CANCER GENETICS, INC
Form S-1/A
August 12, 2013
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As filed with the Securities and Exchange Commission on August 12, 2013

Registration No. 333-189117

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 4 to

Form S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

CANCER GENETICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	8071	04-3462475
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

201 Route 17 North 2nd Floor

Rutherford, NJ 07070

(201) 528-9200

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

Panna L. Sharma

Chief Executive Officer

Cancer Genetics, Inc.

201 Route 17 North 2nd Floor

Rutherford, NJ 07070

(201) 528-9200

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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(973) 597-2564	

Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ¨

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions 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 x

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the Registration Statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS **SUBJECT TO COMPLETION** **DATED AUGUST 12, 2013**

$15,000,000 of Shares

Common Stock

We are offering $15,000,000 of shares of our common stock pursuant to this prospectus.

Our common stock is presently quoted on the OTCQB Marketplace operated by the OTC Markets Group, Inc., or the OTCQB, under the symbol CGIX . We have applied to list our common stock on The NASDAQ Capital Market under the same symbol. On July 31, 2013, the last reported sale price of our common stock on the OTCQB was $11.50 per share.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act) and, as such, we elected to comply with certain reduced public company reporting requirements.

Investing in our common stock involves risk. See Risk Factors beginning on page 10 of this prospectus for a discussion of information that should be considered in connection with an investment in our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public offering price	$	$
Discounts and commissions to underwriters(1)	$	$
Offering proceeds to us, before expenses	$	$

(1) The underwriters will receive compensation in addition to the underwriting discount. See Underwriting beginning on page 150 of this prospectus for a description of compensation payable to the underwriters.

We have granted a 45-day option to the representative of the underwriters to purchase up to $2,250,000 of additional shares of common stock solely to cover over-allotments, if any.

The underwriters expect to deliver the shares against payment therefor on or about , 2013.

Sole Book-Running Manager

Aegis Capital Corp

Co-Lead Manager

Feltl and Company

, 2013

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with different information. We are not making an offer of these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information contained in this prospectus is accurate as of the date on the front of this prospectus only. Our business, financial condition, results of operations and prospects may have changed since that date.

Information contained in our website does not constitute part of this prospectus.

We use MatBA®, UroGenRA , UGenRA , FHACT , FReCAD , Expand DX , Select Genomation Report and the Cancer Genetics logo as trademarks in the United States and elsewhere. All other trademarks or trade names referred to in this prospectus are the property of their respective owners.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that they have gathered their information from sources they believe to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

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SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the Risk Factors section of this prospectus and the consolidated financial statements and related notes appearing at the end of this prospectus before making an investment decision.

Unless the context provides otherwise, all references in this prospectus to Cancer Genetics, CGI, we, us, our, the Company, or similar terms, refer to Cancer Genetics, Inc. and its wholly owned subsidiary, Cancer Genetics Italia, S.r.L.

Our Company

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. The proprietary tests we are developing 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 recently have begun to provide our proprietary tests and services along with a comprehensive range of non-proprietary oncology-focused tests and laboratory services that we have provided historically to oncologists and pathologists at hospitals, cancer centers, and physician offices, as well as to biopharmaceutical companies and clinical research organizations for their clinical trials. 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 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. During the first quarter of 2011, we received CLIA approval for, and commercially launched, MatBA®-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®-SLL, our proprietary microarray for risk stratification in small lymphocytic lymphoma (SLL), and we are currently offering MatBA®-SLL in our laboratory. In 2013, we received CLIA approval for MatBA®-DLBCL, our proprietary microarray for diagnosis, prognosis and patient monitoring in diffuse large B cell lymphoma (DLBCL), MatBA®-MCL, our proprietary microarray for diagnosis, prognosis and patient monitoring in mantle cell lymphoma (MCL) and UroGenRA -Kidney, our proprietary microarray for patient management and treatment protocols in kidney cancer (UroGenRA -Kidney). 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 a joint venture in May 2013 with Mayo Foundation for Medical Education and Research (Mayo) which, once funded by us, will focus on developing oncology diagnostic services and tests utilizing next-generation sequencing. Additionally, we have research collaborations with Memorial Sloan-Kettering Cancer Center and the Cleveland Clinic to validate our kidney-cancer microarray UroGenRA -Kidney.

We believe that we can be successful by offering cancer professionals a fully-integrated menu of oncology-focused proprietary and non-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

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information we learn through performing the nonproprietary 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. 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 will become a key component in the standard of care for personalized cancer treatment.

Market Overview

Despite many advances in the treatment of cancer, it remains one of the greatest areas of unmet medical need. The World Health Organization attributed 7.6 million deaths worldwide to cancer-related causes in 2008. 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.

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

Limitations of Traditional Cancer Diagnostics

Cancer is difficult to diagnose due to its varying morphology and genetic complexity. 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. 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. Cells that are deemed cancerous are graded on a level of progression of disease and aggressiveness.

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, thereby enabling personalized treatments based on cancer analysis at its most basic genetic level. These tests both define the cancer subtype and help determine the best course of treatment by detecting genetic mutations, gene fusions and DNA copy number changes, all of which are possible causes of or precursors to malignant growth. 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 and is commonly performed using DNA microarrays and probes.

Our Proprietary Genomic Tests and Services

Our clinical laboratory is accredited under CLIA to perform our first proprietary test, MatBA®-CLL, which is also, to our knowledge based on our informal communications with New York State Department of Health personnel, the first oncology microarray to be approved by the New York State Department of Health, one of the only state governmental agencies that reviews the clinical utility of new laboratory developed tests (LDTs). The test has been validated by us in a clinical study using over 320 CLL specimens in conjunction with a leading CLL thought leader, Dr. Kanti Rai at Long Island Jewish / North Shore Hospital. Another data set of over 200 DLBCL specimens is being analyzed for additional biomarkers in conjunction with Dr. Julie Teruya-Feldstein at Memorial Sloan-Kettering Cancer Center. There are approximately 14,500 new cases of CLL diagnosed in the United States each year, and these cases require risk stratification and guidance on patient

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management and treatment issues at multiple points during the course of the disease. Prior to the introduction of MatBA®-CLL, clinicians had to rely on diagnostic tests that provided limited information on the genetic abnormalities associated with CLL. In contrast, MatBA®-CLL identifies a much broader range of genomic markers associated with CLL, providing improved diagnostic and prognostic value and critical information for clinicians to consider in planning patient treatment. The MatBA® platform was developed by us under the guidance of Dr. Raju Chaganti, our Chairman and one of our founders. Dr. Chaganti founded one of the earliest comprehensive clinical cytogenetic laboratories focused on cancer in the United States at Memorial Sloan-Kettering Cancer Center, where he is on the faculty of the Department of Medicine and Cell Biology Program and the incumbent of the William E. Snee Chair.

In collaboration with Memorial Sloan-Kettering Cancer Center and Long Island Jewish / North Shore Hospital, we have completed the validation of MatBA®-SLL and are now offering MatBA®-SLL in our laboratory. Also in collaboration with Memorial Sloan-Kettering Cancer Center, we recently completed the validation of MatBA®-DLBCL and MatBA®-MCL and are now offering both in our laboratory. We are also validating the MatBA® microarray in follicular lymphoma (FL). Collectively, these lymphomas represent over 70% of the mature B cell cancers (neoplasms) and over 66,000 newly diagnosed cancer cases each year in the United States. Our MatBA® array has been designed to measure genetic markers at 80 specific genomic sites where genetic alterations are associated with mature B cell neoplasms.

We are also developing microarray tests for the diagnosis, prognosis and theranosis of a range of urogenital cancers. These include the UroGenRA microarray for kidney, prostate and bladder cancers and the UGenRA microarray for endometrial (lining of the uterus), ovarian and cervical cancers. UroGenRA detects genomic changes in over 100 regions of the human genome with potential diagnostic and/or prognostic value in one or more of these types of cancer. We have validated UroGenRA for kidney cancer and initiated clinical validation for UroGenRA targeting prostate cancer, both in collaboration with Memorial Sloan-Kettering Cancer Center. In addition, we completed a clinical validation for UroGenRA targeting kidney cancer in collaboration with the Cleveland Clinic. Our UGenRA microarray has been designed as a platform to detect genomic changes occurring in 83 regions of the human genome that have been linked to endometrial, ovarian and cervical cancers. In addition, we develop and manufacture a portfolio of fluorescence *in situ* hybridization (FISH) based DNA probes focused on blood-based and solid cancers that we currently sell outside the United States. We have filed five patent applications with the U.S. Patent and Trademark Office and two international (PCT) applications covering our microarrays. We also have two issued U.S. patents, a U.S. patent application, a European application and a Canadian application (which has been allowed) covering our other proprietary probe products.

We are an early-stage company and only have recently begun launching our proprietary microarray tests for use in our CLIA-accredited clinical laboratory. 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 oncology testing services to a limited number of oncologists, pathologists and community hospitals located mostly in the eastern and midwestern United States. In 2012, we generated approximately 85% of our revenue from laboratory services, approximately 13% from government grants and 2% from sales of our DNA probes, which are currently only sold outside the United States. In 2011, we generated approximately 87% of our revenue from laboratory services, approximately 10% from government grants and approximately 3% from sales of our DNA probes. Our non-proprietary laboratory testing services include molecular testing, sequencing, mutational analysis, flow cytometry testing, histology testing and cytology testing and they are described in more detail in the section entitled Description of the Business-Laboratory 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 their clinical trials. This service was branded Select One® in December 2011.

The non-proprietary testing services offered by us 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

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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 insights that we develop in delivering the non-proprietary services are often leveraged in the development of our proprietary programs and now increasingly in the validation of our proprietary programs (such as MatBA®) for clinical use.

In this prospectus, we use the terms microarray test, oncology microarray and DNA microarray interchangeably to refer to DNA-based tests that focus on multiple targets in the genomic sequence of a cancer cell. We use the terms probe , DNA probe or FISH-based DNA probe interchangeably to refer to DNA-based tests that focus on a single genomic abnormality. Finally, the terms tests and tests and services are used throughout this prospectus to refer to all of our laboratory tests, whether microarrays, probes, other genomic-based tests or other laboratory tests or services that we offer in our laboratory.

Our Strategy

Our objective is to be a leader in the development and commercialization of proprietary genomic tests and services. We aim to provide a full service solution for oncology professionals to improve the diagnosis, prognosis, theranosis and treatment of hematological, urogenital and HPV-associated cancers. To achieve this objective, we intend to:

- continue investing in our portfolio by developing and commercializing additional proprietary genomic tests and services;
- continue our focus on rapidly applying genomic research to routine clinical cancer diagnostics (translational oncology) and drive innovation and cost efficiency in diagnostics by developing next generation sequencing offerings through our joint venture with Mayo Clinic;
- enhance our efforts to partner with community hospitals;
- increase our focus on providing biopharmaceutical companies and clinical research organizations with our proprietary genomic tests and services through our SelectOne offering;
- increase our geographic coverage by expanding our scalable sales and marketing capabilities; and
- continue to reduce costs associated with the development, manufacture and interpretation of our proprietary genomic tests and services and to work with healthcare providers and other payers to demonstrate the value of our testing in providing cost efficient and accountable care.

We will continue offering our proprietary tests in the United States as LDTs and internationally as CE-marked in vitro diagnostic products. In addition, as part of our long term strategy, we plan to seek Food and Drug Administration (FDA) clearance or approval to expand the commercial use of our tests to other laboratories and testing sites. 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 MatBA®-CLL, MatBA®-SLL, MatBA®-DLBCL, MatBA®-MCL and UroGenRA -Kidney 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 emphasize partnering with community hospitals, where approximately 85% of all cancer patients in the United States are initially diagnosed, through our program called Expand Dx , which was specifically designed to meet the needs of community hospitals. We believe our proprietary tests and services will enable community hospitals to optimize and expand their oncology services to better serve their cancer patients and reduce costs associated with cancer care. We are also focused on developing relationships with biopharmaceutical companies and clinical research organizations who can leverage our proprietary genomic tests and services to increase efficiency of their clinical trials.

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Risks That We Face

An investment in our common stock involves a high degree of risk. You should carefully consider the risks summarized below. The risks are discussed more fully in the Risk Factors section of this prospectus immediately following this prospectus summary. These risks include, but are not limited to, the following:

- we are an early-stage company with a cumulative net loss through June 30, 2013 of approximately $55.7 million and we may never achieve sustained profitability;
- our business depends upon our ability to increase sales of our laboratory tests and services;
- we will need additional financing to meet our liquidity needs, including approximately $6.0 million to repay outstanding indebtedness due on April 1, 2014 and substantial additional capital to fund our operations thereafter;
- we need to clinically validate our pipeline of microarray tests currently in development;
- our business depends on our ability to continually develop and commercialize novel and innovative diagnostic cancer tests and services;
- our business depends on executing on our sales and marketing strategy for our proprietary tests and gaining acceptance of our tests in the market;
- our business depends on satisfying United States (including FDA) and international regulatory requirements with respect to our tests and services and many of these requirements are new and still evolving;
- our business depends on being able to obtain adequate reimbursement from governmental and other third-party payors for our tests and services (for the year ended December 31, 2012, approximately 18% of our revenues came from Medicare or Medicaid, approximately 37% of our revenue came from direct bill customers and 30% of our revenues came from private insurance carriers and other third party payors);
- our business depends on our ability to effectively compete with other genomic-based diagnostic tests and services that now exist or may hereafter be developed;
- we need to maintain our clinical collaborations and enter into new collaboration agreements with highly regarded organizations in the cancer field in order to, among other things, have access to both thought leaders in the field and samples to validate our proprietary tests;
- we depend on our ability to attract and retain scientists, clinicians and sales personnel with extensive experience in oncology, who are in short supply; and

we need to obtain or maintain patents or other appropriate protection for the intellectual property utilized in our proprietary tests and services.

Company Information

We maintain our principal executive offices at 201 Route 17 North, 2nd Floor, Rutherford, New Jersey 07070. Our telephone number is (201) 528-9200 and our website address is www.cancergenetics.com. The information contained in, and that can be accessed through, our website is not incorporated into and is not part of this prospectus.

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The Offering

Common stock offered by us	$15,000,000 of shares of our common stock
Over-allotment option	We have granted the underwriters a 45-day option to purchase up to $2,250,000 of additional shares of our common stock from us at the public offering price less underwriting discounts and commissions.
Common stock outstanding after this offering	5,621,038
Use of proceeds	We estimate that the net proceeds from our sale of shares of our common stock in this offering will be approximately $13.5 million, or approximately $15.6 million if the underwriters exercise their over-allotment option in full, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We currently expect to use the net proceeds from this offering as follows: • approximately $3.5 million to repay certain outstanding indebtedness; • $1.0 million to fund our initial contribution to our joint venture with Mayo; • approximately $5.0 million to hire additional sales and marketing personnel and support increased sales and marketing activities; • approximately $2.0 million to fund further research and development, potential regulatory submissions and the potential commercial launch of our proprietary tests and potential collaborations; and • the balance for general corporate purposes and to fund ongoing operations and expansion of the business.
Risk Factors	See the section entitled Risk Factors beginning on page 10 of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Market Symbol and Listing	Our common stock is currently quoted on the OTCQB under the symbol CGIX . We have applied to have our common stock listed on The NASDAQ Capital Market under the same symbol.

The number of shares of our common stock that will be outstanding immediately after this offering is based on 4,316,691 shares of common stock outstanding as of June 30, 2013, and assumes the issuance and sale of $15,000,000 of shares of our common stock in this offering at an assumed public offering price of $11.50 per share, which was the last reported sale price of our common stock on the OTCQB on July 31, 2013.

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The number of shares of our common stock outstanding after this offering excludes:

- 507,610 shares of our common stock issuable upon the exercise of stock options as of June 30, 2013, with a weighted average exercise price of $7.61 per share, which includes 459,610 shares of our common stock issuable upon the exercise of stock options issued under our equity incentive plans and 48,000 shares of our common stock issuable upon the exercise of stock options issued outside of our equity incentive plans;

- 1,926,477 additional shares of our common stock issuable upon the exercise of outstanding warrants as of June 30, 2013, at a weighted average exercise price of $12.15 per share;

- 440,390 additional shares of our common stock reserved for future issuance under our equity incentive plans as of June 30, 2013; and

- 10,000 shares of our common stock issuable to Mayo pursuant to our affiliation agreement with Mayo.

