140,000     | \$ 15,134,000 |
| Accruals and reserves                | 509,000           | 486,000       |
| Non-qualified stock options          | 877,000           | 844,000       |
| Research and development tax credits | 603,000           | 477,000       |
| Derivative warrant liability         | 26,000            | 26,000        |
| Investment in joint venture          | 163,000           |               |
| Other                                | 5,000             | 7,000         |
| <b>Total deferred tax assets</b>     | <b>19,323,000</b> | 16,974,000    |
| Less valuation allowance             | (19,303,000)      | (16,947,000)  |
| <b>Net deferred tax assets</b>       | <b>20,000</b>     | 27,000        |
| Deferred tax liabilities             |                   |               |
| Fixed assets                         | (20,000)          | (27,000)      |
| <b>Net deferred taxes</b>            | <b>\$</b>         | <b>\$</b>     |

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Due to a history of losses we have generated since inception, we believe it is more-likely-than-not that all of the deferred tax assets will not be realized as of December 31, 2013 and 2012. Therefore, we have recorded a full valuation allowance on our deferred tax assets. We have net operating loss carryforwards for federal income tax purposes of approximately \$44,000,000 as of December 31, 2013. The net operating loss carryforwards will begin to expire in 2027. Utilization of these carryforwards is subject to limitation due to ownership changes that may delay the utilization of a portion of the carryforwards.

On January 22, 2013, we executed a sale of \$8,018,107 of gross State of New Jersey NOL carryforwards, resulting in the receipt of \$663,900. The proceeds were recorded as an income tax benefit for the year ended December 31, 2013. The Company transferred the NOL carryforwards through the Technology Business Tax Certificate Transfer Program sponsored by the New Jersey Economic Development Authority.

At December 31, 2013 and 2012 we had no uncertain tax positions.

## **Subsequent Event**

The Company received approval from the State of New Jersey to sell \$22,301,643 of gross state NOL carryforwards and executed a sale in January, 2014 of carryforwards relating to tax years 2009 through 2012, resulting in the receipt of \$1,813,941. The Company transferred the NOL carryforwards through the Technology Business Tax Certificate Transfer Program sponsored by the New Jersey Economic Development Authority. The proceeds were recorded as an income tax benefit in January, 2014.

## ***Note 10. Capital Stock***

### ***IPO***

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

### ***Secondary Offering***

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

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

### ***Follow-On Offering***

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

*Preferred Stock*

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

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***Note 11. Stock Option Plans***

We have two equity incentive plans: the 2008 Stock Option Plan (the 2008 Plan ) and the 2011 Equity Incentive Plan (the 2011 Plan , and together with the 2008 Plan, the Stock Option Plans ). The 2011 Plan was approved by the Board of Directors on June 30, 2011 and was subsequently ratified by stockholders. The 2011 Plan originally authorized the issuance of up to 150,000 shares of common stock under several types of equity awards including stock options, stock appreciation rights, restricted stock awards and other awards defined in the 2011 Plan. On October 12, 2012, the Board of Directors voted to amend the 2011 Plan. The amendment increases the number of shares available for grant under the 2011 Plan from 150,000 to 350,000 shares. This amendment has been ratified by our stockholders.

The Board of Directors adopted the 2008 Plan on April 29, 2008 and reserved 251,475 shares of common stock for issuance under the plan. On April 1, 2010, the stockholders voted to increase the number of shares reserved by the plan to 550,000. The 2008 Plan is meant to provide additional incentive to officers, employees and consultants to remain in our employment. We are authorized to issue incentive stock options or non-statutory stock options to eligible participants. Options granted are generally exercisable for up to 10 years.

At December 31, 2013, no shares remain available for future awards under the 2008 Plan and 28,594 shares remain available for future awards under the 2011 Plan.

As of December 31, 2013, no stock appreciation rights and 7,500 shares of restricted stock had been awarded under the Stock Option Plans.

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

During 2011, 35,650 options were amended to increase the exercise price from \$4.00 to \$4.80 based upon a retrospective valuation of our common stock as of the date of grant. The options did not result in the recognition of incremental compensation cost.

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

Additionally, subject to the adoption of a new equity plan or amendment to increase the shares available for issuance under the 2011 Plan, 50,000 shares of restricted stock have been approved to be issued to the Company's Chief Executive Officer. Recognition of compensation expense related to these shares of restricted stock will begin at the date of the new plan adoption or amendment of the 2011 Plan, which is when the employee will begin to benefit from, or be adversely affected by, changes in the Company's stock price.

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A summary of employee and nonemployee stock option activity for the years ended December 31, 2013, 2012 and 2011 is as follows:

|                                | <b>Options Outstanding</b> | <b>Weighted-</b> | <b>Weighted-</b>       | <b>Aggregate</b> |
|--------------------------------|----------------------------|------------------|------------------------|------------------|
|                                | <b>Number of</b>           | <b>Average</b>   | <b>Average</b>         | <b>Intrinsic</b> |
|                                | <b>Shares</b>              | <b>Exercise</b>  | <b>Remaining</b>       | <b>Value</b>     |
|                                |                            | <b>Price</b>     | <b>Contractual</b>     |                  |
|                                |                            |                  | <b>Term (in years)</b> |                  |
| Outstanding January 1, 2011    | 511,660                    | \$ 10.90         | 8.97                   | \$ 1,693,760     |
| Granted                        | 67,615                     | 26.73            |                        |                  |
| Cancelled or expired           | (19,285)                   | 11.78            |                        |                  |
| Outstanding December 31, 2011  | 559,990                    | \$ 12.85         | 8.10                   | \$ 11,737,710    |
| Granted                        | 2,400                      | 33.80            |                        |                  |
| Cancelled or expired           | (9,050)                    | 23.43            |                        |                  |
| Outstanding December 31, 2012  | 553,340                    | \$ 12.76         | 7.13                   | \$ 1,142,432     |
| Granted                        | 426,762                    | 14.57            |                        |                  |
| Exercised                      | (164)                      | 10.00            |                        |                  |
| Cancelled or expired           | (106,396)                  | 20.46            |                        |                  |
| Outstanding December 31, 2013  | 873,542                    | \$ 10.83         | 7.75                   | \$ 3,138,539     |
| Exercisable, December 31, 2013 | 413,103                    | \$ 7.21          | 6.08                   | \$ 2,726,095     |

Aggregate intrinsic value represents the difference between the fair value of our common stock and the exercise price of outstanding, in-the-money options. The fair value of our common stock was \$13.78 as of December 31, 2013 and the estimated fair value of our common stock was \$9.60 and \$33.80 as of December 31, 2012 and 2011, respectively. During the year ended December 31, 2013, we received \$1,640 from the exercise of options. The options exercised in 2013 had a total intrinsic value of \$1,630. Options were not exercised in 2012 or 2011.

As of December 31, 2013, total unrecognized compensation cost related to nonvested stock options granted to employees was \$4,176,050, which we expect to recognize over the next 3.92 years.

As of December 31, 2013 and 2012, total unrecognized compensation cost related to nonvested stock options granted to non-employees was \$94,359 and \$190,500, respectively, which we expect to recognize over the next 1.78 and 0.50 years, respectively. The estimate of unrecognized nonemployee compensation is based on the fair value of the nonvested options as of December 31, 2013 and 2012.

The following table summarizes information about outstanding and vested stock options granted to employees and non-employees as of December 31, 2013 as follows:

| <b>Exercise Price</b> | <b>Options Outstanding</b> | <b>Options Vested and Exercisable</b> |
|-----------------------|----------------------------|---------------------------------------|
|-----------------------|----------------------------|---------------------------------------|

|       | <b>Number<br/>of<br/>Shares<br/>Outstanding</b> | <b>Weighted-<br/>Average<br/>Remaining<br/>Contractual<br/>Life (in years)</b> | <b>Weighted-<br/>Average<br/>Exercise<br/>Price</b> | <b>Number of<br/>Shares</b> | <b>Weighted-<br/>Average<br/>Exercise Price</b> |
|-------|---|--|---|-----------------------------|---|
| 4.00  | 175,000   | 5.33   | \$ 4.00   | 175,000                     | \$ 4.00   |
| 4.80  | 33,340  | 6.05   | 4.80  | 26,936                      | 4.80  |
| 10.00 | 291,990   | 6.81   | 10.00   | 204,380                     | 10.00   |
| 11.75 | 5,600   | 9.29   | 11.75   |                             | 11.75   |
| 12.50 | 200   | 6.94   | 12.50   | 120                         | 12.50   |
| 12.55 | 10,000  | 9.95   | 12.55   |                             | 12.55   |
| 13.81 | 3,000   | 9.90   | 13.81   |                             | 13.81   |
| 14.18 | 5,500   | 9.88   | 14.18   |                             | 14.18   |
| 15.39 | 348,912   | 9.77   | 15.39   | 6,667                       | 15.39   |
| Total | 873,542   | 7.75   | \$ 10.83  | 413,103                     | \$ 7.21   |

