NanoString Technologies Inc Form 424B4 June 26, 2013 Table of Contents

> Filed Pursuant to Rule 424(b)(4) Registration No. 333-188704

**PROSPECTUS** 

# 5,400,000 Shares

# **COMMON STOCK**

This is the initial public offering of shares of common stock of NanoString Technologies, Inc. NanoString Technologies is selling 5,400,000 shares of common stock. Prior to this offering, there has been no public market for our common stock. The initial public offering price is \$10.00 per share.

Our common stock has been approved for listing on The NASDAQ Global Market under the symbol NSTG.

NanoString Technologies is an emerging growth company as defined under the federal securities laws and, as such, may elect to comply with certain reduced public company reporting requirements for this and future filings.

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	Per Share	Total
Initial public offering price	\$10.00	\$54,000,000
Underwriting discounts and commissions	\$0.70	\$3,780,000
Proceeds to NanoString Technologies, Inc. before expenses <sup>(1)</sup>	\$9.30	\$50,220,000

(1)		TT 1 '4'
	) See	Underwriting.

We have granted the underwriters an option to purchase up to 810,000 additional shares of common stock to cover overallotments.

Investment entities affiliated with certain of our principal stockholders and certain of our other existing stockholders, including one of our directors, have expressed interest in acquiring shares of our common stock in this offering. We have requested the representatives of the underwriters allocate shares in this offering to these investors. It is currently anticipated that the aggregate number of shares to be purchased by these investors in this offering will be 1,006,341 shares.

Investing in our common stock involves a high degree of risk. See <u>Risk Factors</u> beginning on page 10.

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.

The underwriters expect to deliver the shares to purchasers on or about July 1, 2013.

# J.P. Morgan

**Morgan Stanley** 

Leerink Swann Baird

June 25, 2013

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We and the underwriters have not authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

Until July 20, 2013, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

For investors outside of the United States: We have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

#### PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. It does not contain all of the information that may be important to you and your investment decision. You should carefully read this entire prospectus, including the matters set forth under Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes.

# NanoString Technologies, Inc.

# Overview

We develop, manufacture and sell robust, intuitive products that unlock scientifically valuable and clinically actionable genomic information from minute amounts of tissue. Our nCounter Analysis System directly profiles hundreds of molecules simultaneously using a novel barcoding technology that is powerful enough for use in research, yet simple enough for use in clinical laboratories worldwide. We market systems and related consumables to researchers in academic, government, and biopharmaceutical laboratories for use in understanding fundamental biology and the molecular basis of disease. We have an installed base of more than 140 systems, which our customers have used to publish more than 220 peer-reviewed papers. As researchers discover how genomic information can be used to improve clinical decision-making, we seek to selectively translate their discoveries into molecular diagnostic products. In September 2012, we received European Union regulatory clearance for our first molecular diagnostic product, the Prosigna Breast Cancer Assay, or Prosigna, an assay providing an assessment of a patient s risk of recurrence for breast cancer and the intrinsic subtype of the patient s tumor. In February 2013, we commercially launched Prosigna in Europe and Israel. In December 2012, we submitted an application, known as a 510(k), to the U.S. Food and Drug Administration, or FDA, seeking clearance in the United States for a version of Prosigna providing an assessment of a patient s risk of recurrence for breast cancer.

The role of genomic information in research and medical practice is evolving rapidly. The advent of new technologies that sequence and digitally count discrete nucleic acids, commonly referred to as next generation sequencing, or NGS, is accelerating the discovery of the relationships between the genome and human disease. Researchers are applying this wealth of new information to identify biological pathways, which are networks of tens or hundreds of genes that act in concert to produce biological functions. Researchers then seek to translate this understanding of the genomic basis of disease into the development of diagnostic tools that can be used to profile an individual patient s biological pathways as well as develop targeted drug therapies. Precise, simple and robust profiling of biological pathways presents both an analytical challenge for researchers and an opportunity to improve patient outcomes in the future.

Our nCounter Analysis System enables research on a scale appropriate for pathway-based biology by digitally quantifying the activity of up to 800 genes simultaneously in a single experiment. The sensitivity and precision of our novel barcoding chemistry allows researchers to measure subtle changes in genomic activity efficiently, which is essential because tissue samples are often available only in very small quantities. This problem is especially acute in cancer research, which is typically conducted using biopsies that are often stored in a format known as formalin-fixed paraffin embedded, or FFPE, which complicates subsequent analysis of genetic material. The nCounter Analysis System is an easy-to-use and flexible solution that allows researchers to efficiently test hypotheses across thousands of different samples. As a result, the nCounter Analysis System is particularly useful for discovering and validating networks of genes that characterize and help predict disease states, enabling the development of diagnostics and medicines designed specifically for treating patients with certain genomic profiles. When researchers succeed in these endeavors, our strategy is to selectively partner with them to translate their discoveries into clinically valuable molecular diagnostic applications.

Prosigna, our first molecular diagnostic test, is based on a collection of 50 genes known as the PAM50 gene signature, which was discovered by several of our life sciences customers. We secured an exclusive worldwide license to the PAM50 gene signature in 2010. Prosigna can provide a breast cancer patient and her physician with a subtype classification based on the fundamental biology of the patient s tumor, as well as a prognostic score that predicts the probability of cancer recurrence over 10 years. Our goal is for physicians to use Prosigna to guide therapeutic decisions so that patients receive only therapeutic interventions from which they are likely to benefit. In 2011, we conducted a clinical study, which we refer to as our TransATAC study, based on material extracted from tumor samples of more than 1,000 evaluable patients from the Arimidex, Tamoxifen, Alone or in Combination, or ATAC, study. In our study, investigators performed Prosigna on these samples that had been previously analyzed using Genomic Health s Oncotype DX, the historical market leader in breast cancer recurrence testing. The results of our TransATAC study demonstrated the ability of Prosigna to indicate risk of recurrence in postmenopausal women with hormone receptor-positive early stage breast cancer treated with endocrine therapy alone. In comparing the risk estimate provided by Prosigna to the risk estimate previously generated using Oncotype DX, investigators concluded that Prosigna is capable of providing more prognostic information than Oncotype DX. Based on the results of this study and multi-site analytical validation studies, we received European Union, or EU, regulatory clearance for Prosigna, known as a CE mark. As part of our preparation for regulatory submission in the United States, we conducted a second clinical study, which we refer to as our ABCSG8 study, based on tumor samples of more than 1,400 evaluable patients from the Austrian Breast & Colorectal Cancer Study Group 8. Our ABCSG8 study confirmed the conclusion that Prosigna can indicate risk of recurrence as previously demonstrated in our TransATAC study. In December 2012, we submitted an application, known as a 510(k), to the FDA seeking clearance in the United States for a version of Prosigna providing an assessment of a patient s risk of recurrence for breast cancer. In March 2013, we received a written response from the FDA requesting additional information for its review of our 510(k) submission. A request for additional information is common following an initial 510(k) submission. In May 2013, we submitted an initial response to the FDA s request for additional information and met with the FDA to discuss our response. If the FDA clears Prosigna, we intend to launch Prosigna in the United States promptly following receipt of such clearance. We are currently planning for this commercial launch in the first quarter of 2014. We plan to conduct future clinical studies to evaluate Prosigna s ability to guide physicians and patients in making additional treatment decisions, including the selection of the appropriate chemotherapy regimen, the duration of adjuvant endocrine therapy, and whether to use adjuvant radiation therapy, and, if such studies are successfully completed, to seek 510(k) clearance or PMA approval in the U.S. for such indications in the future.

Prosigna will be regulated as an *in vitro* diagnostic test and we intend to distribute it as a kit for use on our nCounter Analysis System in clinical laboratories after regulatory authorizations are obtained. We expect that our future diagnostic products will be regulated and distributed in a similar manner. This is in contrast to most complex genomic tests, which are currently regulated as services and are usually offered only by a limited number of specialized laboratories. The current centralized laboratory model for complex genomic testing can result in complicated logistics for the treating physician, including slower test result turnaround times and limited international access to tests as compared to local testing. In addition, most clinical laboratories cannot currently share in the revenue associated with offering patients complex genomic tests. We believe that our decentralized model will transform the current paradigm of complex genomic testing by allowing physicians worldwide to provide more comprehensive personalized diagnoses, broadening patient access, and increasing the degree to which clinical laboratories can profit by providing molecular diagnostic testing services.

We generated revenue of \$11.7 million, \$17.8 million and \$23.0 million in 2010, 2011 and 2012, respectively, and \$5.7 million in the three months ended March 31, 2013, while incurring net losses of \$12.8 million, \$10.9 million and \$17.7 million in 2010, 2011 and 2012, respectively, and \$7.3 million in the three months ended March 31, 2013.

# **Investment Highlights**

Highly synergistic life sciences tools and molecular diagnostics business model. Our nCounter Analysis System s key attributes appeal specifically to life sciences researchers focused on pathway-based biology. When these researchers identify clinically valuable genomic targets, we believe that we are well positioned to selectively in-license their discoveries and translate them into molecular diagnostic products. To date, we have secured access to Prosigna as well as one other gene signature with the potential to become a molecular diagnostic product, both of which were invented by our research customers.

Platform optimized for pathway-based biology. Our system s ability to precisely measure subtle changes in the activity of hundreds of genes simultaneously within precious tissue samples is a significant advantage over traditional tools. While powerful enough for advanced research applications, our system s reliability and simplified workflow enables use in clinical laboratories worldwide. Innovations to improve the cost, performance, and footprint of our system will expand the range of customers that can benefit from using our platform in research and diagnostic applications.

Recurring sales of proprietary consumables create a predictable revenue stream. Because we are the exclusive provider of proprietary reagents for the nCounter Analysis System, the growth of our installed instrument base should drive an increasingly predictable stream of recurring consumable revenue. In 2010, 2011 and 2012, our average consumable revenue per installed instrument exceeded \$100,000 per year.

Decentralized approach to complex genomic testing. We believe that offering molecular diagnostics as in vitro diagnostic kits for use in local clinical laboratories will improve patient care by reducing turnaround times and allowing physicians worldwide, many of whom do not currently have access to these tests, to provide more comprehensive personalized diagnoses. In addition to broadening patient access, our decentralized business model will allow hospitals and pathology laboratories to profit by in-sourcing their molecular diagnostic testing services.

Clinically validated assay targeting the significant and growing breast cancer diagnostics market. We recently received an EU regulatory clearance for Prosigna, an assay providing an assessment of a patient s risk of recurrence for breast cancer and the intrinsic subtype of the patient s tumor, and in February 2013 we commercially launched Prosigna in Europe and Israel. In December 2012, we submitted an application, known as a 510(k), to the FDA seeking clearance in the United States for a version of Prosigna providing an assessment of a patient s risk of recurrence for breast cancer. Our TransATAC clinical study of material extracted from tumor samples from more than 1,000 evaluable patients that had been previously analyzed using Genomic Health s Oncotype DX, the historical market leader, provided evidence of clinical validity of Prosigna in predicting the risk of distant recurrence of breast cancer, and the investigators concluded that Prosigna is capable of providing more prognostic information than Oncotype DX. Our recently completed ABCSG8 clinical study based on tumor samples of more than 1,400 evaluable patients confirmed the conclusion that Prosigna can indicate risk of recurrence as previously demonstrated in our TransATAC study. We intend to pursue further clinical studies evaluating our test s ability to inform treatment decisions for which no genomic diagnostic tests are currently available.

Capital efficient in vitro diagnostics business model. We believe that our in vitro diagnostics business model is more capital efficient than the clinical laboratory services model and has the potential to become profitable on a small revenue base. Our diagnostics business leverages many of the capabilities of our life sciences business, including our technology platform and product development, manufacturing, and administrative functions. Because we provide in vitro diagnostics kits rather than clinical laboratory services, we do not incur the costs of clinical laboratory infrastructure, sample logistics, or contracting with and billing managed care organizations. We believe that our customers

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will be motivated by the potential to improve patient care, broaden patient access and profit from testing services based on Prosigna and other potential nCounter-based diagnostics, which will encourage market adoption and potentially reduce sales and marketing expenditures relative to a centralized laboratory model.

# **Our Target Markets**

Over the last decade, methods of measuring genomic information have advanced substantially. However pathway-based research and the development of diagnostic tests require analysis of multiple genes and sensitivity to small changes in expression, which can be challenging for traditional genomic tools. In general, DNA microarrays and tube-based PCR methods require complex, time-consuming workflows and relatively large amounts of sample tissue to accurately characterize biological pathway activation. In both life sciences research and clinical medicine, there is a growing need for improved technologies that can precisely and rapidly measure the activation state of hundreds of genes simultaneously across a large number of precious samples, thereby providing a simple and reliable means to characterize biological pathways within minute tissue specimens.

# Life Sciences Research

According to Strategic Directions International, Inc., life sciences researchers spent approximately \$28 billion on tools and related consumables in 2011. In the decade since the completion of the Human Genome Project, improvements in NGS technology have greatly reduced the cost of sequencing a human genome and increased throughput and precision, which has led to an abundance of new biological information. In order to gather insights from this information, researchers must first distill and then efficiently analyze large pools of data. Gene expression analysis has emerged as a primary tool that researchers use to extract meaningful insights from networks of genes, which enables them to validate and then translate their findings into the development of diagnostics and medicines. According to Percepta Associates, a provider of consulting services to bioscience companies, the 2012 global market for gene expression profiling products is estimated to be \$1.2 billion.

# **Molecular Diagnostics**

According to Frost and Sullivan, the molecular diagnostics market totaled approximately \$4.1 billion in 2010 and is expected to reach \$6.2 billion by 2014. Growth in the molecular diagnostics market has been driven by technological innovations that have increased sensitivity, decreased turnaround times, simplified workflow, and lowered costs when compared to other techniques. In addition, the medical community has seen a trend in favor of decentralized diagnostic testing as a result of the convenience of local testing, hospitals and medical centers increasingly viewing their laboratories as profit centers and a need to increase access to tests for patients outside of the United States. We believe that there is an opportunity to improve the quality of diagnosis and treatment of diseases by developing and commercializing comprehensive, simple and widely available diagnostic products based on gene expression analysis. Molecular diagnostics have had a significant impact on the treatment of breast cancer, which had a worldwide incidence of 1.4 million per year in 2008 according to the World Health Organization. Over the last decade, genomic tests for breast cancer have improved the accuracy of prognosis and efficacy of treatment by assessing the risk of cancer recurrence for individual patients.

# **Our Solution**

Our nCounter Analysis System is an automated, multi-application, digital detection and counting system which directly profiles hundreds of molecules simultaneously using a novel barcoding technology that is powerful enough for use in research, yet simple enough for use in clinical laboratories worldwide. Our nCounter Analysis System consists of two automated instruments that prepare and analyze tissue samples using proprietary reagents that we call CodeSets, which can only be obtained from us. Our life sciences research customers

purchase instruments from us and then purchase our panels or custom CodeSets and related consumables for the specific experiment they wish to conduct. Beginning with Prosigna, our future diagnostics customers will either purchase or lease instruments from us and also purchase one of our diagnostic kits for each test that they intend to run. Our nCounter Analysis System offers a number of compelling advantages, including:

Optimized for Pathway-Based Biology. The nCounter Analysis System can profile up to 800 molecules in a single test tube, which allows researchers to analyze interactions among hundreds of genes that mediate biological pathways. In addition, our nCounter Analysis System offers customers the freedom to order panels or custom CodeSets specific to their experiment.

Digital Precision. Our molecular barcodes hybridize directly to the target molecules in a sample allowing them to be counted. This generates digital data (1 molecule = 1 count) of excellent quality over a wide dynamic range of measurements. Our nCounter Analysis System provides excellent reproducibility and avoids the potential bias that may be introduced by the sample division and extended amplification that are generally required for qPCR-based techniques.

Simple Workflow. The nCounter Analysis System s minimal sample preparation and automated workflow enable the performance of gene expression analysis across hundreds of genes simultaneously in approximately 24 hours with only approximately 15 minutes of hands-on preparation time. Our nCounter Analysis System generates data that customers can evaluate without the use of complex bioinformatics.

Flexible Sample Requirements. The nCounter Analysis System is able to unlock genomic information from minute amounts of a variety of challenging tissue samples, including FFPE samples, cell lysates, and single cells.

# **Our Strategy**

Our goal is to provide products that empower scientists to understand the molecular basis of disease and empower physicians to put genomic medicine into practice. To accomplish this goal, we intend to continue providing technologies that are powerful enough for research, yet simple and robust enough for use in clinical laboratories worldwide.

Our strategy includes the following key elements:

Establish the nCounter Analysis System as the global standard for gene expression analysis.

Expand the installed base of the nCounter Analysis System in biopharmaceutical and academic research.

Broaden the addressable market of the nCounter Analysis System through continued innovation.

Build a menu of proprietary diagnostic products in collaboration with researchers.

Execute high quality clinical studies to support regulatory authorizations, market adoption and reimbursement of diagnostic products.

Enable clinical laboratories worldwide to provide complex genomic testing using our in vitro diagnostic products.

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Drive physician demand for nCounter Analysis System-based diagnostic products.

Capture capital efficiencies stemming from our diagnostics business model.

# **Risks Associated With Our Business**

Our business is subject to numerous risks, including:

We have incurred losses since we were formed and expect to incur losses in the future. We cannot be certain that we will achieve or sustain profitability.

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Our financial results may vary significantly from quarter to quarter which may adversely affect our stock price.

If we do not obtain regulatory clearance or approval to market our products for diagnostic purposes, we will be limited to marketing our products for research use only. In addition, if regulatory limitations are placed on our diagnostic products our business and growth will be harmed.

Approval and/or clearance by the FDA and foreign regulatory authorities for our diagnostic tests will take significant time and require significant research, development and clinical study expenditures, may result in a clearance that does not allow us to differentiate our diagnostic tests, including Prosigna, from alternatives and ultimately may not succeed.

The life sciences research and diagnostics markets are highly competitive. If we fail to compete effectively, our business and operating results will suffer.

If Medicare and other third-party payors in the United States and foreign countries do not approve reimbursement for diagnostic tests enabled by our technology, the commercial success of our diagnostic products would be compromised.

If we are unable to protect our intellectual property effectively, our business would be harmed. For additional information about the risks we face, please see the section of this prospectus captioned Risk Factors.

# **Corporate History and Information**

We were incorporated in Delaware in June 2003. Our principal executive offices are located at 530 Fairview Avenue, N., Suite 2000, Seattle, Washington 98109. Our telephone number is (206) 378-6266. Our website address is www.nanostring.com. Information contained on the website is not incorporated by reference into this prospectus, and should not be considered to be part of this prospectus.

Unless the context indicates otherwise, as used in this prospectus, the terms NanoString, we, us and our refer to NanoString Technologies, Ir and its subsidiaries, NanoString Technologies Europe Limited, NanoString Technologies SAS, NanoString Technologies Asia Pacific Limited and NanoString Technologies International, Inc. We use NanoString, NanoString Technologies in Counter Molecules that Count Prosigna and other marks as trademarks in the United States and other countries. This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the or symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

# The Offering

Common stock offered by us 5,400,000 shares

14,594,745 shares (or 15,404,745 if the underwriters exercise their overallotment option Common stock to be outstanding after this offering

in full)

810,000 shares Overallotment option

Use of proceeds

We intend to use the net proceeds from this offering to: (1) commercialize Prosigna after obtaining regulatory authorization, including establishing a dedicated oncology sales force; (2) expand the clinical utility of Prosigna and to develop other potential diagnostic product opportunities; (3) expand life sciences commercial operations to grow and support the installed base of our nCounter Analysis Systems among life sciences research customers in the United States and internationally; (4) develop new life sciences applications, chemistry and instrumentation for our nCounter technology platform; and (5) for working capital and other general corporate purposes. We may also use a portion of the net proceeds to acquire, license and invest in complementary products, technologies or businesses; however, we currently have no agreements or commitments to complete any such transaction. See Use of Proceeds.

Proposed NASDAQ trading symbol

NSTG

The number of shares of common stock to be outstanding following this offering is based on 9,194,745 shares of common stock outstanding as of March 31, 2013, and excludes:

1,806,273 shares of common stock issuable upon exercise of options outstanding as of March 31, 2013, at a weighted-average exercise price of \$3.02 per share;

1,984,972 shares of common stock reserved for future issuance under stock-based compensation plans, including 1,562,500 shares of common stock reserved for issuance under the 2013 Equity Incentive Plan, which will become effective on the date of this prospectus, and any future automatic increase in shares reserved for issuance under such plan, 281,250 shares of common stock reserved for issuance under the 2013 Employee Stock Purchase Plan, and any future automatic increase in shares reserved for issuance under such plan, and 141,222 shares of common stock reserved for issuance under the 2004 Stock Option Plan as of March 31, 2013, which shares will be added to the 2013 Equity Incentive Plan upon effectiveness of such plan;

607,187 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2013, at a weighted-average exercise price of \$8.69 per share, after conversion of the convertible preferred stock; and

10,418 shares of common stock issuable upon the exercise of warrants at an exercise price of \$14.40 per share, after conversion of the convertible preferred stock, issued in connection with the April 2013 term loan borrowing under our credit facility. Unless otherwise indicated, this prospectus reflects and assumes the following:

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a 1-for-32 reverse stock split of our common stock and preferred stock effected on June 12, 2013;

the conversion of all outstanding shares of convertible preferred stock into an aggregate of 8,631,427 shares of common stock upon the closing of this offering;

the filing of the certificate of incorporation immediately prior to the closing of this offering; and

no exercise by the underwriters of their overallotment option.

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# **Summary Consolidated Financial Data**

We have derived the following summary of statements of operations data for the years ended December 31, 2010, 2011 and 2012 from audited financial statements appearing elsewhere in this prospectus. We derived the following statements of comprehensive income for the three months ended March 31, 2012 and 2013 and the balance sheet data as of March 31, 2013 from unaudited interim financial statements included elsewhere in this prospectus. In the opinion of management, the unaudited interim financial statements reflect all adjustments, which include normal recurring adjustments, necessary for a fair presentation of the financial statements. Historical results are not necessarily indicative of the results that may be expected in the future and the results for the three months ended March 31, 2013 are not necessarily indicative of the results that may be expected for the full year or any other period. The summary financial data set forth below should be read together with the financial statements and the related notes to those statements, as well as the sections of this prospectus captioned Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations.

	Year Ended December 31, 2010 2011 2012		Three Months Ended March 31, 2012 2013		
	2010		ds, except per sh		2010
Consolidated Statements of Comprehensive Income:			,	,	
Revenue	\$ 11,730	\$ 17,800	\$ 22,973	\$ 4,502	\$ 5,676
Costs and expenses:					
Cost of revenue	9,128	9,777	12,361	2,656	2,882
Research and development	7,547	8,990	11,635	2,197	3,059
Selling, general and administrative	8,027	9,529	15,486	3,167	6,126
Total costs and expenses	24,702	28,296	39,482	8,020	12,067
Loss from operations	(12,972)	(10,496)	(16,509)	(3,518)	(6,391)
Other income (expense):					
Interest income	29	10	21	7	3
Interest expense	(94)	(599)	(804)	(112)	(385)
Other income (expense)	254	80	(29)	(13)	(4)
Revaluation of preferred stock warrant liability	15	73	(387)	26	(482)
Total other income (expense)	204	(436)	(1,199)	(92)	(868)
Net loss	\$ (12,768)	\$ (10,932)	\$ (17,708)	(3,610)	(7,259)
Accretion of mandatorily redeemable convertible preferred stock	(4,351)	(5,251)	(7,533)	(1,793)	(2,342)
Net loss attributable to common stockholders	\$ (17,119)	\$ (16,183)	\$ (25,241)	\$ (5,403)	\$ (9,601)
Net loss per share basic and diluted	\$ (54.17)	\$ (50.10)	\$ (71.10)	\$ (16.52)	\$ (17.88)
Shares used in computing basic and diluted net loss per share	316	323	355	327	537
Pro forma net loss per share basic and diluted (unaudited) <sup>(1)</sup>			\$ (2.16)		\$ (0.74)
Shares used in computing pro forma net loss per share, basic and diluted (unaudited) <sup>(1)</sup>			8,018		9,168

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	As of March 31, 2013 Pro Forma		
	Actual (In th		justed <sup>(2)</sup>
Consolidated Balance Sheet Data:			
Cash and cash equivalents	\$ 11,794	\$	61,050
Working capital	12,250		61,506
Total assets	29,575		76,495
Total long-term debt	12,835		12,835
Mandatorily redeemable convertible preferred stock	105,964		
Total stockholders equity (deficit)	(102,808)		54,090

- (1) Pro forma net loss per share represents net loss divided by the pro forma weighted-average shares outstanding, as though the 1-for-32 reverse stock split of our common stock and preferred stock and the conversion of the preferred stock into common stock occurred on the first day of the relevant period. Pro forma weighted-average shares outstanding reflects the 1-for-32 reverse stock split of our common stock and preferred stock and the conversion of the preferred stock (using the if-converted method) into common stock as though the conversion had occurred on the first day of the relevant period.
- (2) Reflects, on a pro forma as adjusted basis, (a) a 1-for-32 reverse stock split of our common stock and preferred stock effected on June 12, 2013, (b) the conversion of all outstanding shares of convertible preferred stock into 8,631,427 shares of common stock upon the closing of this offering, (c) the conversion of warrants to purchase 604,563 shares of preferred stock into warrants to purchase 607,187 shares of common stock and (d) the sale and issuance by us of 5,400,000 shares of common stock in this offering at the initial price to public of \$10.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses of \$3.3 million, \$2.3 million of which were incurred as of March 31, 2013.

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#### RISK FACTORS

Investing in our common stock involves a high degree of risk. Before making an investment decision, you should carefully consider the risks and uncertainties described below, which we believe are the material risks associated with our business and this offering. Our business, financial condition, operating results or growth prospects could be harmed by any of these risks. In that event, the trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to all of the other information contained in this prospectus, including our financial statements and related notes.

#### Risks Related to our Business and Strategy

We have incurred losses since we were formed and expect to incur losses in the future. We cannot be certain that we will achieve or sustain profitability.

We have incurred losses since we were formed and expect to incur losses in the future. We incurred net losses of \$12.8 million, \$10.9 million, \$17.7 million, \$3.6 million and \$7.3 million in 2010, 2011 and 2012 and the three months ended March 31, 2012 and 2013, respectively. As of March 31, 2013, we had an accumulated deficit of \$102.8 million. We expect that our losses will continue for at least the next several years as we will be required to invest significant additional funds toward development and commercialization of our technology. We also expect that our selling, general and administrative expenses will continue to increase due to the additional costs associated with establishing a dedicated oncology diagnostics sales force and the increased administrative costs associated with being a public company. Our ability to achieve or sustain profitability is based on numerous factors, many of which are beyond our control, including the market acceptance of our products, future product development and our market penetration and margins. We may never be able to generate sufficient revenue to achieve or sustain profitability.

# Our financial results may vary significantly from quarter to quarter which may adversely affect our stock price.

Investors should consider our business and prospects in light of the risks and difficulties we expect to encounter in the new, uncertain and rapidly evolving markets in which we compete. Because these markets are new and evolving, predicting their future growth and size is difficult. We expect that our visibility into future sales of our products, including volumes, prices and product mix between instruments and consumables, will continue to be limited and could result in unexpected fluctuations in our quarterly and annual operating results.

Numerous other factors, many of which are outside our control, may cause or contribute to significant fluctuations in our quarterly and annual operating results. These fluctuations may make financial planning and forecasting difficult. In addition, these fluctuations may result in unanticipated decreases in our available cash, which could negatively affect our business and prospects. Factors that may contribute to fluctuations in our operating results include many of the risks described in this section. In addition, one or more of such factors may cause our revenue or operating expenses in one period to be disproportionately higher or lower relative to the others. Our products involve a significant capital commitment by our customers and accordingly involve a lengthy sales cycle. We may expend significant effort in attempting to make a particular sale, which may be deferred by the customer or never occur. Accordingly, comparing our operating results on a period-to-period basis may not be meaningful, and investors should not rely on our past results as an indication of our future performance. If such fluctuations occur or if our operating results deviate from our expectations or the expectations of securities analysts, our stock price may be adversely affected.

# If we do not achieve, sustain or successfully manage our anticipated growth, our business and growth prospects will be harmed.

We have experienced significant revenue growth in a short period of time. We may not achieve similar growth rates in future periods. Investors should not rely on our operating results for any prior periods as an indication of our future operating performance. If we are unable to maintain adequate revenue growth, our

financial results could suffer and our stock price could decline. Furthermore, growth will place significant strains on our management and our operational and financial systems and processes. For example, commercialization of the Prosigna Breast Cancer Assay, or Prosigna, in Europe and development and commercialization of this test and other diagnostic products worldwide are key elements of our growth strategy and will require us to hire and retain additional sales and marketing, regulatory, manufacturing and quality assurance personnel. If we do not successfully forecast the timing of regulatory clearance or approval for product marketing and subsequent demand for our diagnostic products or manage our anticipated expenses accordingly, our operating results will be harmed.

Our future success is dependent upon our ability to expand our customer base and introduce new applications.

Our current customer base is primarily composed of academic institutions, government laboratories and biopharmaceutical companies that perform analyses using our nCounter Analysis System for research use only. Our success will depend, in part, upon our ability to increase our market penetration among these customers and to expand our market by developing and marketing new life sciences applications, developing a lower cost instrument that would be attractive to more researchers, and introducing diagnostic products into clinical laboratories after obtaining regulatory authorization. For example, we must convince physicians and third-party payors that our diagnostic products, such as Prosigna, are cost effective in obtaining prognostic information that can inform treatment decisions and that our nCounter Analysis System could enable an equivalent or superior approach that lessens reliance on centralized laboratories. Furthermore, we expect that increasing the installed base of our nCounter Analysis Systems will drive demand for our relatively high margin consumable products. If we are not able to successfully increase our installed base of nCounter Analysis Systems, sales of our consumable products and our margins may not meet expectations. Attracting new customers and introducing new applications requires substantial time and expense. Any failure to expand our existing customer base, or launch new applications, would adversely affect our ability to improve our operating results.

Our life sciences research business depends on levels of research and development spending by academic and governmental research institutions and biopharmaceutical companies, a reduction in which could limit demand for our products and adversely affect our business and operating results.

In the near term, we expect that our revenue will be derived primarily from sales of our nCounter Analysis Systems to academic institutions, governmental laboratories and biopharmaceutical companies worldwide for research applications. The demand for our products will depend in part upon the research and development budgets of these customers, which are impacted by factors beyond our control, such as:

changes in government programs that provide funding to research institutions and companies;
macroeconomic conditions and the political climate;
changes in the regulatory environment;
differences in budgetary cycles;
market-driven pressures to consolidate operations and reduce costs; and

market acceptance of relatively new technologies, such as ours.

For example, in the United States, automatic across-the-board cuts in government spending, or sequestration, took effect on March 1, 2013. These cuts will impact the budgets of government agencies, such as the National Institutes of Health, which provide significant funding for cancer research and other diseases, however, as of the date of this prospectus the full impact of the cuts is unknown. We believe that the uncertainty regarding the availability of research funding, including the potential impact of sequestration, has adversely affected our historical operating results and any continuing uncertainty may adversely affect sales to customers or potential customers that rely on government funding. In addition, academic, governmental and other research institutions that fund research and development activities may be subject to stringent budgetary constraints that could result in spending reductions, reduced allocations or budget cutbacks, which could jeopardize the ability of these customers to purchase our products.

Our operating results may fluctuate substantially due to reductions and delays in research and development expenditures by these customers. Any decrease in our customers budgets or expenditures, or in the size, scope or frequency of capital or operating expenditures, could materially and adversely affect our business, operating results and financial condition.

Our sales cycle is lengthy and variable, which makes it difficult for us to forecast revenue and other operating results.

Our sales process involves numerous interactions with multiple individuals within an organization, and often includes in-depth analysis by potential customers of our products, performance of proof-of-principle studies, preparation of extensive documentation and a lengthy review process. As a result of these factors, the large capital investment required in purchasing our instruments and the budget cycles of our customers, the time from initial contact with a customer to our receipt of a purchase order can vary significantly and be up to 12 months or longer. Given the length and uncertainty of our sales cycle, we have in the past experienced, and likely will in the future experience, fluctuations in our instrument sales on a period-to-period basis. In addition, any failure to meet customer expectations could result in customers choosing to retain their existing systems or to purchase systems other than ours.

Our reliance on distributors for sales of our life sciences systems outside of the United States could limit or prevent us from selling our diagnostic tests in foreign markets and impact our revenue.

As of March 31, 2013, we have established exclusive distribution agreements for our nCounter Analysis System in the life sciences research market within parts of Europe, the Middle East, Asia Pacific and South America. We intend to continue to grow our business internationally, and to do so we must attract additional distributors to maximize the commercial opportunity for our products. There is no guarantee, if we do seek to enter into such arrangements, that we will be successful in attracting desirable sales and distribution partners or that we will be able to enter into such arrangements on favorable terms. Distributors may not commit the necessary resources to market and sell our products to the level of our expectations or may choose to favor marketing the products of our competitors. If current or future distributors do not perform adequately, or we are unable to enter into effective arrangements with distributors in particular geographic areas, we may not realize long-term international revenue growth.

If we do not obtain regulatory clearance or approval to market our products for diagnostic purposes, we will be limited to marketing our products for research use only. In addition, if regulatory limitations are placed on our diagnostic products our business and growth will be harmed.