Except for historical financial information or as otherwise indicated herein, all information in this prospectus, including the number of shares that will be outstanding after this offering, assumes no exercise by the underwriters of their option to purchase up to $2,250,000 of additional shares of our common stock from us in this offering.

We effected a 1-for-2 reverse stock split on February 8, 2013 and a 1-for-2.5 reverse stock split on March 1, 2013. Unless we indicate otherwise, all references to share numbers in this prospectus reflect the effects of these reverse stock splits.

Unless otherwise stated, all information contained in this prospectus reflects an assumed public offering price of $11.50 per share, which was the last reported sale price of our common stock on the OTCQB on July 31, 2013.

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SUMMARY CONSOLIDATED FINANCIAL DATA

The following table sets forth our summary statement of operations data for the years ended December 31, 2012, 2011 and 2010 derived from our audited consolidated financial statements and related notes included elsewhere in this prospectus. The unaudited selected consolidated statements of operations data for the six months ended June 30, 2013 and 2012, and the unaudited consolidated balance sheet data as of June 30, 2013, are derived from our unaudited consolidated financial statements, which are included elsewhere in this prospectus. Our financial statements are prepared and presented in accordance with generally accepted accounting principles in the United States. Our unaudited consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and, in the opinion of management, include all adjustments, consisting of normal recurring adjustments necessary for a fair presentation of our financial condition as of such dates and our results of operations for such periods. Our historical results are not necessarily indicative of the results to be expected for any future periods and our interim results are not necessarily indicative of the results to be expected for the full fiscal year.

Pro forma net loss per share of common stock for the six months ended June 30, 2013 reflects the sale of 690,000 shares of common stock in our initial public offering, the automatic conversion of all outstanding shares of our preferred stock into 1,287,325 shares of common stock upon completion of our initial public offering and the conversion of promissory notes and accrued interest in the amount of $9.6 million, at a conversion price of $10.00 per share, which was our initial public offering price, into an aggregate of 963,430 shares of our common stock, all as if they were outstanding for the entire six-month period. Pro forma net loss per share of common stock for the year ended December 31, 2012, reflects the sale of 690,000 shares of common stock in our initial public offering, the automatic conversion of all outstanding shares of our preferred stock into 1,287,325 shares of common stock upon completion of our initial public offering, the conversion of promissory notes and accrued interest in the amount of $9.6 million, at a conversion price of $10.00 per share, which was our initial public offering price, into an aggregate of 963,430 shares of our common stock, all as if they were outstanding for the entire year, and the resulting recognition of unamortized debt discount and fees of $3.5 million, financing fees of $0.4 million and a contingently recognizable beneficial conversion feature in the converted debt of $3.0 million.

The pro forma balance sheet data reflects the pro forma balance sheet data at June 30, 2013 as adjusted to reflect our receipt of the net proceeds from the sale by us in this offering of 1,304,347 shares of common stock at the assumed public offering price of $11.50 per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and the repayment of outstanding indebtedness of approximately $3.5 million resulting in fees and prepayment penalties of $0.2 million.

You should read this information together with the sections entitled Capitalization, Selected Consolidated Financial Data, Management s Discussion and Analysis of Financial Condition & Results of Operations and our consolidated financial statements and related notes included elsewhere in this prospectus.

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(dollars in thousands, except share and per share data)	Six Months Ended June 30, 2013	Six Months Ended June 30, 2012	Year Ended December 31, 2012	Year Ended December 31, 2011	Year Ended December 31, 2010
STATEMENT OF OPERATIONS DATA:					
Revenue	$ 3,050	$ 1,983	$ 4,302	$ 3,019	$ 2,522
Cost of revenues	2,349	1,909	3,929	3,117	3,516
Gross Profit	701	74	373	(98)	(995)
Operating Expenses					
Research and development	951	1,050	2,112	2,074	1,167
General and administrative	2,961	2,329	4,503	4,439	3,446
Sales and marketing	832	716	1,399	1,574	716
Total operating expenses	4,744	4,095	8,014	8,087	5,329
(Loss) income from operations	(4,043)	(4,021)	(7,641)	(8,185)	(6,323)
Total other income (expense)	(3,403)	1,088	975	(11,702)	(2,084)
(Loss) income before income taxes	(7,446)	(2,933)	(6,666)	(19,887)	(8,407)
Reserve for income tax provision (benefit)	(664)				
Net income (loss)	$ (6,782)	$ (2,932)	$ (6,666)	$ (19,887)	$ (8,407)
Net income (loss) per share:					
basic	$ (2.54)	$ (2.19)	$ (4.97)	$ (15.61)	$ (6.71)
diluted	(4.46)	(4.20)	(10.55)	(15.61)	(6.71)
Weighted average shares of common stock outstanding used in computing net income (loss) per share:					
basic	2,667,799	1,337,702	1,342,174	1,274,153	1,253,231
diluted	2,667,799	1,421,313	1,346,161	1,274,153	1,253,231
Pro forma net (loss) per share of common stock:					
basic	$ (1.58)		$ (3.17)		
diluted	(2.77)		(4.92)		
Weighted average shares of common stock outstanding used in computing pro forma net (loss) per share:					
basic	4,299,858		4,282,929		
diluted	4,299,858		4,286,916		

(dollars in thousands)	As of June 30, 2013 Actual	As of June 30, 2013 Pro Forma
BALANCE SHEET DATA:		
Cash and cash equivalents	$ 1,941	$ 11,957
Total Assets	6,456	16,327
Total Liabilities	13,325	9,681
Total Stockholders Equity (Deficit)	$ (6,869)	$ 6,646

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RISK FACTORS

An investment in our common stock involves a high degree of risk. You should consider carefully the specific risk factors described below in addition to the other information contained in this prospectus, including our consolidated financial statements and related notes included elsewhere in the prospectus, before making your investment decision. If any of these risks actually occurs, our business, financial condition, results of operations or prospects could be materially and adversely affected. This could cause the trading price of our common stock to decline and you could lose all or part of your investment.

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 $6.7 million, $19.9 million and $8.4 million for fiscal years ended December 31, 2012, 2011 and 2010, respectively. From our inception in April 1999 through June 30, 2013, we had an accumulated deficit of $55.7 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 profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

As described in Note 18 of our accompanying financial statements, our auditors have issued a going concern opinion on our 2012 financial statements, expressing substantial doubt that we can continue as an ongoing business for the next twelve months after issuance of their report. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in us.

We need to raise additional capital immediately, and over the next twelve months, to satisfy debt obligations and to operate our business.

We believe our current cash resources will be sufficient to satisfy our liquidity requirements at our current level of operations only through August 31, 2013 and then only if we are able to extend payment of $3.5 million in outstanding indebtedness that matures on August 15, 2013. We need to raise additional financing in the near term, through this offering or otherwise, to repay certain indebtedness and fund our current level of operations. Even if further extensions of the $3.5 million in debt due on August 15, 2013 are obtained, we anticipate that we will need to secure additional financing to provide sufficient cash for normal operations. We also need to raise additional capital, through this offering or otherwise, to make the payments of $1.0 million due with respect to our joint venture with Mayo by each of July 31, 2013 and January 31, 2014 and to satisfy indebtedness of approximately $6.0 million due on April 1, 2014. We have had discussion with Mayo to extend the July 31 payment, and, while no assurances can be given, we believe they will not declare a default and will agree to an extension. If Mayo were to declare us in default, it would materially and adversely impact our prospects for developing oncology diagnostic services and tests utilizing next generation sequencing. We currently do not have any research and development programs focused on oncology diagnostic services and tests utilizing next generation sequencing. If Mayo were to declare us in default, it could delay the development of our oncology diagnostic services and tests utilizing next generation sequencing, and it could increase our costs to

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further this effort on our own. If Mayo were to declare us in default and terminate our joint venture, we would need to find a new partner with which to collaborate or build our own research and development program for oncology diagnostic services and tests utilizing next generation sequencing. A substitute partner may not be available at all or may only be available on terms less favorable than our current agreement with Mayo. We also are seeking to extend the maturity of our indebtedness. If we are unable to extend the Wells Fargo debt or secure additional financing, we would scale back our general and administrative activities and certain research and development activities. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all. 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.

We will also need to raise additional capital to expand our business to meet our long-term business objectives. 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 may significantly impact our ability to expand our business. For further discussion of our liquidity requirements as they relate to our long-term plans, see the section entitled Liquidity and Capital Resources Capital Resources and Expenditure Requirements .

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®-CLL, MatBA®-SLL, MatBA®-DLBCL, MatBA®-MCL and UroGenRA -Kidney microarrays through our CLIA-accredited and state licensed laboratory. We also recently launched FHACT for use as a diagnostic tool for cervical cancer in non-U.S. markets. We are in varying stages of research and development for other diagnostic tests that we may offer. 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 MatBA® 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.

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;

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- 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 developing oncology diagnostic services and tests utilizing next generation sequencing. The agreement requires an initial $1.0 million capital contribution by us by July 31, 2013, which we have not made. Although no assurances can be given, from conversations with Mayo we believe it will not declare a default and will extend the July 31 due date to permit us to complete this offering. The agreement also requires aggregate total capital contributions by us of up to $6.0 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

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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 MatBA® microarrays or our UroGenRA Kidney microarray 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.

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

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- 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 a substantial amount of indebtedness, which could have a material adverse effect on our financial condition and our ability to fund operations, obtain additional financing and react to changes in our business.

We have substantial indebtedness for borrowed money. As of June 30, 2013, we had indebtedness for borrowed money in the aggregate principal amount of $9.5 million, which consists of $6.0 million due under our existing line of credit with Wells Fargo Bank, N.A. (Wells Fargo), $1.5 million due to Dr. Pecora and NNJCA under the December 2011 financing transaction and $2.0 million due to DAM. Substantially all of our assets, including our intellectual property, are pledged as collateral under our existing lines of credit and the term loans. Our significant debt could limit our ability to satisfy our obligations, limit our ability to operate our business and impair our competitive position. For example, it could:

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

We will need to raise additional capital immediately and over the next twelve months to repay indebtedness, to fund our existing operations and to develop and commercialize new tests and technologies and expand our operations.

We need to raise additional capital immediately, through this offering or otherwise, to repay approximately $3.5 million in outstanding indebtedness that matures on August 15, 2013. Even if such

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indebtedness were further extended, we need to secure additional financing to provide cash for normal operations in the near term. We also need to raise additional capital to satisfy indebtedness of approximately $6.0 million due to Wells Fargo on April 1, 2014. If we are unable to extend the Wells Fargo debt or secure additional financing, we would scale back our general and administrative activities and certain of our research and development activities. Additionally, we will need to raise capital to expand our business to meet our long-term business objectives, including to:

- increase our sales and marketing efforts to drive market adoption and address competitive developments;
- fund development 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 at least $1.0 million and 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;
- 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

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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.

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

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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 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., Qiagen N.V. and Response Genetics, Inc., and many private companies, including Agendia B.V. and Foundation Medicine, Inc. We expect that pharmaceutical and biopharmaceutical companies will increasingly focus attention and resources on the personalized diagnostic sector as the potential and prevalence increases for molecularly targeted oncology therapies approved by FDA along with companion diagnostics. For example, FDA has recently approved two such agents Xalkori crizotinib from Pfizer Inc. along with its companion anaplastic lymphoma kinase FISH test from Abbott Laboratories, Inc. and Zelboraf vemurafenib from Genentech USA Incorporated and Daiichi-Sankyo Inc. along with its companion B-RAF kinase V600 mutation test from Roche Molecular Systems, Inc. These two recent FDA approvals are only the second and third instances of simultaneous approvals of a drug and companion diagnostic, the first being the 1998 approval of Genentech, Inc. s Herceptin trastuzumab for HER2 positive breast cancer along with the HercepTest from partner Dako A/S.

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

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

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

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

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period. For example, there was one site which represented more than 10% of our revenue for the year ended December 31, 2010 that generated less than 10% of our revenue for the year ended December 31, 2011. 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. For the six months ended June 30, 2013 and 2012 our top five test order sites accounted for 69% and 61%, respectively, of our clinical testing volumes, with 27% and 48%, respectively, of the volume coming from community hospitals. The top five test ordering sites during the three months ended June 30, 2013 and 2012 accounted for 74% and 62% respectively, of our clinical testing volumes, with 23% and 52% respectively, of the volume coming from community hospitals. For the year ended December 31, 2012, our top five test ordering sites accounted for 58% of our clinical testing volume with approximately 46% of the volume coming from community hospitals. For the year ended December 31, 2011, our top five test ordering sites represented approximately 63% of our clinical testing volume, with approximately 29% of the volume coming from community hospitals. For the year ended December 31, 2011, we generated revenue from two test ordering sites that represented 10% or more of our revenue: a community hospital accounted for approximately 18% of our revenue and a community oncology practice accounted for approximately 11% of our revenue. For the year ended December 31, 2012, three test ordering sites accounted for 10% or more of our revenue; a university teaching center accounted for approximately 11%; a clinical trial client accounted for approximately 13% and a community hospital network accounted for approximately 10%. For the six months ended June 30, 2013, there was one site which accounted for more than 10% of our revenue: a clinical trial client accounted for approximately 38% of our revenue. For the six months ended June 30, 2012, there were four sites which each accounted for approximately 10% or more of our clinical revenue: a university teaching center accounting for approximately 17%; a community hospital accounted for approximately 12%; and a clinical trial client and a community hospital network each accounted for approximately 11%. During the three months ended June 30, 2013, there was one site which accounted for more than 10% of our revenue: a clinical trial client accounted for approximately 50% of our revenue. During the three months ended June 30, 2012, there were three sites which each accounted for 10% or more of our clinical revenue: a university teaching center accounting for approximately 13%, a community hospital accounted for approximately 11%, and a community hospital network 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, 2012, our research and development expenses were $2.1 million, which was 49% of our net revenues, 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 net revenues and our sales and marketing expenses were $1.6 million, which was 52% of revenue. For the year ended December 31, 2010, our research and development expenses were $1.2 million, which was 46% of revenue, and our sales and marketing expenses were $716,000, which was 28% of revenue. We expect our expenses to continue to increase, in absolute dollars, for the foreseeable future as we seek to expand the clinical utility of our diagnostic tests, drive adoption of and reimbursement for our diagnostic tests and develop new tests. As a result, we will need to generate significant revenues in order to achieve sustained profitability.

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.

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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 after we complete our initial public offering 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.

The loss of our Chairman or key members of our executive management team could adversely affect our business.

Our success in implementing our business strategy depends largely on the skills, experience and performance of our Chairman of our board of directors, Dr. Raju Chaganti, key members of our executive management team and others in key management positions, including Panna L. Sharma, our Chief Executive Officer, Elizabeth A. Czerepak, our Chief Financial Officer, and Jane Houldsworth, Ph.D., our Vice President of Research and Development. The collective efforts of each of these persons working as a team will be critical to us as we continue to develop our technologies, tests and research and development and sales programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies and implementing our business strategy. Our Chief Executive Officer, Chief Financial Officer and Vice President of Research and Development have employment agreements, however, the existence of an employment agreement does not guarantee retention of members of our executive management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. We do not maintain key person insurance on any of our employees except our Chief Executive Officer.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

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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

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limited 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 its 2013 Physician Fee Schedule Final Rule (the Final Rule). In the Final Rule, CMS called for a reduction of approximately 26.5% in the 2013 conversion factor that is used to calculate physician reimbursement. However, the American Taxpayer Relief Act of 2012, which was signed into law on January 2, 2013, 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 qualify as clinical laboratory tests. Our reimbursement could be adversely affected by CMS action in this area. If

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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, 2012, we derived approximately 32% of our total revenue from private insurance, including managed care organizations and other health care insurance providers, 18% from government payor programs, most of which was derived from Medicare and 37% from direct-bill customers, including hospitals and other laboratories. In addition, for the year ended December 31, 2011, we derived approximately 13% of revenue from grants. 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.

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

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to seek FDA clearance or approval so we can sell our proprietary tests outside our laboratory; however, we need to conduct additional clinical validation activities on our proprietary tests before we can submit an application for FDA approval or clearance. Clinical trials must be conducted in compliance with FDA regulations or FDA may take enforcement action or reject the data. The data collected from these clinical trials may ultimately be used to support market clearance or approval for our tests. Once commenced, we believe it would likely take two years or more to conduct the studies and trials necessary to obtain 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

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program or making false statements in connection with the delivery of or payment for health care benefits, items or services;

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 settled a government claim related to operations at our former Milford, Massachusetts laboratory from 2003 to 2004.