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The fair value of options granted to employees is estimated on the grant date using the Black-Scholes option valuation model. This valuation model for stock-based compensation expense requires us to make assumptions and judgments about the variables used in the calculation, including the fair value of our common stock (see Note 13), the expected term (the period of time that the options granted are expected to be outstanding), the volatility of our common stock, a risk-free interest rate, and expected dividends. We also estimate forfeitures of unvested stock options. To the extent actual forfeitures differ from the estimates, the difference will be recorded as a cumulative adjustment in the period estimates are revised. No compensation cost is recorded for options that do not vest. We use the simplified calculation of expected life described in the SEC's Staff Accounting Bulletin No. 107, *Share-Based Payment*, and volatility is based on an average of the historical volatilities of the common stock of four entities with characteristics similar to those of the Company. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option. We use an expected dividend yield of zero, as we do not anticipate paying any dividends in the foreseeable future. Expected forfeitures are assumed to be zero due to the small number of plan participants and the plan design which has monthly vesting after an initial cliff vesting period.

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

|  | <b>Year Ended December 31,</b> |             |             |
|--|--------------------------------|-------------|-------------|
|  | <b>2013</b>                    | <b>2012</b> | <b>2011</b> |
| Volatility   | 76.60%                         | 77.39%      | 76.13%      |
| Risk free interest rate  | 1.79%                          | 1.43%       | 2.67%       |
| Dividend yield   |                                |             |             |
| Term (years)   | 6.14                           | 6.50        | 6.44        |
| Weighted-average fair value of options granted during the period | \$ 9.85                        | \$ 23.35    | \$ 10.60    |

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

|                         | <b>Year Ended December 31,</b> |             |             |
|-------------------------|--------------------------------|-------------|-------------|
|                         | <b>2013</b>                    | <b>2012</b> | <b>2011</b> |
| Volatility              | 75.68%                         | 75.01%      | 75.45%      |
| Risk free interest rate | 1.53%                          | 1.26%       | 2.85%       |
| Dividend yield          |                                |             |             |
| Term (years)            | 7.68                           | 8.28        | 9.23        |

In October 2013, we issued 2,500 shares of fully vested restricted stock to Mr. Thompson with a grant date fair value of \$15.39 per share. In December 2013, we issued 5,000 shares of restricted stock to an employee with a grant date fair value of \$12.55 per share. At December 31, 2013, 7,500 restricted shares were outstanding and 2,500 were vested. Also, at December 31, 2013 there was \$61,913 of unrecognized compensation cost related to unvested restricted stock which we expect to recognize over 3.04 years.





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The following table presents the effects of stock-based compensation related to stock option and restricted stock awards to employees and nonemployees on our Statement of Operations during the periods presented:

|                                       | <b>Year Ended December 31,</b> |                   |                   |
|---------------------------------------|--------------------------------|-------------------|-------------------|
|                                       | <b>2013</b>                    | <b>2012</b>       | <b>2011</b>       |
| Cost of revenues                      | \$ 41,470                      | \$ 11,753         | \$ 9,603          |
| Research and development              | 114,189                        | 460,321           | 423,950           |
| General and administrative            | 516,127                        | 297,175           | 263,693           |
| Sales and marketing                   | 63,359                         | 146,112           | 245,871           |
| <b>Total stock-based compensation</b> | <b>\$ 735,145</b>              | <b>\$ 915,361</b> | <b>\$ 943,117</b> |

On October 10, 2013 (the Grant Date), the Compensation Committee granted each the Company's Chief Executive Officer and Vice President Research and Development an option to purchase 200,000 shares and 10,000 shares, respectively, of the Company's common stock at an exercise price of \$15.39 per share (the closing price of a share of common stock on The NASDAQ Capital Market on the business day immediately prior to the Grant Date). The options are scheduled to expire on the tenth anniversary of the Grant Date and are scheduled to vest over a period of five years from the Grant Date. The vesting of the option granted to the Chief Executive Officer may be accelerated upon the achievement of certain milestones. In addition, the Company committed to issue 50,000 restricted shares of common stock to the Chief Executive Officer subject to the adoption of a new equity plan or amendment to increase the shares available for issuance under the 2011 Plan.

On October 10, 2013, the Company granted each non-employee director, other than the chairman of the board, options to purchase 10,000 shares of Common Stock at an exercise price of \$15.39 (the closing price of a share of common stock on The NASDAQ Capital Market on October 9, 2013), resulting in a total grant of 60,000 options.

On October 10, 2013, the Company granted its incoming chairman of the audit committee, options to purchase 12,312 shares of Common Stock at an exercise price of \$15.39 and the Company granted its outgoing chairman of the audit committee 2,500 fully vested shares of restricted stock in recognition of his past service as chairman of the audit committee.

On October 10, 2013, the Company's board of directors adopted a compensation policy for its non-employee directors, other than the chairman of the board who is compensated pursuant to the terms of a separate consulting agreement. This policy provides for the following cash compensation to the Company's non-employee directors, other than the chairman of the board:

each non-employee director will receive an annual base fee of \$10,000; and

in addition to the \$10,000 annual base fee, the chairman of the audit committee will receive an annual fee of \$10,000.

This policy provides for the following equity compensation to the Company's non-employee directors, other than our chairman of the board:

each non-employee director, other than the chairman of the board, will receive bi-annual restricted stock awards of 5,000 shares of common stock; and

each non-employee director, other than the chairman of the board, will receive annual option grants to purchase 10,000 shares of common stock.

The restricted stock awards and option grants will each vest in two equal annual installments. Equity grants under the director compensation policy are subject to the adoption of a new equity plan or amendment to increase the shares available for issuance under the 2011 Plan.

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All fees under the director compensation policy will be paid on a quarterly basis and no per meeting fees will be paid. The Company will also reimburse non-employee directors for reasonable expenses incurred in connection with attending board and committee meetings.

## **Subsequent Events**

On January 3, 2014, the board of directors appointed John Pappajohn to serve as the Chairman of the Board, a position previously held by Dr. Raju S.K. Chaganti, effective January 6, 2014. As compensation for serving as the Chairman of the Board, the Company will pay Mr. Pappajohn \$100,000 per year and will grant to Mr. Pappajohn, subject to the approval by the Company's stockholders of a new equity incentive plan or the amendment of the Company's existing equity incentive plan, 25,000 restricted shares of the Company's common stock, and options to purchase an aggregate of 100,000 shares of the Company's common stock. The options will have a term of ten years from the date on which they are granted. The restricted stock and the options will each vest in two equal installments on the one year anniversary and the two year anniversary of the date on which Mr. Pappajohn becomes the Chairman of the Board.

In February, 2014, the Company received \$2,020 from a former employee who exercised options to purchase 202 shares of common stock at \$10.00 per share.

In February, 2014, the Company modified the vesting terms of 10,000 stock options issued to a former board member, resulting in stock-based compensation expense of \$83,000 and which will be reflected in General and administrative expense in the Company's 10-Q for the quarterly period ended March 31, 2014.

In February, 2014, pursuant to the terms of his renewed consulting agreement, Dr. Chaganti will receive, subject to the adoption of a new equity plan or amendment to increase the shares available for issuance under the 2011 Equity Plan, an option to purchase 200,000 shares of our common stock at a purchase price of \$15.89 per share.

In March 2013, the Company announced the appointment of a new Chief Financial Officer effective April 1, 2014. The Company will grant, subject to the adoption of a new equity plan or amendment to increase the shares available for issuance under the 2011 Equity Plan, an option to purchase 90,000 shares of our common stock and 10,000 shares of restricted stock.

On March 17, 2014, the Company announced that its Chief Financial Officer, Elizabeth Czerepak, will resign effective March 31, 2014. In connection with Ms. Czerepak's resignation, the Company and Ms. Czerepak have entered into a separation agreement (the "Separation Agreement"). The Separation Agreement provides for severance benefits of, among other things: one year's salary of \$250,000; a lump sum payment equal to \$125,000; her accrued 2013 annual bonus of \$125,000; a bonus of \$25,000 for the first quarter of 2014, and; payout of accrued paid-time-off of approximately \$25,000. The Separation Agreement also provides for the acceleration of all stock options held by her and the expiration date on her options will be extended until December 31, 2014. The acceleration of the vesting terms of the stock options held by her will result in stock-based compensation expense of approximately \$124,000. Expenses of approximately \$525,000 incurred under the Separation Agreement will be reflected General and administrative expense in the Company's 10-Q for the quarterly period ended March 31, 2014.