We recently obtained a CE mark for our first diagnostic product, Prosigna, which permits us to market that assay for diagnostic purposes in Europe, and we intend to seek regulatory authorization in other countries outside of the United States. In Europe, Prosigna can be used to provide a subtype classification based on the fundamental biology of an individual s breast tumor, as well as a prognostic score that indicates the probability of cancer recurrence over 10 years. In February 2013, we commercially launched Prosigna in Europe and Israel, but we do not have regulatory clearance or approval to market any other product for diagnostic purposes or to market Prosigna for diagnostic purposes in any other market. Other than with respect to Prosigna in such jurisdictions, we are limited to marketing our products for research use only, which means that we cannot make any diagnostic or clinical claims. We intend to seek regulatory authorizations in other jurisdictions to market Prosigna for diagnostic purposes; however, we cannot assure investors that we will be successful in doing so. In December 2012, we submitted an application, known as a 510(k), to the FDA seeking clearance in the United States for a version of Prosigna providing an assessment of a patient s risk of recurrence for breast cancer. In March 2013, we received a written response from the FDA requesting additional information for its review of our 510(k) submission. In the FDA s March 2013 written response to our 510(k) submission, the FDA communicated, among other things, that we would need to provide further support before the FDA could determine whether the pending 510(k) application, if cleared, would allow us to include a risk score and three distinct risk groups in patient reports for all patients tested. In May 2013, we submitted an initial response to the

FDA s request for additional information and met with the FDA to discuss our response. In this meeting, we discussed, among other issues raised by the FDA, the specific elements and format of a potential report generated by Prosigna, including the appropriate name for the risk score, the appropriate graphic presentation of the risk score, and, specifically for the potential report for node-positive patients, the numerical range of the risk score and the appropriate number of risk groups. We cannot guarantee that we will obtain clearance. For example, even though the results of our clinical studies that used samples from the ATAC study and the ABCSG8 study of postmenopausal women with hormone receptor-positive, or HR+, early stage breast cancer were favorable, there is no guarantee that any future studies will be successful or that the FDA will provide clearance of Prosigna based on the studies we have completed. If the FDA requires additional studies, we may be required to expend considerable resources to conduct them, which would greatly increase our costs, divert resources away from other programs and halt or delay the path to commercialization. If we do not obtain such clearance, we will be limited to marketing our products for research use only within the United States. In addition, even if we obtain clearance for Prosigna, the prognostic information ultimately reported could be limited. For example, if we do obtain clearance from the FDA to market Prosigna in the United States, the test may be limited to classifying patients into categories according to the risk of recurrence of breast cancer, such as high/intermediate/low risk or high/low risk. If Prosigna is not cleared by the FDA to indicate a specific risk score or if Prosigna is limited to classifying node-negative patients into high or low risk groups only, the prognostic information provided by Prosigna and our ability to differentiate our test from alternatives may be adversely affected in the United States. Similarly, if we do not obtain regulatory clearance or approval of future products or future indications for diagnostic purposes, for instance approval to allow for reporting of the subtype classification based on the fundamental biology of an individual s breast cancer, if unexpected regulatory limitations are placed on our products or if we fail to successfully commercialize such products, the market potential for our diagnostic products would be constrained, and our business and growth prospects would be adversely affected.

# If Prosigna fails to achieve and sustain sufficient market acceptance, we will not generate expected revenue, and our prospects may be harmed.

Currently, most oncologists seeking sophisticated gene expression analysis for diagnosing and profiling breast cancer in their patients ship tissue samples to a limited number of centralized laboratories typically located in the United States. We may experience reluctance, or refusal, on the part of physicians to order, and third-party payors to pay for, Prosigna if the results of our research and clinical studies, and our sales and marketing activities relating to communication of these results, do not convey to physicians, third-party payors and patients that Prosigna provides equivalent or better prognostic information.

In Europe, Prosigna may be used for intrinsic subtyping of breast cancer and in the future we intend to seek approval from the FDA for such use. Intrinsic subtyping will be a new methodology in categorizing breast cancer patients, and we may have to overcome resistance among physicians to adopting it for the marketing of our products to be successful. Even if we are able to obtain regulatory approval from the FDA, the use of intrinsic subtyping and thus Prosigna may not be included in breast cancer treatment guidelines. In addition, breast cancer treatment guidelines recommend that chemotherapy be considered in many cases, in combination with other patient factors. Accordingly, physicians may be reluctant to order a test, such as Prosigna, that may suggest recommending against chemotherapy. Furthermore, our diagnostic tests would be performed by pathologists in local laboratories, rather than by a vendor in a remote centralized laboratory, which will require us to educate pathologists regarding the benefits of this business model.

These hurdles may make it difficult to convince health care providers that tests using our technologies are appropriate options for cancer diagnostics, may be equivalent or superior to available tests, and may be at least as cost effective as alternative technologies, and thus we may encounter significant difficulty in broadening market acceptance of Prosigna.

As part of our current business model, we will seek to enter into strategic collaborations and licensing arrangements with third parties to develop diagnostic tests.

We have relied, and expect to continue to rely, on strategic collaborations and licensing agreements with third parties for discoveries based on which we develop diagnostic tests. For example, we licensed the rights to

intellectual property that forms the basis of Prosigna from Bioclassifier, LLC, which was founded by several of our life sciences research customers engaged in translational research. In addition, in February 2013, we secured an option from The Broad Institute, a leading non-profit molecular medicine institute in Cambridge, Massachusetts, to acquire an exclusive worldwide license for a gene signature that could be used, after appropriate regulatory authorization, for a second molecular diagnostic product focused on hepatocellular carcinoma, or HCC. We intend to enter into more such arrangements with our life sciences customers and other researchers for future diagnostic products. However, there is no assurance that we will be successful in doing so. In particular, our life sciences research customers are not obligated to collaborate with us or license technology to us, and they may choose to develop diagnostic products themselves or collaborate with our competitors. Establishing collaborations and licensing arrangements is difficult and time-consuming. Discussions may not lead to collaborations or licenses on favorable terms, if at all. To the extent we agree to work exclusively with a party in a given area, our opportunities to collaborate with others could be limited. Potential collaborators or licensors may elect not to work with us based upon their assessment of our financial, regulatory or intellectual property position. Even if we establish new relationships, they may never result in the successful development or commercialization of future tests

New diagnostic product development involves a lengthy and complex process, and we may be unable to commercialize on a timely basis, or at all, any of the tests we develop.

Few research and development projects result in successful commercial products, and success in early clinical studies often is not replicated in later studies. For example, even though the results of our clinical studies that used samples from the ATAC study and ABCSG8 study of postmenopausal women with HR+ early stage breast cancer were favorable, there is no guarantee that any future studies will be successful, that the FDA will provide clearance of Prosigna based on the studies we have completed or if FDA provides clearance, that the prognostic information that may be reported will differentiate our test from alternatives in the United States. At any point, we may abandon development of a product candidate or we may be required to expend considerable resources repeating clinical studies, which would adversely impact potential revenue and our expenses. In addition, any delay in product development would provide others with additional time to commercialize competing products before we do, which in turn may adversely affect our growth prospects and operating results.

Our research and development efforts will be hindered if we are not able to contract with third parties for access to archival tissue samples.

Under standard clinical practice, tumor biopsies removed from patients are preserved and stored in formalin-fixed paraffin embedded, or FFPE, format. We rely on our ability to secure access to these archived FFPE tumor biopsy samples, as well as information pertaining to the clinical outcomes of the patients from which they were derived for our clinical development activities. Others compete with us for access to these samples. Additionally, the process of negotiating access to archived samples is lengthy because it typically involves numerous parties and approval levels to resolve complex issues such as usage rights, institutional review board approval, privacy rights, publication rights, intellectual property ownership and research parameters. If we are not able to negotiate access to archived tumor tissue samples with hospitals, clinical partners, pharmaceutical companies, or companies developing therapeutics on a timely basis, or at all, or if other laboratories or our competitors secure access to these samples before us, our ability to research, develop and commercialize future products will be limited or delayed.

The life sciences research and diagnostic markets are highly competitive. If we fail to compete effectively, our business and operating results will suffer.

We face significant competition in the life sciences research and diagnostics markets. We currently compete with both established and early stage life sciences research companies that design, manufacture and market instruments and consumables for gene expression analysis, single-cell analysis, polymerase chain reaction, or PCR, digital PCR, other nucleic acid detection and additional applications. These companies use well established laboratory techniques such as microarrays or quantitative PCR, or qPCR, as well as newer technologies such as next generation sequencing. We believe our principal competitors in the life sciences research market are

Affymetrix, Agilent Technologies, Bio-Rad, Exiqon, Fluidigm, High Throughput Genomics, Illumina, Life Technologies, Luminex, Perkin Elmer, Qiagen and Roche Applied Science. In addition, there are a number of new market entrants in the process of developing novel technologies for the life sciences market, including companies such as RainDance Technologies and Wafergen Bio-Systems.

We will also compete with commercial diagnostics companies. We believe our principal competitor in the breast cancer diagnostics market will be Genomic Health, which provides gene expression analysis at its central laboratory in Redwood City, California and currently commands a substantial majority of the market. We also expect to face competition from companies such as Agendia, Clarient (a GE Healthcare company), Genoptix (a division of Novartis) and bioMeriéux, which also offer services by means of centralized laboratories that profile gene or protein expression in breast cancer. In Europe, we will also face regional competition from smaller companies such as Sividon Diagnostics, maker of EndoPredict, a distributed test for breast cancer recurrence, and other independent laboratories.

Most of our current competitors are either publicly traded, or are divisions of publicly-traded companies, and enjoy a number of competitive advantages over us, including:

greater name and brand recognition, financial and human resources;
broader product lines;
larger sales forces and more established distributor networks;
substantial intellectual property portfolios;
larger and more established customer bases and relationships; and
better established, larger scale, and lower cost manufacturing capabilities.  e that the principal competitive factors in all of our target markets include:
cost of capital equipment;
cost of consumables and supplies;
reputation among customers;
innovation in product offerings;
flexibility and ease-of-use;
accuracy and reproducibility of results; and

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compatibility with existing laboratory processes, tools and methods. We believe that additional competitive factors specific to the diagnostics market include:

breadth of clinical decisions that can be influenced by information generated by tests;

volume, quality, and strength of clinical and analytical validation data;

availability of reimbursement for testing services; and

economic benefit accrued to customers based on testing services enabled by products.

We cannot assure investors that our products will compete favorably or that we will be successful in the face of increasing competition from new products and technologies introduced by our existing competitors or new companies entering our markets. In addition, we cannot assure investors that our competitors do not have or will not develop products or technologies that currently or in the future will enable them to produce competitive products with greater capabilities or at lower costs than ours. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

We have limited experience in marketing and selling our products, and if we are unable to successfully commercialize our products, our business may be adversely affected.

We have limited experience marketing and selling our products. Our nCounter Analysis System was introduced for sale in the life sciences research market in 2008, and was introduced for sale in the diagnostics

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market in Europe and Israel in connection with the February 2013 commercial launch of Prosigna in those markets. We sell our products through our own sales force in North America and through a combination of our own sales force and distributors in Europe, Asia Pacific and South America. In the future, we intend to establish distributor relationships in other parts of the world; however, we may not be able to market and sell our products effectively.

Our future sales of diagnostic products will depend in large part on our ability to successfully establish an oncology diagnostics sales force and to increase the scope of our marketing efforts. Because we have no experience in marketing and selling our products in the diagnostics market, our ability to forecast demand, the infrastructure required to support such demand and the sales cycle to diagnostics customers is unproven. If we do not build an efficient and effective sales force targeting this market, our business and operating results will be adversely affected.

We may not be able to develop new products or enhance the capabilities of our systems to keep pace with rapidly changing technology and customer requirements, which could have a material adverse effect on our business and operating results.

Our success depends on our ability to develop new products and applications for our technology in existing and new markets, while improving the performance and cost-effectiveness of our systems. New technologies, techniques or products could emerge that might offer better combinations of price and performance than our current or future products and systems. Existing markets for our products, including gene expression analysis, single-cell analysis and copy number variation, as well as potential markets for our diagnostic product candidates, are characterized by rapid technological change and innovation. It is critical to our success that we anticipate changes in technology and customer requirements and to successfully introduce new, enhanced and competitive technologies to meet our customers and prospective customers needs on a timely and cost-effective basis. At the same time, however, we must carefully manage the introduction by us of new products. If customers believe that such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory of older products as we transition to new products and our experience in managing product transitions is very limited. If we do not successfully innovate and introduce new technology into our product lines or manage the transitions to new product offerings, our revenues, results of operations and business will be adversely impacted.

Competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and as new companies enter the market with new technologies.

New market opportunities may not develop as quickly as we expect, limiting our ability to successfully market and sell our products.

The market for our products is new and evolving. Accordingly, we expect the application of our technologies to emerging opportunities will take several years to develop and mature and we cannot be certain that these market opportunities will develop as we expect. For example, in September 2012, we launched a single cell gene expression application for our nCounter Analysis System, which applies our technology to, amongst other things, improve single cell analytic workflow for gene expression analysis. The future growth of the single cell analysis market depends on many factors beyond our control, including recognition and acceptance of our applications by the scientific community and the growth, prevalence and costs of competing methods of genomic analysis. If the markets for single cell analysis or others do not develop as we expect, our business may be adversely affected. In addition, we commercially launched Prosigna in Europe and Israel in February 2013 and we intend to offer Prosigna in other countries outside of the United States. Genomic testing for breast cancer is not widely available outside of the United States and the market for such tests is new. The future growth of the market for genomic breast cancer testing will depend on physicians acceptance of such testing and the availability of reimbursement for such tests. Our success in these new markets will depend to a large extent on our ability to successfully market, sell and establish reimbursement for products using our technologies. If we are

not able to successfully market and sell our products or to achieve the revenue or margins we expect, our operating results may be harmed and we may not recover our product development and marketing expenditures.

We are dependent on single source suppliers for some of the components and materials used in our products, and the loss of any of these suppliers could harm our business.

We rely on Precision System Science, Co., Ltd of Chiba, Japan, to build our nCounter Prep Station and Korvis LLC of Corvallis, Oregon, to build our nCounter Digital Analyzer. Each of these contract manufacturers are sole suppliers. Since our contracts with these instrument suppliers do not commit them to carry inventory or make available any particular quantities, they may give other customers needs higher priority than ours, and we may not be able to obtain adequate supplies in a timely manner or on commercially reasonable terms. We also rely on sole suppliers for various components we use to manufacture our consumable products. We periodically forecast our needs for such components and enter into standard purchase orders with them. If we were to lose such suppliers, there can be no assurance that we will be able to identify or enter into agreements with alternative suppliers on a timely basis on acceptable terms, if at all. If we should encounter delays or difficulties in securing the quality and quantity of materials we require for our products our supply chain would be interrupted which would adversely affect sales. If any of these events occur, our business and operating results could be harmed.

If our Seattle facility becomes unavailable or inoperable, we will be unable to continue manufacturing our consumables or process sales orders, and our business will be harmed.

We manufacture our consumable products in our facility in Seattle, Washington. In addition, our Seattle facility is the center for order processing, receipt of our prep station and digital analyzer manufactured by third-party contract manufacturers and shipping products to customers. Our facility and the equipment we use to manufacture our consumable products would be costly, and would require substantial lead time, to repair or replace. Seattle is situated near active earthquake fault lines. The facility may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes and power outages, which may render it difficult or impossible for us to produce our tests for some period of time. The inability to manufacture consumables or to ship products to customers for even a short period of time may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, 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.

We expect to generate a substantial portion of our revenue internationally and are subject to various risks relating to our international activities which could adversely affect our operating results.

During 2010, 2011 and 2012 and the three months ended March 31, 2013, approximately 9%, 21%, 31% and 21%, respectively, of our revenue was generated from sales to customers located outside of North America. We believe that a significant percentage of our future revenue will come from international sources as we expand our overseas operations and develop opportunities in additional areas. Engaging in international business involves a number of difficulties and risks, including:

required compliance with existing and changing foreign regulatory requirements and laws;

required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act and U.K. Bribery Act, data privacy requirements, labor laws and anti-competition regulations;

export or import restrictions;

various reimbursement and insurance regimes;

laws and business practices favoring local companies;

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longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;

political and economic instability;

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potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;

difficulties and costs of staffing and managing foreign operations; and

difficulties protecting or procuring intellectual property rights.

As we expand internationally our results of operations and cash flows will become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Historically, most of our revenue has been denominated in U.S. dollars, although we have sold our products and services in local currency outside of the United States, principally the Euro. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States. As our operations in countries outside of the United States grow, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. For example, if the value of the U.S. dollar increases relative to foreign currencies, in the absence of a corresponding change in local currency prices, our revenue could be adversely affected as we convert revenue from local currencies to U.S. dollars.

If we dedicate significant resources to our international operations and are unable to manage these risks effectively, our business, operating results and prospects will suffer.

The enactment of legislation implementing changes in the U.S. taxation of international business activities or the adoption of other tax reform policies could materially impact our future financial position and results of operations.

Recent changes to U.S. tax laws, including limitations on the ability of taxpayers to claim and utilize foreign tax credits and the deferral of certain tax deductions until earnings outside of the United States are repatriated to the United States, as well as changes to U.S. tax laws that may be enacted in the future, could impact the tax treatment of future foreign earnings. Should the scale of our international business activities expand, any changes in the U.S. taxation of such activities could increase our worldwide effective tax rate and harm our future financial position and results of operations.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2012, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of approximately \$62.2 million, which expire in various years beginning in 2023, if not utilized. A lack of future taxable income would adversely affect our ability to utilize these NOLs. In addition, under Section 382 of the Internal Revenue Code, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We may have already experienced one or more ownership changes. Depending on the timing of any future utilization of our carryforwards, we may be limited as to the amount that can be utilized each year as a result of such previous ownership changes. However, we do not believe such limitations will cause our NOL and credit carryforwards to expire unutilized. In addition, future changes in our stock ownership, including this or future offerings, as well as other changes that may be outside of our control, could result in additional ownership changes under Section 382 of the Internal Revenue Code. Our NOLs may also be impaired under similar provisions of state law. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Provisions of our debt instruments may restrict our ability to pursue our business strategies.

Our credit facility requires us, and any debt instruments we may enter into in the future may require us, to comply with various covenants that limit our ability to, among other things:

complete mergers or acquisitions;

incur indebtedness:

dispose of assets;

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encumber assets;

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pay dividends or make other distributions to holders of our capital stock;

make specified investments;

change certain key management personnel; and

engage in transactions with our affiliates.

These restrictions could inhibit our ability to pursue our business strategies. In addition, we are subject to a financial covenant based on life sciences revenue. If we default under our credit facility, and such event of default was not cured or waived, the lenders could terminate commitments to lend and cause all amounts outstanding with respect to the debt to be due and payable immediately, which in turn could result in cross defaults under other debt instruments. Our assets and cash flow may not be sufficient to fully repay borrowings under all of our outstanding debt instruments if some or all of these instruments are accelerated upon a default.

We may incur additional indebtedness in the future. The debt instruments governing such indebtedness could contain provisions that are as, or more, restrictive than our existing debt instruments. If we are unable to repay, refinance or restructure our indebtedness when payment is due, the lenders could proceed against the collateral granted to them to secure such indebtedness or force us into bankruptcy or liquidation.

We may need to raise additional capital, which may not be available on favorable terms, if at all, and which may cause dilution to stockholders, restrict our operations or adversely affect our ability to operate our business.

We may need or decide to raise additional funds through public or private debt or equity financing. We cannot be certain that we will be able to obtain additional financing on favorable terms, if at all, and any additional financings could result in additional dilution to our then existing stockholders. If we raise funds by issuing equity securities, the percentage ownership of our stockholders will be reduced. If we need additional capital and cannot raise it on acceptable terms, we may not be able to meet our business objectives, our stock price may fall and investors may lose some or all of their investment.

Acquisitions or joint ventures could disrupt our business, cause dilution to our stockholders and otherwise harm our business.

We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses. We have not made any acquisitions to date, and our ability to do so successfully is unproven. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

disruption in our relationships with customers, distributors or suppliers as a result of such a transaction;

unanticipated liabilities related to acquired companies;

difficulties integrating acquired personnel, technologies and operations into our existing business;

diversion of management time and focus from operating our business to acquisition integration challenges;

increases in our expenses and reductions in our cash available for operations and other uses; and

possible write-offs or impairment charges relating to acquired businesses.

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Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the anticipated benefit of any acquisition may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

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# If we are unable to recruit, train and retain key personnel, we may not achieve our goals.

Our future success depends on our ability to recruit, train, retain and motivate key personnel, including our senior management, research and development, manufacturing and sales and marketing personnel. Competition for qualified personnel is intense, particularly in the Seattle, Washington area. Our growth depends, in particular, on attracting, retaining and motivating highly-trained sales personnel with the necessary scientific background and ability to understand our systems at a technical level to effectively identify and sell to potential new customers. In particular, the commercial launch of Prosigna requires us to establish a dedicated oncology diagnostics sales force to fully optimize the breast cancer diagnostic market opportunity. We do not maintain fixed term employment contracts or key man life insurance with any of our employees. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to attract, train, retain and motivate qualified personnel could materially harm our operating results and growth prospects.

# Undetected errors or defects in our products could harm our reputation, decrease market acceptance of our products or expose us to product liability claims.

Our products may contain undetected errors or defects when first introduced or as new versions are released. Since our current customers use our products for research and may, if cleared or approved, in the future use them for diagnostic applications, disruptions or other performance problems with our products may damage our customers business and could harm our reputation. If that occurs, we may incur significant costs, the attention of our key personnel could be diverted, or other significant customer relations problems may arise. We may also be subject to warranty and liability claims for damages related to errors or defects in our products. A material liability claim or other occurrence that harms our reputation or decreases market acceptance of our products could harm our business and operating results.

The sale and use of products or services based on our technologies, or activities related to our research and clinical studies, could lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect which resulted in the failure to adequately perform the analysis for which it was designed. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We cannot assure investors that our product liability insurance would adequately protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

# We face risks related to handling of hazardous materials and other regulations governing environmental safety.

Our operations are subject to complex and stringent environmental, health, safety and other governmental laws and regulations that both public officials and private individuals may seek to enforce. Our activities that are subject to these regulations include, among other things, our use of hazardous materials and the generation, transportation and storage of waste. We could discover that we or an acquired business is not in material compliance with these regulations. Existing laws and regulations may also be revised or reinterpreted, or new laws and regulations may become applicable to us, whether retroactively or prospectively, that may have a negative effect on our business and results of operations. It is also impossible to eliminate completely the risk of accidental environmental contamination or injury to individuals. In such an event, we could be liable for any damages that result, which could adversely affect our business.

# Risks Related to Government Regulation and Diagnostic Product Reimbursement

Our research use only products for the life sciences market could become subject to regulation as medical devices by the FDA or other regulatory agencies in the future which could increase our costs and delay our commercialization efforts, thereby materially and adversely affecting our life sciences business and results of operations.

In the United States, our products are currently labeled and sold for research use only, or RUO, and not for the diagnosis or treatment of disease, and are sold to pharmaceutical and biotechnology companies, academic institutions and life sciences laboratories. Because such products are not intended for use in clinical practice in diagnostics, and the products cannot include clinical or diagnostic claims, they are not subject to regulation by the FDA as medical devices. In particular, while the FDA regulations require that RUO products be labeled, For Research Use Only. Not for use in diagnostic procedures, the regulations do not subject such products to the FDA s pre- and post- market controls for medical devices. However, in June 2011, the FDA issued a draft guidance document that, if finalized as drafted, could restrict the provision of our RUO products, and it is unclear whether the FDA will issue a final guidance and if so what the contents of the guidance will be. If in the future the FDA modifies its approach to regulating our products labeled for research use only, it could reduce our revenue or increase our costs and adversely affect our business, prospects, results of operations or financial condition. In the event that the FDA requires marketing authorization of our RUO products in the future, there can be no assurance that the FDA will ultimately grant any clearance or approval requested by us in a timely manner, or at all.

Approval and/or clearance by the FDA and foreign regulatory authorities for our diagnostic tests will take significant time and require significant research, development and clinical study expenditures and ultimately may not succeed.

Before we begin to label and market our products for use as clinical diagnostics in the United States, thereby subjecting them to FDA regulation as medical devices, unless an exemption applies, we would be required to obtain either prior 510(k) clearance or prior pre-market approval, or PMA, from the FDA. In December 2012, we submitted an application, known as a 510(k), to the FDA seeking clearance in the United States for a version of Prosigna. In March 2013, we received a written response from the FDA requesting additional information for its review of our 510(k) submission. A request for additional information is common following an initial 510(k) submission. In May 2013, we submitted an initial response to the FDA s request for additional information and met with the FDA to discuss our response. In this meeting, we discussed, among other issues raised by the FDA, the specific elements and format of a potential report generated by Prosigna, including the appropriate name for the risk score, the appropriate graphic presentation of the risk score, and, specifically for the potential report for node-positive patients, the numerical range of the risk score and the appropriate number of risk groups. Based on pre-submission interactions with the FDA and the FDA s written response to our 510(k) submission, we expect Agendia s MammaPrint to serve as the legally marketed predicate that, if Prosigna is cleared, would enable us to market a version of Prosigna in the United States to assess a patient s risk of recurrence for breast cancer. In the FDA s written response to our 510(k) submission, the FDA communicated, among other things, that we would need to provide further support before the FDA could determine whether the pending 510(k) application, if cleared, would allow us to include a risk score and three distinct risk groups in patient reports for all patients tested. If Prosigna is not cleared by the FDA to include a specific risk score or if Prosigna is limited to classifying node-negative patients into high or low risk groups only, the prognostic information provided by Prosigna and our ability to differentiate our test from alternatives may be adversely affected in the United States. As with all in vitro diagnostic products, the FDA reserves the right to redefine the regulatory path at the time of submission or during the review process, and could require a more burdensome approach, including a PMA. In the future we plan to submit a separate application for approval of Prosigna to report intrinsic subtype, and we expect that this application will require a PMA supported by additional clinical studies. We intend to pursue additional intended uses for Prosigna, which may require more burdensome regulatory processes than the 510(k) clearance process, including PMAs. Even if granted, a 510(k) clearance or PMA approval for any future product would likely place substantial restrictions on how our device is marketed or sold, and the FDA will continue to place considerable restrictions on our products, including, but not limited to, quality system regulations, or QSR, registering

manufacturing facilities, listing the products with the FDA, and complying with labeling, marketing, complaint handling, adverse event and medical device reporting requirements and corrections and removals. Obtaining FDA clearance or approval for diagnostics can be expensive and uncertain, and generally takes from several months to several years, and generally requires detailed and comprehensive scientific and clinical data. Notwithstanding the expense, these efforts may never result in FDA approval or clearance. Even if we were to obtain regulatory approval or clearance, it may not be for the uses we believe are important or commercially attractive, in which case we would not be permitted to market our product for those uses.

Sales of our diagnostic products outside the United States will be subject to foreign regulatory requirements governing clinical studies, vigilance reporting, marketing approval, manufacturing, product licensing, pricing and reimbursement. These regulatory requirements vary greatly from country to country. As a result, the time required to obtain approvals outside the United States may differ from that required to obtain FDA approval and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA and foreign regulatory authorities could require additional testing. In addition, FDA regulates exports of medical devices. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to commercialize our diagnostic products outside of the United States.

We expect to rely on third parties to conduct any future studies of our diagnostic products that may be required by the FDA or other regulatory authorities, and those third parties may not perform satisfactorily.

We do not have the ability to independently conduct the clinical studies or other studies that may be required to obtain FDA and other regulatory clearance or approval for our diagnostic products, including Prosigna. Accordingly, we expect to rely on third parties, such as medical institutions and clinical investigators, to conduct such studies. Our reliance on these third parties for clinical development activities will reduce our control over these activities. These third-party contractors may not complete activities on schedule or conduct studies in accordance with regulatory requirements or our study design. Our reliance on third parties that we do not control will not relieve us of any applicable requirement to prepare, and ensure compliance with, various procedures required under good clinical practices. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our diagnostic products.

Even if we are able to obtain regulatory approval or clearance for our diagnostic products, we will continue to be subject to ongoing and extensive regulatory requirements, and our failure to comply with these requirements could substantially harm our business.

If we receive regulatory approval or clearance for our diagnostic products, we will be subject to ongoing FDA obligations and continued regulatory oversight and review, such as compliance with QSRs, inspections by the FDA, continued adverse event and malfunction reporting, corrections and removals reporting, registration and listing, and promotional restrictions, and we may also be subject to additional FDA post-marketing obligations. If we are not able to maintain regulatory compliance, we may not be permitted to market our diagnostic products and/or may be subject to fines, injunctions, and civil penalties; recall or seizure of products; operating restrictions; and criminal prosecution. In addition, we may be subject to similar regulatory regimes of foreign jurisdictions.

If Medicare and other third-party payors in the United States and foreign countries do not approve reimbursement for diagnostic tests enabled by our technology, the commercial success of our diagnostic products would be compromised.

Successful commercialization of our diagnostic products depends, in large part, on the availability of adequate reimbursement for testing services that our diagnostic products enable from government insurance plans, managed care organizations and private insurance plans. There is significant uncertainty surrounding third-party reimbursement for the use of tests that incorporate new technology, such as Prosigna. If we are unable to obtain positive policy decisions from third-party payors approving reimbursement for our tests at adequate levels, the commercial success of our products would be compromised and our revenue would be significantly limited. Even if we do obtain reimbursement for our tests, Medicare, Medicaid and private and other payors may withdraw their coverage policies, cancel their contracts with us at any time, review and adjust the rate of reimbursement, require co-payments from patients or stop paying for our tests, which would reduce revenue for testing services based on our technology, and indirectly, demand for diagnostic products. In addition, insurers, including managed care organizations as well as government payors such as Medicare and Medicaid, have increased their efforts to control the cost, utilization and delivery of healthcare services, which may include decreased coverage or reduced reimbursement. From time to time, Congress has considered and implemented changes to the Medicare fee schedules in conjunction with budgetary legislation, and pricing and payment terms, including the possible requirement of a patient co-payment for Medicare beneficiaries for tests covered by Medicare, and are subject to change at any time. Reductions in the reimbursement rate of third-party payors have occurred and may occur in the future. Reductions in the prices at which testing services based on our technology are reimbursed could have a negative impact on our revenue.

In many countries outside of the United States, various coverage, pricing and reimbursement approvals are required. We expect that it will take several years to establish broad coverage and reimbursement for testing services based on our products with payors in countries outside of the United States, and our efforts may not be successful.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and other federal and state laws applicable to our marketing practices. If we are unable to comply, or have not complied, with such laws, we could face substantial penalties.

If we obtain FDA approval or clearance for any of our diagnostic product candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal and state anti-kickback statutes and state and federal marketing compliance laws. These laws may impact, among other things, our proposed sales and marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

the federal Anti-kickback Law and state anti-kickback prohibitions;

the federal physician self-referral prohibition, commonly known as the Stark Law, and the state equivalents;

the federal Health Insurance Portability and Accountability Act of 1996, as amended;

the Medicare civil money penalty and exclusion requirements; and

the federal False Claims Act civil and criminal penalties and state equivalents.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Healthcare policy changes, including recently enacted legislation reforming the United States healthcare system, may have a material adverse effect on our financial condition and results of operations.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the PPACA, enacted in March 2010, makes changes that are expected to significantly impact the pharmaceutical and medical device industries and clinical laboratories. Beginning in 2013, each medical device manufacturer will have to pay a sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. We expect that the new tax may apply to some or all of our diagnostic products. The PPACA also 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 and a productivity adjustment to the Clinical Laboratory Fee Schedule. These or any future proposed or mandated reductions in payments may apply to some or all of the clinical laboratory tests that our diagnostics customers use our technology to deliver to Medicare beneficiaries, and may indirectly reduce demand for our diagnostic products.

Other significant measures contained in the PPACA include coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The PPACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. In addition, the PPACA establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce health care expenditures, which may have a negative impact on payment rates for services, including our tests. The IPAB proposals may impact payments for clinical laboratory services that our future diagnostics customers use our technology to deliver beginning in 2016 and for hospital services beginning in 2020, and may indirectly reduce demand for our diagnostic products.

In addition to the PPACA, the effect of which cannot presently be quantified, various healthcare reform proposals have also emerged from federal and state governments. Changes in healthcare policy, such as the creation of broad test utilization limits for diagnostic products in general or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially impact the sales of our tests, increase costs and divert management s attention from our business. Such co-payments by Medicare beneficiaries for laboratory services were discussed as possible cost savings for the Medicare program as part of the debt ceiling budget discussions in mid-2011 and may be enacted in the future. In addition, sales of our tests outside of the United States will subject us to foreign regulatory requirements, which may also change over time.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation and the expansion in government s effect on the United States healthcare industry may result in decreased profits to us, lower reimbursements by payors for our products or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.

#### **Risks Related to Intellectual Property**

If we are unable to protect our intellectual property effectively, our business would be harmed.

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. As of May 31, 2013, we owned or exclusively licensed five issued U.S. patents and approximately 24 pending U.S. patent applications, including provisional and non-provisional filings. We also owned or licensed approximately 64 pending and granted counterpart applications worldwide, including 22 country-specific validations of three

European patents. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

We cannot assure investors that any of our currently pending or future patent applications will result in issued patents, and we cannot predict how long it will take for such patents to be issued. Further, we cannot assure investors that other parties will not challenge any patents issued to us or that courts or regulatory agencies will hold our patents to be valid or enforceable. We cannot guarantee investors that we will be successful in defending challenges made against our patents and patent applications. Any successful third-party challenge to our patents could result in the third party or the unenforceability or invalidity of such patents.

The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies patents has emerged to date in the United States. Furthermore, in the biotechnology field, courts frequently render opinions that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for analyzing or comparing DNA.

In particular, the patent positions of companies engaged in development and commercialization of genomic diagnostic tests, like Prosigna, are particularly uncertain. Various courts, including the U.S. Supreme Court, have recently rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to genomic diagnostics. Specifically these decisions stand for the proposition that patent claims that recite laws of nature (for example, the relationships between gene expression levels and the likelihood of risk of recurrence of cancer) are not themselves patentable unless those patent claims have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws rather than patent drafting efforts designed to monopolize the law of nature itself. What constitutes a sufficient additional feature is uncertain. Accordingly, this evolving case law in the United States may adversely impact our ability to obtain new patents and may facilitate third-party challenges to our existing owned and licensed patents. One of our main areas of intellectual property, namely patents we license directed to the use of gene expression markers as part of genomic diagnostic tests, may be affected by these decisions.

The laws of some non-U.S. countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. For example:

We might not have been the first to make the inventions covered by each of our pending patent applications.

We might not have been the first to file patent applications for these inventions.

Others may independently develop similar or alternative products and technologies or duplicate any of our products and technologies.