From 2000 to 2004, we operated a clinical laboratory in Milford, Massachusetts providing cancer screening services, principally chromosome karyotyping. 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 (together, the Government) 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. While we did not and do not admit any liability nor concede that the claims of the Government are well founded, we entered into a settlement agreement and paid the Government $1 million in exchange for a release only of all common law claims. No release is specifically given with respect to other liabilities, including liabilities under the False Claims Act, and administrative liabilities, including mandatory and permissive exclusion from federal health care programs. Based on our understandings with government officials with whom we have negotiated such settlement, we do not expect the government to pursue any further claims with respect to the matters described above, but no assurances can be given.

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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.

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 s standards for electronic transactions, which establish standards for common health care transactions. Given the complexity of the HIPAA, HITECH and state privacy restrictions, the possibility that the regulations may change, and the fact that the regulations are subject to changing and potentially conflicting interpretation, our ability to comply with the HIPAA, HITECH and state privacy requirements is uncertain and the costs of compliance are significant. To the extent that we submit electronic health care claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied. Additionally, the costs of complying with any changes to the HIPAA, HITECH and state privacy restrictions may have a negative impact on our operations. We could be subject to criminal penalties and civil sanctions for failing to comply with the HIPAA, HITECH and state privacy restrictions, which could result in the incurrence of significant monetary penalties.

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 in-license a biomarker used in our FHACT probe from the National Cancer Institute.

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,

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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 cannot 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 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. The Abbott patents are due to expire in or about 2017. Unless we obtain a license from Abbott Laboratories, Inc. for use of blocking DNA or otherwise cross-license other satisfactory third party technology, we will not be able to sell our probes in the United States until the Abbott patents expire. 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.

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

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

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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 certain company know-how, trade secrets and technological innovations designed to provide us with a competitive advantage in the market place as trade secrets. Currently, we have only two issued U.S. patents and twelve pending patent applications, which includes both U.S. and foreign 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 as well as the misuse of our patents and other intellectual property, particularly in foreign countries where we have not filed for patent protection.

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

More recently a suit brought in the U.S. District Court for the Southern District of New York by multiple plaintiffs, including the American Civil Liberties Union, against Myriad Genetics, Inc. and the USPTO will likely have an impact on the entire biotechnology industry. Specifically, the case involves certain of Myriad Genetics, Inc. s U.S. patents related to the breast cancer susceptibility genes BRCA1 and BRCA2. Plaintiffs allege, among other things, that gene-related patents (as a whole) stifle diagnostic testing and research that could lead to cures in the future. In that regard, plaintiffs filed motions for summary judgment alleging, among other things, that breast cancer genes are not patentable subject matter.

On March 29, 2010, the court granted summary judgment finding that BRCA1 and BRCA2 patents are invalid under the machine-or-transformation test discussed above. On July 29, 2011, the Federal Circuit upheld the lower court on the invalidity of all but one of the process claims as failing the machine-or-transformation test, but reversed the lower court s decision as to isolated genes, holding them patentable. On March 26, 2012, the U.S. Supreme Court vacated the Federal Circuit decision, and ordered the appellate court to reconsider the case in light of the recent Supreme Court decision in *Mayo v. Prometheus* discussed above.

In keeping with the Supreme Court s mandate, on August 16, 2012, the Federal Circuit applied the *Prometheus* standard to the method claims and maintained its prior ruling, i.e. that all but one of the process claims violated the machine or transformation test. The Court also affirmed its position that Myriad s: (1) gene patents (whether claiming cDNA or isolated DNA) were valid; (2) diagnostic method patents comparing or analyzing sequences were invalid; and (3) separate therapeutic screening method patent involving transformed cells was valid.

However, on June 14, 2013, the United States Supreme Court unanimously ruled 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 are patent-eligible because cDNA is not naturally occurring. In overruling the Federal Circuit, and finding Myriad s claims to the isolated form of

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naturally occurring DNA molecules invalid as a product of nature, the Supreme Court focused on the informational content of the isolated DNA. The Court found 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.

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.

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Risks Relating to Our Common Stock and this Offering

There has been a limited trading market for our common stock and almost no market activity to date.

Currently, our common stock is available for quotation on the OTCQB under the symbol CGIX . However, prior to April 2013, there was no trading activity in our common stock and limited trading has occurred to date. It is anticipated that there will continue to be a limited trading market for our common stock on the OTCQB. We have applied to have our common stock listed on The NASDAQ Capital Market and trading is expected to start upon the effectiveness of this registration statement. Although we believe that this offering and the NASDAQ listing will improve the liquidity of our common stock, this offering may not improve trading volume, reduce volatility or stabilize our share price. A lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your 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.

An active trading market may not develop for our common stock, and you may not be able to sell your stock at or above the public offering price per share.

There is a very limited trading market for our common stock, and the market for our common stock may be highly volatile or may decline regardless of our operating performance. An active public market for our common stock may not develop or be sustained after this offering. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market in our common stock or how liquid that market might become. If an active market does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at the time you wish to sell them, at a price that is attractive to you, or at all.

The public offering price per share has been determined based on the bid price on our common stock on the OTCQB and through negotiation between us and representatives of the underwriters, and may not be indicative of the market price for our common stock after this offering. You may not be able to sell your shares at or above the public offering price per share.

The NASDAQ Capital Market may not list our securities for quotation on its exchange which could limit investors ability to make transactions in our securities and subject us to additional trading restrictions.

We anticipate that our securities will be listed on The NASDAQ Capital Market, a national securities exchange, upon consummation of this offering. Although, after giving effect to this offering, we expect to meet, on a pro forma basis, The NASDAQ Capital Market s minimum initial listing standards, which generally mandate that we meet certain requirements relating to stockholders equity, market capitalization, aggregate market value of publicly held shares and distribution requirements, we cannot assure you that we will be able to meet those initial listing requirements. If The NASDAQ Capital Market does not list our securities for trading on its exchange, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity with respect to our securities;
- a determination that our shares of common stock are penny stock which will require brokers trading in our shares of common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our shares of common stock;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as covered securities.

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Because we expect that our common stock will be listed on The NASDAQ Capital Market, our common stock will be covered securities. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. Further, if we were no longer listed on The NASDAQ Capital Market, our common stock would not be covered securities and we would be subject to regulation in each state in which we offer our securities.

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

If after listing 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.

If our shares become subject to the penny stock rules, this may make it more difficult to sell our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00 (other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). The OTCQB does not meet such requirements and if the price of our common stock is less than $5.00, our common stock will be deemed penny stocks. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that prior to effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser s written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stock holders may have difficulty selling their shares.

The price of our common stock may be volatile, and the market price of our common stock after this offering may drop below the price you pay.

Our public offering price per share may vary from the market price of our common stock after the offering. If an active market for our stock develops and continues, our stock price nevertheless may be volatile. Market prices for securities of early-stage life sciences companies have historically been particularly volatile. As a result of this volatility, you may not be able to sell your common stock at or above the public offering price per share. 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;

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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.

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.

The shares you purchase in this offering will experience immediate and substantial dilution.

The public offering price per share of our common stock will be substantially higher than the net tangible book value per share of our common stock immediately after the offering. At the assumed public offering price of $11.50 per share (which was the last reported sale price per share of our common stock on the OTCQB on July 31, 2013), purchasers of our common stock will incur immediate dilution of $10.38 per share in the net tangible book value of their purchased shares. Conversely, the shares of our common stock that our existing stockholders currently own will receive a material increase in net tangible book value per share. See Dilution.

You may be diluted by exercises of outstanding options and warrants.

As of June 30, 2013, we had outstanding options to purchase an aggregate of 507,610 shares of our common stock at a weighted average exercise price of $7.61 per share and warrants to purchase an aggregate of 1,926,477 shares of our common stock at a weighted average exercise price of $12.15 per share. The exercise of such outstanding options and warrants will result in further dilution of your investment. In addition, you may experience additional dilution if we issue common stock in the future. As a result of this dilution, you may receive significantly less in net tangible book value than the full purchase price you paid for the shares in the event of liquidation.

Future sales of our common stock, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.

Sales of substantial amounts of our common stock in the public market after this offering, or the perception that these sales may occur, could materially and adversely affect the price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. The shares of common stock sold in this offering will be freely tradable, without restriction, in the public market, except for any shares sold to our affiliates.

In connection with this offering, we, our officers and directors and holders of 5% or more of our outstanding common stock have agreed, subject to limited exceptions, not to issue, sell or transfer any shares of

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common stock for 90 days after the date of this prospectus without the consent of Aegis Capital Corp. Additionally, in connection with our initial public offering, our officers, directors and certain stockholders agreed, subject to limited exceptions, not to sell or transfer any shares of common stock for 180 days after April 4, 2013 without the consent of Aegis Capital Corp. However, Aegis Capital Corp. may release these shares from any restrictions at any time. We cannot predict what effect, if any, market sales of shares held by any stockholder or the availability of shares for future sale will have on the market price of our common stock.

Approximately 3,446,827 shares of common stock may be sold in the public market by existing stockholders on or about 181 days after April 4, 2013, subject to volume and other limitations imposed under the federal securities laws. Sales of substantial amounts of our common stock in the public market after the completion of this offering, or the perception that such sales could occur, could adversely affect the market price of our common stock and could materially impair our ability to raise capital through offerings of our common stock.

In addition, as of June 30, 2013, we had outstanding options to purchase 507,610 shares of our common stock and outstanding warrants to purchase an aggregate of 1,926,477 shares of our common stock. We plan to register for offer and sale the shares of common stock that are reserved for issuance pursuant to outstanding options. Shares covered by such registration statements upon the exercise of stock options generally will be eligible for sale in the public market, except that affiliates will continue to be subject to volume limitations and other requirements of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. The issuance or sale of such shares could depress the market price of our common stock.

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 will continue to have substantial influence over us after this offering and could delay or prevent a change in corporate control.

Our directors and executive officers, together with their affiliates, beneficially own approximately 55.5% of our outstanding common stock-based on the number of shares outstanding on July 31, 2013 and, upon the closing of this offering, including 1,304,347 shares of our common stock that we are selling in this offering, assuming the issuance and sale of $15 million of shares of our common stock at an assumed public offering price of $11.50 per share, which was the last reported sale price on our common stock on July 31, 2013, and assuming no exercise of the underwriters over-allotment option, will beneficially own approximately 45.2% of our outstanding shares of common stock. These stockholders, acting together, have significant influence over the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, have significant influence over our management and affairs. Accordingly, this concentration of ownership might harm the market price of our common stock by:

delaying, deferring or preventing a change in control;

impeding a merger, consolidation, takeover or other business combination involving us; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

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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, we are now required to document 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 may choose not to 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.

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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 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.

Our management will have broad discretion over the use of the proceeds we receive in this offering, and may not apply the proceeds in ways that increase the value of your investment.

We estimate that net proceeds of the sale of the common stock that we are offering will be approximately $13.5 million, or $15.6 million, if the underwriters exercise their over-allotment option in full. We currently intend to use the net proceeds of the offering to repay indebtedness of approximately $3.5 million, to fund further research and development, potential regulatory submissions; to hire additional sales and marketing personnel and support increased sales and marketing activities; to fund ongoing operations and expansion of the business; and to fund our initial $1.0 million contribution to our joint venture with Mayo. However, we will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the proceeds of this offering. The actual amounts and timing of our expenditures depends on numerous factors, including the success of our efforts to market our MatBA® microarrays, to obtain regulatory approval to sell our MatBA microarrays outside our clinical laboratory, the timing and progress of our discovery, research and development activities for the tests in our pipeline, the success of our efforts to increase sales of our laboratory services, the success of our efforts to expand our international sales, our ability to continue to reduce manufacturing

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costs by leveraging operations in low cost countries, changes in regulatory requirements for LDTs, and other unforeseen regulatory or compliance costs. The costs and timing of test discovery and development activities, particularly conducting clinical validation studies and obtaining regulatory clearance or approval, are highly uncertain, subject to substantial risks and can often change. Depending on the outcome of these activities, our plans and priorities may change and we may apply the net proceeds of this offering differently than we currently anticipate. Moreover, you will not have the opportunity to influence our decision on how to use the proceeds from this offering. We may use the proceeds for corporate purposes that do not immediately enhance our prospects for the future or increase the value of your investment. See the Section entitled Use of Proceeds.

Existing shareholders may have viewed our initial public offering process unfavorably.

The process of effecting an initial public offering took considerable time and involved two reverse stock splits. Some of our current shareholders have invested in our securities at prices which were above the initial public offering price per share. No assurances can be given as whether any shareholders will seek to take actions against the Company or the board with respect to our initial public offering process.

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

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

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

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

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

We do not intend to pay cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial performance, contractual restrictions, restrictions imposed by applicable law

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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 credit may be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. The limitations apply if an ownership change, as defined by Section 382, occurs. 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 increases by more than 50 percentage points over their lowest ownership percentage at any time during the applicable testing period (typically three years). If we have experienced an ownership change at any time since our formation, we may already be subject to limitations on our ability to utilize our existing net operating losses and other tax attributes to offset taxable income. In addition, future changes in our stock ownership, which may be outside of our control, may trigger an ownership change and, consequently, Section 382 and 383 limitations. 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 may be subject to limitations, which could potentially result in increased future tax liability to us.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements, including statements regarding the progress and timing of our product development, the goals of our development activities, estimates of the potential markets for our product candidates, estimates of the capacity of manufacturing and other facilities to support our products, our expected future revenues, operations and expenditures and projected cash needs. The forward-looking statements are contained principally in the sections entitled Prospectus Summary, Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and Business. These statements relate to future events of our financial performance and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. Those risks and uncertainties include, among others:

- 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 short-term and long-term 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 a rapidly advancing market;
- 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, 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 retain 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;

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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.

Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, expects, plans, anticipates, believes, estimates, projects, predicts, poten 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. 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 prospectus 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 prospectus. You should read this prospectus and the documents referenced in this prospectus and filed as exhibits to the registration statement, of which this prospectus is a part, 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.

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USE OF PROCEEDS

We estimate that we will receive net proceeds from this offering of approximately $13.5 million, or approximately $15.6 million if the underwriters exercise their over-allotment option in full, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses.

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

- approximately $3.5 million to repay certain outstanding indebtedness, as described below;
- $1.0 million to fund our initial contribution to our joint venture with Mayo;
- approximately $5.0 million to hire additional sales and marketing personnel and support increased sales and marketing activities;
- approximately $2.0 million to fund further research and development, potential regulatory submissions (including but not limited to the costs for seeking FDA approval to commercially launch our proprietary genomic-based diagnostic tests) and the potential commercial launch of our proprietary tests and potential collaborations; and
- the balance for general corporate purposes and to fund ongoing operations and expansion of our business.

The expected use of net proceeds of this offering represents our current intentions based upon our present plan and business conditions. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. For example, if we identify opportunities that we believe are in the best interests of our stockholders, we may use a portion of the net proceeds from this offering to acquire, invest in or license complementary products, technologies or businesses although we have no current commitments, understandings or agreements to do so. We will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the proceeds of this offering. The actual amounts and timing of our actual expenditures depend on numerous factors, including the success of our efforts to market MatBA®-CLL, MatBA®-SLL and MatBA®-DLCBL, MatBA®-MCL and UroGenRA -Kidney to obtain regulatory approval to sell our proprietary microarrays outside our clinical laboratory, the timing and progress of our discovery, research and development activities for the tests in our pipeline, the success of our efforts to increase sales of our laboratory services, the success of our efforts to expand our international sales, our ability to continue to reduce manufacturing costs by leveraging operations in low cost countries, changes in regulatory requirements for LDTs, and other unforeseen regulatory or compliance costs. The costs and timing of test discovery and development activities, particularly conducting clinical validation studies and obtaining regulatory clearance or approval, are highly uncertain, subject to substantial risks and can often change. Depending on the outcome of these activities, our plans and priorities may change and we may apply the net proceeds of this offering differently than we currently anticipate.

As of June 30, 2013, an aggregate of $2.0 million in principal remained outstanding under the DAM credit facility. Effective January 1, 2012, the DAM debt bears interest at an annual rate of 10.0%, and is due on August 15, 2013.

As of June 30, 2013, an aggregate of $1.5 million in principal remained outstanding pursuant to a credit agreement, including $1.0 million with NNJCA Capital, LLC, a limited liability company of which Dr. Andrew Pecora, one of our directors, is a member and $0.5 million with a private entity owned by Dr. Pecora. The loan bears an annual interest rate equal to the prime rate plus 6.25% (9.50% at June 30, 2013) and is due on August 15, 2013.