## ***Note 12. Warrants***

We have issued certain warrants which contain an exercise price adjustment feature in the event we issue additional equity instruments at a price lower than the exercise price of the warrant. The warrants are described herein as derivative warrants. For all derivative warrants, in the event equity instruments are issued at a price lower than the exercise price of the warrant, the exercise price is adjusted to the price of the new equity instruments issued (price

adjustment feature). For certain of these warrants, the number of shares underlying the warrant is also adjusted to an amount computed by dividing the proceeds of the warrant under its original terms by the revised exercise price (share adjustment feature). These warrants are initially recorded as a warrant

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liability at fair value with a corresponding entry to the loan guarantee fee asset, debt discount, additional paid-in capital or expense dependent upon the service provided in exchange for the warrant grant. Subsequently, any change in fair value is recognized in earnings until such time as the warrants are exercised, amended or expire.

In connection with debt guarantees and extensions, we issued 1,051,506 warrants to Mr. Pappajohn, a member of our Board of Directors and stockholder, at various dates (see Note 17). These warrants are initially recorded at fair value as a loan guarantee fee amortized over the period of the guarantee to interest expense. The aggregate issue date fair value of the debt guarantee warrants was \$1,555,000 in 2012, and \$831,000 in 2011. There were no debt guarantee warrants issued in 2013.

In connection with the acquisition of a line of credit, we issued 60,000 warrants to DAM in March 2011 with an initial estimated fair value of \$1,019,000. In March 2012 in exchange for an extension of that line, we issued 15,000 warrants with an initial estimated fair value of \$306,000. See Note 6.

We issued 200 warrants to a consultant for services provided in February and March 2011 and 4,000 warrants to a member of our Board of Directors in connection with the March 2011 line of credit agreement with DAM. These warrants were recorded as consulting expense at an initial estimated fair value of \$69,000 and expire in March 2016.

On September 30, 2011, certain holders of derivative warrants to purchase 228,288 shares of common stock with an exercise price of \$4.00 agreed to an amendment to their warrants to remove the exercise price adjustment feature. As of September 30, 2011, the fair value of these warrants of \$6,415,000 was reclassified from the warrant liability to equity.

In connection with the December 2011 Financing Transaction we granted a total of 112,940 warrants at various dates to Mr. Pappajohn, Dr. Pecora and NNJCA. The aggregate issue date fair value of these financing fee warrants was \$1,522,000 in 2012 and \$951,000 in 2011. In October 2012, 37,646 of these warrants were surrendered in exchange for an increase to the prepayment penalty, and 75,294 were amended in exchange for 20,669 additional warrants with an initial estimated fair value of \$606,000. Also in October 2012, Mr. Pappajohn agreed to extend a portion of the debt's maturity date and in exchange we issued 9,412 additional warrants with an initial estimated fair value of \$267,000. See Note 6.

In connection with the 2012 Convertible Debt Financing Transaction, we granted a total of 28,235 warrants to Mr. Pappajohn and Mr. Oman with an initial estimated fair value of \$1,107,000. In October 2012, these warrants were surrendered in exchange for additional financing and 114,510 new warrants with an initial estimated fair value of \$4,090,000. See Note 6.

On September 6, 2012, we extended the maturity date of warrants to purchase 70,598 shares of our common stock which were due to expire on September 10, 2012 to September 28, 2012. On September 27, 2012, we extended the maturity date of 65,328 of these warrants to September 10, 2013. In exchange, the warrants became subject to a lock-up agreement for 180 days after the consummation of an IPO on the same terms as other lock-up agreements in favor of the underwriters of an offering. We determined the fair value of the warrant extensions to be approximately \$144,000, which was recorded as general and administrative expense.

On October 22, 2012, in exchange for amending warrants issued in connection with his guarantee of the Wells Fargo debt, we issued warrants to purchase 10,157 shares of our common stock to Mr. Pappajohn with an exercise price equal to the lesser of (i) \$42.50 per share and (ii) the IPO or merger price per share. These warrants were recorded as a financing fee expense at an estimated fair value of \$298,000.

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In connection with the December 2012 Bridge Financing transaction, we granted 23,529 warrants to Mr. Pappajohn with an initial estimated fair value of \$837,000. See Note 6.

During 2012, warrants to purchase 54,910 shares were exercised and \$690,227 was received and recorded as increases to common stock and additional paid-in capital. An additional 15,164 warrants expired unexercised.

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

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

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

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

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

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

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

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

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

On October 7, 2013 and October 8, 2013, warrant holders exercised warrants to purchase 33,868 shares of common stock, at exercise prices ranging from \$10.00 to \$14.10 per share, using the net issuance exercise method whereby 23,188 shares were surrendered as payment in full of the exercise price resulting in a net issuance of 10,680 shares.

**Subsequent Events**

In January, 2013, the Company received \$950 from a warrant holder who exercised warrants to purchase 95 shares of common stock at \$10.00 per share.



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The following table summarizes the warrant activity for the years ending December 31, 2013, 2012 and 2011:

| Warrants<br>Outstanding<br>January 1,<br>2011 | 2011<br>Warrants<br>Issued | 2011<br>Warrants<br>Exercised | 2011<br>Warrants<br>Amended | Warrants<br>Outstanding<br>December 31,<br>2011 | 2012<br>Warrants<br>Issued | 2012<br>Warrants<br>Exercised | 2012<br>Warrants<br>Surrendered | 2012<br>Warrants<br>Expired | Warrants<br>Outstanding<br>December 31,<br>2012 | 2013<br>Warrants<br>Issued | 2013<br>Warrants<br>Exercised |
|---|----------------------------|-------------------------------|-----------------------------|---|----------------------------|-------------------------------|---------------------------------|-----------------------------|---|----------------------------|-------------------------------|
| 12,411  |                            | (3,546)                       |                             | 8,865   |                            | (2,482)                       |                                 | (6,383)                     |   |                            |                               |
|   |                            |                               | 228,288                     | 228,288   |                            |                               |                                 |                             | 228,288   |                            | (54,000)                      |
| 30,000  |                            |                               |                             | 30,000  |                            | (30,000)                      |                                 |                             |   |                            |                               |
| 89,214  |                            |                               |                             | 89,214  |                            | (18,616)                      |                                 | (5,269)                     | 65,329  |                            | (29,868)                      |
| 31,625  |                            | (3,546)                       | 228,288                     | 356,367   |                            | (51,098)                      |                                 | (11,652)                    | 293,617   |                            | (83,868)                      |
| 7,325   |                            |                               |                             | 7,325   |                            | (3,812)                       |                                 | (3,513)                     |   |                            |                               |
|   | 60,000                     |                               |                             | 60,000  |                            |                               |                                 |                             | 60,000  |                            |                               |
|   | 42,353                     |                               |                             | 42,353  | 189,117                    |                               | (156,176)                       |                             | 75,294  |                            |                               |
|   |                            |                               |                             |   | 54,314                     |                               |                                 |                             | 54,314  | 2,941                      |                               |
|   |                            |                               |                             |   | 120,865                    |                               |                                 |                             | 120,865   | 6,471                      |                               |
| 28,288  |                            |                               | (228,288)                   |   |                            |                               |                                 |                             |   |                            |                               |
| 12,000  |                            |                               |                             | 212,000   |                            |                               |                                 |                             | 212,000   |                            |                               |
| 100,000                                       |                            |                               |                             | 100,000   |                            |                               |                                 |                             | 100,000   |                            |                               |
|   | 40,000                     |                               |                             | 40,000  |                            |                               |                                 |                             | 40,000  |                            |                               |
|   |                            |                               |                             |   | 75,392                     |                               | (37,000)                        |                             | 38,392  |                            |                               |
|   |                            |                               |                             |   | 37,000                     |                               |                                 |                             | 37,000  |                            |                               |
| 52,464  |                            |                               |                             | 52,464  |                            |                               |                                 |                             |   |                            | (34,034)                      |
| 4,030   |                            |                               |                             | 4,030   |                            |                               |                                 |                             | 4,030   |                            |                               |
| 10,000  |                            |                               |                             | 10,000  |                            |                               |                                 |                             | 10,000  |                            |                               |
|   | 200                        |                               |                             | 200   |                            |                               |                                 |                             | 200   |                            |                               |
|   | 4,000                      |                               |                             | 4,000   |                            |                               |                                 |                             | 4,000   |                            |                               |
| 14,107  | 146,553                    |                               | (228,288)                   | 532,372   | 476,688                    | (3,812)                       | (193,176)                       | (3,513)                     | 808,559   | 9,412                      | (34,034)                      |
| 45,732  | 146,553                    | (3,546)                       |                             | 888,739   | 476,688                    | (54,910)                      | (193,176)                       | (15,165)                    | 1,102,176                                       | 9,412                      | (117,902)                     |

- A These warrants are subject to fair value accounting and contain exercise price and number of share adjustment features. See Note 13.
- B These warrants are subject to fair value accounting and contain an exercise price adjustment feature. See Note 13.
- C On February 11, 2013, these warrants held by John Pappajohn were amended to limit the adjustment feature(s) to \$15.00 per share in an initial public offering (totaling 530,022 warrants).
- D The exercise price and/or number of share adjustment features of these warrants expired and are no longer subject to fair value accounting after our initial public offering.
- E On April 10, 2013 the Company completed the IPO at \$10.00 per share. The shares of common stock issuable upon the exercise of warrants outstanding as of April 10, 2013 increased by 838,889 shares and the exercise prices of 1,656,860 warrants were adjusted as a result of the share and exercise price adjustment features described above.
- F Weighted average exercise prices are as of December 31, 2013.