It is possible that none of our pending patent applications will result in issued patents, and even if they issue as patents, they may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties.

We may not develop additional proprietary products and technologies that are patentable.

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The patents of others may have an adverse effect on our business.

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We apply for patents covering our products and technologies and uses thereof, as we deem appropriate. However, we may fail to apply for patents on important products and technologies in a timely fashion or at all.

In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, corporate partners and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If our intellectual property is not adequately protected so as to protect our market against competitors products and methods, our competitive position could be adversely affected, as could our business.

We have not yet registered certain of our trademarks, including Prosigna, in all of our potential markets. If we apply to register these trademarks, our applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

To the extent our intellectual property, including licensed intellectual property, offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition. If our intellectual property does not provide adequate protection against our competitors products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

We depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from selling our products.

We rely on licenses in order to be able to use various proprietary technologies that are material to our business, including our core digital molecular barcoding technology licensed from the Institute for Systems Biology and technology relating to Prosigna licensed from Bioclassifier, LLC. We do not own the patents that underlie these licenses. Our rights to use these technologies and employ the inventions claimed in the licensed patents are subject to the continuation of and compliance with the terms of those licenses.

In some cases, we do not control the prosecution, maintenance, or filing of the patents to which we hold licenses, or the enforcement of these patents against third parties. Some of our patents and patent applications were either acquired from another company who acquired those patents and patent applications from yet another company, or are licensed from a third party. Thus, these patents and patent applications are not written by us or our attorneys, and we did not have control over the drafting and prosecution. The former patent owners and our licensors might not have given the same attention to the drafting and prosecution of these patents and applications as we would have if we had been the owners of the patents and applications and had control over the drafting and prosecution. We cannot be certain that drafting or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

Enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents is often subject to the control or cooperation of our licensors. Certain of our licenses contain provisions that allow

the licensor to terminate the license upon specific conditions. Our rights under the licenses are subject to our continued compliance with the terms of the license, including the payment of royalties due under the license. Because of the complexity of our products and the patents we have licensed, determining the scope of the license and related royalty obligation can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the license or termination of the license. If a licensor believed we were not paying the royalties due under the license or were otherwise not in compliance with the terms of the license, the licensor might attempt to revoke the license. If such an attempt were successful, we might be barred from producing and selling some or all of our products.

In addition, certain of the patents we have licensed relate to technology that was developed with U.S. government grants. Federal regulations impose certain domestic manufacturing requirements with respect to some of our products embodying these patents.

We may be involved in lawsuits to protect or enforce our patents and proprietary rights, to determine the scope, coverage and validity of others proprietary rights, or to defend against third-party claims of intellectual property infringement, any of which could be time-intensive and costly and may adversely impact our business or stock price.

We have received notices of claims of infringement and misappropriation or misuse of other parties proprietary rights in the past and may from time to time receive additional notices. Some of these claims may lead to litigation. We cannot assure investors that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets, infringement by us of third-party patents and trademarks or other rights, or the validity of our patents, trademarks or other rights, will not be asserted or prosecuted against us.

Litigation may be necessary for us to enforce our patent and proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. Litigation could result in substantial legal fees and could adversely affect the scope of our patent protection. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us, and we might not be able to obtain licenses to technology that we require. Even if such licenses are obtainable, they may not be available at a reasonable cost. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products. In addition, if we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, scope and coverage of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. Any litigation that may be necessary in the future could result in substantial costs and diversion of resources and could have a material adverse effect on our business, operating results or financial condition.

As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. Our competitors and others may now and in the future have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product revenue and against whom our own patents may provide little or no deterrence or protection. Therefore, our commercial success may depend in part on our non-infringement of the patents or proprietary rights of third parties. We are aware of a third party, Genomic Health, Inc., that has issued U.S. patents and pending patent applications that claim methods of using certain genes that are included in Prosigna. We believe that Prosigna will not infringe any valid issued claim. Numerous significant intellectual property issues have been litigated, and will likely continue to be litigated, between existing and new participants in our existing and targeted markets and competitors may assert that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into those markets. Third parties may assert that we are employing their proprietary technology without authorization. In addition, our competitors and others may have patents or may in the future obtain patents and claim that use of our products infringes these patents. We could incur substantial costs and divert the attention of our management and technical personnel in defending against

any of these claims. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and obtain one or more licenses from third parties, or be prohibited from selling certain products. We may not be able to obtain these licenses at a reasonable cost, if at all. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. In addition, we could encounter delays in product introductions while we attempt to develop alternative methods or products to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing products, and the prohibition of sale of any of our products could materially affect our ability to grow and gain market acceptance for our products.

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

In addition, our agreements with some of our suppliers, distributors, customers and other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims against us, including the claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify any of these third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our employees former employers.

Many of our employees were previously employed at universities or other life sciences companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. A loss of key research personnel work product could hamper or prevent our ability to commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Our products contain third-party open source software components, and failure to comply with the terms of the underlying open source software licenses could restrict our ability to sell our products.

Our products contain software tools licensed by third-party authors under open source licenses. Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the code. Some open source licenses contain requirements that we make available source code for modifications or derivative works we create based upon the type of open source software we use. If we combine our proprietary software with open source software in a certain manner, we could, under certain open source licenses, be required to release the source code of our proprietary software to the public. This would allow our competitors to create similar products with less development effort and time and ultimately could result in a loss of product sales.

Although we monitor our use of open source software to avoid subjecting our products to conditions we do not intend, the terms of many open source licenses have not been interpreted by U.S. courts, and there is a risk that these licenses could be construed in a way that could impose unanticipated conditions or restrictions on our

ability to commercialize our products. Moreover, we cannot assure investors that our processes for controlling our use of open source software in our products will be effective. If we are held to have breached the terms of an open source software license, we could be required to seek licenses from third parties to continue offering our products on terms that are not economically feasible, to re-engineer our products, to discontinue the sale of our products if re-engineering could not be accomplished on a timely basis, or to make generally available, in source code form, our proprietary code, any of which could adversely affect our business, operating results, and financial condition.

We use third-party software that may be difficult to replace or cause errors or failures of our products that could lead to lost customers or harm to our reputation.

We use software licensed from third parties in our products. In the future, this software may not be available to us on commercially reasonable terms, or at all. Any loss of the right to use any of this software could result in delays in the production of our products until equivalent technology is either developed by us, or, if available, is identified, obtained and integrated, which could harm our business. In addition, any errors or defects in third- party software, or other third-party software failures could result in errors, defects or cause our products to fail, which could harm our business and be costly to correct. Many of these providers attempt to impose limitations on their liability for such errors, defects or failures, and if enforceable, we may have additional liability to our customers or third-party providers that could harm our reputation and increase our operating costs.

We will need to maintain our relationships with third-party software providers and to obtain software from such providers that does not contain any errors or defects. Any failure to do so could adversely impact our ability to deliver reliable products to our customers and could harm our results of operations.

## Risks Related to Being a Public Company

Complying with the laws and regulations affecting public companies will increase our costs and the demands on management and could harm our operating results.

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. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and The NASDAQ Global Market impose numerous requirements on public companies, including requiring changes in corporate governance practices. Also, the Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel will need to devote a substantial amount of time to compliance with these laws and regulations. These requirements have increased and will continue to increase our legal, accounting, and financial compliance costs and have made and will continue to make some activities more time consuming and costly. For example, we expect these rules and regulations to 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 to incur substantial costs to maintain the same or similar coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or our board committees or as executive officers.

The Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. In particular, beginning January 1, 2014, Section 404 of the Sarbanes-Oxley Act, or Section 404, will require us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm potentially to attest to, the effectiveness of our internal control over financial reporting. As an emerging growth company. We expect to avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption when we cease to be an emerging growth company. When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance

with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Furthermore, investor perceptions of our company may suffer if deficiencies are found, and this could cause a decline in the market price of our stock. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our stated operating results and harm our reputation. If we are unable to implement these requirements effectively or efficiently, it could harm our operations, financial reporting, or financial results and could result in an adverse opinion on our internal controls from our independent registered public accounting firm.

We are an emerging growth company, and any decision on our part to comply only with certain reduced reporting and 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 Jumpstart Our Business Startups, or JOBS, Act enacted in April 2012, 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 have our independent registered public accounting firm audit our internal control over financial reporting under Section 404, 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 stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the completion of this offering, although, if we have more than \$1.0 billion in annual revenue, if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of June 30 of any year, or we issue more than \$1.0 billion of non-convertible debt over a three-year period before the end of that five-year period, we would cease to be an emerging growth company as of the following December 31. We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

As an emerging growth company the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. We have elected to use this extended transition period under the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make our common stock less attractive to investors.

## Risks Related to Our Common Stock and this Offering

We expect that our stock price will fluctuate significantly and investors may not be able to resell their shares at or above the initial public offering price.

The trading price of our common stock following this offering may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

actual or anticipated quarterly variation in our results of operations or the results of our competitors;

announcements by us or our competitors of new products, significant contracts, commercial relationships or capital commitments;

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failure to obtain or delays in obtaining product approvals or clearances from the FDA or foreign regulators; adverse regulatory or reimbursement announcements; issuance of new or changed securities analysts reports or recommendations for our stock; developments or disputes concerning our intellectual property or other proprietary rights; commencement of, or our involvement in, litigation; market conditions in the life sciences research and molecular diagnostics markets; manufacturing disruptions; any future sales of our common stock or other securities; any change to the composition of the board of directors or key personnel; expiration of contractual lock-up agreements with our executive officers, directors and security holders; announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments; general economic conditions and slow or negative growth of our markets; and

the other factors described in this section of the prospectus captioned Risk Factors.

The stock market in general, and market prices for the securities of health technology companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. In several recent situations where the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

# An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. Although our common stock has been approved for listing on The NASDAQ Global Market, an active trading market for our shares may never develop or be sustained following this offering. The initial price to public for our common stock was determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. The lack of an active market may impair investors ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable, may reduce the fair market value of their shares and may impair our ability to raise capital.

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If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts who cover us issues an adverse opinion about our company, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

# Future sales of our common stock in the public market could cause our stock price to fall.

Our stock price could decline as a result of sales of a large number of shares of our common stock after this offering or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

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Upon completion of this offering, 14,601,766 shares of our common stock will be outstanding (15,411,766 shares of common stock will be outstanding assuming exercise of the underwriters overallotment option in full), based on our shares outstanding as of May 31, 2013. All shares of common stock expected to be sold in this offering will be freely tradable without restriction or further registration under the Securities Act unless held by our affiliates, as that term is defined in Rule 144 under the Securities Act. The resale of the remaining 9,201,766 shares, or 63.02% of our outstanding shares after this offering, are currently prohibited or otherwise restricted as a result of securities law provisions, market standoff agreements entered into by our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters; however, subject to applicable securities law restrictions, these shares will be able to be sold in the public market beginning 180 days after the date of this prospectus. In addition, the shares subject to outstanding options and warrants, of which options and warrants to purchase 1,314,738 shares and 617,605 shares, respectively, were exercisable as of May 31, 2013, and the shares reserved for future issuance under our stock option and equity incentive plans will become available for sale immediately upon the exercise of such options and the expiration of any applicable market stand-off or lock-up agreements. For more information see the section of this prospectus captioned Shares Eligible for Future Sale.

Holders of approximately 9,535,713 shares (including the shares underlying the warrants described in the section of this prospectus captioned Shares Eligible for Future Sale Warrants ), or 65.31%, of our common stock, will have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register the offer and sale of all shares of common stock that we may issue under our equity compensation plans. Once we register the offer and sale of shares for the holders of registration rights and option holders, they can be freely sold in the public market upon issuance, subject to the lock-up agreements described in the section of this prospectus captioned Underwriting.

In addition, in the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

Our executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned approximately 81.13% of our capital stock as of May 31, 2013, and we expect that upon completion of this offering, that same group will beneficially own at least 53.80% of our capital stock or 58.98% if investment entities affiliated with certain of our principal stockholders and certain of our other existing stockholders purchase a number of shares of common stock equal to that for which they have expressed an interest in purchasing, of which 7.67% will be beneficially owned by our executive officers. Accordingly, after this offering, our executive officers, directors and principal stockholders will be able to determine the composition of the board of directors, retain the voting power to approve all matters requiring stockholder approval, including mergers and other business combinations, and continue to have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material adverse effect on our stock price and may prevent attempts by our stockholders to replace or remove the board of directors or management.

Our management team has broad discretion to use the net proceeds from this offering and its investment of these proceeds may not yield a favorable return. They may invest the proceeds of this offering in ways with which investors disagree.

Our management has broad discretion as to how to spend and invest the proceeds from this offering and we may spend or invest these proceeds in a way with which our stockholders disagree. Accordingly, investors will

need to rely on our judgment with respect to the use of these proceeds. We intend to use the proceeds from this offering to: (1) commercialize Prosigna after obtaining regulatory authorization, including establishing a dedicated oncology sales force; (2) expand the clinical utility of Prosigna and to develop other potential diagnostic product opportunities; (3) expand life sciences commercial operations to grow and support the installed base of our nCounter Analysis Systems among life sciences research customers in the United States and internationally; (4) develop new life sciences applications, chemistry and instrumentation for our nCounter technology platform; and (5) for working capital and other general corporate purposes. We may also use a portion of the net proceeds to acquire, license and invest in complementary products, technologies or businesses; however, we currently have no agreements or commitments to complete any such transaction. These uses may not yield a favorable return to our stockholders.

We cannot specify with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering. In addition, the amount, allocation and timing of our actual expenditures will depend upon numerous factors, including the revenue generated from the sale of our products to life sciences customers and the sale of Prosigna. Accordingly, we will have broad discretion in using these proceeds. Until the net proceeds are used, they may be placed in investments that do not produce significant income or that may lose value.

Anti-takeover provisions in our charter documents and under Delaware or Washington law could make an acquisition of us difficult, limit attempts by our stockholders to replace or remove our current management and limit our stock price.

Provisions of our certificate of incorporation and bylaws to be effective immediately following consummation of this offering may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our stock. Among other things, the certificate of incorporation and bylaws will:

permit the board of directors to issue up to 15,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;

provide that the authorized number of directors may be changed only by resolution of the board of directors;

provide that all vacancies, including newly-created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

divide the board of directors into three classes;

provide that a director may only be removed from the board of directors by the stockholders for cause;

require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be taken by written consent;

provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and meet specific requirements as to the form and content of a stockholder s notice;

prevent cumulative voting rights (therefore allowing the holders of a plurality of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);

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provide that special meetings of our stockholders may be called only by the chairman of the board, our chief executive officer or by the board of directors; and

provide that stockholders will be permitted to amend the bylaws only upon receiving at least two-thirds of the total votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

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In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder. Likewise, because our principal executive offices are located in Washington, the anti-takeover provisions of the Washington Business Corporation Act may apply to us under certain circumstances now or in the future. These provisions prohibit a target corporation from engaging in any of a broad range of business combinations with any stockholder constituting an acquiring person for a period of five years following the date on which the stockholder became an acquiring person. See the section of this prospectus captioned Description of Capital Stock Anti-Takeover Effects of Delaware and Washington Law and Our Certificate of Incorporation and Bylaws for additional information.

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that are based on management s beliefs and assumptions and on information currently available to management. Some of the statements under Prospectus Summary, Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and Business and elsewhere in this prospectus contain forward-looking statements. In some cases, you can identify forward-looking statements by the following words: may, will, could, would, should, expect, intend, plan, anticipate, continue, ongoing or the negative of these terms or other comparable terminology, although not all forward-loc predict, project, potential, statements contain these words.

These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this prospectus include, but are not limited to, statements about:

our ability to successfully commercialize Prosigna, our first product for which we have obtained a CE mark in the European Union;
our ability to secure regulatory clearance or approval, domestically and internationally, for the clinical use of our products, including a version of Prosigna in the United States;
the implementation of our business model and strategic plans for our business;
the regulatory regime for our products, domestically and internationally;
our strategic relationships, including with patentholders of our technologies, manufacturers and distributors of our products, and third parties who conduct our clinical studies;
our intellectual property position;
our expected use of proceeds;
our expectations regarding the market size and growth potential for our life sciences and diagnostic businesses;
any estimates regarding expenses, future revenues, capital requirements, and stock performance; and
our ability to sustain and manage growth, including our ability to develop new products and enter new markets

In addition, you should refer to the Risk Factors section of this prospectus for a discussion of other important factors that may cause actual results to differ materially from those expressed or implied by the forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future

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events or otherwise, except as required by law. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933 do not protect any forward-looking statements that we make in connection with this offering.

This prospectus contains market data and industry forecasts that were obtained from industry publications. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified any third-party information. While we believe the market position, market opportunity and market size information included in this prospectus is generally reliable, such information is inherently imprecise.

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#### USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the shares of common stock in this offering will be approximately \$46.9 million, or approximately \$54.5 million if the underwriters exercise their overallotment option in full, based upon the initial price to public of \$10.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses.

We currently expect to use the net proceeds from this offering as follows:

approximately \$20 million to commercialize Prosigna after obtaining regulatory authorization, including establishing a dedicated oncology sales force;

approximately \$10 million to expand the clinical utility of Prosigna and to develop other potential diagnostic product opportunities;

approximately \$5 million to expand life sciences commercial operations to grow and support the installed base of our nCounter Analysis Systems among life sciences research customers in the United States and internationally;

approximately \$5 million to develop new life sciences applications, chemistry and instrumentation for our nCounter technology platform; and

for working capital and other general corporate purposes.

We may also use a portion of the net proceeds to acquire, license and invest in complementary products, technologies or businesses; however, we currently have no agreements or commitments to complete any such transaction.

We cannot specify with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering. In addition, the amount, allocation and timing of our actual expenditures will depend upon numerous factors, including the revenue generated from the sale of our products to life sciences customers and the sale of Prosigna. Accordingly, we will have broad discretion in using these proceeds. Pending their uses, we plan to invest the net proceeds of this offering in short-term, interest-bearing, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

## DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock or any other securities. We anticipate that we will retain all available funds and any future earnings, if any, for use in the operation of our business and do not anticipate paying cash dividends in the foreseeable future. In addition, our credit facility materially restricts, and future debt instruments we issue may materially restrict, our ability to pay dividends on our common stock. Payment of future cash dividends, if any, will be at the discretion of the board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, the requirements of current or then-existing debt instruments and other factors the board of directors deems relevant.

#### **CAPITALIZATION**

The following table summarizes our capitalization as of March 31, 2013:

on an actual basis: and

on a pro forma as adjusted basis, to reflect (1) a 1-for-32 reverse stock split of our common stock and preferred stock effected on June 12, 2013, (2) the conversion of all outstanding shares of convertible preferred stock into 8,631,427 shares of common stock upon the closing of this offering, (3) the conversion of warrants to purchase 604,563 shares of preferred stock into warrants to purchase 607,187 shares of common stock and (4) the sale and issuance by us of 5,400,000 shares of common stock in this offering at the initial price to public of \$10.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses of \$3.3 million, \$2.3 million of which were incurred as of March 31, 2013.

Investors should read the information in this table together with the financial statements and related notes to those statements, as well as the sections of this prospectus captioned Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations.

	As of March 31, 2013			
	Actual (In thousands, except	Pro Forma As Adjusted per share amounts)		
Total long-term debt	\$ 12,835	\$ 12,835		
Mandatorily redeemable convertible preferred stock, \$0.0001 par value per share; issuable in series, 8,978,672 authorized, 8,118,240 shares issued and outstanding, actual; no shares authorized, no shares issued or outstanding, pro forma as adjusted	105.964			
Stockholders equity (deficit):				
Preferred stock, \$0.0001 par value per share; no shares authorized, issued or outstanding, actual; 15,000,000 authorized, no shares issued or outstanding, pro forma as adjusted				
Common stock, \$0.0001 par value per share, 11,712,500 shares authorized, 563,318 shares issued and outstanding, actual; 150,000,000 shares authorized, 14,594,745 shares issued and				
outstanding, pro forma as adjusted		1		
Additional paid-in capital		156,897		
Accumulated deficit	(102,808)	(102,808)		
Total stockholders equity (deficit)	(102,808)	54,090		
Total capitalization	\$ 15,991	\$ 66,925		

The number of shares of common stock to be outstanding following this offering is based on 9,194,745 shares of common stock outstanding as of March 31, 2013, giving effect to the conversion of all outstanding shares of convertible preferred stock into an aggregate of 8,631,427 shares of common stock upon the closing of this offering. The outstanding share information in the table above excludes as of March 31, 2013:

1,806,273 shares of common stock issuable upon exercise of options outstanding as of March 31, 2013, at a weighted-average exercise price of \$3.02 per share;

1,984,972 shares of common stock reserved for future issuance under stock-based compensation plans, including 1,562,500 shares of common stock reserved for issuance under the 2013 Equity Incentive Plan, which will become effective on the date of this prospectus, and any future automatic increase in shares reserved for issuance under such plan, 281,250 shares of common stock

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reserved for issuance under the 2013 Employee Stock Purchase Plan, and any future automatic increase in shares reserved for issuance under such plan, and 141,222 shares of common stock reserved for issuance under the 2004 Stock Option Plan as of March 31, 2013, which shares will be added to the 2013 Equity Incentive Plan upon effectiveness of such plan;

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607,187 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2013, at a weighted-average exercise price of \$8.69 per share, after conversion of the convertible preferred stock; and

10,418 shares of common stock issuable upon the exercise of warrants at an exercise price of \$14.40 per share, after conversion of the convertible preferred stock, issued in connection with the April 2013 term loan borrowing under our credit facility.

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#### DILUTION

Investors purchasing our common stock in this offering will experience immediate and substantial dilution in the pro forma net tangible book value of their shares of common stock. Dilution in pro forma net tangible book value represents the difference between the price to public per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after the offering.

Historical net tangible book value (deficit) per share represents our total tangible assets (total assets less intangible assets) less total liabilities divided by the number of shares of outstanding common stock. After giving effect to (1) a 1-for-32 reverse stock split of our common stock and preferred stock effected on June 12, 2013, (2) the conversion of all outstanding shares of convertible preferred stock into 8,631,427 shares of common stock upon the closing of this offering and (3) the conversion of warrants to purchase 604,563 shares of preferred stock into warrants to purchase 607,187 shares of common stock, the pro forma net tangible book value as of March 31, 2013 would have been approximately \$4.8 million, or \$0.53 per share.

After giving effect to the issuance of 5,400,000 shares of common stock in this offering at the initial price to public of \$10.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses, the pro forma as adjusted net tangible book value as of March 31, 2013 would have been approximately \$54.1 million, or \$3.71 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$3.18 per share to existing stockholders and an immediate dilution of \$6.29 per share to new investors purchasing common stock in this offering.

The following table illustrates this dilution on a per share basis to new investors:

Initial price to public per share		\$ 10.00
Pro forma net tangible book value per share before this offering	\$ 0.53	
Increase in net tangible book value per share attributable to investors participating in this offering	3.18	
Pro forma as adjusted net tangible book value per share, as adjusted to give effect to this offering		3.71
Pro forma dilution per share to investors participating in this offering		\$ 6.29

If the underwriters exercise their option in full to purchase \$10,000 additional shares of common stock in this offering, the pro forma as adjusted net tangible book value per share after the offering would be \$4.00 per share, the increase in the pro forma net tangible book value per share to existing stockholders would be \$3.47 per share and the pro forma dilution to new investors purchasing common stock in this offering would be \$6.00 per share.

The following table summarizes, on a pro forma basis as of March 31, 2013, the differences between the number of shares of common stock purchased from us, the total consideration and the weighted-average price per share paid by existing stockholders and by investors participating in this offering at the initial price to public of \$10.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses (in thousands, except per share amounts):

					Weighted- Average
	Shares P	urchased	<b>Total Cons</b>	ideration	Price
	Number	Percent	Amount	Percent	Per Share
Existing stockholders before this offering	9,195	63.0%	\$ 83,800	60.8%	\$ 9.11
Investors participating in this offering	5,400	37.0	54,000	39.2	10.00
Total	14,595	100.0%	\$ 137,800	100.0%	

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The number of shares of common stock to be outstanding following this offering is based on 9,194,745 shares of common stock outstanding as of March 31, 2013, giving effect to the conversion of all outstanding shares of convertible preferred stock into an aggregate of 8,631,427 shares of common stock upon the closing of this offering. The outstanding share information in the table above excludes as of March 31, 2013:

1,806,273 shares of common stock issuable upon exercise of options outstanding as of March 31, 2013, at a weighted-average exercise price of \$3.02 per share;

1,984,972 shares of common stock reserved for future issuance under stock-based compensation plans, including 1,562,500 shares of common stock reserved for issuance under the 2013 Equity Incentive Plan, which will become effective on the date of this prospectus, and any future automatic increase in shares reserved for issuance under such plan, 281,250 shares of common stock reserved for issuance under the 2013 Employee Stock Purchase Plan, and any future automatic increase in shares reserved for issuance under such plan, and 141,222 shares of common stock reserved for issuance under the 2004 Stock Option Plan as of March 31, 2013, which shares will be added to the 2013 Equity Incentive Plan upon effectiveness of such plan;

607,187 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2013, at a weighted-average exercise price of \$8.69 per share, after conversion of the convertible preferred stock; and

10,418 shares of common stock issuable upon the exercise of warrants at an exercise price of \$14.40 per share, after conversion of the convertible preferred stock, issued in connection with the April 2013 term loan borrowing under our credit facility.

Share reserves for the equity incentive plans will also be subject to automatic annual increases in accordance with the terms of the plans. To the extent that new options are issued under the equity benefit plans or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering.

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#### SELECTED FINANCIAL DATA

The following selected statement of operations data for the years ended December 31, 2010, 2011 and 2012 and the balance sheet data as of December 31, 2011 and 2012 have been derived from audited financial statements included elsewhere in this prospectus. The selected statements of comprehensive income for the three months ended March 31, 2012 and 2013 and the balance sheet data as of March 31, 2013 have been derived from unaudited interim financial statements included elsewhere in this prospectus. The selected statements of comprehensive income for the years ended December 31, 2008 and 2009 and the balance sheet data as of December 31, 2008, 2009 and 2010 have been derived from audited financial statements which are not included in this prospectus. In the opinion of management, the unaudited interim financial statements reflect all adjustments, which include only normal recurring adjustments, necessary for a fair presentation of the financial statements. Historical results are not necessarily indicative of the results that may be expected in the future and the results for the three months ended March 31, 2013 are not necessarily indicative of results to be expected for the full year or any other period. You should read the following selected financial and other data below in conjunction with the financial statements and related notes included elsewhere in this prospectus and the sections of this prospectus captioned Management s Discussion and Analysis of Financial Condition and Results of Operations.

	2008	Year 2009	Three Months Ended March 31, 2012 2013				
<b>Consolidated Statements of Comprehensive</b>			(In thousands,	except per sita	ire uniounes)		
Income:							
Revenue	\$ 1,613	\$ 7,288	\$ 11,730	\$ 17,800	\$ 22,973	\$ 4,502	\$ 5,676
Costs and expenses:							
Cost of revenue	1,450	5,874	9,128	9,777	12,361	2,656	2,882
Research and development	4,428	4,550	7,547	8,990	11,635	2,197	3,059
Selling, general and administrative	4,513	5,464	8,027	9,529	15,486	3,167	6,126
Total costs and expenses	10,391	15,888	24,702	28,296	39,482	8,020	12,067
Loss from operations	(8,778)	(8,600)	(12,972)	(10,496)	(16,509)	(3,518)	(6,391)
Other income (expense):							
Interest income	51	64	29	10	21	7	3
Interest expense	(193)	(320)	(94)	(599)	(804)	(112)	(385)
Other income (expense)			254	80	(29)	(13)	(4)
Revaluation of preferred stock warrant liability	35	19	15	73	(387)	26	(482)
Total other income (expense)	(107)	(237)	204	(436)	(1,199)	(92)	(868)
Net loss	\$ (8,885)	\$ (8,837)	\$ (12,768)	\$ (10,932)	\$ (17,708)	(3,610)	(7,259)
Accretion of mandatorily redeemable convertible preferred stock	(1,708)	(2,551)	(4,351)	(5,251)	(7,533)	(1,793)	(2,342)
Net loss attributable to common stockholders	\$ (10,593)	\$ (11,388)	\$ (17,119)	\$ (16,183)	\$ (25,241)	\$ (5,403)	\$ (9,601)
Net loss per share basic and diluted	\$ (34.50)	\$ (36.62)	\$ (54.17)	\$ (50.10)	\$ (71.10)	\$ (16.52)	\$ (17.88)
Shares used in computing basic and diluted net loss per share	307	311	316	323	355	327	537
Pro forma net loss per share basic and diluted (unaudited) <sup>(1)</sup>					\$ (2.16)		\$ (0.74)

Shares used in computing pro forma net loss per share, basic and diluted (unaudited)<sup>(1)</sup>

8,018

9,168

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			As of March 31,				
	2008	2009 2010 (In		2011 usands)	2012	2013	
Consolidated Balance Sheet Data:			,	,			
Cash and cash equivalents	\$ 3,508	\$ 1,739	\$ 4,366	\$ 10,868	\$ 21,692	\$ 11,794	
Working capital	(4,224)	1,385	2,944	12,236	19,937	12,250	
Total assets	9,564	9,367	13,275	24,584	37,406	29,575	
Total long-term debt	8,878	1,274	1,829	1,887	12,759	12,835	
Mandatorily redeemable convertible preferred stock	21,276	38,551	57,887	80,957	103,622	105,964	
Total stockholders deficit	(25,194)	(36,565)	(53,517)	(69,451)	(93,760)	(102,808)	

(1) Pro forma net loss per share represents net loss divided by the pro forma weighted-average shares outstanding, as though the 1-for-32 reverse stock split of our common stock and preferred stock and the conversion of the preferred stock into common stock occurred on the first day of the relevant period. Pro forma weighted-average shares outstanding reflects the 1-for-32 reverse stock split of our common stock and preferred stock and the conversion of the preferred stock (using the if-converted method) into common stock as though the conversion had occurred on the first day of the relevant period.

#### MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION

#### AND RESULTS OF OPERATIONS

You should read the following discussion and analysis together with the financial statements and the related notes to those statements included elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in the section of the prospectus captioned Risk Factors and elsewhere in this prospectus, our actual results may differ materially from those anticipated in these forward-looking statements.

#### Overview

We develop, manufacture and sell robust, intuitive products that unlock scientifically valuable and clinically actionable genomic information from minute amounts of tissue. Our nCounter Analysis System directly profiles hundreds of molecules simultaneously using a novel barcoding technology that is powerful enough for use in research, yet simple enough for use in clinical laboratories worldwide. We market systems and related consumables to researchers in academic, government, and biopharmaceutical laboratories for use in understanding fundamental biology and the molecular basis of disease. We have an installed base of more than 140 systems, which our customers have used to publish more than 220 peer-reviewed papers. As researchers discover how genomic information can be used to improve clinical decision-making, we seek to selectively translate their discoveries into molecular diagnostic products. In September 2012, we received European Union regulatory clearance for our first molecular diagnostic product, the Prosigna Breast Cancer Assay, or Prosigna, an assay providing an assessment of a patient s risk of recurrence for breast cancer and the intrinsic subtype of the patient s tumor. In February 2013, we commercially launched Prosigna in Europe and Israel. In December 2012, we submitted an application, known as a 510(k), to the FDA seeking clearance in the United States for a version of Prosigna providing an assessment of a patient s risk of recurrence for breast cancer.

The following is a chronology of some of our most significant achievements:

in 2003 the company was founded and in early 2004 we acquired an exclusive license to our core digital barcoding technology;

in October 2008 we sold our first nCounter Analysis System;

in April 2010 we obtained ISO 13485:2003 classification (which specifies requirements for a quality management system for medical device manufacturing) for our manufacturing facility and launched our miRNA application;

in July 2010 we licensed the intellectual property rights that form the basis of Prosigna, our first molecular diagnostic development program, and had our first pre-submission meeting with the FDA;

in October 2011 we launched the second generation of our nCounter Analysis System;

in December 2011 we announced the results from our first study clinically validating Prosigna, the TransATAC study;

in September 2012 we obtained CE mark designation for Prosigna and launched our Single Cell Gene Expression application;

in December 2012, we announced the results from our second study clinically validating Prosigna, our ABCSG8 study, which were consistent with the conclusions of our TransATAC study, and submitted to the FDA a 510(k) application seeking clearance to market a version of Prosigna in the United States; and

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in February 2013, we commercially launched Prosigna in Europe and Israel and we secured an option from a customer to acquire an exclusive worldwide license for a gene signature that could be used, after appropriate regulatory authorization, for a molecular diagnostic product focused on hepatocellular carcinoma, or HCC.

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We derive a substantial majority of our revenue from the sale of our products, which consist of our nCounter instruments and related proprietary consumables, which we call CodeSets and Master Kits. We sell two types of CodeSets: custom orders and standard sets, which we call panels. We also derive revenue from processing fees related to proof-of-principle studies we conduct for potential customers and extended service contracts for our nCounter Analysis Systems.

Until recently, we have sold our products for research use only. After buying an nCounter Analysis System, customers purchase consumables from us for use in their experiments. Our instruments are designed to work only with our consumable products. Accordingly, as the installed base of our instruments grows, we expect recurring revenue from consumable sales to become an increasingly important driver of our operating results. The nCounter Analysis System is currently available for research use only in the United States.