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MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market for Our Common Stock

Our common stock is currently quoted on the OTCQB under the symbol CGIX. Prior to the closing of our initial public offering on April 10, 2013, no public trades occurred in our common stock. 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. Such 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.

	Fiscal Year 2013	
	High	Low
Second Quarter	$ 11.75	$ 8.50
Third Quarter(1)	$ 11.57	$ 10.10

(1) From July 1, 2013 through July 31, 2013.

Holders

As of June 30, 2013, we had approximately 192 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, 8th Floor, New York, New York, 10004.

Dividends

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

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CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2013:

- on an actual basis; and
- on a pro forma basis to give effect to (i) our receipt of net proceeds of approximately $13.5 million from the sale of 1,304,347 shares of the common stock we are offering at the public offering an assumed price of $11.50 per share (which was the last reported sale price per share of our common stock on the OTCQB on July 31, 2013) after deducting underwriting discounts and commissions and estimated offering expenses payable by us and (ii) the repayment of outstanding indebtedness of approximately $3.5 million resulting in recognition of $0.2 million in unamortized fees.

You should read this table together with the sections entitled Use of Proceeds and Management s Discussion and Analysis of Financial Condition and Results of Operations as well as our financial statements and the related notes, which appear elsewhere in this prospectus.

	As of June 30, 2013 (unaudited)	
($ in thousands)	**Actual**	**Pro Forma**
Cash and cash equivalents	$ 1,941	$ 11,957
Long term debt and lines of credit	$ 9,561	$ 6,064
Convertible preferred stock, Series A 588,000 shares authorized, no shares issued and outstanding, actual and pro forma	$	$
Convertible preferred stock, Series B 2,000,000 shares authorized, no shares issued and outstanding, actual and pro forma	$	$
Common stock, additional paid-in capital and treasury stock 100,000,000 shares authorized, 4,316,691 shares issued and outstanding, actual; 100,000,000 shares authorized, 5,621,038 shares issued and outstanding, pro forma	$ 48,865	$ 62,385
Accumulated deficit	$ (55,734)	$ (55,739)
Total stockholders equity (deficit)	$ (6,869)	$ 6,646
Total capitalization	$ 2,692	$ 12,710

The number of shares of common stock to be outstanding after the offering is based on the pro forma number of shares outstanding as of June 30, 2013. This number excludes:

- 507,610 shares of our common stock issuable upon the exercise of stock options as of June 30, 2013, with a weighted average exercise price of $7.61 per share, which includes 459,610 shares of our common stock issuable upon the exercise of stock options issued under our equity incentive plans and 48,000 shares of our common stock issuable upon the exercise of stock options issued outside of our equity incentive plans;
- 1,926,477 additional shares of our common stock issuable upon the exercise of outstanding warrants as of June 30, 2013, at a weighted average exercise price of $12.15 per share, of which certain warrants were exercised after June 30, 2013 and before the date of this prospectus resulting in the issuance of 27,928 shares of common stock;

440,390 additional shares of our common stock to be reserved for future issuance under our equity incentive plans as of June 30, 2013;

10,000 shares of our common stock issuable to Mayo pursuant to our affiliation agreement with Mayo; and

any shares of our common stock issuable upon exercise of the underwriters over-allotment option.

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DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per share of our common stock in this offering and our pro forma as adjusted net tangible book value per share immediately after this offering. We calculate net tangible book value per share by dividing our net tangible book value, which is tangible assets less total liabilities less debt discounts and financing fees related to debt to be paid as a result of this offering, by the number of outstanding shares of our common stock. Our net tangible book value (deficit) as of June 30, 2013 was approximately $(7.4) million, or approximately $(1.71) per share. Upon completion of this offering, our pro forma net tangible book value as of June 30, 2013 will be approximately $6.3 million or approximately $1.12 per share. This represents an immediate increase in pro forma net tangible book value of $2.83 per share to our existing stockholders and an immediate dilution of $10.38 per share to new investors purchasing our common stock in this offering. The following table illustrates the per share dilution:

Assumed public offering price per share		$ 11.50
Net tangible book value per share as of June 30, 2013	$ (1.71)	
Increase in net tangible book value per share after this offering	2.83	
Pro forma net tangible book value per share after this offering		1.12
Dilution in pro forma net tangible book value per share to new investors		$ 10.38

The information above assumes that the underwriters do not exercise their over-allotment option. If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value will increase to $1.44 per share, representing an immediate increase to existing stockholders of $3.15 per share and an immediate dilution of $10.06 per share to new investors. If any shares are issued upon exercise of outstanding options or warrants, new investors will experience further dilution.

The following table summarizes, on a pro forma as adjusted basis as of June 30, 2013, the differences between the number of shares of common stock purchased from us, the total consideration and the average price per share paid by existing stockholders and by investors participating in this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses, at an assumed public offering price of $11.50 per share (the closing bid price of our common stock on July 31, 2013).

	Shares Purchased		Total Consideration		Average Price
	Number	%	Amount	%	Per Share
Existing stockholders	4,316,691	77	$ 33,257,363	69	$ 7.70
New investors	1,304,347	23	$ 15,000,000	31	11.50
Total	5,621,038	100	$ 48,257,363	100	$ 8.59

The number of shares purchased from us by existing stockholders is based on 4,316,691 shares of our common stock outstanding as of June 30, 2013. This number excludes:

- 507,610 shares of our common stock issuable upon the exercise of stock options as of June 30, 2013, with a weighted average exercise price of $7.61 per share, which includes 459,610 shares of our common stock issuable upon the exercise of stock options issued under our equity incentive plans and 48,000 shares of our common stock issuable upon the exercise of stock options issued outside of our equity incentive plans;

1,926,477 additional shares of our common stock issuable upon the exercise of outstanding warrants as of June 30, 2013, at a weighted average exercise price of $12.15 per share, of which certain warrants were exercised after June 30, 2013 and before the date of this prospectus resulting in the issuance of 27,928 shares of common stock;

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440,390 additional shares of our common stock reserved for future issuance under our equity incentive plans as of June 30, 2013;

10,000 shares of our common stock issuable to Mayo pursuant to our affiliation agreement with Mayo; and

any shares of our common stock issuable upon exercise of the underwriters over-allotment option.

A $1.00 increase (decrease) in the assumed public offering price of $11.50 per share would increase (decrease) our pro forma as adjusted net tangible book value by approximately $1.2 million, our as adjusted net tangible book value per share by approximately $0.21 and dilution per share to new investors by approximately $0.79, assuming that the number of shares offered by us remains the same. A 100,000 increase (decrease) in the number of shares offered by us would increase (decrease) our pro forma as adjusted net tangible book value by approximately $1.1 million, our as adjusted net tangible book value per share by approximately $0.17 and dilution per share to new investors by approximately $0.17.

To the extent that the underwriters over-allotment option is exercised or any warrants or options are exercised, there will be further dilution to investors.

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SELECTED HISTORICAL FINANCIAL DATA

The following table summarizes our selected consolidated financial data for the periods and as of the dates indicated. Our selected statements of operations data for each of the years in the periods ended December 31, 2010, 2011 and 2012, and our selected consolidated balance sheet data as of December 31, 2011 and 2012, have been derived from our audited consolidated financial statements and their related notes, which are included elsewhere in this prospectus. Our selected consolidated statements of operations data for each of the years ended December 31, 2008 and 2009, and our selected consolidated balance sheet data as of December 31, 2008, 2009 and 2010 have been derived from audited consolidated financial statements that are not included in this prospectus. The unaudited selected consolidated statements of operations data for the six months ended June 30, 2013 and 2012, and the unaudited consolidated balance sheet data as of June 30, 2013, are derived from our unaudited consolidated financial statements, which are included elsewhere in this prospectus. Our unaudited consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and, in the opinion of management, include all adjustments, consisting of normal recurring adjustments necessary for a fair presentation of our financial condition as of such dates and our results of operations for such periods. Our historical results are not necessarily indicative of the results to be expected for any future periods and our interim results are not necessarily indicative of the results to be expected for the full fiscal year. Our selected consolidated financial data should be read together with the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations and with our consolidated financial statements and their related notes, which are included elsewhere in this prospectus.

	Six Months Ended June 30,		Year Ended December 31,				
(dollars in thousands, except for share and per share data)	2013	2012	2012	2011	2010	2009	2008
Statements of Operations Data:							
Net Revenues	$ 3,050	$ 1,983	$ 4,302	$ 3,019	$ 2,522	$ 1,666	$ 1,680
Cost of revenues	2,349	1,909	3,929	3,117	3,516	2,532	2,223
Gross Profit (loss)	701	74	373	(98)	(995)	(866)	(543)
Operating expenses:							
Research and development	951	1,050	2,112	2,074	1,167	1,336	608
General and administrative	2,961	2,329	4,503	4,439	3,446	1,845	1,390
Sales and marketing	832	716	1,399	1,574	716	239	336
Total operating expenses	4,744	4,095	8,014	8,087	5,329	3,420	2,334
(Loss) income from operations	(4,043)	(4,021)	(7,641)	(8,185)	(6,323)	(4,286)	(2,877)
Interest expense	(1,683)	(1,948)	(4,701)	(1,314)	(792)	(2,092)	(266)
Interest and other income (expense)	1				734	3	18
Change in fair value of warrant liability	5,129	3,036	7,538	(10,388)	(2,026)	(953)	
Loss on debt and warrant restructuring	(6,850)		(1,862)				
Tax benefit (expense)	664						
Net income (loss)	$ (6,782)	$ (2,933)	$ (6,666)	$ (19,887)	$ (8,407)	$ (7,328)	$ (3,124)
Net income (loss) per common share:							
Basic	$ (2.54)	$ (2.19)	$ (4.97)	$ (15.61)	$ (6.71)	$ (8.05)	$ (4.13)
Diluted	(4.46)	(4.20)	(10.55)	(15.61)	(6.71)	(8.05)	(4.13)
Weighted-average common shares outstanding used in computing net income (loss) per share:							
Basic	2,667,799	1,337,702	1,342,174	1,274,153	1,253,231	910,801	756,519
Diluted	2,667,799	1,421,313	1,346,161	1,274,153	1,253,231	910,801	756,519

Pro forma net loss per share of common stock(1):		
Basic	$ (1.58)	$ (3.17)
Diluted	(2.77)	(4.92)

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(1) The pro forma net loss per share of common stock for the six months ended June 30, 2013 reflects the sale of 690,000 shares of common stock in our initial public offering, the automatic conversion of all outstanding shares of our preferred stock into 1,287,325 shares of common stock upon completion of our initial public offering and the conversion of promissory notes and accrued interest in the amount of $9.6 million, at a conversion price of $10.00 per share, which was our initial public offering price, into an aggregate of 963,430 shares of our common stock all as if they were outstanding for the entire six-month period. The pro forma net loss per share of common stock for the year ended December 31, 2012, gives effect to the sale of 690,000 shares of common stock in our initial public offering at a public offering price of $10.00 per share, conversion of our Series A and Series B preferred stock into 1,287,325 shares of common stock upon consummation of our initial public offering, the conversion of promissory notes and accrued interest in the amount of $9.6 million, at a conversion price of $10.00 per share, into an aggregate of 963,430 shares of common stock, all as if they were outstanding for the entire year. Pro forma net loss per share for the year ended December 31, 2012 reflects the recognition of unamortized debt discount and fees of $3.5 million, financing fees of $0.4 million, and a contingently recognizable beneficial conversion feature in the converted debt of $3.0 million.

	As of June 30, 2013	As of December 31, 2012	2011	2010	2009	2008
(dollars in thousands)						
Consolidated Balance Sheet Data:						
Cash and cash equivalents	$ 1,941	$ 820	$ 2,417	$ 1,779	$ 30	$ 28
Working capital	(8,726)	(9,612)	(1,078)	1,785	(1,303)	(341)
Total assets	6,455	8,952	7,031	5,302	2,590	2,567
Current and long-term notes payable	1,564	6,277	2,012	100	245	140
Lines of credit	7,997	8,871	8,437	6,000	6,410	2,850
Warrant liability	518	12,549	11,113	4,270	1,436	
Accumulated deficit	(55,734)	(48,935)	(42,269)	(22,382)	(13,975)	(6,436)
Total stockholder s (deficit)	$ (6,869)	$ (23,981)	$ (19,065)	$ (6,736)	$ (6,711)	$ (1,226)

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MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION

AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read together with our consolidated financial statements and related notes included elsewhere in the prospectus. This discussion contains forward-looking statements based upon our current plans, estimates, beliefs and expectations that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the sections entitled Risk Factors, Special Note Regarding Forward-Looking Statements and elsewhere in this prospectus. The share numbers in the following discussion reflect a 1-for-2 reverse stock split that we effected February 8, 2013 as well as the 1-for-2.5 reverse stock split that we effected March 1, 2013.

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 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 six 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®-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®-SLL, our proprietary microarray for risk stratification in small lymphocytic lymphoma (SLL), and we are currently offering MatBA®-SLL in our laboratory. In February 2013, we received CLIA approval for MatBA®-DLBCL, our proprietary microarray for diagnosis, prognosis and patient monitoring in diffuse large B cell lymphoma (DLBCL). In May 2013, we commercially launched UroGenRA™, 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. Revenues from our proprietary MatBA® test represented approximately 4% of our 2012 revenues. 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.

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 a joint venture in May 2013 with Mayo Foundation for Medical Education and Research which, once funded by us, will focus on developing oncology diagnostic services and tests utilizing next-generation sequencing. Additionally, we agreed to a research collaboration with Memorial Sloan-Kettering Cancer Center and the Cleveland Clinic to validate our renal-cancer microarray, UroGenRA -Renal.

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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®) for clinical use.

We believe that we can be successful by offering cancer professionals a fully-integrated menu of oncology-focused proprietary and non-proprietary tests and customized laboratory services. Based on our discussions with leading researchers in the oncology field and 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 believe our proprietary tests provide superior diagnostic and prognostic values than currently available tests. In particular, our proprietary tests deliver a level of genomic information not provided by other currently available tests. For example, the majority of current cytogenetic analysis for CLL and SLL that is available in clinical laboratories today assesses gain and loss in genomic material at four specific sites. There are two other marketed arrays for CLL (GenPath/Bioreference Laboratories and Quest) of which we are aware. Both of these arrays report out gains and losses at four to five genomic sites. MatBA®-CLL, on the other hand, is designed to report out gains and losses at twenty genomic sites and MatBA®-SLL can report out gains and losses at thirteen genomic sites. 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 will become a key component in the standard of care for personalized cancer treatment.

We will offer our proprietary tests in the United States as laboratory developed tests (LDTs) and internationally as CE-marked in vitro diagnostic products. In addition, as part of our long-term strategy we plan to 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 propriety 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 emphasize 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.

We expect to continue to incur significant losses for the near future. We incurred losses of $6.7 million and $19.9 million for fiscal years ended December 31, 2012 and 2011, respectively. As of June 30, 2013, we had an accumulated deficit of $55.7 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 losses in 2011 and 2010, whereas in 2012 and the first half of 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.