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The following tables summarize the assumptions used in computing the fair value of derivative warrants subject to fair value accounting at the date of issue during the years ended December 31, 2013, 2012 and 2011 and at December 31, 2013, April 5, 2013 (IPO valuation date) and December 31, 2012. In computing the fair value of the warrants, if the stated exercise price of the warrants exceeded the assumed value of the Company stock at the date the fair value was being computed, the exercise price and number of shares (if applicable) underlying the warrants were adjusted to reflect an assumed trigger of the price and/or share adjustment features related to the applicable warrants. Such adjustments were only applicable to 2012 and 2013 due to the relative price of the warrants and the assumed Company stock price:

|                         | Issued During<br>the Year Ended<br>December 31, |          | As of<br>December 31, |          | IPO Date         |
|-------------------------|---|----------|-----------------------|----------|------------------|
|                         | 2012  | 2011     | 2013                  | 2012     | April 5,<br>2013 |
| <b>Debt Guarantee</b>   |   |          |                       |          |                  |
| Exercise Price          | \$ 9.60   | \$ 32.45 | \$ 10.00              | \$ 28.78 | \$ 13.56         |
| Expected life (years)   | 4.66  | 5.00     | 0.83                  | 2.66     | 2.42             |
| Expected volatility     | 80.05%  | 77.35%   | 57.33%                | 67.71%   | 66.37%           |
| Risk-free interest rate | 0.82%   | 1.76%    | 0.13%                 | 0.37%    | 0.32%            |
| Expected dividend yield | 0.00%   | 0.00%    | 0.00%                 | 0.00%    | 0.00%            |

|                         | As of December 31, |         |
|-------------------------|--------------------|---------|
|                         | 2013               | 2012    |
| <b>Series B</b>         |                    |         |
| Exercise Price          | \$ 10.00           | \$ 9.60 |
| Expected life (years)   | 1.92               | 2.92    |
| Expected volatility     | 59.26%             | 61.44%  |
| Risk-free interest rate | 0.38%              | 0.36%   |
| Expected dividend yield | 0.00%              | 0.00%   |

|                         | As of December 31, |         | IPO Date      |
|-------------------------|--------------------|---------|---------------|
|                         | 2013               | 2012    | April 5, 2013 |
| <b>Consulting</b>       |                    |         |               |
| Exercise Price          | \$ 10.00           | \$ 9.60 | \$ 10.00      |
| Expected life (years)   | 2.14               | 2.48    | 2.33          |
| Expected volatility     | 62.63%             | 63.29%  | 63.20%        |
| Risk-free interest rate | 0.38%              | 0.28%   | 0.27%         |
| Expected dividend yield | 0.00%              | 0.00%   | 0.00%         |

|  | Issued During<br>the Year Ended<br>December 31, | As of December 31, | IPO Date |
|--|---|--------------------|----------|
|  |   |                    | April 5, |

|                         | 2013     | 2012     | 2013     | 2012    | 2013     |
|-------------------------|----------|----------|----------|---------|----------|
| <b>Financing</b>        |          |          |          |         |          |
| Exercise Price          | \$ 13.34 | \$ 23.69 | \$ 10.00 | \$ 9.60 | \$ 13.21 |
| Expected life (years)   | 9.78     | 6.81     | 2.25     | 6.66    | 8.30     |
| Expected volatility     | 74.70%   | 77.74%   | 64.40%   | 73.38%  | 73.22%   |
| Risk-free interest rate | 1.95%    | 1.19%    | 0.38%    | 1.06%   | 1.44%    |
| Expected dividend yield | 0.00%    | 0.00%    | 0.00%    | 0.00%   | 0.00%    |

The assumed ranges of Company stock prices used in computing the warrant fair value for warrants issued during the year is as follows: in 2013, \$9.60 \$20.26; in 2012, \$9.60 \$33.80; in 2011, \$ 11.90 \$33.80. In

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determining the fair value of warrants issued at each reporting date, the assumed Company stock price was \$13.78 (the closing price on the NASDAQ Capital Market) at December 31, 2013 and \$9.60 (per an external valuation estimate) at December 31, 2012.

The following table summarizes the derivative warrant activity subject to fair value accounting for the years ended December 31, 2013, 2012 and 2011:

|  | <b>Issued with<br/>Series A<br/>Preferred<br/>Stock</b> | <b>Issued with<br/>Series B<br/>Preferred<br/>Stock</b> | <b>Issued For<br/>Debt<br/>Guarantee</b> | <b>Issued<br/>For<br/>Consulting</b> | <b>Issued For<br/>Financing</b> | <b>Total</b> |
|--|---|---|--|--------------------------------------|---------------------------------|--------------|
| Fair value of warrants outstanding as of December 31, 2010 | \$ 63,000   | \$ 314,000  | \$ 3,793,000                             | \$ 100,000                           | \$                              | \$ 4,270,000 |
| Fair value of warrants issued                              |   |   | 831,000                                  | 69,000                               | 1,970,000                       | 2,870,000    |
| Warrants amended   |   |   | (6,415,000)                              |                                      |                                 | (6,415,000)  |
| Change in fair value of warrants                           | 157,000   | 846,000   | 8,784,000                                | 278,000                              | 323,000                         | 10,388,000   |
| Fair value of warrants outstanding as of December 31, 2011 | 220,000   | 1,160,000   | 6,993,000                                | 447,000                              | 2,293,000                       | 11,113,000   |
| Fair value of warrants issued                              |   |   | 1,583,000                                |                                      | 4,961,000                       | 6,544,000    |
| Fair value of warrants exercised                           | (55,000)  |   |  |                                      |                                 | (55,000)     |
| Warrant restructuring                                      |   |   | 268,000                                  |                                      | 2,217,000                       | 2,485,000    |
| Change in fair value of warrants                           | (165,000)   | (930,000)   | (3,165,000)                              | (300,000)                            | (2,978,000)                     | (7,538,000)  |
| Fair value of warrants outstanding as of December 31, 2012 |   | 230,000   | 5,679,000                                | 147,000                              | 6,493,000                       | 12,549,000   |
| Fair value of warrants issued                              |   |   |  |                                      | 268,000                         | 268,000      |
| Fair value of warrants exercised                           |   | (420,000)   |  |                                      |                                 | (420,000)    |
| Reclassification to equity in IPO                          |   |   | (2,514,000)                              | (108,000)                            | (4,548,000)                     | (7,170,000)  |
| Change in fair value of warrants                           |   | 307,000   | (3,101,000)                              | (38,000)                             | (1,801,000)                     | (4,633,000)  |
| Fair value of warrants outstanding as of December 31, 2013 | \$  | \$ 117,000  | \$ 64,000                                | \$ 1,000                             | \$ 412,000                      | \$ 594,000   |

***Note 14. Fair Value Measurements***

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. The Fair Value Measurements and Disclosures Topic of the FASB Accounting Standards Codification requires the use of valuation techniques that are consistent with the market approach, the income approach and/or the cost approach. Inputs to valuation techniques refer to the assumptions that market participants would use in pricing the asset or liability. Inputs may be observable, meaning those that reflect the assumptions market participants would use in pricing the asset or liability developed based on market data obtained from independent sources, or unobservable, meaning those that reflect our own assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. In that regard, the Topic establishes a fair value hierarchy for valuation inputs that give the highest priority to quoted prices in active markets for identical assets or liabilities and the lowest priority to unobservable inputs.

