NanoString Technologies Inc Form S-1/A June 13, 2013 <u>Table of Contents</u>

As filed with the Securities and Exchange Commission on June 13, 2013

Registration No. 333-188704

#### **UNITED STATES**

#### SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### **AMENDMENT NO. 1**

ТО

#### FORM S-1

#### **REGISTRATION STATEMENT Under The Securities Act of 1933**

### NANOSTRING TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

**Delaware** (State or other jurisdiction of incorporation or organization) 3826 (Primary Standard Industrial Classification Code Number) 530 Fairview Avenue, N., Suite 2000 **20-0094687** (I.R.S. Employer Identification Number)

Seattle, Washington 98109

#### (206) 378-6266

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

#### **R. Bradley Gray**

#### **President and Chief Executive Officer**

#### 530 Fairview Avenue, N., Suite 2000

#### Seattle, Washington 98109

#### (206) 378-6266

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

Copies to:

| Patrick J. Schultheis             | Alan F. Denenberg            |
|-----------------------------------|------------------------------|
| Wilson Sonsini Goodrich & Rosati, | Davis Polk & Wardwell LLP    |
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| Seattle, Washington 98104         | (650) 752-2000               |

#### (206) 883-2500

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

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

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

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

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

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

Large accelerated filer "

Common Stock,

Accelerated filer "

Non-accelerated filer x (Do not check if a smaller reporting company) Smaller reporting company "

#### CALCULATION OF REGISTRATION FEE

| Title of each class of          | Proposed<br>maximum            |                                  |
|---------------------------------|--------------------------------|----------------------------------|
| securities to be registered     | aggregate<br>offering price(1) | Amount of<br>registration fee(2) |
| a, par value \$0.0001 per share | \$ 93,150,000                  | \$ 12,705.66                     |

(1) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes shares that the underwriters have the option to purchase to cover overallotments, if any.

(2) The registrant previously paid a registration fee of \$11,764.50 with the initial filing of this registration statement.

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

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

**PROSPECTUS** (Subject to Completion)

Issued June 13, 2013

### 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 expected to be between \$13.00 and \$15.00 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.

|   | Per Share | Total |
|---|-----------|-------|
| Initial public offering price                             | \$        | \$    |
| Underwriting discounts and commissions                    | \$        | \$    |
| Proceeds to NanoString Technologies, Inc. before expenses | \$        | \$    |

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 not currently anticipated that the aggregate purchase price of the shares to be purchased by these investors in this offering will exceed \$10.0 million.

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 , 2013.

J.P. Morgan

Leerink Swann

**Morgan Stanley** 

Baird

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, 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 , 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.

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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.

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#### **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 Onco*type* 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 Onco*type* 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

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

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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.

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 nCounter 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 <sup>®</sup> 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.

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#### The Offering

| Common stock offered by us                         | 5,400,000 shares   |
|--|--|
| Common stock to be outstanding after this offering | 14,594,745 shares (or 15,404,745 if the underwriters exercise their overallotment option in full)  |
| Overallotment option                               | 810,000 shares   |
| 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 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:

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, |              | Three Months Ended<br>March 31, |            |            |
|---|-------------------------|--------------|---------------------------------|------------|------------|
|   | 2010                    | 2011         | 2012                            | 2012       | 2013       |
| Consolidated Statements of Comprehensive Income:  |                         | (In thousand | ds, except per sh               | are data)  |            |
| 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      |
|   |                         |              |                                 |            |            |

|  | Actual    | As of March 31, 2013<br>Pro Forma<br>Actual As Adjusted <sup>(2)</sup><br>(In thousands) |        |  |
|--|-----------|--|--------|--|
| Consolidated Balance Sheet Data:                   |           |  |        |  |
| Cash and cash equivalents                          | \$ 11,794 | \$   | 81,138 |  |
| Working capital                                    | 12,250    |  | 81,594 |  |
| Total assets                                       | 29,575    |  | 96,583 |  |
| Total long-term debt                               | 12,835    |  | 12,835 |  |
| Mandatorily redeemable convertible preferred stock | 105,964   |  |        |  |
| Total stockholders equity (deficit)                | (102,808) |  | 74,178 |  |

- (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 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 an assumed initial price to public of \$14.00 per share, the mid-point of the range reflected on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses. Each \$1.00 increase (decrease) in the assumed initial price to public of \$14.00 per share, would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders deficit by approximately \$5.0 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the underwriting discounts and commissions and estimated offering. Each increase (decrease) of 1,000,000 in the number of shares offered by us would increase (decrease) each of cash and cash equivalents, working capital, total assets offered by us would increase (decrease) ach of cash and commissions and estimated offering expenses. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of 1,000,000 in the number of shares offered by us would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders deficit by approximately \$13.0 million, assuming that the assumed initial price to public remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses. The pro forma as adjusted information discussed above is illustrative only and will adjust based on the ac
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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.