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

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and a contingently recognizable beneficial conversion feature in the converted debt of $3.0 million. For the six months ended June 30, 2013, the change in the fair value of our warrant liability resulted in $5.1 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 six months ended June 30, 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 launched MatBA®-CLL in the first quarter 2011 for use in our clinical laboratory, we received CLIA approval for MatBA®-SLL in January 2012, we received CLIA approval for MatBA®-DLBCL in February 2013, we commercially launched UroGenRA™ 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, including FDA. 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 2012 was generated principally through our clinical laboratory services, with approximately 13% of our revenue from government research grants such as the National Cancer Institute, and approximately 2% of our revenue from sales of our DNA probes, which are only sold outside the United States. The clinical laboratory industry is highly competitive, and our relationship with the decision-maker at hospitals, cancer centers or physician offices 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. For the year ended 2012, our top five test ordering sites accounted for 58% of our clinical testing volume with approximately 46% of the volume coming from community hospitals. For the year ended December 31, 2011, our top five test ordering sites represented approximately 63% of our clinical testing volume, with approximately 29% of the volume coming from community hospitals. For the year ended December 31, 2011, we generated revenue from two test ordering sites that represented 10% or more of our revenue: a community hospital accounted for approximately 18% of our revenue and a community oncology practice accounted for approximately 11% of our revenue. For the year ended December 31, 2012, three test ordering sites accounted for 10% or more of our revenue; a university teaching center accounted for approximately 11%; a clinical trial client accounted for approximately 13% and a community hospital accounted for approximately 10%. The loss of any one of these test ordering sites would not

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materially adversely affect our results of operations. The top five test ordering sites during the six months ended June 30, 2013 and 2012 accounted for 69% and 61%, respectively, of our clinical testing volumes, with 27% and 48%, respectively, of the volume coming from community hospitals. During the six months ended June 30, 2013, there was one site which accounted for more than 10% of our revenue: a clinical trial client accounted for approximately 38% of our revenue. During the six months ended June 30, 2012, there were four sites which each accounted for approximately 10% or more of our clinical revenue: a university teaching center accounting for approximately 17%; a community hospital accounted for approximately 12%, and; a clinical trial client and a community hospital network each accounted for approximately 11%. The top five test ordering sites during the three months ended June 30, 2013 and 2012 accounted for 74% and 62% respectively, of our clinical testing volumes, with 23% and 52% respectively, of the volume coming from community hospitals. During the three months ended June 30, 2013, there was one site which accounted for more than 10% of our revenue: a clinical trial client accounted for approximately 50% of our revenue. During the three months ended June 30, 2012, there were three sites which each accounted for 10% or more of our clinical revenue: a university teaching center accounting for approximately 13%, a community hospital accounted for approximately 11%, and a community hospital network accounted for approximately 11%.

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, biopharmaceutical 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 insurer. The billing arrangements generally are dictated by our customers and in accordance with state and federal law. In 2012, private insurance accounted for approximately 30% of our total revenue, Medicare accounted for approximately 18% of our total revenue, direct bill clients accounted for 37% of our total revenue and the balance of our revenue was attributable to grants and sales of our DNA probes. In 2011, private insurance accounted for approximately 51% of our total revenue, Medicare accounted for approximately 24% of our total revenue, direct-bill clients comprised approximately 12% 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. It is too early in our development to predict whether our experience during 2012 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, attempting to negotiate improved terms with our suppliers and exploring relocating our manufacturing operations to a lower cost-base country.

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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 an affiliation agreement to form 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 expect our sales and marketing expenses to increase significantly after we complete our initial public offering 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 and other general expenses. We expect that our general and administrative expenses will increase 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.

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates based on historical experience and make various assumptions, which management believes to be reasonable under the circumstances, which form the basis for judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

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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, which are included elsewhere in this prospectus, 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.

Revenue Recognition

Revenue is recognized in accordance with 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 of an arrangement exists; (2) delivery has occurred and title and the risks and rewards of ownership have been transferred to the client 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, revenue is recorded based upon the contractually agreed upon fee schedule. When assessing collectability, we consider whether we have sufficient payment history to reliably estimate a payor s individual payment patterns. For new tests where there is no evidence of payment history at the time the tests are completed, we only recognize revenues once reimbursement experience can be established. We then recognize revenue equal to the amount of cash received. Sales of probes are recorded on the shipping date. We do not bill customers for shipping and handling fees and we do not collect any sales or other taxes.

Accounts Receivable and Bad Debts

Accounts receivable are carried at original invoice amount less an estimate for contractual adjustments and doubtful receivables based on a review of all outstanding amounts on a periodic basis. The estimate for doubtful receivables is determined from an analysis of the accounts receivable on a quarterly basis, and is recorded as bad debt expense. Since we only recognize revenue to the extent we expect 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. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received.

Stock-Based Compensation Expense

We account for stock-based compensation under the provisions of FASB ASC Topic 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 (Black Scholes valuation model). The value of the portion of the award that is ultimately expected to vest is

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recognized as expense over the requisite service periods using the straight-line method. We estimate forfeitures at the time of grant and revise our estimates in subsequent periods if actual forfeitures differ from those estimates. At June 30, 2013, we had unrecognized compensation cost related to nonvested employee stock options of approximately $879,831, which amount is expected to be recognized over the next 2.8 years.

We account for stock-based compensation awards to non-employees in accordance with FASB ASC Topic 505-50, *Equity-Based Payments to Non-Employees* (ASC 505-50). 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. All issuances of equity instruments issued to non-employees as consideration for goods or services received by us are accounted for based on the fair value of the equity instruments issued. These awards are recorded in expense and additional paid-in capital in stockholders equity over the applicable service periods based on the fair value of the options at the end of each period. As of June 30, 2013, we had total unrecognized compensation cost related to nonvested stock options granted to non-employees of approximately $27,300, which amount is expected to be recognized over the next quarter. The estimate of unrecognized non-employee compensation is based on the fair value of the nonvested options as of June 30, 2013.

Calculating the fair value of stock-based awards requires the input of highly subjective assumptions into the Black Scholes valuation model. Stock-based compensation expense is significant to our financial statements and is calculated using our best estimate, which involves inherent uncertainties, and the application of our management s judgment. Significant estimates include the fair value of our common stock at the date of grant, the expected life of the stock option, stock price volatility, risk-free interest rate and forfeiture rates.

Common Stock Valuation

Prior to the quotation of shares of our common stock on the OTCQB, our board of directors determined a reasonable estimate of the then-current fair value of our common stock for purposes of granting stock-based compensation based on input from management and valuation reports prepared by an independent third-party valuation specialist. We determined the fair value of our common stock utilizing methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, which we refer to as the AICPA Practice Aid. In addition, we exercised judgment in evaluating and assessing the foregoing based on several factors including:

- the nature and history of our business;
- our historical operating and financial results;
- the market value of companies that are engaged in a similar business to ours;
- the lack of marketability of our common stock;
- the price at which shares of our equity instruments have been sold;
- our progress in developing our technology;
- the overall inherent risks associated with our business at the time stock option grants or warrants were approved; and
- the overall equity market conditions and general economic trends.

We relied upon the option pricing model, or OPM, and the probability-weighted expected return method, or PWERM, to allocate our company value to each of our classes of stock. If the valuation date approximated the close of recent or expected financings by third parties, we placed

greater reliance on the OPM. If no such recent or expected financings were available at the valuation date, we placed greater reliance on the PWERM.

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Probability-Weighted Expected Return Method. PWERM values each class of equity based on an analysis of the range of potential future enterprise values of the Company and the manner in which those values would accrue to the owners of the different classes of equity. This method involves estimating the overall value of the subject company under various liquidity event scenarios and allocating the value to the various share classes based on their respective claim on the proceeds as of the date of each event. These different scenarios typically include an initial public offering, an acquisition, or a liquidation of the business, each resulting in a different value. For each scenario, the future value of each share class is calculated and discounted to a present value. The results of each scenario are then probability-weighted in order to arrive at an estimate of fair value for each share class as of a current date.

We used the PWERM to allocate our estimated enterprise value between our preferred stock and common stock. At certain periods, we also utilized the OPM as described below. Under the PWERM, we analyzed the value of our company using several scenarios, which included an initial public offering (IPO Scenario), reverse merger (Reverse Merger Scenario), acquisition (Sale Scenario), discounted cash flow method (Private Company Scenario) and a liquidation of assets (Liquidation Scenario).

The IPO Scenario and Reverse Merger Scenario were based on market multiples of comparable publicly traded companies. We selected a subset of public companies we considered to be most similar to our company. We determined that each of the selected public companies was comparable to our company at the respective valuation date because they are molecular diagnostic or genetic analysis companies, generally in the early stages of commercialization. As of each valuation date, we evaluated the multiples of projected revenue of these companies and applied these multiples to our projected revenue. We furthermore evaluated this indication of value in relation to valuation considerations provided by an investment banking firm.

The Sale Scenario was based on multiples observed in mergers, acquisitions, and financings of comparable companies. In this analysis, we identified transactions involving certain comparable molecular diagnostic or genetic analysis companies and applied the median multiple of revenue from these transactions to our projected revenue.

The Private Company Scenario was based on an income approach. The income approach estimates the present value of future estimated cash flows, based upon forecasted revenues and costs. These future cash flows are discounted to their present values using a discount rate which is derived using the build-up approach and are consistent with the required rates of return described in the AICPA Practice Aid. Our discount rates for common stock decreased from 41.4% at December 31, 2010 to 29% at December 31, 2012 as our stage of development progressed.

The Liquidation Scenario was based on the asset accumulation method which contemplated the sale of assets and winding up of operations.

We determined the value of our preferred stock and common stock under each scenario by allocating the equity value to each class of stock and discounting the value back to the present using a risk-adjusted discount rate. In certain scenarios, a large portion of the equity value is allocated to the convertible preferred stock to incorporate higher aggregate liquidation preferences. We then weighted the present value of the common stock under each scenario based upon the probability of each scenario occurring in order to determine a final indication of value for the common stock.

Option Pricing Model. OPM uses option theory to value the various classes of a company s securities in light of their respective claims to the enterprise value. Total shareholders equity value is allocated to the various share classes based upon their respective claims on a series of call options with strike prices at various value levels depending upon the rights and preferences of each class. A Black-Scholes closed form option pricing model is typically employed in this analysis, with an option term assumption that is consistent with our expected time to a liquidity event and a volatility assumption based on the estimated stock price volatility of a peer group of comparable public companies over a similar term.

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We applied the OPM by using the price of preferred stock issued by us to sophisticated investors in arms-length transactions and the backsolve method to derive the value of common stock. We estimated the volatility of our shares at 90% based on the expected term to a liquidity event.

We granted stock options between January 1, 2010 and June 30, 2013 with exercise prices between $4.00 and $33.80 per share. Information regarding our stock option grants to our employees and certain consultants since January 1, 2010 is summarized as follows:

Date of issuance	Number of options granted	Exercise price	Common stock value	Option fair value(1)
January 19, 2010	35,650	$ 4.80(2)	$ 4.80	$ 3.3 - 3.55
January 19, 2010	7,750	$ 4.00(3)	$ 4.80	$ 3.3 - 3.55
April 1, 2010	196,860	$ 12.50(8)	$ 7.25	$ 4.55
June 10, 2010	2,350	$ 12.50(8)	$ 7.25	$ 4.50
June 11, 2010	150	$ 12.50	$ 7.25	$ 4.50
August 15, 2010	20,000	$ 25.00(8)	$ 11.75(4)	$ 8.50
September 15, 2010	60,000	$ 25.00(8)	$ 11.75(4)	$ 8.50
October 12, 2010	10,000	$ 12.50	$ 11.75	$ 8.00
December 9, 2010	7,300	$ 12.50(8)	$ 11.75	$ 8.10
December 9, 2010	600	$ 25.00(8)	$ 11.75	$ 6.70
February 8, 2011	50,000	$ 25.00(8)	$ 11.90	$ 6.80
April 1, 2011	2,300	$ 25.75(5)	$ 25.75	$ 18.05
April 1, 2011	240	$ 25.00(6)	$ 25.75	$ 18.05
October 5, 2011	7,074	$ 31.65(8)	$ 31.65	$ 21.45
December 29, 2011	8,000	$ 33.80	$ 33.80	$ 22.55
February 9, 2012	2,400	$ 33.80(8)	$ 33.80	$ 23.35
April 1, 2012	8,000	$ 10.00(7)	$ 10.00	$
April 3, 2012	2,000	$ 10.00(7)	$ 10.00	$
April 8, 2012	16,000	$ 10.00(7)	$ 10.00	$
May 3, 2012	600	$ 10.00(7)	$ 10.00	$
June 15, 2012	600	$ 10.00(7)	$ 10.00	$
June 18, 2012	500	$ 10.00(7)	$ 10.00	$
July 9, 2012	2,800	$ 10.00(7)	$ 10.00	$
August 8, 2012	15,000	$ 10.00(7)	$ 10.00	$
September 10, 2012	800	$ 10.00(7)	$ 10.00	$
September 17, 2012	1,400	$ 10.00(7)	$ 10.00	$
September 24, 2012	1,400	$ 10.00(7)	$ 10.00	$
April 17, 2013	5,850	$ 11.75	$ 11.75	$

(1) Option fair value determined using the Black-Scholes option pricing model using the input assumptions outlined above.

(2) These options were subsequently amended from an exercise price of $4.00 to $4.80. The option fair value was calculated using the exercise price prior to amendment. There was no measurement period adjustment because the exercise price increased.

(3) These options were not amended to change the exercise price as they were forfeited, exercised, or expired prior to such amendment.

(4) These options were granted to non-employees directors, with a ten year term. Non-employee directors options are subsequently valued as of each vesting date. This common stock value and option fair value reflect the grant date values.

(5) These options were subsequently amended from an exercise price of $25.00 to $25.75. The option fair value was calculated using the exercise price prior to amendment. There was no measurement period adjustment because the exercise price increased.

(6) These options were not amended to change the exercise price as they were forfeited or expired prior to such amendment.

(7) These grants have been issued upon the consummation of our initial public offering and have an exercise price equal to our initial public offering price of $10.00 per share.

(8) On April 10, 2013, 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.

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The following table summarizes the significant assumptions we used in our valuations to determine the fair value of our common stock as of the date indicated.

	12/31/09	3/31/10	6/30/10	9/30/10	12/31/10	3/31/11	6/30/11	9/30/11	12/31/11	3/31/12	6/30/12	9/30/12	12/31/12
Option Pricing Model	20%	30%	70%	80%	60%	10%	0%	0%	0%	0%	0%	0%	0%
Probability-Weighted Expected Return Method	80%	70%	30%	20%	40%	90%	100%	100%	100%	100%	100%	100%	100%
IPO	10%	10%	15%	15%	15%	35%	55%	65%	80%	95%	95%	95%	95%
Reverse Merger	20%	20%	20%	20%	25%	30%	20%	15%	5%	0%	0%	0%	
Acquisition	5%	5%	5%	5%	10%	10%	5%	10%	10%	0%	0%	0%	
Private Company	55%	55%	50%	50%	45%	20%	15%	10%	5%	5%	5%	5%	5%
Liquidation	10%	10%	10%	10%	5%	5%	5%	0%	0%	0%	0%	0%	
Lack of Marketability Discount	30%	30%	30%	30%	30%	25%	15%	10%	10%	2.5%	4%	4%	4%
Stock Value	4.80	7.25	10.45	11.75	11.90	25.75	32.45	31.65	33.80	31.60	29.85	18.70	9.60

We engaged an independent third-party valuation specialist to perform retrospective valuations as of December 31, 2009 and March 31, 2010 and contemporaneous valuations as of December 31, 2010, March 31, 2011, June 30, 2011, September 30, 2011, December 31, 2011, March 31, 2012, June 30, 2012 and December 31, 2012. For the value of common stock as of June 30, 2010 and December 31, 2010, we applied valuation approaches consistent, where appropriate, with those performed by the third-party valuation specialist. We used the common stock value of the valuation date closest to the option grant date, where appropriate, in our calculation of stock option expense.

No single event caused the valuation of our common stock to increase or decrease from January 2010 to December 31, 2012, rather it has been a combination of the following factors that lead to the changes in the fair value of the underlying common stock.

December 31, 2009. By the fourth quarter of 2009, the U.S. capital markets had stabilized from the period of very high volatility in 2008 and 2009. We achieved a number of milestones in this quarter including a historical revenue high since moving to our new facility. We formed a subsidiary in Italy, CGI Italia, and began operations of our probe distributions. We began discussions on a preferred stock Series B offering and obtained further access to our Wells Fargo line of credit. We relied 20% on the OPM using anticipated pricing of the Series B preferred stock offering.

March 31, 2010. During this quarter, U.S. market indices trended positive. In addition, the subset of public companies we considered to be most similar to our company significantly outperformed the broader market. We made significant progress in this period by hiring Panna Sharma as our Chief Executive Officer on April 1, 2010. This is a critical milestone because we had not had a Chief Executive Officer since October 2009 when our previous Chief Executive Officer transitioned to general counsel. We prepared new projections based on our renewed strategy and timeline given the new Chief Executive Officer and management team s experience. We entered into a Supply and Distribution Agreement on March 17, 2010 that enabled us to market our DNA probes outside the United States. The agreement also provided us with access to proprietary fluorescent dye labeling technology. The most significant technical milestone during this period was our receipt of the initial validation data and successful sample data set for our first proprietary test, MatBA® -CLL. As the preferred stock Series B offering was in progress in this period, we relied 30% on the OPM using the backsolve method. Under the PWERM approach, we assessed the likelihood of an initial public offering and reverse merger to have increased due to the milestones achieved and proceeds received from the Series B offering.