The fair value hierarchy is as follows:

Level 1: Quoted prices (unadjusted) for identical assets or liabilities in active markets that we have the ability to access as of the measurement date.

Level 2: Significant other observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data.

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Level 3: Significant unobservable inputs that reflect our own assumptions about the assumptions that market participants would use in pricing an asset or liability.

The following table summarizes the financial liabilities measured at fair value on a recurring basis segregated by the level of valuation inputs within the fair value hierarchy utilized to measure fair value:

|                   | Total      | 2013   |   |   |
|-------------------|------------|--|---|---|
|                   |            | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Warrant liability | \$ 594,000 |  |   | \$ 594,000                                |

|                   | Total         | 2012   |   |   |
|-------------------|---------------|--|---|---|
|                   |               | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Warrant liability | \$ 12,549,000 |  |   | \$ 12,549,000                             |

The warrant liability consists of stock warrants we issued that contain an exercise price adjustment feature. In accordance with derivative accounting for warrants, we calculated the fair value of warrants and the assumptions used are described in Note 13, Fair Value of Warrants. Realized and unrealized gains and losses related to the change in fair value of the warrant liability are included in other income (expense) on the Consolidated Statement of Operations.

A table summarizing the activity for the derivative warrant liability which is measured at fair value using Level 3 inputs is presented in Note 13.

**Note 15. Contingencies**

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

From 2000 to 2004, we operated a clinical laboratory in Milford, Massachusetts providing cancer screening services. The clinical laboratory participated in the Medicare program. The Office of the Inspector General of the U.S. Department of Health and Human Services and the United States Department of Justice informed us in February 2009 that they were contemplating commencing a civil False Claims Act action against us with respect to certain alleged improper billing practices and overpayments relating to operations at the Milford, Massachusetts clinical laboratory. In January 2012, we executed a settlement agreement with the United States Department of Justice. Pursuant to the

settlement agreement, we neither admitted liability nor conceded that the claims of the United States are well founded. In January 2012, we paid to the United States the sum of \$1,000,000 in connection with the investigation. We received \$400,000 in December 2011 from our insurance carrier related to this matter. The net amount shown in our statement of operations is a net recovery of \$200,000 in 2011 and an expense of \$800,000 in 2010.

***Note 16. Joint Venture Agreement***

In November 2011, we entered into an affiliation agreement with the Mayo Foundation for Medical Education and Research ( Mayo ), subsequently amended. Under the agreement, we formed a joint venture with Mayo in May 2013 to focus on developing oncology diagnostic services and tests utilizing next generation sequencing.



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The joint venture is a limited liability company, with each party initially holding fifty percent of the issued and outstanding membership interests of the new entity (the "JV"). The agreement also requires aggregate total capital contributions by us of up to \$5.0 million over the next two and a half years. We currently anticipate that we will make capital contributions of \$1.0 million in the second quarter of 2014 and \$2.0 million each on the first and second anniversaries of the closing date, respectively, with the latter two installments subject to the JV's achievement of certain operational milestones agreed upon by the board of governors of the JV. In exchange for its membership interests, Mayo's capital contribution will take the form of cash, staff, services, hardware and software resources, laboratory space and instrumentation, the fair market value of which will be approximately equal to \$6 million. Mayo's continued contribution will also be conditioned upon the JV's achievement of certain milestones. The operation of the joint venture may also divert management time from operating our business. No assurances can be given that we will be able to fully fund 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.

In exchange for the membership interests in the JV, we made an initial capital contribution of \$1.0 million in October 2013. In addition, in October 2013, we issued 10,000 shares of our common stock to Mayo pursuant to our affiliation agreement with Mayo and recorded an expense of approximately \$175,000. We also recorded additional expense of approximately \$231,000 during the fourth quarter of 2013 related to shares issued to Mayo in November of 2011 as the JV achieved certain performance milestones. We currently anticipate that we will make an additional capital contribution of \$1.0 million in the second quarter of 2014.

***Note 17. Related Party Transactions***

John Pappajohn, a member of the Board of Directors and stockholder, personally guarantees our revolving line of credit with Wells Fargo Bank through April 1, 2014. As consideration for his guarantee, as well as each of the eight extensions of this facility through December 31, 2013, Mr. Pappajohn received warrants to purchase an aggregate of 1,051,506 shares of common stock of which Mr. Pappajohn assigned warrants to purchase 284,000 shares of common stock to certain third parties. Warrants to purchase 395,825 shares of common stock have been exercised by Mr. Pappajohn through December 31, 2013. After adjustment pursuant to the terms of the warrants in conjunction with our IPO, the number of these warrants outstanding retained by Mr. Pappajohn was 585,645 at \$15.00 per share and 44,288 at \$4.00 per share (See Notes 6 and 12).

In addition, John Pappajohn also had loaned us an aggregate of \$6,750,000 (all of which was converted into 675,000 shares of common stock at the IPO price of \$10.00 per share). In connection with these loans, Mr. Pappajohn received warrants to purchase an aggregate of 202,630 shares of common stock. After adjustment pursuant to the terms of the warrants in conjunction with our IPO, the number of warrants outstanding was 436,079 at \$15.00 per share at December 31, 2013 (See Notes 6 and 12).

Andrew Pecora (indirectly through an investment company), when a member of our board of directors, and NNJCA, a limited liability company of which Dr. Pecora is a member originally provided \$500,000 and \$1.5 million of financing, respectively, under a Credit Agreement dated as of December 21, 2011, as amended and restated as of February 13, 2012. On April 10, 2013, NNJCA converted \$500,000 of its outstanding indebtedness into 50,000 shares of our common stock at the IPO price of \$10.00 per share concurrent with our IPO. On August 19, 2013, the remaining principal under these notes were repaid to Dr. Pecora and NNJCA using a portion of the proceeds from our Secondary Offering. The loan bore an annual interest rate equal to the prime rate plus 6.25% (9.50% at August 19, 2013). We paid a pre-payment penalty due to Pecora and NNJCA of \$130,000 of which \$32,667 was paid upon

conversion of the notes and the remaining balance paid on August 19, 2013.

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On May 19, 2006, we issued a convertible promissory note in favor of our then Chairman and founder, Dr. Chaganti, the holder, which obligated us to pay the holder the sum of \$100,000, together with interest at the rate of 8.5% per annum, due April 1, 2014. Interest expense totaled \$2,400, \$8,400, and \$8,400 for the years ended December 31, 2013, 2012, and 2011, respectively (see Note 4 for additional information regarding the conversion of the promissory note into common stock concurrent with our IPO on April 10, 2013). Pursuant to a consulting and advisory agreement, Dr. Chaganti also received options to purchase a total of 36,000 shares of common stock at a price of \$10.00 per share which vested over a two year period. Total non-cash stock-based compensation recognized under the consulting agreement for the years ended December 31, 2013, 2012 and 2011 were \$76,220, \$430,600 and \$401,250, respectively. Additionally, on September 15, 2010, we entered into a three-year consulting agreement with Dr. Chaganti which was subsequently renewed through December 31, 2016 pursuant to which Dr. Chaganti receives \$5,000 per month for providing consulting and technical support services. Total expenses for each of the years ended December 31, 2013, 2012 and 2011 were \$60,000. In addition, Dr. Chaganti received a non-qualified stock option to purchase 60,000 shares of common stock at a purchase price of \$25.00 per share vesting quarterly beginning October 1, 2010 and which are fully vested at December 31, 2013. Pursuant to the terms of the renewed consulting agreement, Dr. Chaganti will receive, subject to the adoption of a new equity plan or amendment to increase the shares available for issuance under the 2011 Equity Plan, an option to purchase 200,000 shares of our common stock at a purchase price of \$15.89 per share. Also pursuant to the consulting agreement, Dr. Chaganti assigned to us all rights to any inventions which he may invent during the course of rendering consulting services to us. In exchange for this assignment, if the USPTO issues a patent for an invention on which Dr. Chaganti is listed as an inventor, we are required to pay Dr. Chaganti (i) a one-time payment of \$50,000 and (ii) 1% of any net revenues we receive from any licensed sales of the invention. As of December 31, 2013, we accrued \$150,000 for three patents that were issued where Dr. Chaganti was listed as inventor.

On July 1, 2010, we entered into a one-year consulting agreement with Edmund Cannon, a member of our board of directors, pursuant to which Mr. Cannon received \$2,000 per calendar quarter for providing consulting services to us in connection with our clinical lab business. The agreement was terminated in 2011. Total expense under the consulting agreement was \$4,000 in 2011.