We have begun to offer instruments and consumables for use in diagnostic testing. We have recently obtained a CE mark for Prosigna, our first diagnostic product, and, in February 2013 we commercially launched Prosigna in Europe, including in France, Germany, Italy, Spain and the United Kingdom, and Israel. In December 2012, we submitted an application, known as a 510(k), to the FDA seeking clearance in the United States for a version of Prosigna providing an assessment of a patient s risk of recurrence for breast cancer. In March 2013, we received a written response from the FDA requesting additional information for its review of our 510(k) submission. A request for additional information is common following an initial 510(k) submission. In May 2013, we submitted an initial response to the FDA s request for additional information and met with the FDA to discuss our response. In this meeting, we discussed, among other issues raised by the FDA, the specific elements and format of a potential report generated by Prosigna, including the appropriate name for the risk score, the appropriate graphic presentation of the risk score, and, specifically for the potential report for node-positive patients, the numerical range of the risk score and the appropriate number of risk groups. If the FDA clears Prosigna, we intend to launch Prosigna in the United States promptly following receipt of such clearance. We are currently planning for this commercial launch in the first quarter of 2014. The commercial launch of Prosigna requires us to establish a dedicated oncology diagnostics sales force. As a result, we expect sales and marketing expenses and operating losses to increase as we market the product in Europe and other countries outside of the United States, and to increase further upon the launch in the United States following clearance from the FDA. In addition, we expect sales in Europe to grow gradually as more systems are installed and Prosigna gains market acceptance and reimbursement by third-party payors becomes mor

We use third-party contract manufacturers to produce the two instruments comprising the nCounter Analysis System. We manufacture consumables at our Seattle, Washington facility. This operating model is designed to be capital efficient and to scale efficiently as our product volumes grow. We focus a substantial portion of our resources on developing new products and solutions. We invested \$7.5 million, \$9.0 million and \$11.6 million in 2010, 2011 and 2012, respectively, in research and development and intend to continue to make significant investments in research and development.

Our total revenue has increased to \$23.0 million in 2012 from \$17.8 million in 2011 and \$11.7 million in 2010, which was driven by the sale of additional nCounter Analysis Systems and consumables for use on our growing installed base of instruments. Historically, we have generated a substantial majority of our revenue from sales to customers in North America; however, we expect sales in other regions to increase over time. We have never been profitable and had net losses of \$12.8 million, \$10.9 million and \$17.7 million in 2010, 2011 and 2012, respectively. For the three months ended March 31, 2013, we had total revenue of \$5.7 million and a net loss of \$7.3 million, and as of March 31, 2013 our accumulated deficit was \$102.8 million.

## **Key Financial Metrics**

We are organized as, and operate in, two reportable segments: our life sciences business and our diagnostics business. Our life sciences business provides instruments, consumables and services for efficiently profiling the activity of hundreds of genes simultaneously from a single tissue sample. Our diagnostics business will provide molecular diagnostic kits to pathology labs enabling complex molecular testing on a decentralized basis.

Our chief operating decision maker is the chief executive officer. The chief operating decision maker reviews financial information presented on a total company basis, accompanied by information about segment revenue and certain direct sales and marketing expenses by segment. Our chief operating decision maker evaluates performance based on these two measures. The chief operating decision maker does not review segment information related to cost of revenue, research and development or other selling, general and administrative expenses.

As of March 31, 2013, we had begun negotiations for initial diagnostic instrument placements but we had not generated any revenue from our diagnostic business. Accordingly, discussion within this Management s Discussion and Analysis of Financial Condition and Results of Operations is primarily directed at trends and changes in our life sciences business. For additional information, see Note 13 Segment Reporting of the financial statements included in this prospectus.

#### Revenue

We generate revenue from the sale of our products and related services. We are organized as, and operate in, two reportable segments: life sciences and diagnostics. For a description of our revenue recognition policies, see the section of this prospectus captioned Critical Accounting Policies and Significant Estimates Revenue Recognition.

#### Product Revenue

Our products consist of our nCounter Analysis System and related consumables. Our nCounter Analysis System typically consists of one nCounter Digital Analyzer and one nCounter Prep Station. The U.S. list price of one nCounter Analysis System is \$235,000. Outside the United States, depending on the country, the list price is generally higher. Systems are sold to distributors at a discount to list price. Related consumables include (1) custom CodeSets, which we manufacture to the specific requirements of an individual researcher, (2) panels, which are standard pre-manufactured CodeSets, and (3) Master Kits, which are ancillary reagents, cartridges, tips and reagent plates required to setup and process samples in our instruments. Product revenue also includes payments for instrument installation. Currently, our customer base is primarily composed of academic institutions, government laboratories, and biopharmaceutical companies that perform analyses using our nCounter Analysis System and purchase consumables for research use only.

#### Service Revenue

Service revenue consists of fees associated with extended service contracts and conducting proof-of-principle studies. We include a one-year warranty with the sale of our instruments and offer extended service contracts, which are purchased by a majority of our customers. We selectively provide proof-of-principle studies to prospective customers in order to help them better understand the benefits of the nCounter Analysis System.

## Revenue by Geography

We sell our life sciences products through our own sales force in the United States, Canada and certain European countries. We sell through distributors in other parts of the world. In the future, we intend to expand our sales force and establish additional distributor relationships outside the United States to better access international markets.

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The following table reflects product revenue by geography and as a percentage of total product revenue, based on the billing address of our customers. North America consists of the United States, Canada and Mexico; and Asia Pacific includes Japan, China, South Korea, Singapore and Australia.

	Year Ended December 31,				Three	Months E	nded March	31,		
	2010		2011		2012		2012	2	2013	3
				(1	Dollars in tho	usands)				
North America	\$ 10,643	91%	\$ 14,044	79%	\$ 15,906	69%	\$ 3,162	70%	\$ 4,477	79%
Europe & Middle East	909	8	2,918	16	4,167	18	992	22	616	11
Asia Pacific	178	1	838	5	2,900	13	348	8	583	10
Total	\$ 11,730	100%	\$ 17,800	100%	\$ 22,973	100%	\$4,502	100%	\$ 5,676	100%

We initially launched the nCounter Analysis System in North America. As we have begun to build out our European direct sales force and enter into agreements with distributors of our products in Europe, the Middle East, Asia Pacific and South America. The absolute amount of revenue generated from geographies outside of North America has increased as well as the relative percentage of total revenue.

Most of our revenue is denominated in U.S. dollars. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States. Changes in foreign currency exchange rates have not materially affected us to date; however, they may become material to us in the future as our operations outside of the United States expand.

#### Cost of Revenue

Cost of revenue consists primarily of costs incurred in the production process, including costs of purchasing instruments from third-party contract manufacturers, consumable component materials and assembly labor and overhead, installation, warranty, service and packaging and delivery costs. In addition, cost of revenue includes royalty costs for licensed technologies included in our products, provisions for slow-moving and obsolete inventory and stock-based compensation expense. We provide a one-year warranty on each nCounter Analysis System sold and establish a reserve for warranty repairs based on historical warranty repair costs incurred.

We expect the average unit costs of our instruments to decline in future periods as a result of our ongoing efforts to develop a lower-cost nCounter Analysis System to expand our market opportunity among smaller laboratories. We expect the unit costs of consumable products to decline as a result of our ongoing efforts to improve our manufacturing processes and expected increases in production volume and yields. Although the unit costs of our custom CodeSets vary, they are generally higher as a percentage of the related revenue than our panels.

## **Operating Expenses**

#### Research and Development

Research and development expenses consist primarily of salaries and benefits, occupancy, laboratory supplies, consulting fees and related costs, costs associated with licensing molecular diagnostics rights and clinical study expenses (including the cost of tissue samples) to support the regulatory approval or clearance of diagnostic products. We have made substantial investments in research and development since our inception. Our research and development efforts have focused primarily on the tasks required to enhance our technologies and to support development and commercialization of new and existing products and applications.

Given the relatively small size of our research and development staff and the limited number of active projects at any given time, we have found that, to date, it has been effective for us to manage our research and development activities on a departmental basis. Accordingly, we do not require employees to report their time by project nor do we allocate our research and development costs to individual projects. The following table shows the composition of total research and development expense by functional area for the periods indicated. Prior to 2012, research and development expense related to our core nCounter platform technology and diagnostic product development were combined.

	Year	Ended Decei	mber 31,		Months Iarch 31,
	2010 2011 2012 (In thousands				2013
Core nCounter platform technology and diagnostic product development	\$ 3,649	\$ 4,359	\$	\$	\$
Core nCounter platform technology			1,537	314	612
Manufacturing process development	878	969	1,183	296	378
Life sciences products and applications	1,848	1,875	2,183	463	736
Diagnostic product development			4,783	648	938
Facility allocation	1,173	1,787	1,949	476	395
Total	\$ 7,548	\$ 8,990	\$ 11,635	\$ 2,197	\$ 3,059

Our clinical studies employ a retrospective / prospective design, which means that we use samples that were previously collected from patients and for which the treatment regimen and ultimate patient outcome is known. Such studies are capital efficient as they do not require recruiting new patients and running prospective trials and they can be completed much more quickly than typical prospective clinical trials. We intend to use a similar approach whenever possible for the additional clinical studies we intend to conduct in support of our future regulatory submissions to expand the indications for Prosigna and for future diagnostic products.

We expect to license additional molecular diagnostic rights as part of our strategy to develop additional diagnostic products. For example, in February 2013 we secured an option from a customer to acquire an exclusive worldwide license for a gene signature that could be used, after appropriate regulatory authorization, to identify patients with cirrhosis who are at highest risk of developing the most common type of liver cancer, HCC, and to determine whether a patient who has been diagnosed with HCC is likely to have a recurrence. The related option fee was expensed in the first quarter of 2013. Such arrangements may include upfront, milestone or annual cash payments and revenue-based royalties. We believe that our continued investment in research and development is essential to our long-term competitive position and expect these expenses to increase in future periods.

#### Selling, General and Administrative

Selling, general and administrative expenses consist primarily of costs for our sales and marketing, finance, human resources, information technology, business development and general management functions, as well as professional services, such as legal, consulting and accounting services. We expect selling, general and administrative expenses to increase in future periods as the number of sales, technical support and marketing and administrative personnel grows and we continue to introduce new products, broaden our customer base and grow our business. In particular, the commercial launch of Prosigna requires us to establish a dedicated oncology diagnostics sales force which will increase selling and marketing expenses significantly. We also expect legal, accounting and compliance costs to increase upon becoming a public company.

#### **Factors Affecting Our Performance**

### Instrument Installed Base

Our future financial performance will be driven in large part by the rate of sales of our nCounter Analysis Systems, which typically consist of one nCounter Digital Analyzer and one nCounter Prep Station. In some cases, our customers increase the throughput of their nCounter Analysis System by purchasing up to three nCounter Prep Stations per nCounter Digital Analyzer. We plan to grow our system sales in the coming years through multiple

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strategies, including expanding our sales efforts outside of the United States and continuing to enhance the underlying technology and applications for both life sciences research and future diagnostics use. As part of this strategy, we have increased our life sciences sales force by over 20% in 2013 in an effort to increase the rate of sales of our nCounter Analysis Systems. Similarly, since January 2013, we have contracted with five additional distributors bringing our total to 11. As our installed base of instruments grows, we solicit feedback from our customers and focus our research and development efforts on enabling the nCounter Analysis System for additional applications, which in turn helps to drive additional sales of our instruments and consumables. We are developing a new generation of the nCounter Analysis System that we believe will increase our addressable market and simplify the procurement processes of our potential customers. The new generation system will be a single instrument with a reduced footprint that combines the prep station and the digital analyzer. We plan to reduce the cost of the new generation system through the adoption of new, less expensive technologies. We are targeting release of the new generation system in 2014.

Our sales process involves numerous interactions with multiple individuals within an organization, and often includes in-depth analysis by potential customers of our products, performance of proof-of-principle studies, preparation of extensive documentation and a lengthy review process. As a result of these factors, the large capital investment required in purchasing our instruments and the budget cycles of our customers, the time from initial contact with a customer to our receipt of a purchase order can vary significantly and be up to 12 months or longer. Given the length and uncertainty of our sales cycle, we have in the past experienced, and likely will in the future experience, fluctuations in our instrument sales on a period-to-period basis. We are developing an nCounter Analysis System that we intend to offer at a lower price, which we believe will simplify the procurement processes of our potential customers as well as increase our addressable market.

We have sold more than 140 nCounter Analysis Systems, which we count based on the number of nCounter Digital Analyzers sold given that a system may couple an analyzer with multiple nCounter Prep Stations. Management focuses on instrument unit sales as a primary indicator of current business success and a leading indicator of likely future sales of consumables.

#### Recurring Consumable Revenue

Our instruments are designed to be used only with our consumables. This closed system model generates recurring revenue from each instrument we sell. Management focuses on recurring consumable revenue per system as an indicator of the continuing value generated by each system. We calculate recurring consumable revenue per system quarterly by dividing consumable revenue recognized in a particular quarter (other than consumable revenue related to proof-of-principle studies) by the total number of nCounter Analysis Systems installed as of the last day in the immediately preceding quarter. We believe that our recurring consumable revenue is driven by our customers—ability to extract value from up to 800 data points per sample and to process hundreds of samples in a relatively short period of time with little hands-on preparation using our nCounter Analysis System, enabling them to process more units of consumables per unit of time. In 2010, 2011 and 2012, our average consumable revenue per system exceeded \$100,000 per year.

As the installed base of the nCounter Analysis Systems expands, consumables revenue is expected to increase and over time should be an increasingly important contributor to our total revenue. Over time, we believe that consumables revenue should be subject to less period-to-period fluctuation than our instrument sales revenue.

#### Revenue Mix and Gross Margin

Our product revenue is derived from sales of the nCounter Analysis System and related consumables. Generally, our consumables have higher gross margins than our instruments. There will be fluctuations in mix between instruments and consumables from period to period. Over time, as our installed base of systems grows, consumables should constitute a larger percentage of total revenue, which would increase our gross margins. In addition, we expect both the average selling price and the manufacturing cost of our instruments to decrease following the introduction of future generations of our nCounter Analysis System. Future instrument selling prices and gross margins may fluctuate as we introduce new products and reduce our product costs and from variability in the timing of new product introductions.

We derive service revenue from extended service contracts, which are purchased by a majority of our customers. Additionally, we selectively provide proof-of-principle studies in connection with prospective sales to customers to demonstrate the performance of our nCounter Analysis System.

The following table reflects instrument, consumable and service revenue in absolute dollars and as percentage of total revenue.

	Year Ended December 31,					Three	Months E	nded March	31,	
	2010		2011		2012		201	2	2013	3
		(Dollars in thousands)								
Product revenue:										
Instruments	\$ 6,472	55%	\$ 7,112	40%	\$ 8,786	38%	\$ 1,500	33%	\$ 1,639	29%
Consumables	5,034	43	9,997	56	13,036	57	2,703	60	3,699	65
Service revenue	224	2	691	4	1,151	5	299	7	338	6
Total	\$ 11,730	100%	\$ 17,800	100%	\$ 22,973	100%	\$ 4,502	100%	\$ 5,676	100%

### Impact of Our Diagnostic Products Strategy

We intend to provide instruments and consumables for use in diagnostic testing, beginning with Prosigna. We recently obtained a CE mark for Prosigna and, in February 2013 we commercially launched Prosigna in Europe, including in France, Germany, Italy, Spain and the United Kingdom, and Israel. In April 2013, we installed the first diagnostic systems in Europe, which will initially be used for clinical studies of Prosigna s impact on adjuvant treatment decisions in early stage breast cancer called decision impact studies. In December 2012, we submitted an application, known as a 510(k), to the FDA seeking clearance in the United States for a version of Prosigna providing an assessment of a patient s risk of recurrence for breast cancer. In March 2013, we received a written response from the FDA requesting additional information for its review of our 510(k) submission. A request for additional information is common following an initial 510(k) submission. In May 2013, we submitted an initial response to the FDA s request for additional information and met with the FDA to discuss our response. The commercial launch of Prosigna requires us to establish a dedicated diagnostics sales force.

We intend to enable medical centers and commercial laboratories to conduct complex molecular diagnostic testing that they are unable to do today. After appropriate regulatory clearance, we will sell nCounter Analysis Systems to customers or lease them under reagent rental arrangements where an instrument is placed at a customer location at minimal direct cost and the customer commits to purchase a minimum volume of consumable diagnostic kits over a period of time. The revenue derived from the sale of diagnostic kits will be driven by a combination of the number of tests performed by our customers as well as the price of each kit. The list price of a Prosigna test in Europe is the equivalent of 1,550 per patient. Although the price of Prosigna and our additional future diagnostic products will depend on many factors, including whether and how much third-party payors will reimburse laboratories for conducting such tests, we expect that the gross margin for our diagnostic kits will be higher than for our life sciences research consumables.

Over time, we intend to build a menu of additional diagnostic tests that can be run on our nCounter Analysis System. As researchers discover how genomic information can be used to improve clinical decision-making, we will seek to in-license intellectual property rights and translate their discoveries into molecular diagnostic products. We in-licensed the rights to intellectual property that forms the basis of Prosigna from Bioclassifier, LLC, which was founded by several of our life sciences research customers. We intend to enter into similar arrangements with our life sciences research customers and other researchers for future diagnostic gene signatures. Our strategy is to target intellectual property rights to potential diagnostic methods that are well understood, have the potential to facilitate changes in treatment with a major impact on outcome and cost, have the potential to support value-based pricing, and for which tissue samples for clinical validation are readily available. For example, in February 2013 we secured an option from a customer to acquire an exclusive worldwide license for a gene signature that could be used, after appropriate regulatory authorization, to identify patients with cirrhosis who are at highest risk of developing HCC and to determine whether a patient who has

been diagnosed with HCC is likely to have a recurrence. This disciplined approach is designed to efficiently focus our research and development investment on development of potential products, rather than discovery of new gene signatures. Licenses may include upfront, milestone and/or annual cash payments and revenue-based royalties. The number and amount of such payments and royalty rates are expected to vary depending on the level of development and commercial potential of in-license opportunities.

We believe that our *in vitro* diagnostics business model is more capital efficient than the clinical laboratory services model and has the potential to become profitable on a relatively small revenue base. Our diagnostics business leverages many of the capabilities of our life sciences business, including our technology platform and product development, manufacturing, and administrative functions. Because we provide *in vitro* diagnostics kits rather than clinical laboratory services, we do not incur the costs of clinical laboratory infrastructure, sample logistics, or contracting with and billing managed care organizations. We believe that our customers will be motivated by the potential to improve patient care, broaden patient access and profit from testing services based on Prosigna and other potential nCounter-based diagnostics, which will encourage market adoption and potentially reduce sales and marketing expenditures relative to a centralized laboratory model.

## **Results of Operations**

### Comparison of Three Months Ended March 31, 2012 and 2013

Revenue; Cost of Revenue; Gross Profit

	Three M Ended Ma		Change 2012 v. 2013	
	2012	2013 (Dollars in	Dollars	Percentage
Revenue:				
Product revenue:				
Instruments	\$ 1,500	\$ 1,639	\$ 139	9%
Consumables	2,703	3,699	996	37
Service revenue	299	338	39	13
Total revenue	4,502	5,676	1,174	26
Cost of revenue	2,656	2,882	226	9
Gross profit	\$ 1,846	\$ 2,794	\$ 948	51
Gross margin	41%	49%		

The increase in instrument revenue was attributable to an increase in the number of systems sold, primarily within North America. The increase in consumable revenue was generally consistent with the increase in our instrument installed base.

The increase in cost of revenue was attributable to an increase in the number of systems sold, as well as the increased costs associated with higher volumes of consumables sold. Gross margin increased due to a shift in product mix, with higher margin consumables representing 65% of total revenues in 2013, versus 60% in the prior year period. Additionally, gross margin on consumables increased in 2013 due to higher manufacturing capacity utilization.

Research and Development Expense

	Thre	e Months		
	Ended	Ended March 31,		2012 v. 2013
	2012	2013	Dollars	Percentage
		(Dollars in	n thousands)	
Research and development expense	\$ 2,197	\$ 3,059	\$ 862	39%

The increase was primarily attributable to a \$0.9 million increase in personnel-related expenses as a result of growth in research and development headcount to support the expansion of our life science business and the formation of our diagnostic business, and a \$0.2 million

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increase in diagnostic external development costs.

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Selling, General and Administrative Expense

	Three	Months		
	Ended 1	March 31,	Change 2	2012 v. 2013
	2012	2013	Dollars	Percentage
		(Dollars i	n thousands)	
Selling general and administrative expense	\$ 3.167	\$ 6.126	\$ 2,959	93%

The increase was primarily attributable to a \$1.3 million increase in personnel-related expenses, primarily related to increased sales and administrative headcount to support the growth and expansion of our business, a \$0.9 million increase in marketing consulting costs, primarily in preparation for the commercial launch of Prosigna, a \$0.2 million increase in corporate and intellectual property-related legal costs, and a \$0.2 million increase in other professional fees and administrative services.

Other Income (Expense), Net

		Three Months Ended March 31,		2012 v. 2013
	2012	2013	Dollars	Percentage
		(Dollars i	n thousands)	
Interest income	\$ 7	\$ 3	\$ (4)	(57)%
Interest expense	(112)	(385)	(273)	244
Other income (expense)	(13)	(4)	9	(69)
Revaluation of preferred stock warrant liability	26	(482)	(508)	(1,954)
Total other income (expense), net	\$ (92)	\$ (868)	\$ (776)	843

The increase in interest expense was driven by the increase in borrowings under our existing credit facility compared to the prior period level of borrowings under our 2010 loan and security agreement and convertible subordinated notes. Our average outstanding indebtedness was \$13.0 million in 2013 compared to less than \$2.0 million in 2012.

The increase in expense from the revaluation of the preferred stock warrant liability was driven by an increase in the valuation of our stock.

### Comparison of Years Ended December 31, 2011 and 2012

Revenue; Cost of Revenue; Gross Profit

	Year l	Ended		
	Decem	ber 31,	Change 2011 v. 2012	
	2011	2012	Dollars	Percentage
		(Dollars in t	housands)	
Revenue:				
Product revenue:				
Instruments	\$ 7,112	\$ 8,786	\$ 1,674	24%
Consumables	9,997	13,036	3,039	30
Service revenue	691	1,151	460	67
Total revenue	17,800	22,973	5,173	29
Cost of revenue	9,777	12,361	2,584	26
Gross profit	\$ 8,023	\$ 10,612	\$ 2,589	32

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Gross margin 45% 46%

The increase in instrument revenue was attributable to an increase in the number of systems sold, primarily related to an increase in sales outside of the United States. The net selling price of our instruments was relatively flat. The increase in consumable revenue was related to our increased instrument installed base. Overall, we derived \$3.3 million in incremental revenue from customers outside of North America as a result of the expansion of our overseas sales and marketing efforts.

The increase in cost of revenue was attributable to an increase in the number of systems sold, as well as the increased costs associated with higher volumes of consumables sold. Gross margin was relatively flat, consistent with the relatively constant product mix in the two years.

Research and Development Expense

	Year	Ended		
	Decen	ber 31,	Change	2011 v. 2012
	2011	2012	Dollars	Percentage
		(Dollars in	thousands)	
Research and development expense	\$ 8,990	\$ 11.635	\$ 2,645	29%

The increase was primarily attributable to a \$2.2 million increase in clinical study and sample acquisition costs and an \$0.8 million increase in facility-related costs due to the expansion of our facility. The increases were offset in part by the absence of \$0.5 million in third-party in-license fees incurred in 2011.

Selling, General and Administrative Expense

	Yea	ar Ended		
	Dece	ember 31,	Change 2	2011 v. 2012
	2011	2012	Dollars	Percentage
		(Dollars in	n thousands)	
Selling, general and administrative expense	\$ 9,529	\$ 15,486	\$ 5,957	63%

The increase was primarily attributable to a \$2.5 million increase in personnel-related expenses as a result of increased sales and administrative headcount to support the growth of our business, \$2.0 million in marketing consulting costs in preparation for the commercial launch of Prosigna, and \$0.9 million in corporate and intellectual property-related legal costs.

Other Income (Expense), Net

		Year Ended December 31,		Change 2011 v. 2012	
	2011	2012	Dollars	Percentage	
		(Dollars in	thousands)		
Interest income	\$ 10	\$ 21	\$ 11	110%	
Interest expense	(599)	(804)	(205)	34	
Other income (expense)	80	(29)	(109)	(136)	
Revaluation of preferred stock warrant liability	73	(387)	(460)	(630)	
Total other income (expense), net	\$ (436)	\$ (1,199)	\$ (763)	175	

The increase in interest expense was driven by the increase in borrowings under our existing credit facility compared to the prior period level of borrowings under our 2010 loan and security agreement and convertible subordinated notes.

The increase in expense from the revaluation of the preferred stock warrant liability was driven by an increase in the valuation of our stock.

## Comparison of Years Ended December 31, 2010 and 2011

Revenue; Cost of Revenue; Gross Profit

		Year Ended December 31,		Change 2010 v. 2011	
	2010	2011 (Dollars in t	Dollars	Percentage	
Revenue:					
Product revenue:					
Instruments	\$ 6,472	\$ 7,112	\$ 640	10%	
Consumables	5,034	9,997	4,963	99	
Service revenue	224	691	467	208	
Total revenue	11,730	17,800	6,070	52	
Cost of revenue	9,128	9,777	649	7	
Gross profit	\$ 2,602	\$ 8,023	\$ 5,421	208	
Gross margin	22%	45%			

The increase in instrument revenue was attributable to an increase in the number of systems sold, which was primarily related to an increase outside of the United States. The net selling price of our instruments was relatively flat. The increase in consumable revenue was related to our increased instrument installed base as well as the introduction of new applications and panel products. Overall, we derived \$2.7 million in incremental revenue from customers outside of North America as a result of the expansion of our overseas sales and marketing efforts.

The increase in cost of revenue was attributable to an increase in the number of systems sold, as well as the increased costs associated with higher volumes of consumables sold. This increase was largely offset by a decrease in manufacturing costs for certain consumable products. Gross margin increased primarily due to manufacturing process improvements, raw material costs reductions, increased manufacturing volumes, and a shift in product mix toward consumables, all of which lowered costs as a percentage of revenue.

Research and Development Expense

	Year E	Ended		
	Decemb	December 31,		2010 v. 2011
	2010	2011	Dollars	Percentage
		(Dollars i	n thousands)	
Research and development expense	\$ 7,547	\$ 8,990	\$ 1,443	19%

The increase was primarily attributable to a \$0.9 million increase in personnel related expenses as a result of increased headcount, a \$0.7 million increase in facility costs as we leased additional space, and \$0.5 million in third-party in-license fees incurred in 2011. Partially offsetting the increase was the absence of \$0.7 million in development costs incurred in 2010 for a second generation of our instruments launched in 2011.

Selling, General and Administrative Expense

	Year 1	Ended		
	Decem	December 31,		2010 v. 2011
	2010	2011	Dollars	Percentage
		(Dollars i	n thousands)	
Selling, general and administrative expense	\$ 8,027	\$ 9,529	\$ 1,502	19%

The increase was primarily attributable to a \$1.6 million increase in personnel-related expenses, largely as a result of increased sales and administrative headcount, and to a lesser extent, an increase in facility costs as we leased additional space. Partially offsetting the increase was

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the reduction of \$0.5 million in consulting fees related to the evaluation of the Prosigna market opportunity.

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Other Income (Expense), Net

		Year Ended December 31.		Change 2010 v. 2011		
	2010	**** *** * /		Percentage		
		(Dollars	in thousands)			
Interest income	\$ 29	\$ 10	\$ (19)	(66%)		
Interest expense	(94)	(599)	(505)	(537)		
Other income (expense)	254	80	(174)	(69)		
Revaluation of preferred stock warrant liability	15	73	58	387		
Total other income (expense), net	\$ 204	\$ (436)	\$ (640)	(314)		

The increase in interest expense was driven by a \$5.0 million increase in borrowings under our 2010 loan and security agreement in November 2010 and the issuance of an aggregate of \$5.0 million in convertible promissory notes in June and September 2011. The decrease in other income was attributable to a one-time payment of \$0.2 million received in 2010 under the Qualifying Therapeutic Discovery Project Program.

## Quarterly Results of Operations

The following tables set forth selected unaudited quarterly statements of operations data for the last nine fiscal quarters. The unaudited interim financial statements for each of these quarters have been prepared on the same basis as the audited financial statements included elsewhere in this prospectus and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to a fair statement of our results of operations and financial position for these periods. These data should be read in conjunction with the audited financial statements and accompanying notes included elsewhere in this prospectus. These quarterly operating results are not necessarily indicative of our operating results for any future period.

	Three Months Ended														
	March 31,	June 30,	Sept	tember 30,	Dec	,			June 30,	Sep		Dec	ember 31,		arch 31,
	2011	2011		2011		2011 (Dol		2012 in thous:	2012		2012		2012		2013
Revenue:						(Du	iiais	III tilous	iiids)						
Product revenue:															
Instruments	\$ 2,060	\$ 1,898	\$	1,078	\$	2,076	\$	1,500	\$ 2,579	\$	2,183	\$	2,524	\$	1,639
Consumables	2,147	2,843		2,634		2,373		2,703	3,054		3,568		3,711		3,699
Service revenue	137	138		181		235		299	310		284		258		338
Total revenue	4,344	4,879		3,893		4,684		4,502	5,943		6,035		6,493		5,676
Costs and expenses:															
Cost of revenue	2,532	2,477		2,189		2,579		2,656	3,334		3,086		3,285		2,882
Research and development	2,620	2,229		1,884		2,257		2,197	2,971		3,085		3,382		3,059
Selling, general and															
administrative	2,327	2,473		2,110		2,619		3,167	3,251		4,170		4,898		6,126
Other (income) expenses	19	67		282		68		92	(42)		360		789		868
Total costs and expenses	7,498	7,246		6,465		7,523		8,112	9,514		10,701		12,354		12,935
•															
Net loss	\$ (3,154)	\$ (2,367)	\$	(2,572)	\$	(2,839)	\$	(3,610)	\$ (3,571)	\$	(4,666)	\$	(5,861)	\$	(7,259)

Consistent with others in our industry, we have experienced variations in revenue related to the ordering patterns of our customers. The third calendar quarter has tended to be relatively weak for instruments and consumables due to summer holidays and vacations of potential academic customers. In addition, we believe that

instrument sales will be stronger in the fourth quarter of each calendar year due to the availability of residual funding for capital expenditures prior to the end of many customers fiscal year and less strong in the first quarter of each calendar year as a result of such expenditures. As a result of such factors, we expect to continue to see seasonality and quarter-to-quarter variations in our revenue, especially related to instruments.

Cost of revenue tends to be higher on a percentage basis in the first calendar quarters due to lower revenue over which we must spread our fixed manufacturing and overhead costs. Product mix from quarter-to-quarter also impacts cost of revenue on a percentage basis.

Research and development expense has varied from quarter-to-quarter due to the timing of license payments and clinical study activity. For example, we incurred a \$0.5 million in-license fee in the first quarter of 2011 and incurred third-party clinical study costs of \$1.0 million, \$0.5 million and \$0.7 million in the second, third and fourth quarter of 2012, respectively. We believe that our continued investment in research and development is essential to our long-term competitive position and expect these expenses to continue to increase in future periods.

Selling, general and administrative expense has increased each quarter in 2012 primarily due to increased sales and marketing headcount and marketing consulting costs in preparation for the commercial launch of Prosigna.

## **Liquidity and Capital Resources**

As of March 31, 2013, we had cash and cash equivalents of \$11.8 million, which consisted of highly-liquid investments with an original maturity of three months or less. Since inception, we have financed our operations primarily through the sale of equity securities and, to a lesser extent, from borrowings. Our principal uses of cash are funding our operations, debt service payments as described below, and capital expenditures.

# Sources of Funds

Our cash used in operations for the year ended December 31, 2012 and the three months ended March 31, 2013 was \$14.8 million and \$9.0 million, respectively. During 2012, we incurred \$13.0 million in term loan borrowings under our credit facility and amended the credit facility to allow for the incurrence of up to an additional \$10.0 million in term loan borrowings. Also in 2012, we issued and sold shares of Series E preferred stock which generated proceeds after offering expenses of \$15.1 million. As of March 31, 2013 we had cash and cash equivalents of \$11.8 million and available borrowing under our credit facility of \$12.0 million, including \$10 million in term loan borrowings. In April 2013, we incurred \$5.0 million of the remaining term loan borrowings and amended our credit facility to allow for the incurrence of the remaining \$5.0 million in term loan borrowings on or before June 30, 2013. In our current mode of operations, our cash, cash equivalents and available borrowing capacity is sufficient to meet our anticipated cash needs at least through the end of 2013. However, our operating plan for 2013 reflects substantial incremental investment in the launch of our first diagnostic product, which we intend to fund through equity financing. Without this additional funding, we will be required to reduce the pace of our investment in the diagnostic product commercialization.

From time to time, we may explore additional financing sources and means to lower our cost of capital, which could include equity, equity-linked and debt financing. There can be no assurance that any additional financing will be available to us on acceptable terms.

#### Credit Facility

In March 2012, we entered into a loan and security agreement, which we refer to as our credit facility, pursuant to which we incurred \$7.5 million in term loan borrowings, which we refer to as Term A borrowings. Pursuant to the credit facility, we incurred an additional \$5.5 million of term loan borrowings in December 2012, which we refer to as Term B borrowings. Also in December 2012 and April 2013, we amended the credit facility to (1) allow for the incurrence on or prior to April 30, 2013 of up to an additional \$5.0 million in term loan borrowings, which we incurred on April 30, 2013 and refer to as Term C borrowings and (2) allow for the incurrence on or prior to June 30, 2013 of up to an additional \$5.0 million in term loan borrowings, which we refer to as Term D borrowings. Prior to incurring the Term D borrowings, we must satisfy a revenue-based milestone. Interest on term loan borrowings is determined at the time of borrowing and accrues at a fixed rate equal to the three month LIBOR

plus 8.39% (subject to a LIBOR floor of 0.50%). Through June 2013, we are required to only pay interest on outstanding term borrowings on a monthly basis. Pursuant to the April 2013 amendment, if the offering contemplated by this prospectus is completed on or prior to June 30, 2013 and generates gross proceeds of at least \$50.0 million, the period during which we are required to only pay interest on outstanding term borrowings will be extended through January 2014 and the maturity date for all term borrowings will be similarly extended by eight months. Following the expiration of the interest only payment period, we are required to pay principal and interest in 29 equal monthly installments, or 30 equal monthly payments if the offering contemplated by this prospectus is completed on or prior to June 30, 2013 and generates gross proceeds of at least \$50.0 million, plus an end of term payment equal to 5.5% of the amount borrowed. We may at our option prepay all of the term loan borrowings by paying the lender, among other things, all principal and accrued interest, the end of term payment plus a make-whole premium. Pursuant to the credit facility, from time to time we can also incur revolver borrowings of up to the lesser of \$2.0 million and a borrowing base tied to the amount of eligible accounts receivable. Interest on revolver borrowings accrues at a floating rate equal to the prime rate plus 3.70% (subject to a floor of 6.95%) and is payable monthly. We are also required to pay a fee of 0.075% per month on the unused portion of the revolver borrowings.