June 30, 2010. In the second quarter of 2010, the enterprise values of the subset of public companies we considered to be most similar to our company declined. However, we closed on an additional $5.6 million of

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Series B proceeds. Therefore, we relied 70% on the OPM using the backsolve method. We also hired a lab director in April 2010 which accelerated the improvement and competitive position of our lab operations. Therefore, we also increased the likelihood of an initial public offering. No options were granted using this common stock valuation; however, warrants were revalued at June 30, 2010 using this common stock valuation.

September 2010. The enterprise values of the subset of public companies we considered to be most similar to our company increased by double digits in the third quarter of 2010. We held additional Series B closings of approximately $1.0 million in July and August 2010 at $5.00 per share of Series B preferred stock. We elected to rely 80% on the OPM using the backsolve method.

December 2010. In the fourth quarter of 2010, we noted significant increases in the enterprise values of the subset of public companies we considered to be most similar to our company. In addition, we achieved certain milestones, including the approval of MatBA®-CLL by CLIA for use as an LDT on November 30, 2010. The final two Series B Preferred Stock closings occurred with gross proceeds of $2.5 million. We had several successful presentations and meetings to introduce the MatBA® microarray at the Annual Meeting and Exposition of the American Society of Hematology in early December 2010. December 2010 was the first month and the fourth quarter of 2010 was the first quarter of positive gross margin for us since entering this growth phase. We hired two key new microarray scientists, both of whom commenced employment in December 2010. In October 2010, we were awarded three grants in lieu of federal income tax credits under the Qualifying Therapeutic Discovery Project Program to help in further validation and commercialization of: (1) FHACT , our proprietary FISH-based assay for detecting copy number changes that are often observed in HPV-associated cancers, (2) FReCaD , our proprietary FISH-based assay, and (3) MatBA®, our microarray developed for the analysis of genomic copy number alterations in mature B-cell neoplasms. As the final Series B Preferred Stock offering had closed, we reduced our reliance on the OPM backsolve method to 60%. With the significant milestones achieved in this quarter, we increased our estimate of the likelihood of a reverse merger and acquisition.

March 2011. The enterprise values of the subset of public companies we considered to be most similar to our company underperformed the market in this quarter. However, we made significant progress toward an initial public offering. We hired Elizabeth Czerepak as Chief Financial Officer, bringing 18 years of pharmaceutical industry experience and nine years of venture capital experience to our Company. We began discussions with various investment banking firms regarding services related to our anticipated initial public offering. Our first quarter revenue improved from the prior year and we prepared revised projections. The New York State Department of Health approved MatBA®-CLL and we commercially launched MatBA-CLL® for use in our clinical laboratory. Scientist Magazine listed our company as a Top 20 Place to Work. We initiated a community hospital outreach program Expand Dx . We completed a $3 million line of credit with DAM Holdings, LLC. We launched a marketing campaign and bulked up our sales force along the eastern coast of the United States. Based on these accomplishments, we assessed the likelihood of an initial public offering or reverse merger to have increased significantly. We reduced our reliance on the OPM backsolve method to 10%. In addition, we reduced the discount for lack of marketability to 25% due to the decreasing term to anticipated liquidity events.

June 2011. While the major U.S. indices were relatively flat this quarter, the subset of public companies we considered to be most similar to our company realized significant appreciation in their enterprise values. By the end of the quarter, we had engaged investment bankers to assist in an initial public offering. Our microarray for kidney, prostate and bladder cancers, UroGenRA™, entered clinical trials. We continued collaborations to evaluate FHACT with the Kamineni Hospital in India. We also signed a Material Transfer Agreement with University of Iowa Research Foundation. We engaged in negotiations on collaboration with Cleveland Clinic. In addition, we set up our first electronic medical records exchange with a physician s office. Based on these milestones, we assessed the likelihood of an initial public offering continued to increase significantly while the likelihood of a reverse merger, acquisition, and remaining a private company declined. We further reduced our reliance on the OPM backsolve method due to the milestones achieved since the Preferred Stock Series B offering closed in the fourth quarter of 2010. We also reduced our discount for lack of marketability as the likelihood of a shorter term liquidity event increased.

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September 2011. The enterprise values of the subset of public companies we considered to be most similar to our company continued to appreciate. However, we revised our projections primarily due to a change in projected timing of our initial public offering. We were drafting an S-1 in anticipation of an initial public offering. We had identified investors and were in negotiations for bridge financing. We received validation of 15 new probes, including FHACT for HPV-associated cancers. Another probe, FReCaD for renal cell carcinoma, was in patient trials. MatBA® products advanced in development. We signed a probe distribution agreement with Labomics S.A. (Belgium) for territories outside the United States. We were in negotiations with Mayo regarding an affiliation agreement. Robert Kaufman was added to our Board of Directors and appointed Chair of Audit Committee. We continued to increase our assessed likelihood of an initial public offering based on the progress made in the third quarter. We also decreased our discount for lack of marketability as the likelihood of a shorter term liquidity event increased.

December 2011. In the fourth quarter of 2011, the enterprise values of the subset of public companies we considered to be most similar to our company underperformed the market. However, we successfully filed an S-1 and closed on $3.0 million of bridge financing. We launched CLL Complete a new, comprehensive set of tests for CLL. We were in advanced negotiations with Kamineni Hospital in India on probe manufacturing collaboration. We signed an affiliation agreement with Mayo. We completed conversion to XiFin Revenue Management System and related documentation of policies and procedures. Our assessment of the likelihood of an initial public offering continued to increase based on our milestones in the fourth quarter.

March 2012. In light of the performance of comparable public companies in the first quarter and capital market conditions in general we reviewed our assumptions regarding pricing for our upcoming initial public offering and lowered our expected initial public offering price per share. We also closed on an additional $3.0 million of bridge financing and received another CLIA approval for a proprietary microarray for SLL.

June 2012. In the second quarter of 2012, the enterprise values of the subset of public companies we considered to be most similar to our company outperformed the market slightly. We successfully migrated probe manufacturing to India during the second quarter. We also expanded our relationship with Roche Servicios, S.A. We are now their service provider for biomarker based cancer treating services in 14 different locations covering Central America and the Caribbean. We did not revise our assessment of the likelihood of an initial public offering, but the delay in receipt of the net proceeds from our anticipated initial public offering did negatively impact our valuation. Furthermore, our valuation did not take into account changing conditions since June 30, 2012, including the negative market conditions we experienced subsequent to June 30, 2012 in trying to effect our initial public offering.

September 2012. In the third quarter of 2012, the enterprise values of the subset of public companies we considered to be most similar to our company were mixed with the majority underperforming the market. We increased our volume of business with a key clinical trials customer. However, we experienced negative market conditions for our initial public offering. We did not revise our assessment of the likelihood of an initial public offering, but the expected initial public offering price per share was significantly lower than in the second quarter of 2012 and the delay in receipt of the net proceeds from our anticipated initial public offering continued to negatively impact our valuation.

December 2012. In the fourth quarter of 2012, we secured our largest order to-date in Select One® and started a collaboration with a university in HPV-related head and neck cancers. However, we continued to experience negative market conditions for our initial public offering. We did not revise our assessment of the likelihood of an initial public offering, but the expected initial public offering price per share was significantly lower than in the third quarter of 2012 and the delay in receipt of the proceeds from our anticipated initial public offering continued to negatively impact our valuation.

The expected life of a stock option represents the weighted average period over which we expect our stock options to remain outstanding. The expected life assumption is based on the Staff Accounting Bulletin 107 (SAB 107), simplified method. SAB 107 provides guidance related to share-based payment transactions with non-employees, and valuation methods, including assumptions such as expected volatility and expected term. As

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we have been operating as a private company since inception with no active market for our stock or stock options, it is not possible to use actual price volatility data. Therefore, we estimated the volatility of our common stock-based on the historical volatility of entities in our industry that have been public for a period of time and are comparable to us in terms of market capitalization and financial position. Using an expected volatility based on the average historical volatility of other entities may result in variability when compared to actual historical volatility once we have a public market for our common stock. We base the risk-free interest rate that we use in the option pricing model on the U.S. Treasury Yield Curve in effect at the time of grant. We have never paid and do not anticipate paying in the foreseeable future any cash dividends and therefore use an expected dividend yield of zero in the option pricing model. In order to properly attribute compensation expense, we estimate pre-vesting forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting forfeitures and record stock-based compensation expense only for those awards that are expected to vest. Due to the small number of employees and design of our option plan, we have used a forfeiture assumption of zero. If the actual forfeiture rate is materially different from our estimate, our stock-based compensation expense could be significantly different from what has been recorded. For stock options granted to employees, we allocate expense on a straight-line basis over the requisite service period.

Because other companies use different models, methods and assumptions, our comparisons to them may be of limited use. If factors change and we employ different assumptions than those described above in future periods, or if we decide to use a different valuation model, the stock-based compensation expense that we record in the future may differ significantly from what we have recorded and could materially affect our operating results. Once this offering is complete and our stock is listed on an exchange, we plan to use the closing price at the end of each reporting period in determining the amount of stock-based compensation expense to record.

Warrant Liability

We have issued certain warrants that include an exercise price adjustment feature in the event that we issue securities for consideration less than the warrants exercise price (referred to as derivative warrants). Effective January 1, 2009, the accounting guidance regarding derivative warrants changed and required that certain of our warrants be recorded as a liability and measured at fair value each quarter with changes in that value recorded in earnings. We record changes in the fair value of these warrants in our statement of operations in the line change in fair value of warrant liability . We measure the fair value of these warrants using the lattice-based binomial valuation model (the Lattice valuation model), using similar assumptions to those described above in the section entitled Stock-Based Compensation Expense. At March 31, 2013, there were exercisable warrants to purchase an aggregate of 1,111,588 shares of common stock outstanding, of which 817,971 contain an exercise price adjustment feature in the event that we issue securities for consideration less than the warrants exercise price. The average remaining life of all of our outstanding common stock warrants as of March 31, 2013 is approximately 3.31 years. Upon the closing of our initial public offering on April 10, 2013, 700,309 derivative warrants with a fair value of $7.0 million were reclassified to equity due to the lapsing of anti-dilution provisions in the warrants. At June 30, 2013, there were exercisable warrants to purchase an aggregate of 1,926,477 shares of common stock outstanding, of which 125,164 contain an exercise price adjustment feature in the event that we issue securities for consideration less than the warrants exercise price.

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. Please see the section entitled Stock-Based Compensation Expense Common Stock Valuation for a detailed description of how we determined the fair value of our common stock at each reporting date. The resulting effect on our net loss is therefore subject to significant fluctuation and will continue to be so until the warrants are exercised, amended or expire. Assuming all other fair value inputs remain constant, we will record non-cash expense when our stock price increases and non-cash income when our stock price decreases.

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The assumptions used in determining fair value represent our management s best estimates, but these estimates involve inherent uncertainties and the application of our management s judgment. As a result, if factors change, including changes in the fair value of our common stock, our fair value estimates could be materially different in the future.

Internal Control over Financial Reporting

For the year ended December 31, 2010, our independent registered public accounting firm identified the following material weaknesses in our internal control over financial reporting: (i) lack of sufficient segregation of duties within accounting functions; (ii) lack of sufficient, qualified accounting personnel to accurately and timely record and report our financial statements in accordance with generally accepted accounting principles and (iii) insufficient corporate record keeping related to equity transactions and contractual arrangements.

We have undertaken measures to remediate the material weaknesses identified above. Specifically, since January 1, 2011 we have hired a new chief financial officer, controller, part-time senior accountant and accounting clerk. In addition, we concluded that additional resources were needed for more complex matters and to assist us with certain financial reporting matters and we have retained such resources on a contract basis. We anticipate that contract resources will be replaced with in-house employees at or around the time we complete our initial public offering.

The addition of these resources has allowed us to properly segregate duties and to accurately and timely prepare financial statements in accordance with generally accepted accounting principles. We have remediated the weakness related to corporate records and equity transactions through a retrospective review of all such arrangements and have developed communication guidelines to ensure that all such arrangements and transactions are monitored and properly recorded and disclosed.

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.

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, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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Results of Operations

Six Months Ended June 30, 2013 and 2012

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

	Six Months Ended June 30,		Change	
	2013	2012	$	%
(dollars in thousands)				
Revenue	$ 3,050	$ 1,983	$ 1,067	54%
Cost of revenues	2,349	1,909	440	23%
Research and development expenses	951	1,050	(99)	(9%)
Sales and marketing expenses	832	716	116	16%
General and administrative expenses	2,961	2,329	632	27%
Total Operating Loss	**(4,043)**	**(4,021)**	**(22)**	**(1%)**
Interest expense, net	(1,682)	(1,948)	266	(14%)
Debt conversion costs	(6,850)		(6,850)	n/a
Change in fair value of warrant liability	5,129	3,036	2,093	69%
Loss before income taxes	**(7,446)**	**(2,933)**	**4,513**	**154%**
Income tax (benefit) expense	(664)		(664)	n/a
Net loss	**$ (6,782)**	**$ (2,933)**	**$ (3,849)**	**131%**

Revenue

Revenue increased 54%, or $1.1 million, to $3.1 million for the six months ended June 30, 2013, from $2.0 million for the six months ended June 30, 2012, due to an increase in test volume and average revenue per test. Our average revenue (excluding grant revenue and probe revenue) per test increased by 7% to $578 per test for the six months ended June 30, 2013, from $542 per test for the six months ended June 30, 2012, principally due to an increase in the average revenue per test attributable to clinical trial services. Our test volume increased by 58% to 5,115 for the six months ended June 30, 2013, from 3,233 for the six months ended June 30, 2012 principally due to an increase in tests performed for a significant clinical trials client. Grant revenue decreased $195,000 to $0 for the six months ended June 30, 2013, from the six months ended June 30, 2012, due to the completion of scheduled drawdowns. MatBA® revenue for the six months ended June 30, 2013 was $397,000 or 13% of revenue, compared to $119,000 or 6% of revenue for the six months ended June 30, 2012.

Revenue from direct bill customers increased 154%, or $1.1 million, to $1.7 million for the six months ended June 30, 2013, from $684,000 for the six months ended June 30, 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 57% for the six months ended June 30, 2013, from 35% for the six months ended June 30, 2012. Revenue from private insurance carriers and other non-Medicare payors increased 23%, or $152,000, to $812,000 for the six months ended June 30, 2013, from $660,000 for the six months ended June 30, 2012, principally due to an increase in testing volume. Revenue from private insurance carriers and other non-Medicare payors as a percentage of total revenue decreased to 27% of total revenue for the six months ended June 30, 2013, from 33% of total revenue for the six months ended June 30, 2012. Revenue from DNA probe sales by CGI Italia increased 163%, or $57,000, to $92,000 for the six months ended June 30, 2013, from $35,000 for the six months ended June 30, 2012, principally due to an increase in sales volume. Revenue from Medicare remained relatively constant at $408,000 for the six months ended June 30, 2013 and $409,000 for the six months ended June 30, 2012, principally due to a higher number of Medicare reimbursed tests, offset by a decrease in average revenue per test reimbursed under Medicare. Revenue from Medicare as a percentage of total revenue decreased to 13% for the six months ended June 30, 2013, from 21% for the six months ended June 30, 2012.

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Cost of Revenues

Cost of revenues increased 23%, or $440,000, to $2.3 million for the six months ended June 30, 2013, from $1.9 million for the six months ended June 30, 2012, principally due to clinical supply costs related to higher test volumes. However, due to scaling efficiencies associated with performing a large amount 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 decreased 9%, or $99,000, to $951,000 for the six months ended June 30, 2013, from $1.1 million for the six months ended June 30, 2012, principally as a result of a decrease in non-employee stock-based compensation related expenses of $180,000 and a decrease of $128,000 in employee compensation related expenses, both of which were partially offset by an increase in supplies expense of $209,000.

Sales and Marketing Expenses. Sales and marketing expenses increased 16%, or $116,000, to $832,000 for the six months ended June 30, 2013, from $716,000 for the six months ended June 30, 2012, principally due to an increase in headcount and compensation-related costs.

General and Administrative Expenses. General and administrative expenses increased 27%, or $632,000 to $3.0 million for the six months ended June 30, 2013, from $2.3 million for the six months ended June 30, 2012, principally due to the write-off of $618,000 of deferred IPO costs and an increase of $327,000 in compensation and headcount-related expenses (including IPO bonuses and stock-based compensation) during 2013 offset by a decrease of $350,000 for the legal settlement which was recorded during the same period in the prior year.