On August 15, 2010, we entered into a two-year consulting agreement with Dr. Pecora, then a member of our board of directors, pursuant to which Dr. Pecora received \$5,000 per month for providing consulting and advisory services. Dr. Pecora also received stock options under the consulting and advisory agreement to purchase a total of 12,000 shares of common stock at price of \$25.00 per share which vested over a two year period. Total expense for 2011 under the consulting agreement was \$45,000 paid in cash and \$235,560 expensed under the stock option plan. The cash component of this agreement was terminated by mutual consent in August 2011. Total expenses for 2013 and 2012 under the consulting agreement were \$0 and \$142,740, respectively expensed under the stock option plan.

In August 2010, we entered into a consulting agreement with Equity Dynamics, Inc., an entity controlled by John Pappajohn, pursuant to which Equity Dynamics, Inc. receives a monthly fee of \$10,000 plus reimbursement of expenses. Total expenses for each 2013 and 2012 under the consulting agreement were \$120,000 per year. As of December 31, 2013 and December 31, 2012, we owed Equity Dynamics, Inc. \$0 and \$132,679, respectively.

We issued 4,000 warrants to Mr. Thompson, a member of our Board of Directors in connection with the March 2011 line of credit agreement with DAM. These warrants were recorded as consulting expense at an initial estimated fair value of \$69,000 and expire in March 2016.

In February 2012, we granted 28,235 warrants proportionately to Pecora and NNJCA upon their funding of \$0.5 million and \$1.5 million, respectively, under a new Credit Agreement. (See Notes 6 and 12). On May 15, 2012 and on August 14, 2012, we issued 4,706 of these warrants proportionately to Pecora and NNJCA (Notes 6 and 12). On

October 15, 2012, Dr. Pecora and NNJCA agreed to surrender warrants to purchase an aggregate of 37,646 shares of our common stock issued in connection with this transaction in exchange for an amendment to increase the pre-payment penalties by \$130,000.

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**Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure**

None.

**Item 9A. Controls and Procedures.**

*Evaluation of Disclosure Controls and Procedures.*

We evaluated, under the supervision and with the participation of the Chief Executive Officer and Chief Financial Officer, the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934 ( Exchange Act ), as amended) as of December 31, 2013, the end of the period covered by this report on Form 10-K. Based on this evaluation, our President and Chief Executive Officer (principal executive officer) and our Chief Financial Officer (principal accounting and financial officer) have concluded that our disclosure controls and procedures were effective at December 31, 2013. Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and were operating in an effective manner for the period covered by this report, and (ii) is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

*Management's Report on Internal Control Over Financial Reporting.*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act and is a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, to:

Provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of our management and directors; and

Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

This annual report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

For the year ended December 31, 2011, our independent registered public accounting firm reported a material weakness in our internal control over financial reporting related to our monitoring of the performance of the third-party service providers we use in our revenue cycle. During 2011, we changed third-party service providers to improve our platform for future growth. After the conversion we identified instances of delayed billings and collection efforts and procedural issues with the timely application of cash receipts.

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Management's remediation plan, which was initiated during fiscal 2012, included the hiring of a dedicated full-time senior accountant to monitor the revenue recognition process and we have improved our monitoring systems for data transmission to our third party billing service provider. We have also established a system with our bank to correct a deficiency in the bank's system that prevented our timely review of electronic deposits.

No other change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the year ended December 31, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

*Changes in internal control over financial reporting.*

There was no change in our internal controls over financial reporting that occurred during the fourth quarter of 2013 that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

**Item 9B. Other Information.**

None.

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**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance.**

The information required by this item with respect to directors is incorporated by reference from the information under the caption "Election of Directors" contained in our Proxy Statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for our 2014 Annual Meeting of Stockholders to be held on May 22, 2014, or Proxy Statement. Certain information required by this item concerning executive officers is set forth in Part I of this Report under the caption "Executive Officers of the Registrant" and is incorporated herein by reference.

Item 405 of Regulation S-K calls for disclosure of any known late filing or failure by an insider to file a report required by Section 16(a) of the Exchange Act. This disclosure is contained in the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to all of our officers and employees, including our President and Chief Executive Officer, our Chief Financial Officer and other employees who perform financial or accounting functions. The Code of Business Conduct and Ethics sets forth the basic principles that guide the business conduct of our employees. Stockholders may request a free copy of our Code of Business Conduct and Ethics by contacting Cancer Genetics, Inc., Attention: Chief Financial Officer, 201 Route 17 North, Rutherford, New Jersey 07070.

To date, there have been no waivers under our Code of Business Conduct. We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics or waivers of such Code granted to executive officers and directors on our website at <http://www.cancergenetics.com> within four business days following the date of such amendment or waiver.

Our Board of Directors has appointed an Audit Committee, comprised of Mr. Keith Brownlie, as Chairman, Dr. Franklyn Prendergast and Mr. Edmund Cannon. The Board of Directors has determined that Mr. Brownlie qualifies as an Audit Committee Financial Expert under the definition outlined by the Securities and Exchange Commission. In addition, each of the members of the Audit Committee qualifies as an independent director under the current rules of The NASDAQ Stock Market and Securities and Exchange Commission rules and regulations.

**Item 11. Executive Compensation.**

The information required by this item is incorporated by reference from the information under the caption "Executive Compensation" contained in the Proxy Statement.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required by this item is incorporated by reference from the information under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation Equity Compensation Plan Information" contained in the Proxy Statement.



**Item 13. Certain Relationships and Related Transactions, and Director Independence.**

The information required by this item is incorporated by reference from the information under the caption Election of Directors Certain Relationships and Related Transactions and Director Independence contained in the Proxy Statement.

**Item 14. Principal Accounting Fees and Services.**

The information required by this item is incorporated by reference from the information under the caption Ratification of the Appointment of Independent Registered Public Accounting Firm Principal Accountant Fees and Services contained in the Proxy Statement.

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**PART IV**

**Item 15. Exhibits, Financial Statement Schedules.**

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

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

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

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**SIGNATURES**

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

**Cancer Genetics, Inc.**

(Registrant)

Date: March 28, 2013

**/s/ Panna L. Sharma**  
**Panna L. Sharma**  
**President and Chief Executive Officer**

**(Principal Executive Officer and duly authorized signatory)**

Date: March 28, 2013

**/s/ Elizabeth Czepak**  
**Elizabeth Czepak**  
**Chief Financial Officer**

**(Principal Financial and Accounting Officer)**

Table of Contents**SIGNATURES AND POWER OF ATTORNEY**

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Panna Sharma and Elizabeth Czerepak, and each of them, his true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to (i) act on, sign and file with the Securities and Exchange Commission any and all amendments to this annual report on Form 10-K together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith and, (iii) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act, this annual report on Form 10-K has been signed by the following persons in the capacities and on the dates indicated.

| <b>Signature</b>  | <b>Title</b>   | <b>Date</b>    |
|---|--|----------------|
| /s/ Panna L. Sharma<br>Panna L. Sharma                              | President, Chief Executive Officer<br>and Director<br><br><i>(Principal Executive Officer)</i>       | March 28, 2014 |
| /s/ Elizabeth A. Czerepak<br>Elizabeth A. Czerepak                  | Chief Financial Officer<br><i>(Principal Financial Officer and<br/>Principal Accounting Officer)</i> | March 28, 2014 |
| /s/ John Pappajohn<br>John Pappajohn                                | Chairman of the Board of Directors   | March 28, 2014 |
| /s/ Keith L. Brownlie<br>Keith L. Brownlie, CPA                     | Director   | March 28, 2014 |
| /s/ Edmund Cannon<br>Edmund Cannon                                  | Director   | March 28, 2014 |
| /s/ Raju S. K. Chaganti<br>Raju S. K. Chaganti, Ph.D.               | Director   | March 28, 2014 |
| /s/ Franklyn G. Prendergast<br>Franklyn G. Prendergast, M.D., Ph.D. | Director   | March 28, 2014 |

/s/ Paul Rothman

Director

March 28, 2014

Paul Rothman, M.D.