The credit facility contains customary conditions to borrowing, events of default and covenants, including covenants that restrict our ability to dispose of assets, merge with or acquire other entities, incur indebtedness, incur encumbrances, make distributions to holders of our capital stock, make investments or engage in transactions with our affiliates. In addition, we must comply with a financial covenant based on life sciences revenue. This financial covenant is measured monthly on a trailing three month basis. We were in compliance with all covenants as of December 31, 2012 and March 31, 2013. Our obligations under the credit facility are secured by substantially all of our assets other than intellectual property.

As of March 31, 2013, we had \$7.5 million of Term A borrowings outstanding and \$5.5 million of Term B borrowings, which each accrue interest at 8.89%. In April 2013, we incurred \$5.0 million of Term C borrowings, which accrues interest at 8.89%.

We issued the lenders warrants to purchase an aggregate of 44,389 shares of our Series D preferred stock in connection with entering into the credit facility and warrants to purchase an additional 32,551 shares of Series D preferred stock in connection with the incurrence of the Term B borrowings. Such warrants have ten year terms and an exercise price of \$8.45 per share. In December 2012 we issued the lenders warrants to purchase an aggregate 20,837 shares of our Series E preferred stock at an exercise price of \$14.40 per share in connection with the amendment of the credit facility. In addition, in April 2013 we issued the lenders warrants to purchase an aggregate of 10,418 shares of our Series E preferred stock at an exercise price of \$14.40 per share in connection with the incurrence of Term C borrowings. It is a condition to the incurrence of any Term D borrowings that we issue the lenders additional warrants to purchase shares of our Series E preferred stock. Assuming we incur the Term D borrowings in full, we would be required to issue the lenders warrants to purchase an aggregate of 10,418 shares of our Series E preferred stock. Following the offering contemplated by this prospectus, such warrants will be exercisable for our common stock.

## Convertible Promissory Notes

In June 2011 and September 2011, we issued approximately \$5.0 million aggregate principal amount of our subordinated convertible promissory notes to existing investors. Interest on the notes accrued on the unpaid principal balance at 8.0% per year. The principal amount of and accrued interest on the subordinated convertible notes converted into an aggregate of 602,172 shares of our Series D preferred stock in November 2011. In addition, we issued warrants to purchase an aggregate of 118,368 shares of our Series D preferred stock at an exercise price of \$8.45 per share to the holders of the subordinated convertible notes. These warrants will expire upon the earliest of (1) November 1, 2018, (2) a change in control of our company and (3) the sale of all or substantially all of our assets. Following the offering contemplated by this prospectus, such warrants will be exercisable for our common stock.

### 2010 Loan and Security Agreement

In November 2010, we amended our then-existing loan and security agreement to provide for up to \$2.0 million of equipment term borrowings and, subject to certain conditions, up to \$3.0 million in revolver

borrowings. Under the agreement, we incurred \$1.9 million of equipment term borrowings, which were payable over periods of up to 36 months in equal monthly installments of principal and interest. In addition, we incurred maximum borrowings under the revolver of \$2.7 million. As amended, interest on borrowings under the 2010 loan and security agreement accrued at a floating rate equal to the bank s prime reference rate (subject to a floor of LIBOR plus 2.5%, or, if LIBOR cannot be determined, then 2.5%), plus up to 1.5% depending on the facility. All of the indebtedness incurred under the 2010 loan and security agreement was repaid in 2012 in connection with the entry into our existing credit facility.

We also issued the lender under the 2010 loan and security agreement warrants to purchase 4,691 shares of our Series B preferred stock at an exercise price of \$17.47 per share. After giving effect to the anti-dilution provisions of such warrant, in connection with the offering contemplated by this prospectus, it will become exercisable for 7,315 shares of our common stock. These warrants will expire in October 2014.

#### Use of Funds

Our principal uses of cash are funding our operations, satisfaction of our obligations under our debt instruments, and other working capital requirements. Over the past several years, our revenue has increased significantly from year to year and, as a result, our cash flows from customer collections have increased. However, our operating expenses have also increased as we have invested in growing our existing life sciences business and in developing Prosigna and preparing it for commercialization. As a result, our cash used in operating activities has either remained relatively constant or increased. We expect our operating cash requirements to increase in the future as we (1) increase sales and marketing activities to expand the installed base of our nCounter Analysis Systems among life sciences research customers, (2) commercialize, and conduct studies to expand the clinical utility of, Prosigna, and (3) develop new applications, chemistry and instruments for our nCounter platform.

We will need to raise additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, our operations and ability to execute our business strategy could be adversely affected. We may seek to raise additional funds through equity, equity-linked or debt financings. If we raise additional funds through the incurrence of indebtedness, such indebtedness would have rights that are senior to holders of our equity securities and could contain covenants that restrict our operations. Any additional equity financing may be dilutive to our stockholders.

## Historical Cash Flow Trends

The following table shows a summary of our cash flows for the periods indicated:

	Years Ended December 31,			Three Months Ended March 31,		
	2010 2011 2012			2012	2013	
		(	In thousands)			
Cash used in operating activities	\$ (10,965)	\$ (10,692)	\$ (14,808)	\$ (2,915)	\$ (9,010)	
Cash used in investing activities	(1,932)	(2,800)	(428)	(132)	(136)	
Cash provided by (used in) financing activities	15,524	19,994	26,060	5,962	(752)	

Operating Cash Flows

We derive operating cash flows from cash collected from the sale of our products and services. These cash flows received are outweighed by our use of cash for operating expenses to support the growth of our business. As a result, we have historically experienced negative cash flows from operating activities as we have expanded our business in the United States and other markets and this will likely continue for the foreseeable future.

Net cash used in operating activities for the three months ended March 31, 2013 consisted of our net loss of \$7.3 million and changes in our operating assets and liabilities of \$3.1 million, which included a \$1.0 million increase in accounts receivable, an \$0.8 million increase in prepaid expenses and a \$1.2 million decrease in accrued liabilities. These uses were partially offset by non-cash expense items such as depreciation and

amortization of our equipment and leasehold improvements of \$0.5 million, revaluation of preferred stock warrant liability of \$0.5 million, stock-based compensation of \$0.2 million and interest accrued on long term debt of \$0.1 million.

Net cash used in operating activities for the three months ended March 31, 2012 consisted of our net loss of \$3.6 million and changes in our operating assets and liabilities of \$0.1 million, which were partially offset by non-cash expense items such as depreciation and amortization of our equipment and leasehold improvements of \$0.5 million, stock-based compensation of \$0.3 million, amortization of debt discounts and issuance cost of \$0.1 million and revaluation of preferred stock warrant liability of \$26,000.

Net cash used in operating activities for 2012 consisted of our net loss of \$17.7 million and changes in our operating assets and liabilities of \$0.4 million, which were partially offset by non-cash expense items such as depreciation and amortization of our equipment and leasehold improvements of \$1.9 million, stock-based compensation of \$0.7 million, revaluation of preferred stock warrant liability of \$0.4 million and amortization of debt discounts and issuance cost of \$0.1 million.

Net cash used in operating activities for 2011 consisted of our net loss of \$10.9 million and changes in our operating assets and liabilities of \$1.8 million, which were partially offset by non-cash expense items including depreciation and amortization of our equipment and leasehold improvements of \$1.5 million, amortization of debt discounts and issuance costs of \$0.3 million and stock-based compensation of \$0.2 million.

Net cash used in operating activities for 2010 consisted of our net loss of \$12.8 million, offset in part by a \$0.6 million change in operating assets and liabilities and non-cash expense items such as depreciation and amortization of our equipment and leasehold improvements of \$1.0 million and stock-based compensation of \$0.1 million.

#### Investing Cash Flows

Net cash used in investing activities for each of the periods presented was primarily for the purchase of laboratory, manufacturing and computer equipment and software to support our expanding infrastructure. In 2011, we leased additional laboratory and office space and incurred \$1.8 million in expenses related to leasehold improvements and our restricted cash related to this leased space increased by \$0.1 million. In 2012 and 2013, we purchased lesser amounts of property and equipment required to support the growth and expansion of our operations. Other than the purchase of nCounter Analysis Systems for loan or rental to clinical laboratories in support of Prosigna commercialization in jurisdictions where we have regulatory authorization, we have no major capital expenditures planned for the remainder of 2013.

## Financing Cash Flows

Historically, we have funded our operations through the issuance of preferred stock and the incurrence of indebtedness.

For the three months ended March 31, 2013, net cash used in financing activities consisted of payments related to deferred offering costs of \$1.0 million and repayments of borrowings of \$0.1 million. This was partially offset by proceeds from the exercise of stock options of \$0.3 million.

For the three months ended March 31, 2012, net cash provided by financing activities consisted of \$7.5 million of borrowing under our credit facility, which was partially offset by repayments of borrowings under our 2010 loan and security agreement of \$1.6 million.

For 2012, net cash provided by financing activities consisted of \$13.0 million of borrowing under our credit facility and \$15.1 million from the issuance of Series E preferred stock. This was partially offset by repayments of borrowings under our 2010 loan and security agreement of \$1.7 million and payments related to deferred offering costs of \$0.6 million.

For 2011, net cash provided by financing activities consisted of the issuance of Series D preferred stock which generated proceeds of \$14.9 million, issuance of our subordinated convertible notes which generated proceeds of \$5.0 million and incurrence of an aggregate of \$5.0 million of borrowings under our 2010 loan and security agreement, which were offset in part by repayment of \$4.9 million of such borrowings.

For 2010, net cash provided by financing activities consisted of the issuance of \$15.0 million of Series C preferred stock and net incurrence of indebtedness under our 2010 loan and security agreement of \$0.5 million.

## **Contractual Obligations**

The following table reflects a summary of our contractual obligations as of December 31, 2012.

	Payments due by period						
Contractual Obligations <sup>(1)</sup>	Less than Total 1 Year 1-3 Years 3-5 Years (In thousands)				More than 5 Years		
Operating lease obligations <sup>(2)</sup>	\$ 7,295	\$ 2,009	\$ 3,950	\$ 1,336	\$		
Long-term debt obligations <sup>(3)</sup>	13,993	3,009	10,984				
Inventory purchase obligations <sup>(4)</sup>	2,604	2,604					
Total	\$ 23,892	\$ 7,622	\$ 14,934	\$ 1,336	\$		

- (1) Excludes royalty obligations based on net sales of products, including royalties payable to the Institute for Systems Biology, as any such amounts are not currently determinable.
- (2) Operating lease costs are primarily for office, laboratory and manufacturing space at our headquarters.
- (3) Includes principal and interest on long-term debt obligations.
- (4) Purchase obligations consist of contractual and legally binding commitments under outstanding purchase orders to purchase long lead time inventory items.

# **Critical Accounting Policies and Significant Estimates**

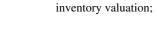
Our discussion and analysis of our financial condition and results of operations are based upon our financial statements which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and related disclosure of contingent assets and liabilities, revenue and expenses at the date of the financial statements. Generally, we base our estimates on historical experience and on various other assumptions in accordance with GAAP that we believe to be reasonable under the circumstances. Actual results may differ from these estimates.

Critical accounting policies and estimates are those that we consider the most important to the portrayal of our financial condition and results of operations because they require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting policies and estimates include those related to:

revenue recognition;

stock-based compensation;

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fair value measurements; and

income taxes.

# Revenue Recognition

We generate revenue from sales of our products and services. Our products consist of our proprietary nCounter Analysis Systems and related consumables. Services consist of extended service contracts and service fees for assay processing.

Revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the price to the customer is fixed or

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determinable; and (4) collectability is reasonably assured. The evaluation of these revenue recognition criteria requires significant management judgment. For instance, we use judgment to assess collectability based on factors such as the customer's creditworthiness and past collection history, if applicable. If we determine that collection of a payment is not reasonably assured, revenue recognition is deferred until receipt of payment. We also use judgment to assess whether a price is fixed or determinable including but not limited to, reviewing contractual terms and conditions related to payment terms.

Some of our sales arrangements involve the delivery or performance of multiple products or services. Significant interpretation is sometimes required to determine the appropriate accounting, including whether the deliverables specified in a multiple element arrangement should be treated as separate units of accounting for revenue recognition purposes, and, if so, how the related sales price should be allocated among the elements, when to recognize revenue for each element, and the period over which revenue should be recognized. Revenue recognition for arrangements with multiple deliverables is based on the individual units of accounting determined to exist in the arrangement. A delivered element is considered a separate unit of accounting when the delivered element has value to the customer on a stand-alone basis. Elements are considered to have stand-alone value when they are sold separately or when the customer could resell the element on a stand-alone basis.

For multiple-element arrangements, we allocate arrangement consideration at the inception of the arrangement to the deliverables based on the relative selling price method. The selling price used for each deliverable is based on vendor-specific objective evidence, or VSOE, if available, third-party evidence, or TPE, if VSOE is not available, or best estimated selling price, or BESP, if neither VSOE nor TPE is available. BESP is determined in a manner consistent with that used to establish the price to sell the deliverable on a stand-alone basis. To date, selling prices have been established by reference to VSOE based on stand alone sales transactions for each deliverable. VSOE is considered to have been established when a substantial majority of individual sales transactions within the previous 12 month period fall within a reasonably narrow range, which we have defined to be plus or minus 15% of the median sales price of actual stand alone sales transactions. Allocated revenue is only recognized for each deliverable when the revenue recognition criteria have been met.

We calibrate our nCounter Analysis System prior to shipment, but it must be recalibrated and tested on installation at the customer premises. Installation and calibration is therefore considered to be essential to the functionality of our nCounter Analysis System. To date, customers have relied upon us to perform the installation and calibration service. Systems and related installation and calibration are considered to be one separate unit of accounting and revenue is recognized once the installation and calibration has been completed.

Revenue from the sales of our products that are not part of multiple element arrangements is recognized when no significant obligations remain undelivered and collection of the receivables is reasonably assured, which is generally when delivery has occurred.

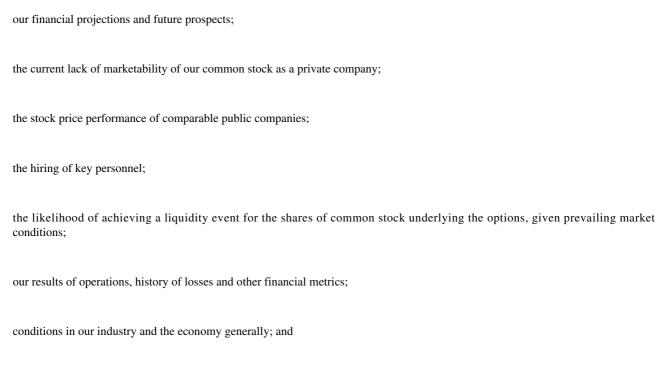
Accruals for estimated warranty expenses are made at the time that the associated revenue is recognized. We use judgment to estimate these accruals and, if we were to experience an increase in warranty claims or if costs of servicing our products under warranty were greater than our estimates, our cost of revenue could be adversely affected in future periods.

Revenue from the sales of our services is recognized when no significant obligations remain undelivered and collection of the receivables is reasonably assured, which is generally when delivery has occurred. We offer extended service contracts on our nCounter Analysis Systems for periods ranging from 12 to 36 months after the end of the standard 12-month warranty period. Revenue from extended service contracts is deferred and recognized in income on a straight-line basis over the contract period.

# Stock-based Compensation

We have granted stock options at exercise prices believed to be equal to the fair value of the common stock underlying such options as determined by the board of directors, with input from management, on the date of grant. Because our common stock is not currently publicly traded, the board of directors exercises significant judgment in determining the fair market value of our common stock. Changes in judgments could have a material impact on our

results of operations and financial position. Members of the board of directors and management team have extensive business, financial and investing experience. In assessing the fair value of our common stock as of option grant dates, the board of directors considered numerous objective and subjective factors including:



contemporaneous valuations of our common stock, including those performed as of December 1, 2011, September 30, 2012, December 31, 2012 and March 31, 2013 by an independent valuation specialist.

As of each stock option grant date listed below, the board of directors believes it made a thorough evaluation of the relevant factors to determine the fair market value of our common stock and accordingly set the exercise price of the options granted equal to its estimate of the fair value of our common stock determined as of such date. On each option grant date, the board of directors considered the most recent valuation of our common stock as one of several factors in estimating the fair value of our common stock. In addition, the board of directors considered changes in our financial condition that had occurred subsequent to the previous valuation date, then-current general economic and market conditions as described more fully below and the other objective and subjective factors described above. Based on these considerations, the board of directors also determined that no significant change in our business or expectations of future business had occurred as of each grant date since the most recent valuation that would have warranted a materially different determination of value of common stock than that suggested by the valuation. The valuations were consistent with the guidance and methods outlined in the AICPA Practice Aid *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, or AICPA Practice Aid, for all option grant dates listed below.

December 2011 Valuation. In conducting the December 2011 valuation of our common stock we used a two-step methodology. First we estimated the enterprise value of our company, and then we allocated the enterprise value to each element of the capital structure, including our common stock, to determine the fair value of a single share of common stock.

We estimated our enterprise value using the guideline public company approach. The guideline public company approach entailed applying the median of the 2011 revenue to enterprise value ratios of public companies similar to us to our revenue projections. Management and the independent valuation specialist considered operational area, size, business model, industry, the description of comparable companies respective businesses set forth in public filings and the stage of their respective product development/commercialization efforts. Life sciences tool companies selected included Complete Genomics, Inc., Enzo Biochem Inc., Harvard Bioscience Inc., Fluidigm Corporation and Affymetrix Inc. Diagnostics companies included CombiMatrix Corporation, Nanosphere, Inc., GenMark Diagnostics, Inc., QIAGEN Marseilles S.A. (formerly Ipsogen SA), Exact Sciences Corporation and Genomic Health Inc. Companies with both life sciences tools and diagnostics businesses included MEDTOX Scientific Inc., Sequenom Inc. and Luminex Corporation. Importantly, like us, all but CombiMatrix and Exact Sciences of the comparable companies generate revenue from the sale of products. Given that our company is relatively unique insofar as it has both a life

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sciences business and a diagnostics business, for the purposes of the valuation it was necessary to include comparable companies that participate solely in either the life sciences or diagnostics business. By taking into account similar numbers of life sciences and diagnostic companies, along with the relatively few number of companies that combine such businesses within a single enterprise, the valuation specialist arrived at a blended multiple representative of our company s then current and future businesses. Based on the performance and stage of our life sciences segment and the

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prospects of and risks associated with our diagnostics segment, the median revenue to enterprise value of such comparable companies equal to 3.5x was selected. Given the consideration of the factors described above, no further adjustments were considered necessary. This multiple was applied to our 2011 revenue projection as of the December 2011 valuation date. The guideline public company approach suggested that our enterprise value was \$59.4 million.

The resulting estimates of our enterprise value were then allocated to the various securities that comprise our capital structure, using the Black-Scholes option pricing model. This option pricing model treats the rights of the holders of preferred and common stock as equivalent to that of call options on any value of the enterprise above certain break points of value based on the claims of lenders and the liquidation preferences and rights of participation and conversion of the holders of preferred stock set forth in our certificate of incorporation. To determine the break points, we made estimates of the anticipated timing of a potential liquidity event and estimates of the volatility of our equity securities based on available information on volatility of stocks of publicly-traded companies similar to ours.

We applied the Black-Scholes option pricing model based on a liquidity event that would occur two years in the future. We assumed a volatility of our common stock of 61%, which corresponds to the third quartile of the volatilities of common stock of the publicly-traded companies deemed to be similar to us. The risk-free interest rate was based on U.S. Treasury Securities matching the expected timing of the liquidity event. Based on this information, we determined the total value of each security in our capital structure and a discount was then applied to reflect the lack of marketability of our common stock based on put option analyses of the publicly-traded companies deemed to be similar to us, which suggested a lack of marketability discount of 46.0%, and the Finnerty Model, which suggested a lack of marketability discount of 24.8%. The put option analysis provides that a privately-held security has the same value as the combination of such security and an at-the-money put option with respect to such security, with the term of such option equal to the expected period that the security will not be publicly traded. The lack of marketability discount, calculated as the ratio of the put value to the value of the security, represents the discount which is deemed necessary to induce a prospective purchaser to purchase the subject company s security instead of an alternative investment identical in all respects other than its marketability. The Finnerty Model provides that the marketability discount of a privately-held security can be estimated by the value of an average strike put option. An average strike put option conveys the right to sell at the average price attained by the subject during the life of the option and the Finnerty Model assumes that investors do not have the unique ability to time the market. If investors are not able to time the market, the restriction has the effect of depriving them of maximum, not average, trading profits. Both approaches, which are supported by the AICPA Practice Aid, were considered in connection with the valuation and it was concluded that a capped lack of marketability discount of 30% was appropriate. The fair value of our common stock suggested by the December 2011 valuation was \$1.92 per share.

*September 2012 Valuation.* The September 2012 valuation was conducted using a hybrid approach consisting of the same methodology as the December 2011 valuation and the probability weighted expected return method, or PWERM. The PWERM method was added in recognition of the increased probability that we would pursue an initial public offering in 2013.

For purposes of the guideline public company approach, the same comparable companies from the December 2011 valuation were considered other than MEDTOX Scientific Inc., which was excluded from the September 2012 valuation because it was acquired by another company in June 2012. Based on the receipt of the CE mark for Prosigna and the success of our TransATAC clinical study, a third quartile revenue to enterprise value multiple was applied to our diagnostics business. A median multiple was applied to our life sciences business given the more mature stage of that business and the impact of the uncertainty regarding government spending on research and development. Given the consideration of the factors described above in the disclosure of the December 2011 valuation, no further adjustments were considered necessary. A weighted-average of the revenue to enterprise value multiples equal to 1.5x, 2.4x and 2.2x, respectively, was applied to our 2012, 2013 and 2014 projected revenue. Our projected revenue was based on our historical financial results, projected growth, the success of our TransATAC clinical study, the receipt of the CE mark for Prosigna and other recent developments. The guideline public company approach suggested that our enterprise value was \$105.5 million.

We then applied the Black-Scholes option pricing model based on the following assumptions: (1) a liquidity event that would occur one and a half years in the future; (2) a volatility of our common stock of 54%, which corresponds to the mean of the volatilities of common stock of the publicly-traded companies deemed to be similar to us; and (3) a risk-free interest rate based on U.S. Treasury Securities matching the expected timing of the liquidity event. The volatilities of publicly-traded life sciences and diagnostics companies is correlated with the regulatory risk associated with their products. Given the reduction of the regulatory risk associated with obtaining the CE mark for Prosigna in September 2012, the mean of the volatilities of the comparable public companies was used for the September 2012 valuation instead of the third quartile of those volatilities used in connection with the December 2011 valuation. Based on this information, we determined the total value of each security in our capital structure. The fair value of our common stock suggested by this methodology was \$4.16 per share.

As part of the PWERM, we estimated the likely outcome of an initial public offering to arrive at a weighted equity value. We estimated a multiple of invested capital to equity value based on the outcome of comparable companies that recently completed initial public offerings. We assumed that an initial public offering would occur in mid-2013 based on a valuation multiple in line with the median of the comparable company analysis. After giving effect to the proceeds we would receive upon exercise of our outstanding warrants and the automatic conversion of our preferred stock in connection with an initial public offering, we determined a per share value of our common stock. We then applied a discount factor derived from the estimated risk-adjusted cost of capital and expected timing of an initial public offering. The fair value of our common stock suggested by this methodology was \$14.72 per share.

After weighting the fair value suggested by the option pricing model at 75% and the fair value suggested by the PWERM at 25%, a discount of 25% was applied to reflect the lack of marketability of our common stock. As with the December 2011 valuation, the put option analysis (which suggested a lack of marketability discount of 36.9%) and the Finnerty Model (which suggested a lack of marketability discount of 20.4%) were considered. It was concluded that a capped lack of marketability discount of 25% was appropriate. The decrease in the lack of marketability discount relative to our December 2011 valuation reflected our evolving view regarding the likelihood and timing of a potential initial public offering. This discount was based on put option analyses of the publicly-traded companies deemed to be similar to us. We concluded that the fair value of our common stock was \$5.12 per share.

December 2012 Valuation. The December 2012 valuation was conducted using the same methodology as the September 2012 valuation.

For purposes of the guideline public company approach, the same comparable companies from the September 2012 valuation were considered. Based on the receipt of the CE mark for Prosigna, the success of our TransATAC and ABCSG8 clinical studies and our plan to develop additional diagnostic products, a third quartile revenue to enterprise value multiple was applied to our diagnostics business given the more mature stage of that business and the impact of the uncertainty regarding government spending on research and development. Given the consideration of the factors described above in the disclosure of the December 2011 valuation, no further adjustments were considered necessary. A median multiple was applied to our life sciences business. A weighted-average of the revenue to enterprise value multiples equal to 1.9x was applied to each of our 2013 and 2014 projected revenue. Our projected revenue was based on our historical financial results, projected growth, the success of our TransATAC and ABCSG8 clinical studies, the receipt of the CE mark for Prosigna and other recent developments. The guideline public company approach suggested that our enterprise value was \$114.7 million. We then applied the Black-Scholes option pricing model based on the following assumptions: (1) a liquidity event that would occur one and a half years in the future; (2) a volatility of our common stock of 58%, which corresponds to the mean of the volatilities of common stock of the publicly traded companies deemed to be similar to us; and (3) a risk-free interest rate based on U.S. Treasury Securities matching the expected timing of the liquidity event. The volatilities of publicly-traded life sciences and diagnostics companies is correlated with the regulatory risk associated with their products. Given the reduction of the regulatory risk associated with obtaining the CE mark for Prosigna in September 2012 and consistent with the September 2012 valuation, the mean of the volatilities of the comparable public companies was used for the December 2012 valuation. Based on this information, we determined the total value of each security in our capital structure. The fair value of our

common stock suggested by this methodology was \$3.20 per share. The decrease in the fair value of our common stock relative to the September 2012 valuation was largely attributable to the sale of Series E preferred stock and the liquidation preference associated with such shares.

As part of the PWERM, we assumed that an initial public offering would occur in mid-2013 based on a valuation multiple in line with the median of the comparable company analysis. After giving effect to the proceeds we would receive upon exercise of our outstanding warrants and the automatic conversion of our preferred stock in connection with an initial public offering, we determined a per share value of our common stock. We then applied a discount factor derived from the estimated risk-adjusted cost of capital and expected timing of an initial public offering. The fair value of our common stock suggested by this methodology was \$15.04 per share.

After weighting the fair value suggested by the option pricing model at 50% and the fair value suggested by the PWERM at 50%, a discount of 25% was applied to reflect the lack of marketability of our common stock. We increased the weighting of the fair value suggested by the PWERM relative to that in the September 2012 valuation given our expectation that the completion of an initial public offering was increasingly likely. As with the previous valuations, the put option analysis (which suggested a lack of marketability discount of 36.1%) and the Finnerty Model (which suggested a lack of marketability discount of 19.9%) were considered. It was concluded that a capped lack of marketability discount of 25% was appropriate. The consistency of the lack of marketability discount relative to our September 2012 valuation reflected our continuing view regarding the timing of a potential initial public offering. This discount was based on put option analyses of the publicly-traded companies deemed to be similar to us. We concluded that the fair value of our common stock was \$6.72 per share.

March 2013 Valuation. The March 2013 valuation was conducted using the same methodology as the December 2012 valuation.

For purposes of the guideline public company approach, the same comparable companies from the December 2012 valuation were considered other than Complete Genomics, Inc., which was excluded from the March 2013 valuation because it was acquired by another company in March 2013. A median quartile revenue to enterprise value multiple was applied to our diagnostics business. This was a decrease from the third quarter revenue to enterprise value multiple applied in the December 2012 valuation. We made this change due to the inclusion of Exact Sciences Corporation, a high growth company in early stages of commercialization, which increased enterprise to revenue multiples. Exact Sciences Corporation was disregarded for the purposes of deriving such multiple in prior valuations because the results of the clinical trial of its colorectal cancer screening test had not yet been published and its inclusion would have required us to make a subjective adjustment to take into account the uncertainty related to the results of the trial. A median multiple was applied to our life sciences business consistent with prior valuations. A weighted-average of the revenue to enterprise value multiples equal to 2.1x was applied to our 2013 projected revenue and 2.5x to our 2014 projected revenue. Our projected revenue was based on our historical financial results, projected growth, the success of our TransATAC and ABCSG8 clinical studies, the receipt of the CE mark for Prosigna, the commercial launch of Prosigna in Europe and Israel in February 2013 and other recent developments. The guideline public company approach suggested that our enterprise value was \$111.2 million.

We then applied the Black-Scholes option pricing model based on the following assumptions: (1) a liquidity event that would occur one and a half years in the future; (2) a volatility of our common stock of 57%, which corresponds to the mean of the volatilities of common stock of the publicly traded companies deemed to be similar to us; and (3) a risk-free interest rate based on U.S. Treasury Securities matching the expected timing of the liquidity event. Based on this information, we determined the total value of each security in our capital structure. The fair value of our common stock suggested by this methodology was \$3.84 per share.

As part of the PWERM, we assumed that an initial public offering would occur in the third quarter of 2013 and we estimated a pre-money equity value in line with the median of initial public offerings by comparable companies. After giving effect to the proceeds we would receive upon exercise of our outstanding warrants and the automatic conversion of our preferred stock in connection with an initial public offering, we determined a per

share value of our common stock. We then applied a discount factor derived from the estimated risk-adjusted cost of capital and expected timing of an initial public offering. The fair value of our common stock suggested by this methodology was \$14.40 per share.

After weighting the fair value suggested by the option pricing model at 35% and the fair value suggested by the PWERM at 65%, a discount of 15% was applied to reflect the lack of marketability of our common stock. We increased the weighting of the fair value suggested by the PWERM relative to that in the December 2012 valuation given our expectation that the probability of a completed initial public offering was more likely. As with the previous valuations, the put option analysis (which suggested a lack of marketability discount of 32.6%) and the Finnerty Model (which suggested a lack of marketability discount of 18.2%) were considered. It was concluded that a capped lack of marketability discount of 15% was appropriate, which we decreased from the December 2012 valuation given our expectation that the probability of a completed initial public offering was more likely. We concluded that the fair value of our common stock was \$8.96 per share.

In connection with the preparation of our financial statements for the nine months ended September 30, 2012, we assessed our estimate of fair value of our common stock for financial reporting purposes given our improving financial performance and prospects, evolving belief during the second half of 2012 that an initial public offering was increasingly viable and the generally improving conditions in the capital markets in the fourth quarter of 2012. We determined that for financial reporting purposes the fair value of our common stock was higher than the board of directors fair market value estimate for each of the option grant dates from March 1, 2012 through September 17, 2012. As a result, we adjusted the fair value per common share as of each such grant date based on the progress of our business at each relevant date. In establishing the fair value of our common stock for the March 2012 option grants, particular emphasis was given to increasing product sales. In establishing the fair value of our common stock for the April 2012 option grants, particular emphasis was given to the March 2012 announcement of the launch of three life sciences applications, the closing of our credit facility which improved our financial position and the hiring of our senior vice president of research and development. In establishing the fair value of our common stock for the May 2012 option grants, particular emphasis was given to the May 2012 acceptance of employment by our senior vice president and general manager of our diagnostics business. In establishing the fair value of our common stock for the September 2012 option grants, particular emphasis was given to the addition of the chairman of our audit committee in July 2012 and the acceptance of employment by our chief financial officer in September 2012. Both of such persons have significant public company experience and their joining our company reflected our evolving belief that an initial public offering was increasingly viable. In establishing the fair value of our common stock for the October 2012 option grants, particular emphasis was given to the September 2012 publication of the Cancer Genome Atlas, which highlighted the importance of intrinsic subtyping enabled by the PAM50 gene signature, the September 2012 announcement of our single cell gene expression application, receipt of the CE mark for Prosigna, our increasing product revenue and the September 2012 valuation of our common stock. In establishing the fair value of our common stock for the January 2013 option grants, particular emphasis was given to the success of our ABCSG8 clinical study, our plans to develop additional diagnostic products, our improved cash position due to the completion of our Series E preferred stock financing and borrowing of \$5.5 million in term loan borrowings under our existing credit facility and the December 2012 valuation of our common stock. In determining the fair value of our common stock for the purpose of establishing the exercise price for the March 2013 option grants, our board of directors gave particular emphasis to the absence of changes to our business that had not already been contemplated by the December 2012 valuation and option grants in January 2013, the poor performance of a diagnostics company s recent initial public offering and the postponement and withdrawal of two other diagnostics companies initial public offerings and the continued uncertainty regarding the impact of the sequestration budget cuts. In determining the fair value of our common stock for the purpose of establishing the exercise price for the May 2013 option grants, our board of directors gave particular emphasis to the absence of changes to our business that had not already been contemplated by the March 2013 valuation.

In connection with the preparation of an amendment to the registration statement of which this prospectus forms a part in late May 2013, we assessed the estimate of fair value of our common stock for financial reporting purposes as of March 1 and May 13, 2013 in light of our evolving views regarding the probability of successfully

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completing an initial public offering in the near term and determined that for financial reporting purposes the fair value of our common stock as of such dates was higher than the board of directors—fair value estimate for the option grant as of such dates. With respect to the March 1, 2013 option grants, for financial reporting purposes we adjusted the fair value per common share as of March 1, 2013 to be consistent with the \$8.96 per share value suggested by the March 2013 valuation. With respect to the May 13, 2013 grants, although there was no significant change in our business that had not already been contemplated by the March 2013 valuation, we determined that it was appropriate to adjust certain assumptions contained in the March 2013 valuation. Specifically, we increased the relative weighting of the PWERM from 65% to 90% and decreased the discount for lack of marketability from 15% to 10%. As a result for financial reporting purposes we adjusted the fair value per common share as of May 1, 2013 to \$12.16.