Interest Income and Expense

Interest expense decreased 14%, or $266,000, to $1.7 million for the six months ended June 30, 2013, from $1.9 million for the six months ended June 30, 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.

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.

Change in Fair Value of Warrant Liability

The change in the fair value of our warrant liability resulted in $5.1 million in non-cash income for the six months ended June 30, 2013, as compared to non-cash income of $3.0 million for the six months ended June 30, 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 period from December 31, 2012 through June 30, 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 125,164 warrants that are still subject to future revaluation.

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During the six months ended June 30, 2012, the fair market value of these common stock warrants decreased as a consequence of a decrease in our stock price and resulted in $3.0 million of non-cash income during this period.

Income Taxes

During the six months ended June 30, 2013, we received $664,000 in cash for the sale of certain state 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:

	Year Ended December 31,		Change	
	2012	**2011**	**$**	**%**
(dollars in thousands)				
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%
Sales and marketing expenses	1,399	1,574	(175)	-11%
General and administrative expenses	4,503	4,439	64	1%
Total Operating Loss	**(7,641)**	**(8,185)**	**544**	**7%**
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)	
Net Loss	**(6,666)**	**(19,887)**	**13,221**	**66%**

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 23% to $548 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® revenue for the year 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

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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 32% 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 Mr. Maione and a $50,000 increase in penalties under the Series B Registration Rights Agreement as we delayed becoming a public company, both of which were offset by a $87,000 decrease in relocation expenses and a $379,000 decrease in bad debt expensed due to billing and collection problems in 2011 which did not recur in 2012.

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.

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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.

Years Ended December 31, 2011 and 2010

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

	Year Ended December 31,		Change	
	2011	**2010**	**$**	**%**
(dollars in thousands)				
Revenue	$ 3,019	$ 2,522	$ 497	20%
Cost of revenues	3,117	3,516	(399)	(11)%
Research and development expenses	2,074	1,167	907	78%
Sales and marketing expenses	1,574	716	858	120%
General and administrative expenses	4,439	3,446	993	29%
Total Operating Loss	**(8,185)**	**(6,323)**	**(1,862)**	**(29)%**
Interest income (expense)	(1,314)	(792)	522	66%
Change in fair value of warrant liability	(10,388)	(2,026)	8,362	413%
Qualifying Therapeutic Discovery Project Grants		733	(733)	(100)%
Net Loss	**$ (19,887)**	**$ (8,407)**	**$ (11,480)**	**(137)%**

Revenue

Revenue increased 20%, or $ 497,000, to $3.0 million for the year ended December 31, 2011, from $2.5 million for the year ended December 31, 2010, principally due to an increase in our test volume as well as an additional $205,000 in grant revenue from National Institutes of Health and Small Business Innovation Research and an additional $75,000 of revenue from probes sales, partially offset by a decrease in revenue per test. Our average revenue (excluding grant revenue and probe revenue) per test decreased by 6% to $713 per test for the year ended December 31, 2011, from $758 per test for the year ended December 31, 2010, principally due to a reduction in the reimbursement level per test we receive for the UroVysion® testing services we provide, partially offset by a change in mix of tests ordered. Our test volume increased by 15% to 3,622 for the year ended December 31, 2011, from 3,146 for the year ended December 31, 2010. The increased sales volume was a result of new customer additions in the northeastern United States, new territory development in the southeastern United States and an increase in orders from certain of our existing test ordering sites. Our increased clinical laboratory capabilities also contributed to the increase in our test volumes. Revenues from our MatBA®-CLL tests in 2011 were immaterial.

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Revenue from private insurance carriers and other non-Medicare payors increased 17%, or $239,000, to $1.6 million for the year ended December 31, 2011, from $1.4 million for the year ended December 31, 2010, principally due to an increase in test volume. Revenue from private insurance carriers and other non-Medicare payors was 54% of total revenue for the year ended December 31, 2011 and 55% of total revenue for the year ended December 31, 2010. Revenue from Medicare increased 18%, or $112,000, to $717,700 for the year ended December 31, 2011, from $606,000 for the year ended December 31, 2010, principally due to an increase in test volume. Revenue from Medicare as a percentage of total revenue remained relatively flat at 24% for the years ended December 31, 2011 and December 31, 2010. Revenue from direct bill customers decreased slightly to $350,000 for the year ended December 31, 2011, from $408,000 for the year ended December 31, 2010. Revenue from direct bill customers as a percentage of total revenue decreased to 12% for the year ended December 31, 2011, from 16% of total revenue for the year ended December 31, 2010, principally due to a shift in focus away from direct bill customers and toward third party payors.

Cost of Revenues

Cost of revenues decreased by 11%, or $399,000, to $3.1 million for the year ended December 31, 2011, from $3.5 million for the year ended December 31, 2010. Even though revenue increased, the cost of revenues decreased as a result of operational efficiencies achieved during 2011.

Operating Expenses

Research and Development Expenses. Research and development expenses increased by 78%, or $907,000, to $2.1 million for the year ended December 31, 2011, from $1.2 million for the year ended December 31, 2010, principally as a result of increased headcount for additional research and development efforts related to our microarray and DNA probe pipeline.

Sales and Marketing Expenses. Sales and marketing expenses increased by 120%, or $858,000, to $1.6 million for the year ended December 31, 2011, from $716,000 for the year ended December 31, 2010. The increase in our sales and marketing expenses was principally due to the expansion of our sales and marketing activities, including hiring additional sales and marketing personnel and utilizing consultants in connection with the launch of our MatBA®-CLL, and the introduction of new DNA probes outside the United States.

General and Administrative Expenses. General and administrative expenses increased by 29%, or $993,000, to $4.4 million from the year ended December 31, 2011, from $3.5 million for the year ended December 31, 2010. This increase was principally due to the increase in our bad debt expense and the recruiting and hiring of additional personnel, including a Chief Financial Officer, Controller, and Director of IT, and a significant increase in professional fees as we prepared to become a public company. Bad debt expense was $373,000 for the year ended December 31, 2011 compared to $46,000 for the year ended December 31, 2010. This increase of $327,000 is principally due to a write down in receivables resulting from a changeover in our billing providers and resulting collection problems during third quarter 2011. We observed that our prior billing company slowed their invoicing activities and collection efforts during the months immediately preceding our transition, effective July 1, 2011, to the new billing company. This resulted in reduced receipts of cash relating to the invoices for that period, during the third quarter 2011. We do not expect any continuing collection problems in the future relating to our transition to a new billing company.

Interest Income and Expense

Interest expense increased by 66%, or $522,000, to $1.3 million for the year ended December 31, 2011, from $792,000 for the year ended December 31, 2010, due to amortization of the consideration paid to John Pappajohn for the guarantee of our loan from Wells Fargo Bank, N.A. (Wells Fargo) and interest related to the March 2011 loan from DAM Holdings, LLC (DAM).

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Change in Fair Value of Warrant Liability

The expense we booked for the change in the fair value of our warrant liability increased by 413%, or $8.4 million to $10.4 million for the year ended December 31, 2011, from $2.0 million for the year ended December 31, 2010, due to an increase in the fair market value of certain of our outstanding common stock warrants that we are required to account for as liabilities, which is principally the result of an increase in our stock price.

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 payments generated from operations.

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 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.

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.

Following our initial public offering, we have the following credit facilities outstanding:

Wells Fargo Line of Credit. In April 2008, we entered into and thereafter fully utilized a line of credit with Wells Fargo in the amount of $1.5 million for the purposes of meeting operating expenses and working capital needs. In July 2008, we increased the line of credit with Wells Fargo to $3.5 million. In March 2009, we increased the facility to $4.5 million. In July 2009, we increased the facility to $5.5 million and in October 2009, we increased the facility to $6.0 million, which we have fully utilized. In July 2010, we extended the maturity date of the facility from July 31, 2010 to July 31, 2011. In June 2011, we extended the maturity date on the facility to July 31, 2012. In February 2012, we extended the maturity date of the facility to July 31, 2013. In October 2012, we extended the maturity date to April 1, 2014. The interest is computed at LIBOR + 1.75%, which was 2.0% as of December 31, 2012. Mr. Pappajohn, a member of our board of directors, has guaranteed the Wells Fargo Line of Credit.

DAM Line of Credit. In March 2011, we entered into, and since have fully utilized, a line of credit with DAM in the amount of $3.0 million for the purposes of meeting operating expenses, including expenses related to our initial public offering process. As consideration, we paid an annual interest rate of 3% on the borrowed funds on a monthly basis and issued DAM warrants to purchase an aggregate of 60,000 shares of common stock at an exercise price of $25.00 per share. Our interest rate under this line of credit increased to 10% per annum, effective January 1, 2012, because such maturity events, including completion of an initial public offering, did

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not occur before January 1, 2012. In March 2012, we extended the maturity date of this facility to April 1, 2013, unless certain maturity events occur prior to April 1, 2013, in exchange for a grant of 15,000 warrants on the same terms as those issued in the December 2011 Financing Transaction described below. On October 16, 2012, DAM Holdings agreed to surrender 15,000 warrants in exchange for a cash interest payment of $52,500 at maturity. In addition, we amended the agreement to provide that the interest rate from January 1, 2012 until a maturity event occurs shall be 10%. After a maturity event occurs, interest begins to compound at a rate of 18% per annum until the balance is paid in full. On February 13, 2013, DAM agreed to convert $1.0 million of outstanding principal amount due to DAM into an aggregate of 100,000 shares of common stock at our initial public offering price of $10.00 per share. On March 19, 2013, DAM agreed to extend the maturity date of this facility to August 15, 2013.

December 2011 Financing Transaction. We entered into a Credit Agreement dated as of December 21, 2011, as amended and restated as of February 13, 2012, 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, for a $6.0 million secured term loan. Mr. Pappajohn provided $4.0 million of financing, NNJCA provided $1.5 million of financing and Dr. Pecora provided $500,000 of financing under the Credit Agreement.

The loan bears an annual interest rate equal to the prime rate plus 6.25% (9.50% at June 30, 2013) and matures on August 15, 2013. The loan is 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. Pursuant to an intercreditor agreement, the lenders have agreed that all amounts due to DAM are to be paid prior to payment to the lenders under this Credit Agreement, but that as between such lenders, following an event of default, all of the security granted by us is to be applied first to repay obligations due to Dr. Pecora and NNJCA, and then to Mr. Pappajohn after they have been paid in full. As Mr. Pappajohn has guaranteed the Wells Fargo debt, in essence under the intercreditor agreement, NNJCA and Dr. Pecora will be junior only to DAM.

In addition, the warrants to purchase an aggregate of 37,646 shares of our common stock issued to Dr. Pecora and NNJCA in connection with this financing were cancelled and the promissory notes issued to Dr. Pecora and NNJCA were amended to increase the pre-payment penalties by $130,000. On February 13, 2013, Mr. Pappajohn agreed to convert $2.0 million of the outstanding principal amount to common stock at the initial public offering price per share upon consummation of our initial public offering and NNJCA agreed to convert $500,000 of the outstanding principal amount due to NNJCA to common stock at the initial public offering price per share upon consummation of our initial public offering. As a result, an aggregate of $1.5 million remained outstanding and payable to NNJCA and Dr. Pecora.

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. As of June 30, 2013, we have outstanding borrowings of $9.5 million. Our largest source of operating cash flow is cash collections from our customers.

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Cash Flows

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

	Six Months Ended June 30,		Year Ended December 31,		
	2013	2012	2012	2011	2010
	(unaudited)				
(in thousands)					
Cash provided by (used in):					
Operating activities	$ (3,766)	$ (4,102)	$ (7,578)	$ (5,073)	$ (5,731)
Investing activities	(124)	(226)	(347)	(113)	(168)
Financing activities	5,011	2,312	6,328	5,824	7,648
Net increase (decrease) in cash and cash equivalents	$ 1,121	$ (2,016)	$ (1,597)	$ 638	$ 1,749

We had cash and cash equivalents of $1.9 million at June 30, 2013, and of $820,000 at December 31, 2012, $2.4 million at December 31, 2011 and $1.8 million at December 31, 2010. The $1.1 million increase in cash and cash equivalents for the six months ended June 30, 2013, was principally the result of the receipt of $5.0 million in proceeds received in our IPO on April 10, 2013 offset by $3.8 million of net cash used in operations. 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 $135,00 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 June 30, 2013, we had total indebtedness of $9.5 million.

Cash Used in Operating Activities

Net cash used in operating activities was $3.8 million for the six months ended June 30, 2013. We used $3.5 million in net cash to run our core operations, which included $490,000 in cash paid for interest. We incurred additional uses of cash as follows: $336,000 for a net decrease in accounts payable, accrued expenses and deferred revenue; $220,000 to increase other current assets which included prepayments for our insurance policies as well as prepayments for consumables and other supplies used to run our operations, and; accounts receivable increased by $413,000. 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

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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.

Net cash used in operating activities was $5.7 million for the year ended December 31, 2010 consisting of a $8.4 million net loss partially offset by $2.0 million change in the fair value of warrant liabilities, $477,000 in equity based compensation expense, $528,000 in amortization of loan guarantee fees, an increase in accounts payable of $447,000 due to cash conservation efforts, an increase in accounts receivable of $570,000 due to collection problems with our prior billing company, an increase in other current assets of $711,000 related to IRS research credit, and $317,000 in depreciation expense.

Cash Used in Investing Activities

Net cash used in investing activities was $124,000 for the six months ended June 30, 2013 and principally resulted from: an increase in our restricted cash related to a $50,000 increase in the Letter of Credit related to our lease; purchases of fixed assets of $43,000; and $32,000 in patent application costs.

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 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 initial public offering, 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.

Net cash used in investing activities was $168,000 for the year ended December 31, 2010 due to purchases of fixed assets and patent costs.

Cash Provided by Financing Activities

Net cash provided by financing activities was $5.0 million for the six months ended June 30, 2013, and primarily consisted of receipt of the proceeds raised in our IPO offset by the payment of $1.9 million in offering costs, including $637,000 in underwriting discounts, expenses and commissions, that were paid in the first half of 2013.

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 initial public offering 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.

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Net cash provided by financing activities was $7.7 million for the year ended December 31, 2010 due to the issuance of the $9.1 million in preferred stock offset by $827,000 in issuance costs, and the net $410,000 payment of an existing line of credit.

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 will need to continue to raise additional capital to fund our operations.

We believe our current cash resources are sufficient to satisfy our liquidity requirements at our current level of operations through August 31, 2013 and then only if we are able to extend payment of $3.5 million in outstanding indebtedness that matures on August 15, 2013. We need to raise additional financing immediately, through this offering discussed below or otherwise, and over the next twelve months, to satisfy debt obligations and operate our business, which financing may not be available on favorable terms, or at all. We have had and will continue to have discussions with certain current and potential investors regarding potential additional financing in the event that this offering is not consummated, but we can provide no assurances that any additional sources of financing will be available to us on favorable terms, or at all. If this offering is not consummated, we must obtain an extension of the $3.5 million indebtedness due August 15, 2013 and we would need to scale back our general and administrative activities and certain of our research and development activities. We can provide no assurances that we will be able to obtain an extension of the $3.5 million indebtedness on favorable terms, or at all, or that any additional sources of financing will be available to us on favorable terms, or at all.

With the anticipated net proceeds from this offering, we believe our cash resources will then be sufficient to satisfy our liquidity requirements at our current level of operations through December 31, 2014, including any additional capital contributions to be made to Mayo, but assuming we can extend the $6.0 million debt currently due to Wells Fargo on April 1, 2014. We have commenced negotiations with Wells Fargo and with Mr. Pappajohn, who serves as a guarantor for such outstanding indebtedness, to further extend the maturity date. However, there can be no assurances that we will be successful, and if we are not successful in obtaining an extension, we expect that we would need to raise additional financing in the first quarter of 2014, which might not be available on favorable terms, if at all. If we are unable to extend the Wells Fargo debt or secure additional financing, we would scale back our general and administrative activities and certain of our research and development 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:

- our ability to secure financing and the amount thereof;
- 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;

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

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; and

other risks discussed in the section entitled Risk Factors in this prospectus.

Even with the proceeds from this offering, we will need to raise additional capital to expand our business to meet our long-term business objectives. 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 expect to make capital contributions of up to $6.0 million over the next three years, subject to negotiating an extension of that agreement, which negotiations have commenced, and 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 will need to continue to raise additional capital to fund our operations.

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.