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| <b>Exhibit<br/>No.</b> | <b>Description</b>   |
|------------------------|--|
| 3.1                    | Third Amended and Restated Certificate of Incorporation of Cancer Genetics, Inc., filed as Exhibit 3.1 to quarterly report on Form 10-Q filed on May 15, 2013 and incorporated herein by reference.  |
| 3.2                    | Amended and Restated Bylaws of Cancer Genetics, Inc., filed as Exhibit 3.4 to Form S-1/A filed on April 30, 2012 (File No. 333-178836) and incorporated herein by reference.   |
| 4.1                    | Specimen Common Stock certificate of Cancer Genetics, Inc., filed as Exhibit 4.1 to Form S-1/A filed on May 16, 2012 (File No. 333-178836) and incorporated herein by reference.   |
| 4.2                    | Registration Rights Agreement, between Cancer Genetics, Inc. and DAM Holdings, LLC, dated March 23, 2011, filed as Exhibit 4.2 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.  |
| 4.3                    | Form of Short Form Cashless Exercise Warrant, filed as Exhibit 4.9 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.  |
| 4.4                    | Form of Medium Form Warrant, filed as Exhibit 4.10 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.  |
| 4.5                    | Form of Long Form Warrant, filed as Exhibit 4.11 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.  |
| 4.6                    | Form of Bridge Financing Warrant issued by Cancer Genetics, Inc. to John Pappajohn, NNJCA Capital, LLC, Pecora and Company and DAM Holdings, LLC, filed as Exhibit 10.36 to Form S-1/A filed on March 13, 2012 (File No. 333-178836) and incorporated herein by reference. |
| 4.7                    | Form of Modified Bridge Warrant issued by Cancer Genetics, Inc. to John Pappajohn and Mark Oman, filed as Exhibit 10.50 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference.  |
| 4.8                    | Form of October 2012 Warrant issued by Cancer Genetics, Inc. to John Pappajohn and Mark Oman, filed as Exhibit 10.53 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference.   |
| 10.1                   | Amended and Restated 2008 Stock Option Plan, filed as Exhibit 10.1 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference.   |
| 10.2                   | Form of Notice of Stock Option Grant under 2008 Stock Option Plan, filed as Exhibit 10.2 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.  |
| 10.3                   | Form of Stock Option Grant Agreement under 2008 Stock Option Plan, filed as Exhibit 10.3 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.  |
| 10.4                   | Form of Exercise Notice and Restricted Stock Purchase Agreement under 2008 Stock Option Plan, filed as Exhibit 10.4 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.   |
| 10.5                   | Amended and Restated 2011 Equity Compensation Plan, filed as Exhibit 10.5 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference.  |

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- 10.6 Form of Stock Option Grant Agreement under 2011 Stock Option Plan, filed as Exhibit 10.6 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.
- 10.7 Form of Indemnification Agreement, filed as Exhibit 10.7 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.

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| <b>Exhibit No.</b> | <b>Description</b>  |
|--------------------|---|
| 10.8               | Consulting Agreement between Cancer Genetics, Inc. and TSG, LLC, dated June 19, 2009, filed as Exhibit 10.8 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.  |
| 10.9               | Medical Director Agreement, between Cancer Genetics, Inc. and Lan Wang, M.D., dated October 9, 2009, filed as Exhibit 10.9 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.                           |
| 10.10              | Consulting Agreement, between Cancer Genetics, Inc. and Edmund Cannon, dated July 1, 2010, filed as Exhibit 10.13 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.                                    |
| 10.11              | Consulting Agreement, between Cancer Genetics, Inc. and Andrew Pecora, dated August 15, 2010, filed as Exhibit 10.14 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.                                 |
| 10.12              | Consulting Agreement, between Cancer Genetics, Inc. and R.S.K. Chaganti, dated September 15, 2010, filed as Exhibit 10.15 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.                            |
| 10.13              | Employment Agreement, between Panna Sharma and Cancer Genetics, Inc., effective as of April 1, 2010, filed as Exhibit 10.17 to Form S-1/A filed on February 14, 2012 (File No. 333-178836) and incorporated herein by reference.                        |
| 10.14              | Employment Agreement, between Elizabeth Czerepak and Cancer Genetics, Inc., effective as of January 1, 2012, filed as Exhibit 10.18 to Form S-1/A filed on February 14, 2012 (File No. 333-178836) and incorporated herein by reference.                |
| 10.15              | Employment Agreement, between Jane Houldsworth El Naggar, Ph.D. and Cancer Genetics, Inc., effective as of January 1, 2012, filed as Exhibit 10.19 to Form S-1/A filed on February 14, 2012 (File No. 333-178836) and incorporated herein by reference. |
| 10.16              | Office Lease Agreement, between Cancer Genetics, Inc. and Onyx Equities, LLC, dated October 9, 2007, filed as Exhibit 10.20 to Form S-1/A filed on April 23, 2012 (File No. 333-178836) and incorporated herein by reference.                           |
| 10.17              | Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated April 29, 2008, filed as Exhibit 10.21 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.                             |
| 10.18              | Security Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated April 29, 2008, filed as Exhibit 10.22 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.                           |
| 10.19              | First Addendum to Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated July 7, 2008, filed as Exhibit 10.23 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.             |
| 10.20              | Second Addendum to Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated March 30, 2009, filed as Exhibit 10.24 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.          |



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- 10.21 Third Addendum to Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated July 2, 2009, filed as Exhibit 10.25 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference
- 10.22 Fourth Addendum to Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated October 21, 2009, filed as Exhibit 10.26 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.

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| <b>Exhibit No.</b> | <b>Description</b>  |
|--------------------|---|
| 10.23              | Fifth Addendum to Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated July 29, 2010, filed as Exhibit 10.27 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.  |
| 10.24              | Credit Agreement, between Cancer Genetics, Inc. and DAM Holdings, LLC, dated March 23, 2011, filed as Exhibit 10.28 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.  |
| 10.25              | Inter-creditor Agreement, between Cancer Genetics, Inc., John Pappajohn and DAM Holdings, LLC, dated March 23, 2011, filed as Exhibit 10.29 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.  |
| 10.26              | General Business Security Agreement, between Cancer Genetics, Inc. and DAM Holdings, LLC, dated March 23, 2011, filed as Exhibit 10.30 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.   |
| 10.27              | Promissory Note, issued by Cancer Genetics, Inc. to DAM Holdings, LLC, dated March 23, 2011, filed as Exhibit 10.31 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.  |
| 10.28              | Sixth Addendum to Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated June 6, 2011, filed as Exhibit 10.32 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.   |
| 10.29              | Amended and Restated Credit Agreement, by and among Cancer Genetics, Inc., John Pappajohn, Pecora and Company and NNJCA Capital, LLC dated February 13, 2012, filed as Exhibit 10.33 to Form S-1/A filed on March 13, 2012 (File No. 333-178836) and incorporated herein by reference.                          |
| 10.30              | Form of Promissory Note issued by Cancer Genetics, Inc. to John Pappajohn, filed as Exhibit 10.34 to Form S-1/A filed on March 13, 2012 (File No. 333-178836) and incorporated herein by reference.   |
| 10.31              | Form of Promissory Note issued by Cancer Genetics, Inc. to NNJCA Capital, LLC and Pecora and Company, filed as Exhibit 10.35 to Form S-1/A filed on March 13, 2012 (File No. 333-178836) and incorporated herein by reference.  |
| 10.32              | Inter-Creditor Agreement, between Cancer Genetics, Inc., John Pappajohn, DAM Holdings, LLC, Pecora and Company, NNJCA Capital, LLC and Equity Dynamics, Inc., dated February 13, 2012, filed as Exhibit 10.37 to Form S-1/A filed on March 13, 2012 (File No. 333-178836) and incorporated herein by reference. |
| 10.33              | Seventh Addendum to Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated February 15, 2012, filed as Exhibit 10.38 to Form S-1/A filed on March 13, 2012 (File No. 333-178836) and incorporated herein by reference.   |
| 10.34              | Amendment to Credit Agreement, between Cancer Genetics, Inc. and DAM Holdings, LLC, dated March 9, 2012, filed as Exhibit 10.33 to Form S-1/A filed on March 13, 2012 (File No. 333-178836) and incorporated herein by reference.   |
| 10.35              | Affiliation Agreement, between Cancer Genetics, Inc. and Mayo Foundation for Medical Education and Research dated November 7, 2011, filed as Exhibit 10.35 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.   |

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- 10.36 Consulting Agreement with Equity Dynamics, Inc., filed as Exhibit 10.38 to Form S-1/A filed on February 14, 2012 (File No. 333-178836) and incorporated herein by reference.
- 10.37 Letter Agreement, between Panna Sharma and Cancer Genetics, Inc., dated March 29, 2012, filed as Exhibit 10.43 to Form S-1/A filed on April 23, 2012 (File No. 333-178836) and incorporated herein by reference.