From January 1, 2012 through the date of this prospectus, we granted stock options with exercise prices and fair value assessments as follows:

			Fair Value		
			Per Common	Intrinsic	
	Common	Common		Value	
	Shares		Financial	Per	
	Underlying	Evansias		Underlying	
	Options	Price	Purposes at	Common	
Grant Date	Granted	Per Share	<b>Grant Date</b>	Share	
March 1, 2012	730,860	\$ 1.92	\$ 2.24	\$ 0.32	
March 26, 2012	39,000	1.92	2.24	0.32	
April 19, 2012	87,563	1.92	2.56	0.64	
May 25, 2012	106,813	1.92	2.88	0.96	
July 17, 2012	22,469	1.92	3.20	1.28	
September 17, 2012	1,563	1.92	4.16	2.24	
October 16, 2012	125,875	5.12	5.12		
January 10, 2013	213,032	6.72	6.72		
March 1, 2013	82,000	6.72	8.96	2.24	
May 13, 2013	19,500	8.96	12.16	3.20	

Based on the initial price to public of \$10.00 per share, the intrinsic value of stock options outstanding at March 31, 2013 was \$12.6 million, of which \$4.4 million and \$8.2 million related to stock options that were vested and unvested, respectively, at that date.

We account for stock-based compensation at fair value. Stock-based compensation costs are recognized based on their grant date fair value estimated using the Black-Scholes option pricing model. Stock-based compensation expense recognized in the statement of operations is based on options ultimately expected to vest and has been reduced by an estimated forfeiture rate based on our historical and expected forfeiture patterns. We use the straight-line method of allocating compensation cost over the requisite service period of the related award.

Determining the fair value of stock-based awards at the grant date under the Black-Scholes option pricing model requires judgment, including estimating the value per share of our common stock, risk-free interest rate, expected term and dividend yield and volatility. The assumptions used in calculating the fair value of stock-based awards represent our best estimates based on management judgment and subjective future expectations. These estimates involve inherent uncertainties. If any of the assumptions used in the Black-Scholes option pricing model significantly change, stock-based compensation for future awards may differ materially from the awards granted previously.

The expected term of options granted is based on historical experience of similar awards and expectations of future employee behavior. The risk-free interest rate for the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of grant. We have not paid and do not anticipate paying cash dividends on our common stock; therefore, the expected dividend yield is assumed to be zero. We based our estimate of volatility on the estimated volatility of similar companies whose share prices are publicly available. For 2010, we based our estimate on a calculation of equity volatility, which is higher than corresponding asset volatility, because we believed that this better reflected the financing and business risk associated with our company given our early stage of development. Additionally, in 2010 we had little debt financing and a relatively low aggregate liquidation

preference associated with our then outstanding classes of preferred stock. As a result, the impact of our capital structure on the fair value of our common stock was more limited than in subsequent periods. For subsequent periods, we determined than an estimate based on asset volatility was more appropriate for determining the fair value of our stock options because our increased levels of debt and aggregate preferred stock liquidation preference represented a significant hurdle before value would accrue to holders of common stock. This change was driven in large part by the issuance by us of Series D preferred stock and the related liquidation preference associated with such shares. Key assumptions utilized in estimating the fair values of stock-based awards are as follows:

	Year	Ended December	Three Months Ended March 31,			
	2010	2011	2012	2012	2013	
Risk-free interest rates	2.42%-3.14%	2.2%-3.14%	0.85%-1.44%	1.23%-1.44%	1.05%-1.11%	
Expected term (years)	6.25	6.25	6.25	6.25	6.25	
Expected dividend yield						
Volatility	92.4%	73.0%	54.0%-61.0%	61.0%	58.0%	

The weighted-average grant date fair value per share of employee stock options granted during 2010, 2011 and 2012 was \$1.74, \$1.83 and \$1.59, respectively. The weighted-average grant date fair value per share of employee stock options granted during the three months ended March 31, 2012 and 2013 was \$1.35 and \$4.23, respectively. The total compensation cost related to unvested stock option grants not yet recognized as of March 31, 2013 was \$2.8 million, and the weighted-average period over which these grants are expected to vest is three years. The total fair value of options vested during 2010, 2011 and 2012 was \$0.1 million, \$0.2 million, and \$0.7 million, respectively. The total fair value of options vested during the three months ended March 31, 2012 and 2013 was \$0.3 million and \$0.2 million, respectively.

#### **Inventory Valuation**

Inventory consists of raw materials, certain component parts to be used in manufacturing our products and finished goods. Inventory is stated at the lower of cost or market. Cost is determined using a standard cost system, whereby the standard costs are updated periodically to reflect current costs and market represents the lower of replacement cost or estimated net realizable value. We record adjustments to inventory for potentially excess, obsolete, slow-moving or impaired items. The business environment in which we operate is subject to rapid changes in technology and customer demand. We regularly review inventory for excess and obsolete products and components, taking into account product life cycle and development plans, product expiration and quality issues, historical experience and our current inventory levels. If actual market conditions are less favorable than anticipated, additional inventory adjustments could be required.

#### Fair Value Measurements

We record preferred stock warrant liability at fair value. We establish fair value using the price that would be received to sell an asset or paid to transfer a financial liability in an orderly transaction between market participants at the measurement date. A fair value hierarchy is used to measure fair value. The three levels of the fair value hierarchy are as follows:

- Level 1 Quoted prices in active markets for identical assets and liabilities.
- Level 2 Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.
- Level 3 Valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

Whenever possible, we use observable market data and rely on unobservable inputs only when observable market data are not available. Preferred stock warrant liability is categorized as Level 3 because it was valued based on unobservable inputs and our judgment due to the absence of quoted market prices, inherent lack of liquidity and

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the long-term nature of such financial instruments. We perform a fair value assessment of the preferred stock warrant inputs on a quarterly basis using the Black-Scholes option pricing model. The assumptions used in the Black-Scholes option pricing model are inherently subjective and involve significant judgment. Changes in our judgments could have a material impact on our results of operations and financial position. Any change in fair value is recognized as a component of other income (expense) on the statements of operations.

#### Income Taxes

We use the liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to the differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to be in effect when such assets and liabilities are recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the year that includes the enactment date. We determine deferred tax assets including net operating losses and liabilities, based on temporary differences between the book and tax bases of assets and liabilities. We believe that it is currently more likely than not that our deferred tax assets will not be realized, and as such, a full valuation allowance is required.

We utilize a two-step approach for evaluating uncertain tax positions. Step one, recognition, requires us to determine if the weight of available evidence indicates that a tax position is more likely than not to be sustained upon audit, including resolution of related appeals or litigation processes, if any. If a tax position is not considered more likely than not to be sustained, no benefits of the position are recognized. If we determine that a position is more likely than not to be sustained, then we proceed to step two, measurement, which is based on the largest amount of benefit which is more likely than not to be realized on effective settlement. This process involves estimating our actual current tax exposure, including assessing the risks associated with tax audits, together with assessing temporary differences resulting from the different treatment of items for tax and financial reporting purposes. If actual results differ from our estimates, our net operating loss and credit carryforwards could be materially impacted.

At December 31, 2012, we had federal net operating loss carryforwards, or NOLs, of approximately \$62.2 million and federal research and experimentation credit carryforwards of approximately \$1.0 million, which may be used to reduce future taxable income or offset income taxes due. These NOLs and credit carryforwards expire beginning in 2023 through 2032.

Our realization of the benefits of the NOLs and credit carryforwards is dependent on sufficient taxable income in future fiscal years. We have established a valuation allowance against the carrying value of our deferred tax assets, as it is not currently more likely than not that we will be able to realize these deferred tax assets. In addition, utilization of NOLs and credits to offset future income subject to taxes may be subject to substantial annual limitations due to the change in ownership provisions of the Internal Revenue Code of 1986, or the Code, and similar state provisions. We may have already experienced one or more ownership changes. Depending on the timing of any future utilization of our carryforwards, we may be limited as to the amount that can be utilized each year as a result of such previous ownership changes. However, we do not believe such limitations will cause our NOL and credit carryforwards to expire unutilized. We are in the process of determining whether this offering would constitute an ownership change resulting in further limitations on our ability to use our net operating loss and tax credit carryforwards. If an ownership change is deemed to have occurred as a result of this offering, potential near term utilization of these assets could be reduced.

We do not anticipate that the amount of our existing unrecognized tax benefits will significantly increase or decrease within the next 12 months. Due to the presence of NOLs in most jurisdictions, our tax years remain open for examination by taxing authorities back to the inception of the company.

## **Recent Accounting Pronouncements**

We have reviewed recent accounting pronouncements and concluded that they are either not applicable to our business or that no material effect is expected on the consolidated financial statements as a result of future adoption.

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As an emerging growth company the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies.

### **Off-Balance Sheet Arrangements**

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or for any other contractually narrow or limited purpose.

#### Inflation

We do not believe that inflation has had a material effect on our business, financial condition or results of operations. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases. Our inability or failure to do so could adversely affect our business, financial condition and results of operations.

#### Quantitative and Qualitative Disclosures about Market Risk

We are exposed to various market risks, including changes in commodity prices and interest rates. Market risk is the potential loss arising from adverse changes in market rates and prices. Prices for our products are denominated in U.S. dollars and, as a result, we do not face significant risk with respect to foreign currency exchange rates.

### Interest Rate Risk

The principal market risk we face is interest rate risk. We had cash and cash equivalents of \$11.8 million as of March 31, 2013, which consisted of highly-liquid investments with an original maturity of three months or less. The goals of our investment policy are liquidity and capital preservation; we do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short term nature of our cash and cash equivalents. Declines in interest rates, however, would reduce future investment income. A 1% decline in interest rates, occurring on April 1, 2013 and sustained throughout the period ended March 31, 2014, would not be material.

As of March 31, 2013, the principal and accrued interest outstanding under our term borrowings was \$13.2 million. The interest rates on our term borrowings under our credit facility are fixed. If overall interest rates had increased by 10% during the periods presented, our interest expense would not have been affected.

## Foreign Currency Exchange Risk

As we expand internationally our results of operations and cash flows will become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Historically, a majority of our revenue has been denominated in U.S. dollars, although we sell our products and services in local currency outside of the United States, principally the Euro. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States. The effect of a 10% adverse change in exchange rates on foreign denominated cash, receivables and payables would not have been material for the periods presented. As our operations in countries outside of the United States grow, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. To date, we have not entered into any material foreign currency hedging contracts although we may do so in the future.

#### BUSINESS

#### Overview

We develop, manufacture and sell robust, intuitive products that unlock scientifically valuable and clinically actionable genomic information from minute amounts of tissue. Our nCounter Analysis System directly profiles hundreds of molecules simultaneously using a novel barcoding technology that is powerful enough for use in research, yet simple enough for use in clinical laboratories worldwide. We market systems and related consumables to researchers in academic, government, and biopharmaceutical laboratories for use in understanding fundamental biology and the molecular basis of disease. We have an installed base of more than 140 systems, which our customers have used to publish more than 220 peer-reviewed papers. As researchers discover how genomic information can be used to improve clinical decision-making, we seek to selectively translate their discoveries into molecular diagnostic products. In September 2012, we received European Union regulatory clearance for our first molecular diagnostic product, the Prosigna Breast Cancer Assay, or Prosigna, an assay providing an assessment of a patient s risk of recurrence for breast cancer and the intrinsic subtype of the patient s tumor. In February 2013, we commercially launched Prosigna in Europe and Israel. In December 2012, we submitted an application, known as a 510(k), to the FDA seeking clearance in the United States for a version of Prosigna providing an assessment of a patient s risk of recurrence for breast cancer.

The role of genomic information in research and medical practice is evolving rapidly. The advent of new technologies that sequence and digitally count discrete nucleic acids, commonly referred to as next generation sequencing, or NGS, is accelerating the discovery of the relationships between the genome and human disease. Researchers are applying this wealth of new information to identify biological pathways, which are networks of tens or hundreds of genes that act in concert to produce biological functions. Researchers then seek to translate this understanding of the genomic basis of disease into the development of diagnostic tools that can be used to profile an individual patient s biological pathways as well as develop targeted drug therapies. Precise, simple and robust profiling of biological pathways presents both an analytical challenge for researchers and an opportunity to improve patient outcomes in the future.

Our nCounter Analysis System enables research on a scale appropriate for pathway-based biology by digitally quantifying the activity of up to 800 genes simultaneously in a single experiment. The sensitivity and precision of our novel barcoding chemistry allows researchers to measure subtle changes in genomic activity efficiently, which is essential because tissue samples are often available only in very small quantities. This problem is especially acute in cancer research, which is typically conducted using biopsies that are often stored in a format known as formalin-fixed paraffin embedded, or FFPE, which complicates subsequent analysis of genetic material. The nCounter Analysis System is an easy-to-use and flexible solution that allows researchers to efficiently test hypotheses across thousands of different samples. As a result, the nCounter Analysis System is particularly useful for discovering and validating networks of genes that characterize and help predict disease states, enabling the development of diagnostics and medicines designed specifically for treating patients with certain genomic profiles. When researchers succeed in these endeavors, our strategy is to selectively partner with them to translate their discoveries into clinically valuable molecular diagnostic applications.

Prosigna, our first molecular diagnostic test, is based on a collection of 50 genes known as the PAM50 gene signature, which was discovered by several of our life sciences customers. We secured an exclusive worldwide license to the PAM50 gene signature in 2010. Prosigna can provide a breast cancer patient and her physician with a subtype classification based on the fundamental biology of the patient stumor, as well as a prognostic score that predicts the probability of cancer recurrence over 10 years. Our goal is for physicians to use Prosigna to guide therapeutic decisions so that patients receive only therapeutic interventions from which they are likely to benefit. In 2011, we conducted a clinical study, which we refer to as our TransATAC study, based on material extracted from tumor samples of more than 1,000 evaluable patients from the ATAC study. In our study, investigators performed Prosigna on these samples that had been previously analyzed using Genomic Health s Oncotype DX, the historical market leader in breast cancer recurrence testing. The results of our TransATAC study demonstrated the ability of Prosigna to indicate risk of recurrence in postmenopausal women with hormone results of this study and multi-site analytical validation studies, we received European Union, or EU, regulatory clearance for Prosigna, known as a CE mark. As part of our preparation for regulatory submission in the United

States, we conducted a second clinical study, which we refer to as our ABCSG8 study, based on tumor samples of more than 1,400 evaluable patients from the Austrian Breast & Colorectal Cancer Study Group 8. Our ABCSG8 study confirmed the conclusion that Prosigna can indicate risk of recurrence as previously demonstrated in our TransATAC study. In December 2012, we submitted an application, known as a 510(k), to the FDA seeking clearance in the United States for a version of Prosigna providing an assessment of a patient s risk of recurrence for breast cancer. In March 2013, we received a written response from the FDA requesting additional information for its review of our 510(k) submission. A request for additional information is common following an initial 510(k) submission. In May 2013, we submitted an initial response to the FDA s request for additional information and met with the FDA to discuss our response. In this meeting, we discussed, among other issues raised by the FDA, the specific elements and format of a potential report generated by Prosigna, including the appropriate name for the risk score, the appropriate graphic presentation of the risk score, and, specifically for the potential report for node-positive patients, the numerical range of the risk score and the appropriate number of risk groups. If the FDA clears Prosigna, we intend to launch Prosigna in the United States promptly following receipt of such clearance. We are currently planning for this commercial launch in the first quarter of 2014. We plan to conduct future clinical studies to evaluate Prosigna s ability to guide physicians and patients in making additional treatment decisions, including the selection of the appropriate chemotherapy regimen and whether to use adjuvant radiation therapy, and, if such studies are successfully completed, to seek 510(k) clearance or PMA approval for such indications in the future.

Prosigna will be regulated as an *in vitro* diagnostic test and we intend to distribute it as a kit for use on our nCounter Analysis System in clinical laboratories after regulatory authorizations are obtained. We expect that our future diagnostic products will be regulated and distributed in a similar manner. This is in contrast to most complex genomic tests, which are currently regulated as services and are usually offered only by a limited number of specialized laboratories. The current centralized laboratory model for complex genomic testing can result in complicated logistics for the treating physician, including slower test result turnaround times and limited international access to tests as compared to local testing. In addition, most clinical laboratories cannot currently share in the revenue associated with offering patients complex genomic tests. We believe that our decentralized model will transform the current paradigm of complex genomic testing by allowing physicians worldwide to provide more comprehensive personalized diagnoses, broadening patient access, and increasing the degree to which clinical laboratories can profit by providing molecular diagnostic testing services.

We generated revenue of \$11.7 million, \$17.8 million and \$23.0 million in 2010, 2011 and 2012, respectively, and \$5.7 million in the three months ended March 31, 2013, while incurring net losses of \$12.8 million, \$10.9 million and \$17.7 million in 2010, 2011 and 2012, respectively, and \$7.3 million in the three months ended March 31, 2013.

### **Our Market Opportunity**

Every living organism has a genome that contains the full set of biological instructions required to build and maintain life. By analyzing the variations in genomes, genes and gene activity in and between organisms, researchers can determine their functions and roles in health and disease. An improved understanding of the genome and its functions allows researchers to drive advancements in scientific discovery. As they make scientific discoveries, researchers have been able to translate some of these findings into clinical applications that improve patient care.

A gene is a specific set of instructions embedded in the DNA of a cell. For a gene to be turned on, or expressed, the cell must first transcribe a copy of its DNA sequence into molecules of messenger RNA. Then, the cell translates the expressed information contained in the RNA into proteins that control most biological processes. In addition to the translated RNAs, there are many types of non-coding RNAs that are involved in many cellular processes and the control of gene expression, including microRNA, or miRNA, and long noncoding RNA, or lncRNA.

Biological pathways are the networks of tens or hundreds of genes that work in concert to produce a biological function. Understanding the activation state of pathways and disruptions in individual elements of these pathways provides significant insight into the fundamental basis of disease and facilitates data driven treatment decisions. Therapeutic interventions, such as drugs, can be used to treat disease by activating or

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inactivating biological pathways that are relevant to disease. As a result, pathway-based biology has become a widely adopted paradigm that researchers use to understand biological processes and has assisted them in the development of diagnostics and drugs to treat disease. To be successful in their research, these scientists need the ability to precisely and simultaneously measure the activation state of the tens or hundreds of genes that comprise biological pathways.

Over the last decade, methods of measuring genomic information have advanced substantially. However pathway-based research and the development of diagnostic tests require analysis of multiple genes and sensitivity to small changes in expression, which can be challenging for traditional genomic tools. In general DNA microarrays and tube-based qPCR methods, require complex, time consuming workflows and relatively large amounts of sample tissue to accurately characterize biological pathway activation. In both life sciences research and clinical medicine, there is a growing need for improved technologies that can precisely and rapidly measure the activation state of hundreds of genes simultaneously across a large number of precious samples, thereby providing a simple and reliable means to characterize biological pathways within minute tissue specimens.

## **Existing Technologies**

#### Microarrays

Microarrays are tools used to measure gene expression based on the relative brightness of a fluorescent dot on a glass, silicon or other semiconductor surface. Microarrays are sometimes referred to as an analog technology because an indirect measurement of the brightness level, rather than a direct measurement of the molecule, is used to infer the level of gene expression. Traditional microarrays are capable of cost effectively analyzing a large number of targets on a small number of samples, however they have limited sensitivity, precision and dynamic range. In addition, the relatively low throughput and complex workflows of microarrays makes them challenging to use in diagnostic applications.

### Next Generation Sequencing

Next generation sequencing, or NGS, is a technology that rapidly sequences nucleic acids, and then uses a computationally intense process to count discrete copies of each nucleic acid. While the primary application of this technology is to decode the sequence of DNA, researchers can also use NGS to quantify gene expression using an application called RNA sequencing, or RNA-Seq, which counts the number of times a specific gene sequence is detected in a sample. This is referred to as a digital technology because it relies on a direct count of molecules, rather than an indirect analog measurement of the level of gene expression. This digital gene expression analysis technology can provide higher sensitivity, precision, and dynamic range than traditional analog gene expression tools, such as microarrays. As a result, RNA-Seq is replacing microarrays as the platform of choice for genome-wide expression analysis in research. In recent years, many innovations have been made to improve the precision, workflow and automation of these systems. However, RNA-Seq is not well suited for diagnostic use in most clinical laboratories due to its complexity, computational intensity, limited throughput and need for expert technicians. In addition, it is challenging to perform RNA-Seq analyses with small amounts of tissue, especially FFPE samples, which is a limiting factor in large scale studies and many clinical applications.

## Real-time or Quantitative Polymerase Chain Reaction

Quantitative polymerase chain reaction, or qPCR, is a technique that can measure gene expression usually on a single target in a particular cell or tissue. First, an enzyme is used to create a complementary DNA, or cDNA, of the RNA target to be measured. Then polymerase chain reaction, or PCR, is used to amplify the cDNA copy through the use of enzymes and repeated heating and cooling cycles, with fluorescent dyes being incorporated during each amplification cycle. Finally, the expression of the gene of interest is inferred based on the number of amplification cycles required for the fluorescent amplified target to become detectable. qPCR is sometimes referred to as an analog technology because the number of cycles of amplification, rather than a direct measure, is used to infer the level of gene expression. The wide availability of qPCR chemistry makes it a popular approach for measuring the expression of a single gene but expanding this method to the analysis of

multiple hundreds of genes requires complex liquid handling automation and process optimization. Recently, researchers have used microfluidic approaches that divide samples across multiple parallel qPCR reactions, each measuring a single gene, in order to profile multiple genes in parallel. This approach requires additional liquid-handling steps and can result in less efficient use of tissue samples. Finally, the use of enzymes in numerous cycles of amplification can introduce distortion and bias into the data, depending on the process controls and expertise of the person conducting the experiment.

## Life Sciences Research

According to Strategic Directions International, Inc., life sciences researchers spent approximately \$28 billion on tools and related consumables in 2011. In the decade since the completion of the Human Genome Project, improvements in NGS technology have greatly reduced the cost of sequencing a human genome and increased throughput and precision, which has led to an abundance of new biological information. In order to gather insights from this information, researchers must first distill and then efficiently analyze large pools of data. Gene expression analysis has emerged as a primary tool that researchers use to extract meaningful insights from networks of genes, which enables them to validate and then translate their findings into the development of diagnostics and medicines. According to Percepta Associates, a provider of consulting services to bioscience companies, the 2012 global market for gene expression profiling products is estimated to be \$1.2 billion.

Academic, government, and biopharmaceutical researchers engaged in gene expression analysis typically focus on making biological discoveries that may lead to the development of relevant medical products and better informed treatment decisions for physicians and patients. They have traditionally performed these experiments using microarrays or qPCR. Recently, RNA-Seq has dramatically enhanced researchers—ability to discover patterns of gene expression that have biological meaning. However, researchers are increasingly performing analyses on a larger number of genes and samples and are seeking new methods of interrogation that would allow them to:

increase the number of genes that can be analyzed simultaneously in order to understand the complete biological pathway involving multiple genes;

improve the overall efficiency of their laboratories by simplifying workflow and accelerating the rate of successfully completing their research;

provide more reliable, precise and reproducible data about targeted genes and biological pathways;

maximize the amount of genomic information extracted from precious tissue samples;

minimize the computational intensity of complex genomic analysis;

process difficult-to-work-with specimens, such as tumor biopsies stored in FFPE format; and

create more systematic and reliable ways to help transition their research discoveries into future clinical products.

We believe that the above items create an opportunity for technologies that are optimized for pathway-based biology. Based on 2011 market data regarding the installed base of microarray systems at that technology s peak, we estimate that the potential market opportunity of our current generation of nCounter Analysis System is approximately 3,000 systems.

#### Molecular Diagnostics

As researchers have discovered links between specific genomic variants and diseases, their discoveries have led to the development of genome-based diagnostics that have the potential to inform therapeutic interventions, predict the risk or onset of disease and detect residual disease on an individualized basis. As a result, these molecular diagnostic tests have made individualized treatment possible and have an

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increasingly important influence on decisions that physicians and patients make regarding treatment and care.

According to Frost and Sullivan, the molecular diagnostics market totaled approximately \$4.1 billion in 2010 and is expected to reach \$6.2 billion by 2014. Growth in the molecular diagnostics market has been driven

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by technological innovations that have increased sensitivity, decreased turnaround times, simplified workflow, and lowered costs when compared to other techniques. In addition, the medical community has seen a trend in favor of decentralized diagnostic testing as a result of the convenience of local testing, hospitals and medical centers increasingly viewing their laboratories as profit centers and a need to increase access to tests for patients outside of the United States. We believe that there is an opportunity to improve the quality of diagnosis and treatment of diseases by developing and commercializing comprehensive, simple and widely available diagnostic products based on gene expression analysis.

Cancer is a disease generally caused by genetic mutations in cells. The behavior of cancer cells is extremely complex, depending on many different genes and the interactions of those genes. It is often impossible for researchers to identify a single gene that adequately signals a more aggressive or less aggressive type of cancer. However, in some cases, researchers have been able to identify more aggressive or less aggressive types of cancer through gene expression analysis of biological pathways. Multi-gene expression analysis has the potential to considerably improve the decisions of oncologists as they care for their patients. Based on the pattern of gene expression, oncologists can determine which specific treatments are most likely to be effective for an individual patient, monitor a patient s response to those treatments, and determine the likelihood of recurrence.

Enhanced understanding of the genomic basis of disease has driven the development of molecular diagnostics for a number of indications. This trend is exemplified by the development of multi-gene tests for breast cancer. Over the last decade, genomic tests for breast cancer have improved the accuracy of prognosis and efficacy of treatment by providing risk assessments particular to individual patients. As a result of individualized risk profiling, thousands of patients have been spared unnecessary treatment while many others have been placed on more appropriate treatment regimens.

These multi-gene breast cancer tests are widely available in the United States, but are not generally available in other countries, despite the fact that the United States accounts for less than 15% of the global annual breast cancer incidence. The following provides a summary of the incidence of breast cancer worldwide in 2008 based on data published by the World Health Organization:

Multi-gene molecular diagnostic tests for breast cancer are provided by several companies today, including Genomic Health, Agendia and Clarient (a GE Healthcare company). These tests are offered as services with the analysis conducted at company-owned centralized laboratories. When a physician orders the test, the pathologist

(1) Ferlay J, Shin HR, Bray F, Forman D, Mathers C and Parkin DM. GLOBOCAN 2008 v2.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 10 [Internet]. Lyon, France: International Agency for Research on Cancer; 2010. Available from: http://globocan.iarc.fr, accessed on 03/11/2012.

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sends a tumor block or thin sections from the biopsy specimen to the centralized laboratory for analysis. The lab operator then uses a multi-gene panel to determine a risk category for each patient, which predicts that individual s likelihood of recurrence. The lab operator typically analyzes the tumor tissue and delivers results to the treating physician within 10 to 14 days of receipt of the tumor sample.

Despite their positive impact on patient care, existing molecular diagnostic tests for breast cancer available prior to Prosigna, which we call first-generation tests, have several limitations, including:

High Frequency of Intermediate Risk Results. The first-generation tests generally sort patients into two or three risk categories, such as high/intermediate/low risk. In clinical practice, patients who are low risk are generally spared chemotherapy and patients who are high risk generally receive chemotherapy. In contrast, there is no standard of care for how intermediate risk patients should be treated. The ambiguity of treatment and outcomes associated with an intermediate risk score is challenging for physicians and unsettling for patients.

Available Exclusively from Specialized Laboratories. The first-generation tests are based on techniques such as qPCR, microarrays or multiplexed immunohistochemistry and are generally administered by highly-skilled technicians usually working in centralized laboratories. This centralized model may result in complicated logistics for the treating physician, including slow test result turnaround times, added shipping and logistics costs and limited international access to tests. In addition, the economic value of providing the centralized genomic tests that improve clinical decision-making has been captured by a small number of specialized laboratories. Most clinical laboratories are unable to perform or profit from these tests. In addition, because most of the specialized laboratories are in the United States, patients living outside of the United States may be challenged to gain access to these genomic tests.

Unclear Utility in Other Treatment Decisions. The first-generation tests were specifically designed to provide a physician with an understanding of the residual risk of recurrence for patients receiving hormonal therapy, thereby informing the physician s decision whether to also administer adjuvant chemotherapy. The genes included in the first-generation tests were selected primarily, and in many cases exclusively, based on the correlation of their expression with the risk of cancer recurrence in such patients. It remains unclear as to whether the specific genes included in these first-generation tests will be able to inform other important treatment decisions, such as the selection of specific adjuvant chemotherapy regimens, the duration of adjuvant endocrine therapy, or the decision of whether to administer adjuvant radiation therapy.

In contrast to the central laboratory-based first-generation molecular diagnostic test for breast cancer, the medical community has seen a trend in favor of decentralized diagnostic testing. Tests for HIV, Hepatitis C, Influenza and MRSA, which were once centralized, are now often conducted in hospital laboratories or at the point of care. We believe that this trend of decentralized testing will continue as a result of many factors, including:

Convenience. We believe that physicians would prefer that molecular diagnostic tests be performed at a local level and in the same laboratory that performs other tests that the physicians may order. Local molecular diagnostic testing could provide physicians the same rapid turnaround of test results that they have learned to expect for other types of tests.

*Economic Advantages.* We believe that hospitals and medical centers desire to make their clinical laboratories profit centers by performing tests and billing third-party payors. As diagnostic technologies become less complicated to administer, hospitals and medical centers tend to favor in-sourcing tests.

*International Availability.* There is a critical need to increase access to molecular diagnostic tests for patients that live outside the United States. Currently, patients living outside the United States may be challenged to gain access to tests that are provided only by specialized laboratories located within the United States. We believe genomic testing will become more available to patients throughout the world when it can be provided by their local clinical laboratories.

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We believe that the market for complex molecular diagnostics will require increased precision, increased breadth of decision making information, and a decentralized approach that is in line with other applications of diagnostic testing.

### **Our Solution**

Our nCounter Analysis System is an automated, multi-application, digital detection and counting system which directly profiles hundreds of molecules simultaneously using a novel barcoding technology that is powerful enough for use in research, yet simple enough for use in clinical laboratories worldwide. Our nCounter Analysis System consists of two automated instruments that prepare and analyze tissue samples using proprietary reagents that we call CodeSets, which can only be obtained from us. Our life sciences research customers purchase instruments from us and then purchase our panels or custom CodeSets and related consumables for the specific experiment they wish to conduct. Beginning with Prosigna, our future diagnostics customers will either purchase or lease instruments from us and also purchase one of our diagnostic kits for each test that they intend to run.

Our nCounter Analysis System offers a number of compelling advantages, including:

Optimized for Pathway-Based Biology. The nCounter Analysis System can profile up to 800 molecules in a single test tube, which allows researchers to analyze interactions among hundreds of genes that mediate biological pathways. In addition, our nCounter Analysis System offers customers the freedom to order panels or custom CodeSets specific to their experiment.

Digital Precision. Our molecular barcodes hybridize directly to the target molecules in a sample allowing them to be counted. This generates digital data (1 molecule = 1 count) of excellent quality over a wide dynamic range of measurements and provides excellent reproducibility.

Simple Workflow. The nCounter Analysis System s minimal sample preparation and automated workflow enable the performance of gene expression analysis across hundreds of genes simultaneously in approximately 24 hours with only approximately 15 minutes of hands-on preparation time. Our nCounter Analysis System generates data that customers can evaluate without the use of complex bioinformatics.

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Flexible Sample Requirements. The nCounter Analysis System is able to unlock genomic information from minute amounts of a variety of challenging tissue samples, including FFPE samples, cell lysates and single cells.

Our nCounter Analysis System supports research and the development of future clinical applications from basic discovery to the development of future molecular diagnostic tests on a single platform. We believe that our nCounter Analysis System is complementary to and synergistic with digital gene expression on next generation sequencers (using RNA-Seq).

Many of our research customers are transitioning their efforts to discover important patterns of gene expression away from the analog technology of microarrays to the digital technology of NGS, using the application RNA-Seq. Often, these customers perform follow-up experiments to validate the results of their RNA-Seq discovery experiments by testing hundreds or thousands of samples. Increasingly, researchers are performing these validation experiments using our nCounter Analysis System, which combines the precision of digital gene expression with the high throughput and simple workflow required to efficiently process large numbers of samples. Because our nCounter Analysis System can directly measure RNA without the use of enzymes or amplification (except for single-cell applications), we believe that researchers view the nCounter Analysis System as providing an independent means of validating that observations made initially using RNA-Seq are real rather than artifacts associated with the complex series of steps necessary for sequencing. In addition, because the operation of our nCounter Analysis System is simple and intuitive, it provides a practical technology enabling the translation of potential biomarkers into diagnostic tests that can be performed in the clinical laboratory, after appropriate regulatory authorization.

The figure below illustrates the current and future uses of and opportunities for digital technology in translational genomics.

#### Life Sciences Research

The nCounter Analysis System enables our life sciences research customers to conduct research on a scale that is well suited for pathway-based biology. The precision, ease of use and flexibility of our nCounter Analysis System allows researchers to efficiently test their hypotheses in thousands of different samples and is particularly useful for identifying networks of genes that characterize and predict disease.

Life Sciences Applications

Our nCounter Analysis System is capable of supporting a number of life sciences applications based upon the measurement of the concentration or amount of a target nucleic acid. Key applications currently supported include:

Gene Expression. Researchers use the nCounter Analysis System to measure the degree to which individual genes in pathways are turned on or off by simultaneously quantifying the amount of messenger RNA, or mRNA, associated with each of up to 800 genes.

Single Cell Gene Expression. Historically, most gene-expression profiling has been performed on populations of cells where observed expression levels represent an average of the unique expression states of each cell within the population. The nCounter Analysis System is capable of measuring gene expression of 20 to 800 genes from a single cell, thereby elucidating previously hidden relationships between individual cells within a population.

miRNA Expression. Researchers can use the nCounter Analysis System to measure the simultaneous expression levels of up to 800 different miRNAs. The nCounter Analysis System is capable of highly multiplexed, direct digital detection and counting of miRNAs in a single reaction without amplification, thereby delivering high levels of sensitivity, specificity, precision, and linearity. We currently enable miRNA experiments for use in tissue from humans, mice, rats, and fruit flies.