For further discussion of the impact of our present indebtedness and access to future financing on our business, see the section of our Prospectus entitled *Risk Factors Risks Related to Our Business and Strategy We have a substantial amount of indebtedness, which could have a material adverse effect on our financial condition and our ability to fund operations, obtain additional financing and react to changes in our business.*

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Future Contractual Obligations

The following table reflects a summary of our estimates of future contractual obligations as of December 31, 2012. 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, 2012. Future events could cause actual payments to differ from these amounts.

	Total	Less than 1 Year	2-3 Years	4-5 Years	More than 5 Years
(dollars in thousands)					
Principal and interest under notes payable and lines of credit	$ 20,426	$ 8,134	$ 12,292	$	$
Capital Lease obligations, including interest, for equipment	26	18	8		
Operating lease obligations relating to corporate headquarters and clinical laboratory	2,941	560	1,198	1,134	49
Total	$ 23,393	$ 8,712	$ 13,498	$ 1,134	$ 49

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 provision for income taxes 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.

Qualitative and Quantitative Disclosures about Market Risk

Our exposure to market risk is limited to our cash, cash equivalents and marketable securities, all of which have maturities of one year or less. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of cash equivalents and investments in a variety of securities that management believes to be of high credit quality. The securities in our investment portfolio are not leveraged, are classified as available for sale and are, due to their short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a material negative impact on the value of our investment portfolio.

We do not have any material foreign currency exposure.

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DESCRIPTION OF THE BUSINESS

Company 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 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. 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 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. 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 Description of the Business Laboratory Services . 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 one of six approved accreditation methods under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), to perform high complexity testing. CLIA certification and accreditation are required before any laboratory, including ours, may perform testing on human specimens for the purpose of obtaining information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health.

Our proprietary tests are based principally on our expertise in specific cancer types, test development methodologies and proprietary algorithms correlating genetic events with disease specific information. During the first quarter of 2011, we commercially launched MatBA®-CLL, our first proprietary microarray test for chronic lymphocytic leukemia (CLL). In January 2012, we received CLIA approval for MatBA®-SLL, our proprietary microarray for risk stratification in small lymphocytic lymphoma (SLL), and we are currently offering MatBA®-SLL in our laboratory. In 2013, we received CLIA approval for MatBA®-DLBCL, our proprietary microarray for diagnosis, prognosis and patient monitory in diffuse large-B-cell lymphoma (DLBCL), MatBA®-MCL, our proprietary microarray for diagnosis, prognosis and patient monitoring in mantle cell lymphoma (MCL) and UroGenRA -Kidney, our proprietary microarray for patient management and treatment protocols in kidney cancer (UroGenRA -Kidney). 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 a joint venture in May 2013 with Mayo Foundation for Medical Education and Research (Mayo) which, once funded by us, will focus on developing oncology diagnostic services and tests utilizing next-generation sequencing. Additionally, we have research collaborations with Memorial Sloan-Kettering Cancer Center and the Cleveland Clinic to validate our renal-cancer microarray, UroGenRA -Kidney.

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®) for clinical use.

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

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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. For example, the majority of current cytogenetic analysis for CLL and SLL that is available in clinical laboratories today assesses gain and loss in genomic material at four specific sites. There are two other marketed arrays for CLL (Combimatrix and Quest) of which we are aware. Both of these arrays report out gains and losses at four to five genomic sites. MatBA®-CLL, on the other hand, reports out gains and losses at twenty genomic sites and MatBA®-SLL reports out gains and losses at fourteen genomic sites. 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 will become a key component in the standard of care for personalized cancer treatment.

MatBA®-CLL is unique in its targeted, proprietary design and has been validated in two independent, clinically robust data sets of specimens in collaboration with Dr. Kanti R. Rai, a renowned CLL oncologist and Chief of the Division of Hematology and Oncology at Long Island Jewish / North Shore Hospital. MatBA®-CLL is, to our knowledge based on our informal communications with New York State Department of Health personnel, the first oncology microarray to be approved by the New York State Department of Health, one of the only state governmental agencies that reviews the performance characteristics and clinical utility of new laboratory developed tests (LDTs).

There are approximately 14,500 new cases of CLL diagnosed in the United States each year, and these cases require risk stratification and guidance on patient management and treatment issues at multiple points during the course of the disease. Prior to the introduction of MatBA®-CLL, clinicians had to rely on diagnostic tests that provided limited information on the genetic abnormalities associated with CLL. In contrast, MatBA®-CLL identifies a much broader range of genomic markers associated with CLL, providing improved diagnostic and prognostic value, as well as critical information about how to best structure a treatment regimen for a patient. We developed the MatBA® platform under the guidance of Dr. Raju Chaganti, our Chairman and one of our founders. Dr. Chaganti founded one of the earliest comprehensive clinical cytogenetic laboratories focused on cancer in the United States at Memorial Sloan-Kettering Cancer Center, where he is on the faculty of the Department of Medicine and is William E. Snee Chair.

In collaboration with Memorial Sloan-Kettering Cancer Center and Long Island Jewish / North Shore Hospital, we have completed the validation of MatBA®-SLL. MatBA®-SLL was CLIA approved in January 2012 and is now offered in our laboratory. We believe that MatBA®-SLL is the only microarray that will permit risk-stratification in this previously underserved cancer subtype. This adaptation of MatBA® for SLL has allowed us to develop a robust mechanism to analyze DNA that is derived from formalin-fixed paraffin-embedded (FFPE) biopsy material. This adaptation has been a critical development which will accelerate the development of our microarrays for other solid tumors or cancers that present themselves as a mass.

Also in collaboration with Memorial Sloan-Kettering Cancer Center, we recently completed the validation of MatBA®-DLBCL and are now offering MatBA®-DLBCL in our laboratory. MatBA®-DLBCL was approved by both New York State and CLIA in late January 2013 for use in a clinical setting to aid in the diagnosis for diffuse large B-cell lymphoma. We believe that MatBA®-DLBCL is the only currently available genomic method for the stratification and prognosis for DLBCL patients. We believe this prognostic information is critical in aiding patients since survival rates for DLBCL tend to be only 50% to 55% approximately and there is significant heterogeneity in how the disease is manifested. Therefore genomic assessment is critical to improving the management of these patients.

We have initiated a 200 specimen clinical validation study for DLBCL with Dr. Julie Teruya-Feldstein, Director of Memorial Sloan-Kettering s Immunohistochemisty Laboratory and a member of that hospital s Institutional Review Board. We have clinically validated MatBA® for mantle-cell lymphoma (MCL), which is an aggressive sub-type of lymphoma, and MatBA®-MCL is now available as an LDT.

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We are also in advanced stages of validating the MatBA® array for prognostic utilization in follicular lymphoma (FL). Collectively, these lymphomas represent over 70% of the mature B cell cancers (neoplasms) and over 66,000 newly diagnosed cancer cases each year in the United States. Our MatBA® array has been designed to measure genetic markers at 80 specific genomic sites where genetic alterations are associated with mature B cell neoplasms.

We are developing microarray tests for the diagnosis, prognosis and theranosis of a range of urogenital cancers. These include the UroGenRA microarray for kidney, prostate and bladder cancers and the UGenRA microarray for endometrial, ovarian and cervical cancers. UroGenRA detects genomic changes in over 100 regions of the human genome with potential diagnostic and/or prognostic value in one or more of these types of cancer. These microarrays have been designed to address specific needs associated with the management of each urogenital cancer. For example, UGenRA Ovarian is designed to address the critical issue of chemotherapeutic resistance while UGenRA Endometrial is designed to distinguish hyperplastic lesions that have a high risk of progression. We have initiated clinical validation for UroGenRA targeting kidney and prostate cancers in collaboration with Memorial Sloan-Kettering Cancer Center. In addition, we have initiated a clinical validation for UGenRA targeting kidney cancer in collaboration with Cleveland Clinic. Our UGenRA microarray has been designed as a platform to detect genomic changes occurring in 83 regions of the human genome that have been linked to endometrial, ovarian and cervical cancers.

Additionally, we develop and manufacture a portfolio of fluorescence *in situ* hybridization (FISH) based DNA probes focused on blood-based and solid cancers. We currently offer 32 CE marked probes and we are in the process of developing two proprietary probes.

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.

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 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. 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 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 plan to 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 MatBA® microarrays 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

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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 2008, the World Health Organization attributed 7.6 million deaths worldwide to cancer-related causes. The 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 that will occur in 2013 in the United States for the major cancers:

Cancer Type	Estimated New Cases For 2013	Estimated Deaths For 2013
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

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cancerous or pre-cancerous conditions. For example, multiple gains or losses on various chromosomes and movement of genetic material among chromosomes (chromosomal translocations), collectively, 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. Technology that can apply this predictive information has the potential to dramatically improve treatment outcomes for patients suffering from cancer.

Limitations of Traditional Cancer Diagnostic Approaches

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, 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 a high risk situation of misclassification that can ultimately prove dangerous or deadly, 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 for analysis is restricted to that used for morphologic analysis (formalin-fixed paraffin-embedded material). For leukemias, where the specimen type is usually blood or bone marrow, this does not present a problem, but enrichment for the cells of interest for analysis is a challenge. 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®-SLL and MatBA®-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

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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:

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. 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.

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 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.

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 can also reveal other genomic rearrangements previously unknown to occur in the cancer genome. Translation of these findings for clinical implementation can also be achieved with a high degree of sensitivity using deep-sequencing at specific nucleotide sequences and can be translated where applicable into FISH or microarray-based assays depending on the aberrations that need to be detected.

To 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. 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.

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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®-CLL, MatBA®-SLL, MatBA®-DLBCL, UroGenRA -Kidney and MatBA®-MCL. We are also developing a number of other microarray-based tests, including additional MatBA®-based tests for additional hematological malignancies, as well as UroGenRA and UGenRA microarray platforms for urogenital cancers. We plan to obtain the necessary regulatory approvals to allow us to commercialize these microarray tests for use outside of our clinical laboratory.

To facilitate the development of additional 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.

C*ontinue 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. We actively integrate the dual disciplines of clinical diagnosis and fundamental research to foster a unique, interdisciplinary approach. This interdisciplinary approach enables us to design our research programs with a clinical outcome in mind, allowing for the rapid deployment of our proprietary microarrays and DNA probes into a clinical setting. We believe that our multidisciplinary approach allows us to rapidly expand our test and service offerings, and differentiates us from other diagnostics and laboratory services providers in the marketplace.

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 focus on providing biopharmaceutical companies and clinical research organizations with our 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

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trials in the United States according to 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 seek additional collaborations and partnerships with the biopharmaceutical community.

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 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.

Continue to reduce the costs associated with the development, manufacture, and interpretation of our proprietary genomic tests and services and to work with healthcare providers and payers to demonstrate the value of our testing in providing cost efficient and accountable care. 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 initiated a program in December 2010 to identify key material components and labor processes involved in the manufacturing of our DNA probes and to date have significantly reduced our overall costs while increasing manufacturing yields and flexibility. We have initiated dialogue with key payers, cost management organizations and insurance providers to demonstrate the 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®-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.

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 in May 2013 which, once funded by us, 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®-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. 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.

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Ability to test on FFPE tissue samples accelerates the time required to validate, develop and patent new tests. 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 tumors diagnosed using minimally invasive technologies where often very small biopsy material is available for diagnostic and prognostic studies. Third, it affords enrichment of 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.

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.

Focus on servicing the comprehensive needs of community hospitals, where approximately 85% of all cancer patients in the United States are initially diagnosed. Through our Expand Dx program, we work with community hospitals to better service their oncology patients. Our proprietary tests, as well as our comprehensive cancer diagnostic testing services, are fully integrated into the Expand Dx program and help the community hospitals deliver a higher value of service to their cancer patients.

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 theranosis). 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.

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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.

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 110,280 expected in 2011) and for approximately 6% of all estimated cancer-related deaths (approximately 35,610 expected in 2011). 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, we expect significant clinical demand for MatBA®.

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MatBA® is designed to detect genomic copy number changes in mature B-cell neoplasms either solely or in a unique combination, thus assisting the clinician in the management of a patient s disease. The test relies on the comparative genomic hybridization of fluorescently differentially-labeled normal DNA and DNA extracted from the cancer specimen (array-CGH). 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® 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 is 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® was custom-designed to represent 80 regions of the human genome which have diagnostic and/or prognostic value in one or more of the mature B-cell neoplasm subtypes as identified through our research and analysis efforts. Unlike other technologies such as FISH, array-CGH using MatBA® simultaneously permits the detection of genomic gains and losses at multiple locations on a chromosome (loci) that characterize the mature B-cell neoplasm subtypes. For each subtype of B-cell neoplasm, cohorts of specimens with full clinical annotation are evaluated using MatBA® 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® Microarrays offered as LDTs

We offer the first application of MatBA® 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®-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®-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 and rigorously 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®-CLL was the first oncology microarray approved for commercial use by the New York State Department of Health.

Approximately 14,500 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®, 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® 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® has greater resolution than that available with prior tests, we can interrogate two different regions or loci on the 13q chromosome. 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. 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® 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-making by the clinician regarding the management of these patients.

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 Leukemiais 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® 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.

In addition we have identified novel biomarkers using MatBA® 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 validated MatBA®-SLL for risk stratification in SLL. In January 2012, MatBA®-SLL was approved under CLIA and accordingly may now be offered as an LDT by our laboratory. This adaptation of MatBA® 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®-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® 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®-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® Microarray in Development

We are now undergoing similar development of MatBA® 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 these diseases. 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®. We believe MatBA® 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 to exceed 376,310 in 2011 according to the American Cancer Society. Gynecologic neoplasms contribute substantially to

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female mortality and morbidity in the United States and are an area where nearly 84,140 new cases are diagnosed each 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.

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 UroGenRA -Kidney in May 2013, and it targets kidney cancer. We are also developing extensions of UroGenRA for bladder and prostate cancers. UGenRA 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 in the commercial development stage. 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

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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.

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 22,240 cases of ovarian cancer diagnosed in the United States each year and approximately 14,030 people 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 12,340 cases of cervical cancer diagnosed and approximately 4,030 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 clinical development stage.

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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 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 plan to make 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 .

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FReCaD Renal Cancer Detection Test

We have developed a proprietary, novel and highly sensitive panel comprised of 20 FISH-based DNA probes for the detection of genomic abnormalities that differentially diagnose the four main subtypes of renal cell carcinoma papillary, clear cell, chromophobe and oncocytoma. Our FReCaD panel provides precise classification of the subtypes of renal cell carcinoma using minimal biopsy material. The test detects chromosomal aberrations as molecular factors that are differentially observed in each of the four main subtypes of renal cancer. Differentiation between benign and malignant, and furthermore between the three malignant subtypes, is essential in treatment management for patients with suspect renal masses.

FReCaD is based on the inherent differential genetic rearrangements of renal cell carcinoma rather than the form or structure of the cells (cell morphology). By detecting the inherent genomic rearrangements specific to renal cancer subtypes, we believe, the FReCaD panel allows a more accurate diagnosis. This results in better treatment decisions, higher remission rates and the prevention of disease progression among patients. A study of 145 *ex-vivo* core biopsies performed at our research laboratory clearly indicated the FReCaD panel combined with morphology improved the classification of renal needle biopsies by 16% above that of morphology alone and together the morphology and the FReCaD panel allowed the accurate detection of renal cell carcinoma in 89% of renal needle biopsies. FReCaD is in the commercial development stage.

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 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 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. In 2011, we generated approximately 87% of our revenue from our non-proprietary laboratory services, approximately 10% from government grants and approximately 3% from sales of our DNA probes.

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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 16 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 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 non-proprietary services are often leveraged in the development of our proprietary programs and now increasingly in the validation of our proprietary programs (such as MatBA®) for clinical use.

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

Microarray based testing (MatBA®-CLL, MatBA®-SLL, MatBA®-DLBCL, MatBA®-MCL and UroGenRA - Kidney): our proprietary microarray test 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;

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 obtained from third parties performed on whole specimen or magnehell separated purified plasma cells;

Flow cytometry testing: Immuno pheno type analysis of specific markers inside cells including specific cytosolic surface protiens, 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.

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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 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 recently 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.

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

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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 both our staff and the laboratory 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 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 $2.1 million, which represents 49% of our net revenue, for the year ended December 31, 2012; $2.1 million, which represents 69% of our net revenue, for the year ended December 31, 2011; and $1.2 million, which represents 46% of our net revenue, for the year ended December 31, 2010. Research and development expenses represented 26% of our total operating expenses for the year ended December 31, 2012, 26% of our total operating expenses for the year ended December 31, 2011, and 22% 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

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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;