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| <b>Exhibit No.</b> | <b>Description</b>  |
|--------------------|---|
| 10.38              | Letter Agreement, between Meadows Office, L.L.C. and Cancer Genetics, Inc., dated January 10, 2008, filed as Exhibit 10.44 to Form S-1/A filed on April 23, 2012 (File No. 333-178836) and incorporated herein by reference.  |
| 10.39              | Letter Agreement, between Meadows Office, L.L.C. and Cancer Genetics, Inc., dated April 6, 2012, filed as Exhibit 10.45 to Form S-1/A filed on April 23, 2012 (File No. 333-178836) and incorporated herein by reference.   |
| 10.40              | Letter of Credit from JPMorgan Chase Bank, N.A., dated April 19, 2012, filed as Exhibit 10.46 to Form S-1/A filed on April 30, 2012 (File No. 333-178836) and incorporated herein by reference.   |
| 10.41              | Letter Agreement between Cancer Genetics, Inc. and John Pappajohn, filed as Exhibit 10.47 to Form S-1/A filed on May 7, 2012 (File No. 333-178836) and incorporated herein by reference.  |
| 10.42              | Confidential Settlement Agreement and Release of All Claims, between and among Louis J. Maione, Esq., Cancer Genetics, Inc., John Pappajohn, Raju Chaganti, Andrew Pecora, Tommy Thompson, Edmund Cannon, Matthew Kinley, Panna Sharma, and GAP Partners, LLP, dated May 2012, filed as Exhibit 10.48 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference. |
| 10.43              | Amendment No. 1 to Affiliation Agreement, between Cancer Genetics, Inc. and Mayo Foundation for Medical Education and Research, dated September 29, 2012, filed as Exhibit 10.49 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference.  |
| 10.44              | Restated Credit Agreement, between Mark Oman and John Pappajohn and Cancer Genetics, Inc., dated October 17, 2012, filed as Exhibit 10.51 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference.   |
| 10.45              | Form of Restated Promissory Note issued by Cancer Genetics, Inc. to John Pappajohn and Mark Oman, filed as Exhibit 10.52 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference.  |
| 10.46              | Restated Registration Rights Agreement, between Cancer Genetics, Inc., Mark Oman and John Pappajohn, dated October 17, 2012, filed as Exhibit 10.54 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference.   |
| 10.47              | Letter Agreement between Cancer Genetics, Inc. and Pecora, filed as Exhibit 10.55 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference.   |
| 10.48              | Letter Agreement between Cancer Genetics, Inc. and NNJCA Capital, LLC, filed as Exhibit 10.56 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference.   |
| 10.49              | Letter Agreement between Cancer Genetics, Inc. and DAM Holdings, Inc., filed as Exhibit 10.57 to Form S-1/A filed on October 23, 2012 (File No. 333-178836) and incorporated herein by reference.   |
| 10.50              | Eighth Addendum to Credit Agreement, between Cancer Genetics, Inc. and Wells Fargo Bank, N.A., dated October 18, 2012, filed as Exhibit 10.58 to Form S-1/A filed on November 16, 2012 (File No. 333-178836) and incorporated herein by reference.  |
| 10.51              | Credit Agreement between John Pappajohn and Cancer Genetics, Inc. dated December 4, 2012, filed as Exhibit 10.59 to Form S-1/A filed on December 14, 2012 (File No. 333-178836) and incorporated herein by reference.   |

- 10.52 Promissory Note issued by Cancer Genetics, Inc. to John Pappajohn dated December 4, 2012, filed as Exhibit 10.60 to Form S-1/A filed on December 14, 2012 (File No. 333-178836) and incorporated herein by reference.

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| <b>Exhibit No.</b> | <b>Description</b>  |
|--------------------|---|
| 10.53              | Amendment No. 2 to Affiliation Agreement between Cancer Genetics, Inc. and Mayo Foundation for Medical Education and Research, dated January 4, 2013, filed as Exhibit 10.61 to Form S-1/A filed on January 8, 2013 (File No. 333-178836) and incorporated herein by reference.                   |
| 10.54              | Written Description of Amendment to Letter Agreement, between Meadows Office, L.L.C. and Cancer Genetics, Inc., dated April 6, 2012, filed as Exhibit 10.62 to Form S-1/A filed on January 8, 2013 (File No. 333-178836) and incorporated herein by reference.                                    |
| 10.55              | Letter Agreement between Cancer Genetics, Inc. and John Pappajohn dated February 11, 2013, filed as Exhibit 10.63 to Form S-1/A filed on February 12, 2013 (File No. 333-178836) and incorporated herein by reference.  |
| 10.56              | Letter Agreement between Cancer Genetics, Inc. and John Pappajohn (on behalf of his spouse) dated February 13, 2013, filed as Exhibit 10.64 to Form S-1/A filed on February 14, 2013 (File No. 333-178836) and incorporated herein by reference.  |
| 10.57              | Letter Agreement between Cancer Genetics, Inc. and NNJCA Capital, LLC dated as of February 13, 2013, filed as Exhibit 10.65 to Form S-1/A filed on February 14, 2013 (File No. 333-178836) and incorporated herein by reference.  |
| 10.58              | Letter Agreement between Cancer Genetics, Inc. and DAM Holdings, LLC dated February 13, 2013, filed as Exhibit 10.66 to Form S-1/A filed on February 14, 2013 (File No. 333-178836) and incorporated herein by reference.   |
| 10.59              | Letter Agreement between Cancer Genetics, Inc. and R.S.K. Chaganti, dated February 13, 2013, filed as Exhibit 10.67 to Form S-1/A filed on March 4, 2013 (File No. 333-178836) and incorporated herein by reference.  |
| 10.60              | Form of Letter Agreement between Cancer Genetics, Inc. and certain warrant holders waiving certain anti-dilution rights, filed as Exhibit 10.68 to Form S-1/A filed on March 4, 2013 (File No. 333-178836) and incorporated herein by reference.  |
| 10.61              | Letter Agreement, between Meadows Office, L.L.C. and Cancer Genetics, Inc., dated March 8, 2013, filed as Exhibit 10.69 to Form S-1/A filed on March 11, 2013 (File No. 333-178836) and incorporated herein by reference.   |
| 10.62              | Letter Amendment dated March 20, 2013 to Letter Agreement, between Meadows Office, L.L.C. and Cancer Genetics, Inc., dated April 6, 2012, filed as Exhibit 10.72 to Form S-1/A filed on March 22, 2013 (File No. 333-178836) and incorporated herein by reference.                                |
| 10.63              | Amendment No. 3 to Affiliation Agreement between the Company and Mayo Foundation for Medical Education and Research, dated May 21, 2013, filed as Exhibit 10.73 to Form S-1 filed on June 5, 2013 (File No. 333-189117) and incorporated herein by reference.                                     |
| 10.64              | Limited Liability Company Agreement of OncoSpire Genomics, LLC, dated May 21, 2013, filed as Exhibit 10.74 to Form S-1/A filed on July 12, 2013 (File No. 333-189117) and incorporated herein by reference.   |
| 10.65              | Joint Development Intellectual Property Agreement, among the Company, Mayo Foundation for Medical Education and Research and OncoSpire Genomics, LLC, dated May 21, 2013, filed as Exhibit 10.75 to Form S-1/A filed on July 12, 2013 (File No. 333-189117) and incorporated herein by reference. |

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- 10.66\* Letter Agreement, between Cancer Genetics, Inc. and Andrew L. Pecora, effective February 18, 2014.
- 10.67\* Consulting Agreement, between Cancer Genetics, Inc. and R.S.K. Chaganti, dated February 19, 2014.

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| <b>Exhibit<br/>No.</b> | <b>Description</b>   |
|------------------------|--|
| 10.68*                 | Separation and General Release Agreement, between Cancer Genetics, Inc. and Elizabeth Czerepak, effective March 31, 2014.  |
| 10.69*                 | Employment Agreement, between Cancer Genetics, Inc. and Edward J. Sitar, dated March 17, 2014.   |
| 21.1                   | Subsidiaries of Cancer Genetics, Inc., filed as Exhibit 21.1 to Form S-1 filed on December 30, 2011 (File No. 333-178836) and incorporated herein by reference.  |
| 23.1*                  | Consent of McGladrey LLP.  |
| 31.1*                  | Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities and Exchange Act of 1934, as amended.  |
| 31.2*                  | Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities and Exchange Act of 1934, as amended.  |
| 32.1**                 | Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.   |
| 32.2**                 | Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.   |
| 101***                 | The following financial statements from this annual report on Form 10-K of Cancer Genetics, Inc. for the year-ended December 31, 2013, filed on March 28, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Income, (iii) the Consolidated Statements of Cash, (iv) the Consolidated Statements of Comprehensive Income and (v) the Notes to the Consolidated Financial Statements. |

\* Filed herewith.

\*\* Furnished herewith.

\*\*\* Users of this interactive data file are advised that, pursuant to Rule 406T of Regulations S-T, this interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.