Copy Number Variation. Researchers can use the nCounter Analysis System to probe for structural variations that result in cells having an abnormal number of copies of one or more sections of the DNA. Researchers are able to conduct large-scale, statistically-powered studies of these copy number variations, or CNVs, by leveraging the nCounter Analysis System s multiplexing capacity to assay up to 800 DNA regions in a single tube, with as little as 300 ng of DNA.

We also support research directed toward particular gene fusions, gene-expression regulatory elements called long non-coding RNA, or lncRNA, and experiments based on a technique used to investigate the DNA targets of transcription factors called chromatin immunoprecipitation, or ChIP.

Case Studies

Our nCounter Analysis System allows researchers to efficiently probe multiple pathways over large number of samples, quickly generating large data sets. Since 2009, more than 220 peer-reviewed papers have been published by researchers using the nCounter Analysis System, including:

Vanderbilt-Ingram Comprehensive Cancer Center Resistance to Breast Cancer Chemotherapy. Approximately 70% of breast cancer patients do not respond completely to neoadjuvant chemotherapy. The goal of this study was to discover the genomic causes of chemotherapy resistance in breast cancer. Researchers designed a 355 gene CodeSet to probe biological pathways that had been associated with chemotherapy resistance in previous studies, and used the nCounter Analysis System to test formalin-fixed paraffin-embedded, or FFPE, tumor biopsies from 49 patients who had been previously treated with neoadjuvant chemotherapy. The data and analysis from this study made specific predictions concerning the mechanism of chemotherapy resistance in breast cancer, and resolved potentially prognostic biomarkers. The results suggest that patients with residual disease following neoadjuvant chemotherapy may benefit from receiving a drug targeted to inhibit a specific biological target, the tyrosine-threonine kinase known as MEK. This study was published in Nature Medicine Online in June 2012.

Pfizer Oncology and Drug Safety Drug Mechanism-of-Action Testing and Biomarker Discovery. The goal of this study was to use a mouse model of human cancer, known as a xenograft, to help establish the mechanism-of-action for a potential breast cancer therapeutic in preclinical development, and to discover biomarkers for enrolling clinical studies. The researchers designed a custom CodeSet targeting 40 genes in the Notch signaling pathway, including receptors, ligands, and regulators. The researchers used the nCounter Analysis System to test tumor samples from 18 xenograft models, of which 10 had shown significant response to the potential therapeutic. The researchers found that the Notch pathway target gene expression correlated with the antitumor efficacy and can potentially serve as biomarkers for proof-of-mechanism and patient enrichment. This study was published in Clinical Cancer Research in July 2012.

The Broad Institute of Harvard and MIT Rapid Identification of Pathogens and Antibiotic Susceptibilities. The goal of this study was to provide proof-of-principle for using RNA transcript signatures to rapidly assess pathogens and antibiotic susceptibilities from a variety of difficult sample types, including blood and urine. This study explored an approach using mRNA detection because mRNA detection allows both genotypic and phenotypic organism response information to be obtained. Making extensive use of pathway-based biology and public-domain gene expression databases, the researchers designed a CodeSet containing approximately 110 gene targets covering different bacteria, viruses, fungi, and parasites. The nCounter Analysis System was then used to successfully screen for a broad spectrum of infectious agents in tissue samples. In addition, the bacterial mRNA response to a brief antibiotic pulse was demonstrated to rapidly differentiate drug-susceptible and drug-resistant organisms using blood and urine samples. The authors concluded from this work that transcriptional signatures could provide a standard approach applicable across a broad range of infectious diseases. This study was published in April 2012 in Proceedings of the National Academy of Sciences.

Memorial Sloan-Kettering Cancer Center Identification of Potential Drug Targets in Lung Cancer. The goal of this study was to discover potential therapeutic targets in lung cancer based on genomic aberrations called fusions in the genes coding for tyrosine kinase proteins. The researchers designed a CodeSet that simultaneously probed 93 kinases at both ends of the mRNA transcript. The researchers then scanned 69 frozen lung adenocarcinomas tumor samples for novel tyrosine kinase fusions by looking for those transcripts showing significantly fewer probes at one end of the transcript. Two novel fusion transcripts were found. One of these, the KIF5B-RET fusion, defines an additional subset of lung cancer that can now be targeted for potential therapeutic development. This work appeared in Clinical Cancer Research in October 2012.

Comprehensive Cancer Center of Ohio State University MicroRNAs and Cancer. The goal of this study was to understand the role of miRNA in the development and progression of a form of brain cancer known as glioblastoma multiforme, or GBM. Researchers used our Human miRNA Expression Assay panel, which simultaneously probes over 700 human and human-viral miRNAs, to scan for differences in miRNA expression between GBM cells in the presence or absence of P53 induction via Nutlin-3a. The researchers found that induction of P53 resulted in the repression of 17 miRNAs. The authors concluded that a combination of Nutlin-3a and two particular miRNAs, miR-25 and miR-32, may provide a route to therapeutic miRNA intervention in cancer. This study was published in April 2012 in Proceedings of the National Academy of Sciences.

Our customers have used the nCounter Analysis System to publish more than 220 peer-reviewed papers. In 2012 alone, our customers published more than 100 peer-reviewed papers incorporating data generated using the nCounter Analysis System. Approximately 30% of the 2012 papers were published in high-impact<sup>(1)</sup> journals that are most widely cited in the research community. The most frequent topic of nCounter-based peer-reviewed publications is cancer research, including biomarker discovery and validation. Other frequent topics include immunology and inflammation, infectious disease and developmental and cell biology.

(1) Science, Nature, Cell, PNAS, or affiliated scientific journals with a SCImago Journal Rank indicator of 5.0 or greater. SCImago. (2007). SJR SCImago Journal & Country Rank. Retrieved March 12, 2013, from http://www.scimagojr.com.

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#### Consumables

Following their purchase of our nCounter Analysis System, our life sciences research customers purchase consumables from us consisting of CodeSets and other consumables that are designed for the specific experiment that they intend to run. Our instruments are designed to be used only with our consumables. This closed system model generates recurring revenue from each instrument we sell. We believe that our recurring consumable revenue is driven by our customers—ability to extract value from up to 800 data points per sample and to process hundreds of samples in a relatively short period of time with little hands-on preparation using our nCounter Analysis System, enabling them to process more units of consumables per unit of time.

#### **Molecular Diagnostics**

We believe that the attributes that make the nCounter Analysis System attractive to researchers also have the potential to make the system attractive to hospitals and clinical laboratories that desire to conduct molecular diagnostic tests. Once approved for a particular diagnostic test, the precision, ease of use and flexibility of the nCounter Analysis System will allow medical technicians in pathology labs to conduct complex molecular diagnostic tests with minimal training.

Prosigna is designed to address the limitations of first-generation tests, including:

Fewer Intermediate Risk Patients in Node-Negative Disease. In our TransATAC study, Prosigna was performed on material extracted from tumor samples from more than 1,000 evaluable patients that were previously analyzed using Genomic Health's Oncotype DX, a widely-used first-generation test that is offered as a laboratory-developed test. Each patient in the study was assigned to a risk group based on risk estimates generated separately by Prosigna and Oncotype DX, and using prospectively defined risk cutoffs. Cutoffs for low, intermediate and high were <10%, 10% to 20% and >20% estimated risk of recurrence, respectively. In a comparison of the sizes of the risk groups in patients with node-negative disease, Prosigna assigned 26% fewer patients to an intermediate score than Oncotype DX. The reduction in the size of the intermediate risk group in node-negative patients is a result primarily of Prosigna's ability to reclassify patients that are classified by Oncotype DX as intermediate risk to high risk. We believe this study provides evidence of Prosigna's potential ability to clarify treatment decisions.

Available on a Decentralized Basis. Prosigna will be available for use on the nCounter Analysis System on a distributed basis in the clinical laboratories of hospitals and medical centers worldwide, which aligns Prosigna with the evolving trend towards decentralized testing. We believe that by distributing molecular diagnostics to local labs, we will provide faster turnaround for patients and enable succinct, comprehensive reports from pathologists, resulting in enhanced patient care. We also believe that this model will increase the degree to which clinical laboratories can profit by providing molecular diagnostic testing services. In addition, our decentralized model can help address the needs of patients outside of the United States by enabling local laboratories to provide testing.

Potentially More Treatment Decisions. Prosigna measures the expression of up to 50 genes, providing a more detailed profile of the biology of a patient s tumor than the first-generation tests. In addition, Prosigna utilizes the concept of intrinsic subtypes, a fundamental method of classifying breast tumors into the four distinct subtypes of that disease. By providing a more detailed view of tumor biology and determining the intrinsic subtype of breast cancer patients, Prosigna has the potential to inform not only the decision of whether to administer adjuvant chemotherapy, but also potentially inform other important treatment decisions. These decisions may include the selection of specific adjuvant chemotherapy for individual patients, the duration of adjuvant endocrine therapy, and the use of adjuvant radiation therapy. We intend to perform clinical studies validating Prosigna s ability to inform additional treatment decisions, and to seek a PMA to enable Prosigna to report these intrinsic subtypes for use in informing clinical decisions within the United States.

We believe that the strengths of our diagnostics platform, which will enable us to commercialize Prosigna on a decentralized basis, could be applied to other cancers after securing the requisite regulatory authorizations. Over time, we intend to identify other tests and develop them for use on our nCounter Analysis System.

## **Our Strategy**

Our goal is to provide products that empower scientists to understand the molecular basis of disease and empower physicians to put genomic medicine into practice. To accomplish this goal, we intend to continue providing technologies that are powerful enough for research, yet simple and robust enough for use in clinical laboratories worldwide.

Our strategy includes the following key elements:

Establish the nCounter Analysis System as the Global Standard for Gene Expression Analysis. We will promote the power of pathway-based biology and the benefits of digitally-quantified gene expression. One element of this strategy is to recognize and publicize the breadth of scientific achievements and peer-reviewed publications in top-tier journals based on our nCounter Analysis System. Since 2009, more than 220 peer-reviewed papers have been published by researchers using the nCounter Analysis System. We plan to also highlight successful examples of using the nCounter Analysis System to translate research discoveries into diagnostic tests, beginning with Prosigna as well as future examples as they emerge.

Expand the Installed Base of the nCounter Analysis Systems in Biopharmaceutical and Academic Research. We will continue to engage with researchers through direct sales efforts in North America and Europe, increasing the installed base of our nCounter Analysis Systems. We will target translational researchers in genome centers, academic medical centers and biopharmaceutical companies. We will continue to focus primarily on cancer researchers, because these researchers recognize the significant value of our technology when analyzing small biopsy samples stored in challenging formats such as FFPE. We also intend to expand our existing geographic reach, both directly and through distributors.

Broaden the Addressable Market of the nCounter Analysis System through Continued Innovation. We will continue to invest in product development efforts that increase the capabilities of our nCounter Analysis System and expand the universe of potential customers. We expect that these investments will lead to additional protocols, enhanced chemistries, and new generations of instruments and software. We will prioritize innovations that increase the flexibility of the nCounter Analysis System to process small and degraded samples, and increase the ease and speed with which users can select target genes and design CodeSets for their particular experimental needs. We will also prioritize innovations that are expected to reduce the cost and footprint of the nCounter Analysis System, which will help us to target a broader range of customers.

Build a Menu of Proprietary Diagnostics in Collaboration with Researchers. We intend to continue cultivating relationships with leading researchers who are working to establish the connection between genomics and clinical decision-making, many of whom are already using the nCounter Analysis System today in their translational research. When these researchers invent new diagnostic methods, we intend to selectively gain exclusive access to these clinically valuable gene signatures through licensing and collaboration arrangements. For example, the intellectual property that forms the basis of Prosigna was in-licensed from Bioclassifier, LLC, which was founded by several of our life sciences research customers. In addition, in February 2013, we secured an option from The Broad Institute to acquire an exclusive worldwide license for a gene signature that could be used, after appropriate regulatory authorization, for a second molecular diagnostic product focused on hepatocellular carcinoma, or HCC. We will seek to enter into similar arrangements with our life sciences research customers and other researchers for future diagnostic gene signatures. Our strategy is to target intellectual property rights to potential diagnostic methods that are well understood, have the potential to facilitate changes in treatment with a major impact on outcome and cost, have the potential to support value-based pricing, and for which tissue samples for clinical validation are readily available. This disciplined approach is designed to efficiently focus our research and development investment on the development of potential products, rather than discovery of new gene signatures. Our initial focus will be on cancer gene signatures with the goal to individualize major treatment decisions so that patients are more likely to receive only those interventions from which they are likely to benefit.

Execute High Quality Clinical Studies to Support Regulatory Authorizations, Market Adoption and Reimbursement of Diagnostic Products. For each diagnostic product we intend to develop, we plan to design

and execute clinical programs that achieve high standards of clinical evidence. Whenever possible, these programs will be designed to achieve Level 1 clinical evidence, the standard generally required for inclusion in clinical practice guidelines. We will take advantage of tissue samples and outcomes from past controlled randomized clinical studies wherever possible. This strategy has been demonstrated in the first two studies for Prosigna where we were able to access the tissue and outcome information from breast cancer drug trials that totaled more than 2,400 evaluable patients.

Enable Clinical Laboratories Worldwide to Provide Complex Genomic Testing Using Our In Vitro Diagnostic Products. We intend to offer diagnostic tests to clinical laboratories worldwide by distributing a menu of nCounter Analysis System-based *in vitro* diagnostic kits. Our strategy is to drive improved and more efficient clinical decisions while allowing laboratories to profit from the valuable testing services enabled by our technology. By providing the nCounter Analysis Systems to labs that already conduct most of the diagnostic testing and control access to tissue samples, we intend to we enable pathologists and labs to provide advanced genomic testing that previously required the shipment of tissue samples to a centralized lab.

Drive Physician Demand for nCounter Analysis System-Based Diagnostic Products. We will continue to establish a commercial organization that will seek to both build an installed base of nCounter Analysis Systems in clinical laboratories in regions where we have secured the necessary regulatory authorizations, and drive orders for nCounter Analysis System-based diagnostic tests toward those laboratories. Our sales force will directly target its efforts on the oncologists and pathologists, and will adopt promotional and marketing practices that have been employed successfully by the biopharmaceutical industry to educate treating physicians on the ability of our molecular tests to inform treatment decisions in accordance with the product labeling. We will communicate with patients, oncologists, pathologists, hospital administrators and other key stakeholders to outline the clinical and economic advantages of bringing complex genomic tests in-house.

Capture Capital Efficiencies Stemming from our Diagnostics Business Model. We plan to leverage the capabilities we have built to support our life sciences business, including our technology platform and product development, manufacturing, and administrative functions, to build our diagnostics business at minimal incremental cost. We will rely on the clinical laboratory infrastructure, sample logistics, managed care contracting and billing operations of our laboratory service customers, further reducing our capital requirement. We intend to coordinate commercial efforts with the sales and marketing personnel of the clinical laboratories offering clinical testing services based on our diagnostic products. We believe that this approach will yield a diagnostics business model that is more capital efficient than a clinical laboratory services model and has the potential to become profitable on a relatively small revenue base.

#### Our Products and Technology

The fundamental technology employed in our nCounter Analysis System was conceived at the Institute for Systems Biology in the laboratories of Dr. Leroy Hood, a renowned pioneer in genomics and personalized medicine. Our life sciences research customers purchase instruments from us and then purchase our panels or custom CodeSets and related consumables for the specific experiment they wish to conduct. Beginning with Prosigna, our future diagnostics customers will either purchase or lease instruments from us and also purchase one of our diagnostic kits for each test that they intend to run.

#### nCounter Analysis System

The nCounter Analysis System is an automated, multi-application, digital detection and counting system consisting of one or more nCounter Prep Stations and one nCounter Digital Analyzer.

Instruments and Software

The nCounter Prep Station is the automated liquid handling component of the nCounter Analysis System that processes samples after they are hybridized and prepares the samples for data collection on the nCounter

Digital Analyzer. The nCounter Digital Analyzer collects data from samples by taking images of the immobilized fluorescent reporters in the sample cartridge and processing the data into output files, which include the target identifier and related count numbers along with a broad set of internal controls that validate the precision of each assay. The currently available nCounter Prep Station and nCounter Digital Analyzer were designed and are manufactured under ISO 13485:2003, the quality standard for *in vitro* diagnostic platforms and medical devices. We also provide our customers with the nSolver Analysis Software, a data analysis program that offers nCounter Analysis System users the ability to quickly and easily quality check, normalize, and analyze their data without having to use any additional software for data analysis.

Simple and Rapid NanoString Workflow

The nCounter Analysis System s simple three step workflow takes approximately 24 hours and requires approximately 15 minutes of hands-on time by the user:

during step 1, up to 12 targeted tissue samples, or up to 48 samples with sample multiplexing, and our CodeSets or diagnostic kits are injected into strip tubes that we provide and allowed to hybridize overnight;

in step 2, the strip tube is loaded into our nCounter Prep Station, which purifies the mixtures and moves them onto a cartridge with 12 flow-cells where the fluorescent barcodes are captured and affixed onto a glass surface of the cartridge and oriented in one direction; and

in step 3, the cartridge is placed into our nCounter Digital Analyzer, which uses fluorescent microscopy and image analysis software to automatically count the barcodes and provide the level of expression of each target in the sample.

A user can process up to approximately 36 samples per day by installing one Prep Station with a single Digital Analyzer. One can increase the number of samples analyzed to 108 samples per day on a single Digital Analyzer if it is coupled with three Prep Stations. The throughput of the nCounter Analysis System can be quadrupled using sample multiplexing for experiments targeting 200 genes or fewer.

## Life Sciences Research

Following purchase of our nCounter Analysis System, life sciences research customers purchase panels and custom CodeSets targeted to a specific experiment.

Panels

We offer more than 20 panels that are pre-manufactured and targeted to a specific experiment, including the following:

*Gene Expression Panels.* Preassembled CodeSets that include all of the consumables required to perform the assay on the nCounter Analysis System. We offer nCounter Gene Expression Panels to conduct a wide variety of gene analysis, including analysis of kinase genes, cancer-related human genes, immunology-related genes, and inflammation-related genes.

miRNA Expression Assay Kits. A family of panels that provide a cost-effective profiling solution capable of highly multiplexed, direct digital detection and counting of up to 800 miRNAs in a single reaction without amplification. These provide our customers with high levels of sensitivity, specificity, precision, and linearity. Separate panels are available for use with samples from humans, mice, rats, and fruit flies.

Cancer Copy Number Variation Panel. Allows researchers to conduct large-scale, copy number variation projects by leveraging the nCounter Analysis System s multiplexing capacity to assay up to 800 regions in a single tube, with as little as 300 ng of starting material.

nCounter Leukemia Fusion Gene Expression Assay Kit. A panel that allows researchers to profile a broad set of fusion genes which result from balanced translocations in different leukemia subtypes. In addition to fusion genes, the kit includes probes for 11 wild-type genes involved in translocations and 12 leukemia-related biomarkers.

*Human Karyotype Panel.* Allows for the simultaneous measurement of all 23 pairs of human chromosomes, including 338 individual regions.

Custom CodeSets

We also work with our customers to develop custom CodeSets to enable them to evaluate specific genes that are the subject of their study. Our customers provide us a list of targets for which we subsequently build a unique CodeSet. Our design process leverages full length sequences for the DNA or RNA molecules that our customers are interested in detecting and prevents cross hybridization to non-target molecules in the sample. The custom CodeSet design process occurs in four distinct steps:

#### Master Kits

Our nCounter Master Kit includes all of the ancillary reagents and plasticware required for our customers to be able to setup and process samples in the nCounter Prep Station and nCounter Digital Analyzer. The components of the Master Kit include the sample cartridge, strip tubes, tips, buffers, and reagent plates.

#### **Molecular Diagnostics**

Our nCounter Analysis System s ability to simultaneously quantify gene expression on tens or hundreds of genes from minimal amounts of FFPE tissue make it well suited for profiling pathway activation in tumor samples. In addition, the nCounter Analysis System has the precision, reproducibility, and simple workflow required of technologies used in clinical laboratories.

We intend to develop and sell diagnostic kits for use in molecular diagnostic testing in clinical laboratories worldwide beginning with Prosigna. Following purchase or lease of our nCounter Analysis System, our future diagnostics customers will purchase *in vitro* diagnostic kits for use in testing patient samples. These customers will use the nCounter Analysis System and *in vitro* diagnostic kits to provide clinical diagnostic services. Initially, Prosigna will be the only kit available for diagnostic use on our nCounter Analysis System. Over time, we intend to develop, obtain regulatory authorization for, and sell additional kits, each of which will enable a unique diagnostic test.

Informing Breast Cancer Treatment using the PAM50 Gene Signature

In 2009, leading cancer researchers first described a new gene expression signature, called PAM50, based on the expression of 50 genes in tumor tissue. PAM50 provides two types of information regarding a breast cancer patient s tumor. First, PAM50 assigns each patient s tumor to one of four intrinsic subtypes, a classification based on the fundamental biology of that individual s breast tumor. Second, PAM50 provides a prognostic risk of recurrence, or ROR, score that assesses the probability that a cancer will recur in the future in patients who will be treated with hormonal therapy.

The intrinsic subtypes of breast cancer were first described in 2000 and have been repeatedly observed across multiple studies and technology platforms. Each patient s breast cancer can be classified into one of four intrinsic subtypes (Luminal A, Luminal B, HER2-enriched, and Basal-like) that describe the fundamental biology of the tumor, conveying valuable information about an individual patient s prognosis and likelihood of response to specific therapies. In June 2011, the widely-recognized St. Gallen International Breast Cancer Treatment Guidelines adopted the intrinsic subtypes as a standard approach to classifying early stage breast cancer, and in general, the basis for systemic therapy recommendations. The PAM50 gene signature represents a molecular approach to intrinsic subtyping and has been described in multiple peer-reviewed publications.

In September 2012 the online edition of the journal Nature published a study of the molecular biology of breast cancer, using the intrinsic subtypes as defined by the PAM50 gene signature as an organizing framework for analyzing genomic and proteomic aberrations. This study, which was an outcome of The Cancer Genome Atlas Initiative and was titled Comprehensive molecular portraits of human breast tumours, represents a thorough description of breast cancer genomics. The study involved the analysis of tissue from 800 breast cancer tumors by a total of six technology platforms, covering genomics, epigenetics, and proteomics. The research concluded that diverse genetic and epigenetic alterations converge phenotypically into the four main breast cancer subtypes defined by PAM50.

Studies using PAM50 and other methods for assigning intrinsic subtype have suggested that PAM50 may be useful in improving several treatments decisions in breast cancer by:

providing prognostic information that may help physicians and patients decide whether the addition of adjuvant chemotherapy to hormonal therapy is appropriate;

providing prognostic information that may help physicians and patients decide whether extended endocrine therapy is appropriate;

providing information that may help physicians choose which adjuvant chemotherapy regimen to select for an individual patient; and

providing information that may help physicians and patients decide whether adjuvant radiation therapy is appropriate. Development and Validation of the Prosigna Breast Cancer Assay

In 2010, we acquired an exclusive worldwide license to develop *in vitro* diagnostic and research products for breast cancer based on the PAM50 gene signature. In 2010, we began developing an *in vitro* diagnostic kit based on the PAM50 gene signature, simplifying and optimizing the test for use on the nCounter Analysis System. In 2011, we performed the first in a series of clinical studies designed to validate the test's ability to provide prognostic information for postmenopausal women with HR+ early stage breast cancer treated with endocrine therapy alone using material extracted from tumor samples from 1,017 patients from the TransATAC population of which 1,007 samples passed prespecified criteria and yielded evaluable results. TransATAC is a translational study group that has used the tumor tissue and data from a subset of the 9,366 women enrolled (1996-2000) in the ATAC (Arimidex, Tamoxifen, Alone or in Combination) trial to study the molecular characteristics of tumors in postmenopausal women with HR+ early stage breast cancer of pathological grade 1, 2 or 3. Access to the samples is controlled by a steering committee of the TransATAC study group. In 2010, we submitted a proposal to the steering committee seeking access to the samples and data to validate Prosigna, and our proposal was approved. In 2011, we jointly designed the study with a member of the TransATAC study

group who subsequently served as the lead investigator in our study. Following the steering committee s approval of our proposed study, we agreed to cover the costs of the study. The TransATAC population had been previously used in 2008 to clinically validate the current market leader in breast cancer prognosis and prediction, Genomic Health s Oncotype DX, which is a laboratory-developed test that is administered using a centralized laboratory service model. Our study used RNA that had been extracted by Genomic Health from 1,017 tumor samples from patients with postmenopausal HR+ early stage breast cancer during the 2008 study. Because both the Oncotype DX results and the outcomes of the patients associated with each RNA sample were known, the study provided an opportunity to measure both the ability of PAM50 to provide prognostic information, and how the prognostic information provided by Prosigna compares to data previously collected using Oncotype DX. Results of our TransATAC study were presented in December 2011 at the CTRC-AACR San Antonio Breast Cancer Symposium and in March 2013 a manuscript describing the results was accepted for publication in the Journal of Clinical Oncology.

In 2012, we performed a second clinical validation study to test the ability of Prosigna to estimate the prognosis of postmenopausal women with HR+ early stage breast cancer treated with endocrine therapy alone that evaluated tumor samples from 1,620 patients enrolled in the Austrian Breast & Colorectal Cancer Study Group 8, or ABCSG8, trial, of which 1,478 samples passed prespecified criteria and yielded evaluable results. The ABCSG8 trial enrolled 3,714 women (1996-2003) to compare the safety and efficacy of tamoxifen alone to sequential treatment with tamoxifen followed by anastrozole in postmenopausal women with HR+ early stage breast cancer of pathological grade 1 or 2. Access to the ABCSG8 samples and data is controlled by the chairman of the ABCSG, who, in 2010, agreed to collaborate with us as the lead investigator on a study to validate Prosigna. In 2011, we jointly designed the study with him and agreed to cover the costs of the study. Investigators at the British Columbia Cancer Agency, or BCCA, performed the Prosigna test using the nCounter Analysis System installed in BCCA s Center for Translational and Applied Genomics on tumor samples which had been stored in FFPE format from participants in the original ABCSG8 study. Results of our ABCSG8 study were presented in December 2012 at the CTRC-AACR San Antonio Breast Cancer Symposium.

Beginning in 2012, we planned and executed a series of prospectively defined analyses of the data sets from the ATAC and ABCSG8 trials designed to clinically validate additional features and benefits of Prosigna. Results from three of these analyses have been presented publicly at medical meetings. At the European Society of Medical Oncology meeting in September 2012, the investigators of our TransATAC study presented results indicating that the ROR score provided by Prosigna adds significant prognostic information to clinical-pathology variables for recurrence between five and 10 years after diagnosis, which is often referred to as late recurrence. In May 2013, a manuscript describing these results was accepted for publication in the Journal of the National Cancer Institute. At the IMPAKT Breast Cancer Conference in May 2013, the investigators of our TransATAC study and our ABCSG8 study presented additional analyses providing further evidence that Prosigna provides valuable information that could assist with treatment decisions by helping to identify patients at highest risk of this late recurrence. In addition, the results of an analysis of the combined data set of the ABCSG8 and ATAC studies was presented during the 2013 Annual American Society of Clinical Oncology, or ASCO, Meeting in June 2013 and demonstrated that Prosigna can identify a clinically significant number of low risk patients with one or two positive nodes. Several additional analyses of the ABCSG8 and ATAC studies are planned or ongoing.

In 2012, we performed a series of multi-site analytical validation studies intended to show that Prosigna provides consistent and reliable results, independent of the specific instrument, laboratory or operator performing the testing. We presented results from these analytical validation studies in March 2013 at the United States & Canadian Academy of Pathology annual meeting.

Clinical Validation of Prosigna for Indicating Prognosis in Postmenopausal HR+ Early Stage Breast Cancer Patients

Our TransATAC and ABCSG8 studies were performed using similar statistical analysis plans, allowing results on the prognostic performance of Prosigna in each study to be compared. Both studies met their primary and secondary objectives, and the data support the following conclusions:

in satisfaction of the primary objective of both studies, the ROR score was significantly related to outcome, and added significant prognostic information about 10 year distant recurrence risk to standard

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clinical-pathological variables in the study populations as a whole. In satisfaction of a secondary objective of both studies, similar results were achieved in all three prospectively defined clinically important subsets of patients: node-negative, node-positive and HER2-negative;

in satisfaction of the primary objective of our ABCSG8 study, the low, intermediate, and high risk patient groups as defined by Prosigna had different distant recurrence free survival rates at 10 years in the study population as a whole, showing that Prosigna can accurately categorize patients based on prognosis; and

in satisfaction of a secondary objective of both studies, patients with different intrinsic subtypes as reported by Prosigna had significantly different outcomes when treated with endocrine therapy alone, reinforcing the power of intrinsic subtyping as a descriptor of breast cancer tumor biology.

When taken together, we believe that our TransATAC and ABCSG8 studies provide strong evidence for Prosigna s clinical validity. The following tables and figures summarize the prognostic performance of Prosigna.

Prosigna s ROR score is significantly related to outcome in both node-negative and node-positive breast cancer patients (TransATAC study)

These curves illustrate the relationship of the ROR score to 10 year risk of distant recurrence in node-negative patients, patients with one to three positive nodes and patients with four or more positive nodes in the TransATAC population. In each subset of patients, as the ROR score increases, so too does 10 year risk of distant recurrence.

Prosigna adds statistically significant prognostic information beyond standard clinical-pathological variables in both studies

TransATAC				ABCSG8			
Patient	Number of			Number of			
population	patients	DLR-X <sup>2</sup>	p-value	patients	DLR-X <sup>2</sup>	p-value	
All evaluable	1,007	34.2	< 0.0001	1,478	53.5	< 0.0001	
Node-negative	739	25.0	< 0.0001	1,047	25.6	< 0.0001	
Node-positive	268	9.3	0.0023	382(1)	26.0	< 0.0001	
Her2-negative	888	28.9	< 0.0001	1,397	47.5	< 0.0001	

(1) Includes patients with only one to three positive nodes.

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The above table shows the prognostic information provided by the ROR score in the TransATAC and ABCSG8 study populations. The statistic DLR-X² measures the amount of prognostic information which the ROR score provides beyond the standard clinical-pathological variables. Since statistical significance is defined as p<0.05, these studies showed that the ROR score is significantly related to outcome and adds statistically significant prognostic information about 10 year distant recurrence risk to standard clinical-pathological variables in the study population as a whole and in all three prospectively defined clinically important subsets of patients in both studies.

Prosigna s risk groups have statistically significant different outcomes in the study populations as a whole

		TransATAC Estimated I	DRFS at		ABCSG8	
		10 years			Estimated DRFS at 10 years	
Risk Group	Number of Patients (%)	Percent [95% CI] <sup>(1)</sup>	p-value <sup>(2)</sup>	Number of Patients (%)	Percent [95% CI] <sup>(1)</sup>	p-value <sup>(2)</sup>
Low	437 (43%)	96% [94%-98%]	< 0.0001	502 (34%)	97% [95%-98%]	0.0093
Intermediate	254 (25%)	86% [81%-90%]	NA	478 (32%)	91% [88%-94%]	NA
High	316 (31%)	63% [57%-69%]	< 0.0001	498 (34%)	80% [76%-83%]	0.0004
Total	1,007 (100%)			1,478 (100%)		

- (1) DRFS = Distant Recurrence Free Survival; CI = Confidence Interval.
- (2) P-value calculated based on comparison to intermediate risk group.

The above table illustrates the result that in both studies the Prosigna-defined risk groups in the study populations as a whole have different 10 year distant recurrence free survival rates. In both studies, the low and high risk groups showed distant recurrence free survivals with statistically significant differences from the intermediate risk group.

Patients with node-negative disease categorized as Luminal A subtype had higher distant recurrence free survival than those categorized as Luminal B subtype

**TransATAC** 

	Estimated DRFS at			<b>Estimated DRFS at</b>		
	Number of	10 yea	ırs		10 year	s
Subtype	Patients (%)	Percent [95% CI] <sup>(1)</sup>	p-value <sup>(2)</sup>	Number of Patients (%)	Percent [95% CI] <sup>(1)</sup>	p-value <sup>(2)</sup>
Luminal A	529 (72%)	94% [92%-96%]	NA	725 (69%)	95% [93%-96%]	NA
Luminal B  Total <sup>(3)</sup>	176 (24%) 705 (95%)	74% [68%-81%]	< 0.0001	284 (27%) 1,009 (96%)	87% [83%-90%]	0.0019
	( )			, ( ,		

ABCSG8

- (1) DRFS = Distant Recurrence Free Survival; CI = Confidence Interval.
- (2) P-value calculated based on comparison to Luminal A group.

(3)

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Total number of patients is less than 100% of evaluable patients because a small number of patients were categorized as Basal-like or HER2-enriched subtypes.

The above table illustrates the result that in both studies intrinsic subtypes as defined by Prosigna in the node-negative patients have different 10 year distant recurrence free survivals. In each study, patients categorized as Luminal A have a statistically significantly higher estimated distant recurrence free survival at 10 years than patients categorized as Luminal B.

Comparison of Prosigna and Oncotype DX Performance in Our TransATAC Study

The TransATAC population had been previously used in 2008 to clinically validate the current market leader in breast cancer prognosis and prediction, Genomic Health s Oncotype DX, which is a laboratory-

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developed test that uses a centralized laboratory service model. The PAM50 study used RNA that had been extracted by Genomic Health from 1,017 tumor samples from patients with postmenopausal HR+ early stage breast cancer during the 2008 study. Because both the Onco*type* DX results and the outcomes of the patients associated with each RNA sample were known, the study provided an opportunity to measure how the prognostic information provided by Prosigna compares to that provided by Onco*type* DX in this study population.

In order to compare how the two tests separated patients according to risk in this study, risk groups were defined based on each test s estimate of the risk of distant recurrence at 10 years within the TransATAC population. Risk score thresholds to define the risk groups were chosen for each test based on the results of our TransATAC study in order to define risk groups that contain patients with the same risk. In order to achieve these comparable risk groups, the cut points used for Onco*type* DX were different than those used by Genomic Health.

For each test, the low risk group was prospectively defined as patients with less than a 10% estimated risk of recurrence. For each test, the intermediate risk group was prospectively defined as patients with between a 10% and 20% estimated risk of recurrence. For each test, the high risk group was prospectively defined as patients with greater than a 20% estimated risk of recurrence. The figure below summarizes the sizes and outcomes of the risk groups defined by each test in patients with node-negative disease.

Prosigna s ROR score identified more high risk patients and fewer intermediate risk patients than

Oncotype DX s RS score in this study in patients with node-negative disease

This figure illustrates the result that, in patients with node-negative disease, Prosigna assigned 26% fewer patients to the intermediate risk group than did Oncotype DX (180 patients vs. 243 patients) in this study. In addition, in patients with node-negative disease, Prosigna assigned more patients to the high risk group than did Oncotype DX; however, the low risk and high risk groups defined by each test have similar outcomes as illustrated by the overlapping Kaplan-Meier curves. This observation led the independent investigators of our TransATAC study to conclude that, in patients with node-negative disease, Prosigna assigned fewer patients to the intermediate risk group than Oncotype DX RS, with equivalent or higher separation between the low and high risk groups.

Clinical validation of Prosigna ability to help identify node-positive early-stage breast cancer patients at low risk of recurrence

In June 2013, we presented results from the combined data analysis of the ATAC and ABCSG8 studies at the Annual American Society of Clinical Oncology, or ASCO, meeting. These results were derived from the analysis of the combined data set and long term follow-up from 2,485 patients in the ABCSG8 and ATAC studies. Node-positive patients in the combined data set were grouped into one of three categories based on the number of positive nodes.

According to current treatment guidelines by the National Comprehensive Cancer Network, or NCCN, postmenopausal women with node-positive, HR+ early-stage breast cancer should be considered high risk and should receive adjuvant chemotherapy in addition to five years of endocrine therapy. The results of both randomized clinical studies and meta-analyses suggest that a substantial portion of women with node-positive

disease may be adequately treated with adjuvant endocrine therapy alone. However, identifying these low risk node-positive patients has been challenging due to the heterogeneity of the node-positive patient population, which includes patients with different numbers of positive lymph nodes and diverse tumor genomics.

The objective of the new study was to determine whether the risk score provided by Prosigna provides additional prognostic information for risk of metastasis over and above standard clinical variables alone in patients with either one positive lymph node, or two to three positive lymph nodes. Of all the patients in the study with one positive node, 40% were categorized as low-risk based on their risk score and experienced an absolute 10-year risk of distant recurrence rate of 6.6%, while 71% were categorized as Luminal A subtype and experienced an absolute 10-year risk of distant recurrence of 8.4%. Separately, the analysis also demonstrated that patients with the Luminal A subtype have statistically significant different risk of metastasis than Luminal B.

The investigators in this study concluded that Prosigna helped identify a subset of postmenopausal women with node-positive HR+ early stage breast cancer, including patients with one positive node, as well as some with two positive nodes that had a low risk of recurrence. The authors concluded that identifying this subset of patients may help physicians assess treatment options, including whether the patients might be adequately treated with adjuvant endocrine therapy alone.

Clinical Validation of Prosigna for Indicating Risk of Late Recurrence in Postmenopausal HR+ Early Stage Breast Cancer

Despite recent improvements in breast cancer treatment, some women with HR+ early-stage breast cancer remain at risk of disease recurrence after remaining recurrence-free for the first five years following diagnosis. Identifying newly diagnosed women with HR+ breast cancer who are at highest risk of having their cancer recur between five and 10 years after diagnosis is a priority for oncologists seeking to help breast cancer patients make more informed treatment decisions. These patients may benefit by extending the duration of their adjuvant endocrine therapy beyond five years.

The ability of Prosigna to estimate risk of recurrence between five and 10 years after diagnosis in postmenopausal women with HR+, node-positive and node-negative early-stage breast cancer has been demonstrated in two independent studies. Results from both of these studies were presented at the IMPAKT Breast Cancer Conference in May 2013.

In one study, the investigators of our TransATAC study assessed and compared the value of five different prognostic scores for indicating risk of distant recurrence in the first five years after diagnosis, and between five and 10 years after diagnosis, for all patients in the ATAC trial. In a multivariate analysis, the ROR score was one of only two genomic prognostic scores that provided additional prognostic information regarding risk of distant recurrence between five and 10 years.

In a second study, the investigators of our ABCSG8 study found that the ROR score provided by Prosigna added prognostic information about the risk of late recurrence of breast cancer to the standard pathological variables in a study population including 1,478 postmenopausal women with hormone receptor positive, node-positive and node-negative early-stage breast cancer who participated in the ABCSG8 trial (p<0.0001). Patients with no recurrence by year five and categorized as low risk based on the ROR score had Distant Recurrence Free Survival, or DRFS, of 98.7% at year 10, while patients with no recurrence by five years and categorized as high risk based on the ROR score had DRFS of 91.5% at year 10. These investigators concluded that, in combination with the late recurrence results from the TransATAC study, Prosigna s ability to indicate risk of late recurrence in postmenopausal HR+ early stage breast cancer has achieved Level 1 clinical evidence, the standard generally required for inclusion in clinical practice guidelines.

Multi-site analytical validation of Prosigna.

Regulatory clearance or approval for *in vitro* diagnostic kits generally requires studies that demonstrate that a diagnostic test can be reliably run in multiple qualified laboratories with adequate precision and reproducibility. In 2012, we performed a series of multi-site analytical validation studies intended to show that Prosigna provides consistent and reliable results, independent of the specific instrument, laboratory or operator performing the

testing. The results of these studies were presented publicly at the United States & Canadian Academy of Pathology annual meeting in March 2013. These results support the ability of the Prosigna assay to generate consistent results when used in qualified clinical labs in different cities and countries.

The objective of these studies was to assess the analytical robustness of Prosigna when used in qualified clinical laboratories. Prosigna assays were run independently at three different testing sites by a total of six different operators using three different reagent lots. Reproducibility was assessed by testing multiple tissue sections from each of 43 FFPE breast tumor blocks across the three sites following review of hematoxylin and eosin stained slides by an independent pathologist at each site. The magnitude of different sources of analytical variation in the assay were further characterized by testing five pooled breast tumor RNA samples more than 100 times each.

When starting with FFPE tissue blocks, these studies showed that Prosigna s reproducibility, including all analytical and pre-analytical variables, was characterized by a total standard deviation of just 2.9 ROR units on a zero-to-100 scale. In addition, there was an average site-to-site concordance of 97% in reporting of intrinsic subtype. When starting from pooled RNA, Prosigna s precision was characterized by a total standard deviation of less than 1 ROR unit. There was no statistically significant bias in results between sites or operators.

Prosigna in the European Union and Other Countries that Recognize the CE Mark.

In September 2012, we obtained CE mark designation for Prosigna for use as a semi-quantitative *in vitro* diagnostic assay using the gene expression profile of cells found in FFPE breast tumor tissue to assess the 10 year risk of distant recurrence in postmenopausal women with HR+ early stage breast cancer treated with endocrine therapy alone. This CE-marked product is indicated for use in patients with either node-negative or node-positive disease, and provides physicians and their patients with the intrinsic subtype of a patient s breast cancer tumor, ROR score, and risk category (high/intermediate/low). In February 2013, we began marketing this test in Europe, including in France, Germany, Italy, Spain and the United Kingdom, and Israel. In April 2013, we installed the first diagnostic systems in Europe, which will initially be used for clinical studies of Prosigna s impact on adjuvant treatment decisions in early stage breast cancer called decision impact studies. The list price of Prosigna kits in Europe is the equivalent of 1,550 per patient.

Prosigna in the United States.

In December 2012, we submitted an application, known as a 510(k), to the FDA seeking clearance in the United States for a version of Prosigna providing an assessment of a patient s risk of recurrence for breast cancer. In March 2013, we received a written response from the FDA requesting additional information for its review of our 510(k) submission. A request for additional information is common following an initial 510(k) submission. In May 2013, we submitted an initial response to the FDA s request for additional information and met with the FDA to discuss our response. If the FDA clears Prosigna, we intend to launch Prosigna in the United States promptly following receipt of such clearance. We are currently planning for this commercial launch in the first quarter of 2014. For this clearance, we are pursuing an intended use as a prognostic indicator for distant recurrence free survival at 10 years in postmenopausal women with HR+ early stage breast cancer treated with adjuvant endocrine therapy alone, when used in conjunction with other clinicopathological factors. We are seeking an intended use in patients with node-negative disease and patients with node-positive (between one and three affected nodes) disease. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating to the FDA s satisfaction that the proposed device is substantially equivalent in intended use and in safety and effectiveness to a previously 510(k) cleared device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for submission of PMA applications. The previously cleared device is known as a predicate. For additional information about the FDA s 510(k) clearance process, please see the section of this prospectus captioned Business Government Regulation. Based on pre-submission interactions with the FDA and the FDA s written response to our 510(k) submission, we expect Agendia s MammaPrint to serve as the legally marketed predicate that would enable us to market a version of Prosigna in the United States that, if cleared, would provide an assessment of a patient s risk of recurrence for breast cancer, but not the patient s intrinsic subtype. In the FDA s written response to our 510(k) submission, the

FDA communicated, among other things, that we would need to provide further support before the FDA could determine whether the pending 510(k) application, if cleared, would allow us to include a risk score and three distinct risk groups in patient reports for all patients tested. In our recent meeting with the FDA, we discussed, among other issues raised by the FDA, the specific elements and format of a potential report generated by Prosigna, including the appropriate name for the risk score, the appropriate graphic presentation of the risk score, and, specifically for the potential report for node-positive patients, the numerical range of the risk score and the appropriate number of risk groups. If we obtain clearance from the FDA, we expect Prosigna to be competitive with other products that are currently available in the United States given the advantages demonstrated by our TransATAC and ABCSG8 clinical studies. In the future, we plan to submit a separate application for approval to report intrinsic subtype. If we obtain approval to report intrinsic subtyping from the FDA, we expect our competitive position in the United States will be enhanced. We expect that this future application will require a PMA supported by additional clinical studies.

#### **Intellectual Property**

We must develop and maintain protection on the proprietary aspects of our technologies in order to remain competitive. We rely on a combination of patents, copyrights, trademarks, trade secret and other intellectual property laws and confidentiality, material transfer agreements, licenses, invention assignment agreements and other contracts to protect our intellectual property rights.

As of May 31, 2013, we owned or exclusively licensed five issued U.S. patents and approximately 24 pending U.S. patent applications, including provisional and non-provisional filings. We also owned or licensed approximately 64 pending and granted counterpart applications worldwide, including 22 country-specific validations of three European patents. The issued U.S. patents that we own or exclusively license are expected to expire between July 3, 2021 and March 28, 2029. We have either sole or joint ownership positions in all of our pending U.S. patent applications. Where we jointly own cases, we have negotiated license or assignment provisions for exclusive rights. For our material nCounter Analysis System and Prosigna product rights, we are the exclusive licensee. We also generally protect our newly developed intellectual property by entering into confidentiality agreements that include intellectual property assignment clauses with our employees, consultants and collaborators.

Our patent applications relate to the following three main areas:

our nCounter Analysis System biology, chemistry, software and hardware;

specific applications for our nCounter Analysis System technology; and

our gene expression markers, methods and algorithms for recurrence and drug response in certain forms of cancer.

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The following patents and patent applications (including expected 20 year expiration dates) relate to our nCounter Analysis System:

Patent and Patent Application Numbers US 7,473,767, US 7,919,237, US 8,148,512, EP Patent No. 1448581, AU Patent No. 2002327202, CA Patent No. 2452712, JP Patent No. 4343682, USSN 13/794,299, USSN 13/027,493 and foreign applications in certain jurisdictions claiming priority to PCT/US2002/021278	Form of Ownership In-licensed from the Institute for Systems Biology	Expected Expiration Date 7/3/2021	<b>Description</b> Directed to compositions and methods of immobilization and detection
EP Patent No. 1963531, AU Patent No. 2006330830, USSN 12/158,953, USSN 13/794,424 and foreign applications in certain jurisdictions claiming priority to PCT/US2006/049274	Co-owned with the Institute for Systems Biology	12/22/2026	Directed to compositions and methods of immobilization and detection
EP Patent No. 1963500, USSN 11/645,270 and foreign applications in certain jurisdictions claiming priority to PCT/US2006/049279	Owned	12/22/2026	Directed to methods of immobilization and detection
US 7,941,279, AU Patent No. 2007268027, JP Patent No. 5081232 and foreign applications in certain jurisdictions claiming priority to PCT/US2007/012130	Owned	5/21/2027	Directed to compositions
US 8,415,102, USSN 13/788,133 and foreign applications in certain jurisdictions claiming priority to PCT/US2008/059959	Owned	4/10/2028	Directed to methods of manufacture
USSN 12/541,131 and foreign applications in certain jurisdictions claiming priority to PCT/US2009/053790	Owned	8/13/2029	Directed to compositions and methods of detection

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The following patent applications (including expected 20 year expiration dates) relate to specific applications for our nCounter Analysis System:

Patent Application Numbers USSN 12/904,078 and foreign applications in certain jurisdictions claiming priority to PCT/US2010/052556	Form of Ownership Owned	Expected Expiration Date 10/13/2030	Description Directed to compositions and methods of detection
USSN 13/025,458 and foreign applications in certain jurisdictions claiming priority to PCT/US2011/024519	Owned	2/11/2031	Directed to compositions and methods of detection
USSN 13/049,682 and foreign applications in certain jurisdictions claiming priority to PCT/US2011/028657	Owned	3/16/2031	Directed to methods of detection
PCT/US2012/030940	Owned	3/28/2032	Directed to compositions and methods of diagnosis
USSN 13/530,848 and PCT/US2012/043799	Owned	6/22/2032	Directed to compositions and methods of detection
Additional pending provisional patent applications	Owned	2033	Directed to nCounter Analysis System methods of use

The following patent applications (including expected 20 year expiration dates) relate to our gene expression markers:

Patent Application Numbers USSN 12/094,898 and foreign applications in certain jurisdictions claiming priority to PCT/US2006/044737	Form of Ownership In-licensed from Bioclassifier, LLC	Expected Expiration Date 11/17/2026	<b>Description</b> Directed to methods of prognosis
USSN 12/995,450 and foreign applications in certain jurisdictions claiming priority to PCT/US2009/045820	In-licensed from Bioclassifier, LLC	6/1/2029	Directed to methods of prognosis
USSN 13/421,367 and PCT/US2012/029226	In-licensed from	3/15/2032	Directed to methods of treatment and determining drug response
USSN 13/690,891 and PCT/US2012/067317	Bioclassifier, LLC In-licensed from	11/30/2032	Directed to methods of treatment and determining drug response
	Bioclassifier, LLC		determining drug response
USSN 13/899,656 and	Owned	5/22/2033	Directed to compositions and methods of using gene expression markers
PCT/US2013/042157			
Additional pending provisional patent applications	Owned or In-licensed from Bioclassifier, LLC	2033	Directed to compositions and methods of using gene expression markers, some of which are owned by NanoString Technologies, Inc. and some of which are encompassed by our license agreement with Bioclassifier, LLC

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We intend to file additional patent applications in the United States and abroad to strengthen our intellectual property rights; however, our patent applications (including the patent applications listed above) may not result in issued patents, and we cannot assure investors that any patents that have issued or might issue will protect our technology. We have received notices of claims of potential infringement from third parties and may receive additional notices in the future. When appropriate, we have taken a license to the intellectual property rights from such third parties. For additional information, see the section of this prospectus captioned Risk Factors Risks Related to Intellectual Property.

We own a number of trademarks and develop names for our new products and as appropriate secure trademark protection for them, including domain name registration, in relevant jurisdictions.

#### **Collaborations**; License Agreements

We have relied, and expect to continue to rely, on strategic collaborations and licensing agreements with third parties. For example, our base molecular barcoding technology is in-licensed from the Institute for Systems Biology and the intellectual property that forms the basis of Prosigna is in-licensed from Bioclassifier, LLC. In addition to the licenses with the Institute for Systems Biology and Bioclassifier, we rely on other license and supply arrangements for proprietary components which require us to pay royalties on the sale of our products. Other life sciences research customers are using our nCounter Analysis System to discover gene expression signatures that we believe could form the basis of future diagnostic products. Currently, we are considering several of these gene signatures for in-licensing. For example, in February 2013 we secured an option from a customer to acquire an exclusive worldwide license for a gene signature that could be used, after appropriate regulatory authorization, to identify patients with cirrhosis who are at highest risk of developing HCC and to determine whether a patient who has been diagnosed with HCC is likely to have a recurrence. Our licensing arrangements with the Institute for Systems Biology and Bioclassifier are discussed below in greater detail.

## Institute for Systems Biology

In 2004, we entered into an agreement with the Institute for Systems Biology pursuant to which the Institute granted to us an exclusive, subject to certain government rights, worldwide license, including the right to sublicense, to the digital molecular barcoding technology on which our nCounter Analysis System is based, including 13 patents and patent applications. We issued 15,625 shares of our common stock to the Institute for Systems Biology as partial consideration for entry into the license agreement. Pursuant to the terms of the amended license agreement, we are required to pay the Institute for Systems Biology royalties on net sales of products sold by us, or our sublicensees, at a low single digit percentage rate. Royalties owed to the Institute for Systems Biology had been subject to annual minimums, which have expired. Through May 31, 2013, we have paid aggregate royalties of \$1.6 million to the Institute for Systems Biology. Unless earlier terminated in accordance with the terms of the amended license agreement, the agreement will terminate upon the expiration of the last to expire patent licensed to us. The Institute for Systems Biology has the right to terminate the agreement under certain situations, including our failure to meet certain diligence requirements or our uncured material breach of the agreement.

## Bioclassifier, LLC

In July 2010, we entered into an exclusive license agreement with Bioclassifier, LLC, pursuant to which Bioclassifier granted to us an exclusive, subject to certain government rights, worldwide license, with the right to sublicense, to certain intellectual property rights and technology, including intellectual property rights that comprise eight non-provisional patent applications as of March 31, 2013, in the field of research products and prognostic and/or diagnostic tests for cancer, including Prosigna. Bioclassifier has licensed these rights from the academic institutions that employed the cancer researchers that discovered or were involved in the initial development of PAM50. This license agreement was amended and restated in February 2012, with the changes retroactively effective to the July 2010 date of the original agreement. Pursuant to the terms of the amended and restated license agreement, we are required to pay Bioclassifier the greater of certain minimum royalty amounts

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and mid-single digit to low double digit percentage royalties on net sales of products and/or methods sold by us that are covered by patent rights or include, use or are technology licensed to us. Our obligation to pay royalties to Bioclassifier expires on a country-by-country basis upon the expiration of the last patent licensed or, if a product or method includes, uses or is technology licensed to us but is not covered by a patent licensed to us, ten years after the first commercial sale of the product or method in such country. We are also required to pay Bioclassifier low to mid double digit percentage of any income received by us from the grant of a sublicense by use to the patents or technology licensed us under the agreement. We are also required to meet certain development and commercialization milestones extending to 2015. Through May 31, 2013, we have paid Bioclassifier \$335,000 of which \$175,000 will be credited against future royalties owed.

Additionally, we are obligated to pay certain fees to Bioclassifier if we do not meet certain milestones within predetermined time periods. The agreement specifies that we will control and be responsible for the costs of prosecuting and enforcing the intellectual property licensed in certain major market countries. The agreement also includes customary rights of termination for Bioclassifier, including for our uncured material breach or our bankruptcy.

## **Research and Development**

We have committed, and expect to continue to commit, significant resources to developing new technologies and products, improving product performance and reliability and reducing costs. We have assembled experienced research and development teams at our Seattle, Washington location with the scientific, engineering, software and process talent that we believe is required to successfully grow our business. As of May 31, 2013, we had approximately 38 employees in research and development, of which 15 hold a Ph.D. degree and seven hold a M.S. degree. We are currently focused on several products and enhancements in both our future diagnostic products and current life sciences research offerings. Our research and development expenses for the years ended December 31, 2010, 2011 and 2012 and the three months ended March 31, 2013 were \$7.5 million, \$9.0 million, \$11.6 million and \$3.1 million, respectively.

## nCounter Technology

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We are continuously seeking to improve the nCounter Analysis System, including improvements to the technology and accessibility. As we make improvements, we anticipate that we will make available new and improved generations of the nCounter Analysis System to be used in both our current life sciences research and future diagnostics businesses.

Our technology development efforts are focused on:

Applications. We plan to develop additional application areas to enable researchers to apply the nCounter Analysis System to new experimental paradigms. Currently, we are focused on expanding our single cell gene expression application, which we introduced in September 2012 to enable researchers to measure the expression of up to 800 genes using as little as 10 picograms of input total RNA (i.e., total RNA content of a single cell). Additional developments in this area may include single-cell-specific CodeSet panels and data analysis software designed to simplify the analysis and interpretation of single cell expression data. In the future, we also intend to add applications designed to probe additional non-coding regions of the genome which serve important regulatory functions.

Chemistry. We are developing new chemistry and associated consumables that are designed to increase the flexibility of the nCounter Analysis System by allowing customers to customize and configure their own CodeSets. Customers would select a set of genes and then assemble a CodeSet by combining generalized detection agents purchased from us with reagents purchased from other manufacturers. Our generalized detection reagents would not require any knowledge of the exact genomic target that is being evaluated, and could be shipped to a customer immediately upon their request, freeing the customer to explore unique genomic targets independent of interaction with us. Over time, we intend to develop advanced chemistries that may increase the number of targets that the nCounter Analysis System can profile in a single sample beyond the current maximum of 800 targets.

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*Instruments.* We are developing a new generation of the nCounter Analysis System that we believe will increase our addressable market and simplify the procurement processes of our potential customers. The new generation system will be a single instrument with a reduced footprint that combines the prep station and the digital analyzer. We plan to reduce the cost of the new generation system through the adoption of new, less expensive technologies. We are targeting release of the new generation system in 2014.

## Expanding Clinical Utility of the Prosigna Breast Cancer Assay

We plan to extend the clinical utility of Prosigna to inform other major treatment decisions in breast cancer, after appropriate regulatory authorization. The decisions about receiving adjuvant chemotherapy or radiation therapy have significant objective quality of life implications because of the acute and long term risk of side effects, some of them severe (including death), that are caused by these treatments. In addition, there are significant health economic consequences to decisions regarding these therapies based both on the cost of the treatments themselves and of treating their side effects. Therefore, a pressing issue is to identify the individual patients who need or are likely to benefit from adjuvant radiation therapy and chemotherapy so that the rest of the patients can be spared these treatments without affecting their long term outcome.

Our efforts to expand the clinical utility of Prosigna are focused on:

Chemotherapy Selection. The first-generation genomic tests for breast cancer have improved physicians ability to determine which individual patients can be safely spared adjuvant chemotherapy. However, for those patients who will go on to receive adjuvant chemotherapy, physicians may select from several commonly used adjuvant chemotherapy regimens, including CMF (cyclophosphamide/methotrexate/5-flouracil), anthracycline-containing regimens or taxane-containing regimens. The first-generation genomic breast cancer tests do not inform the selection of specific adjuvant chemotherapy regimen. Over the past several years, studies have been presented and published that suggest that the PAM50 gene signature, which is the basis of Prosigna, can inform the selection of adjuvant chemotherapy regimen. In 2012, U.S.-based researchers published a study indicating that a qPCR-based version of PAM50 predicted which breast cancer patients benefit from anthracycline-based chemotherapy regimens. In 2013, Spanish researchers published a study indicating that Prosigna predicted which breast cancer patients benefit from gemcitabine. In 2013, Spanish researchers published a study demonstrating that the proliferation score of a qPCR-based version of PAM50 predicted which breast cancer patients benefit from weekly paclitaxel. In the future, we intend to perform clinical studies designed to demonstrate that Prosigna can aid in the selection of chemotherapy regimen in breast cancer patients. We have secured access to tissue samples and outcomes from two randomized, controlled clinical studies that may be used in an effort to clinically validate this intended use.

Radiation Therapy in Early Stage Breast Cancer. Recently presented research suggests that by determining a patient s intrinsic subtype, physicians could identify those patients who do not benefit from adjuvant radiation therapy. In a previously conducted clinical trial that enrolled postmenopausal women with T1/T2, node-negative early stage breast cancer, patients with Luminal A tumors (approximately 50% of the patients enrolled in the trial) received little or no benefit from adjuvant radiation therapy, whereas patients with tumors of other subtypes received significant benefit. We intend to conduct clinical studies to validate the ability of intrinsic subtype as determined by Prosigna to identify postmenopausal women with early stage breast cancer who are likely to receive little or no benefit from treatment with adjuvant radiation therapy. We have secured access to tissue samples and outcomes from one randomized, controlled clinical study that may be used for clinically validating this intended use.

Ductal Carcinoma in situ Treatment. Ductal Carcinoma in situ, or DCIS, Treatment, is characterized by a clonal proliferation of epithelial cells confined within the lumen of the mammary duct. DCIS is usually asymptomatic; however, screening mammography programs have led to a substantial increase in the incidence of DCIS in the past two decades so that it represented 20% of breast cancers diagnosed in the United States in 2004, according to the National Cancer Institute s Surveillance, Epidemiology

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and End Results Program. The major clinical risk in DCIS is its progression to invasive carcinoma. Since DCIS has a variable natural history, the major treatment decision relates to how aggressively to treat DCIS when it is diagnosed. Mastectomy is a highly effective, although radical, treatment for DCIS as it is curative in 98 to 99% of patients with either gross or mammographically detected DCIS. A recent study has demonstrated that a multi-gene assay containing a subset of the genes used in the Onco*type* DX test could identify a group of patients with such a low risk of recurrent DCIS that they are unlikely to benefit from treatment beyond limited surgical resection. These data suggest other genomic tests, including Prosigna, may also be able to identify low risk patients who may be spared aggressive treatment. We intend to conduct clinical studies to validate the ability of Prosigna to identify DCIS patients who may be spared aggressive treatment. We have applied for access to a cohort of DCIS tissue samples from patients entered into a randomized, controlled clinical trial with long-term follow-up, and have received approval from the relevant committee within the institution controlling these samples.

Our clinical studies to date have employed a retrospective / prospective design, which means that we use samples that were previously collected from patients and for which the treatment regimen and ultimate outcome of each patient are known. Such studies are capital efficient as they do not require recruiting new patients and running prospective trials and they can be completed much more quickly than typical prospective clinical trials. We intend to use a similar approach whenever possible for the additional clinical studies we intend to conduct in support of our future regulatory submissions seeking to expand the indications for Prosigna and for future diagnostic products.

In the future, we do intend to participate in prospective clinical studies that require recruiting new patients. Thus far, we have accepted invitations to participate in two such prospective studies that are being organized and sponsored by cooperative groups. We are not and do not expect to be financially responsible for conducting either trial; however, we may provide in-kind support through the contribution of Prosigna in vitro diagnostic kits or sale of kits at a discounted price. These studies are:

RxSPONDER trial (SWOG 1007). The RxSPONDER trial is a Phase III clinical trial organized by the Southwest Oncology Group and sponsored by the National Cancer Institute. The primary objective of this trial is to determine the effect of endocrine therapy with versus without chemotherapy in patients with node-positive breast cancer who do not have high Recurrence Scores (RS) by Oncotype DX. The trial also has several secondary objectives related to other breast cancer assays, including PAM50. One secondary objective is to perform other assays or tests (in particular the ROR score) as they are developed and validated that measure potential benefit of chemotherapy, and to compare them to Oncotype DX. Another secondary objective is to determine the role of other assays, including PAM50, as indicators of Disease Free Survival, Distant Disease Free Survival, and Local Disease Free Interval of patients randomized to chemotherapy versus no chemotherapy.

Optimal Personalised Treatment of early breast cancer using Multi-parameter Analysis (OPTIMA) trial. The OPTIMA trial is a multi-center partially blind randomized clinical trial of early stage breast cancer patients in the United Kingdom. The OPTIMA trial seeks to advance the development of personalized medicine in breast cancer by using multi-parameter tests to help identify those women who are likely to benefit from chemotherapy and helping spare those who are unlikely to benefit from an unnecessary and unpleasant treatment. In the United Kingdom, the OPTIMA study population would ordinarily be treated with a combination of chemotherapy and endocrine therapy. The OPTIMA trial compares the management of patients using test-directed assignment to chemotherapy with standard management (i.e., chemotherapy) in a non-inferiority design. OPTIMA prelim is the preliminary phase of the study sponsored by the U.K. Health Technology Assessment of the National Institute of Health Research which will evaluate the performance and health-economics of alternative multi-parameter tests to determine which technology should be evaluated in the main trial. This decision will be informed by a combined primary outcome measure including concordance of test results, cost-effectiveness and deliverability of pathology services. All patients in the OPTIMA prelim trial will be tested with the Oncotype DX test as well as additional biomarkers and tests, including Prosigna.

In addition, we are exploring potential clinical studies with the goal of investigating Prosigna s ability to provide other clinically useful information to physicians treating women with HR+ early stage breast cancer, including identifying which patients are likely to benefit from adjuvant chemotherapy or extending adjuvant endocrine therapy beyond five years.

#### Future Molecular Diagnostic Kits

In addition to the development of Prosigna, we are currently evaluating several molecular signatures which have the potential to create additional diagnostic products. We intend to license rights to molecular diagnostic intellectual property as part of our strategy to develop additional diagnostic products, with a particular focus on licensing rights from our life sciences research customers who are seeking to translate their research into clinical products after the necessary regulatory authorizations are secured. We intend to target intellectual property rights that are well understood, have the potential to facilitate changes in treatment with a major impact on outcome and cost, have the potential to support value-based pricing and with respect to which tissue samples for clinical validation are readily available.

In February 2013, we secured an option to acquire an exclusive worldwide license for a 186 gene signature that could be used, after appropriate regulatory authorization, to determine the prognosis of patients diagnosed with the most common type of liver cancer, HCC, or with hepatitis C-related early-stage cirrhosis. We secured the option from The Broad Institute acting on behalf of the inventors institutions. During the period in which the option can be exercised, we plan to assess the feasibility of developing an *in vitro* diagnostic assay based on the HCC gene signature for use on the nCounter Analysis System.

HCC, a form of liver cancer, is an increasingly prevalent clinical diagnosis and is the third most common cause of cancer-related death globally. While incidence rates of HCC have been lower in the United States than in many countries historically, domestic age-adjusted HCC incidence rates have doubled in recent decades. In fact, primary liver cancer mortality rates have increased faster than mortality rates for any other leading cause of cancer in the United States. HCC develops from advanced fibrosis of the liver, or cirrhosis, which is estimated to affect one to two percent of the world s population. The prognosis for patients with advanced HCC is poor, with a reported five-year survival rate of approximately 10%, thus it is important that patients be diagnosed with HCC when it is at an early stage and treatable with surgery. Since there is a high rate of recurrence of HCC after the treatment of the primary tumor, it is important to identify those patients with a high risk of recurrence so that these recurrences can be treated before advanced disease develops.

A paper in the New England Journal of Medicine in 2008 by Hoshida, et al, described the HCC gene signature in connection with a method for conducting gene expression analysis on RNA extracted from liver tissue adjacent to HCC tumors. Using this method, the authors discovered a 186-gene signature which identifies those HCC patients who have a poor prognosis because of a high rate of recurrence after primary treatment. This gene signature was highly correlated with survival in a training set of 82 Japanese patients and was validated in an independent set of 225 patients from the United States and Europe. A paper published online in January 2013 in the journal Gastroenterology demonstrated that this same 186-gene signature also identifies those patients with hepatitis C-related early-stage cirrhosis who have a poor prognosis because of their high rate of developing HCC.

## **Sales and Marketing**

We began selling nCounter Analysis Systems to life sciences researchers in 2008 and began sales efforts in the diagnostics market in Europe, including in France, Germany, Italy, Spain and the United Kingdom, and Israel in connection with the February 2013 commercial launch of Prosigna in those markets. We sell our life sciences research products primarily through our own sales force in North America and through a combination of direct and distributor channels in Europe, the Middle East, Asia Pacific and South America. We have agreements with 11 distributors, each of which is exclusive within a certain territory for our life sciences research business only. In the event the distributor does not meet minimum performance requirements, we may terminate the distribution agreement or convert from an exclusive to non-exclusive arrangement within the territory, allowing us to enter into arrangements with other distributors for the territory. None of our customers represented more than 10% of our revenue for the years ended December 31, 2010, 2011 or 2012 or the three months ended March 31, 2013.

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## Life Sciences Research

Our sales and marketing efforts in the life sciences market are targeted at department heads, research laboratory directors, principal investigators, core facility directors, and research scientists at leading academic institutions, biopharmaceutical companies, publicly and privately-funded research institutions and contract research organizations. We seek to increase awareness of our products among our target customers through direct sales calls, trade shows, seminars, academic conferences, web presence and other forms of internet marketing.

Our nCounter Analysis Systems are relatively new to the life sciences market place and our instruments require a significant capital investment. Our sales process involves numerous interactions with multiple people within an organization, and often includes in-depth analysis by potential customers of our products, proof-of-principle studies, preparation of extensive documentation and a lengthy review process. As a result of these factors, the large capital investment required in purchasing our instruments and the budget cycles of our customers, the time from initial contact with a customer to our receipt of a purchase order can vary significantly and be up to 12 months or longer. Given the length and uncertainty of our sales cycle, we have in the past experienced, and likely will in the future experience, fluctuations in our instrument sales on a period-to-period basis. We are developing an nCounter Analysis System that we intend to offer at a lower price, which we believe will simplify the procurement processes of our potential customers as well as increase our addressable market. We also continue to develop enhancements to both the chemistries and assays that are run on the nCounter Analysis System, which may drive further adoption.

#### **Molecular Diagnostics**

We intend to sell instruments and consumables for use in diagnostic testing, beginning with Prosigna, via a three-pronged effort. First, we will seek to establish third-party reimbursement and patient access for clinical testing services that our diagnostics customers will provide based upon our products by educating third-party payors regarding the clinical utility and health economic value of the clinical tests enabled by our technology. Second, we will seek to establish an installed base of nCounter Analysis Systems by selling or leasing instruments to select clinical laboratories, with initial sales efforts directed at large commercial laboratories and academic medical centers that treat a high volume of breast cancer patients. Third, we will dri