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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

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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

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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. We believe 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

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

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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;

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

political and economic instability;

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:

dispose of assets;

complete mergers or acquisitions;

incur indebtedness;

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.

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.

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#### **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

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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 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.

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# 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.

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

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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

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;

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 we expect that our common stock will be 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 57.50% 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 (assuming an initial price to public of \$14.00, the midpoint of the range on the cover page of this prospectus), 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

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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.

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#### 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 \$67.0 million, or approximately \$77.6 million if the underwriters exercise their overallotment option in full, based upon an assumed initial price to public of \$14.00 per share, the mid-point of the range reflected on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses. Each \$1.00 increase (decrease) in the assumed initial price to public of \$14.00 per share would increase (decrease) the net proceeds to us from this offering by approximately \$5.0 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) the net proceeds to us from this offering by approximately \$13.0 million, assuming that the assumed initial price to public remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the initial price to public or the number of shares by these amounts would have a material effect on uses of the proceeds from this offering, although it may accelerate the time at which we will need to seek additional capital.

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

approximately \$25 million to commercialize Prosigna after obtaining regulatory authorization, including establishing a dedicated oncology sales force;

approximately \$15 million to expand the clinical utility of Prosigna and to develop other potential diagnostic product opportunities;

approximately \$15 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 \$10 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.

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#### **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.

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#### 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 an assumed initial price to public of \$14.00 per share, the mid-point of the range reflected on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses.

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 Marc                      | h 31, 2013  |
|--|---------------------------------|---|
|  | Actual<br>(In thousands, except | Pro Forma<br>As Adjusted <sup>(1)</sup><br>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   |                                 | 176,985   |
| Accumulated deficit  | (102,808)                       | (102,808)   |
| Total stockholders equity (deficit)  | (102,808)                       | 74,178  |
| Total capitalization   | \$ 15,991                       | \$ 87,013   |

(1) Each \$1.00 increase (decrease) in the assumed initial price to public of \$14.00 per share, the mid-point of the range reflected on the cover page of this prospectus, would increase (decrease) each of additional paid-in capital, total stockholders deficit and total capitalization by approximately \$5.0 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) each of additional paid-in capital, total stockholders deficit and total capitalization by approximately \$13.0 million, assuming that the assumed initial price to public remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses. The pro forma as adjusted information discussed above is illustrative only and will adjust based on the actual initial price to public and other terms of this offering determined at pricing.

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 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.

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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 an assumed initial price to public of \$14.00 per share (the midpoint of the price range set forth on the cover of this prospectus), 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 \$74.2 million, or \$5.08 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$4.55 per share to existing stockholders and an immediate dilution of \$8.92 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:

| Assumed initial price to public per share  |         | \$ 14.00 |
|--|---------|----------|
| 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 | 4.55    |          |
| Pro forma as adjusted net tangible book value per share, as adjusted to give effect to this offering   |         | 5.08     |
| Pro forma dilution per share to investors participating in this offering                               |         | \$ 8.92  |

Each \$1.00 increase (decrease) in the assumed initial price to public of \$14.00 per share would increase (decrease) the pro forma as adjusted net tangible book value by approximately \$5.0 million, or approximately \$0.34 per share, and increase (decrease) the pro forma dilution per share to investors in this offering by approximately \$0.66 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses. We may also increase or decrease the number of shares we are offering. An increase of 1,000,000 in the number of shares offered by us would increase the pro forma as adjusted net tangible book value by approximately \$13.0 million, or \$0.51 per share, and the pro forma dilution per share to investors in this offering would be \$8.41 per share, assuming that the assumed initial price to public remains the same, and after deducting the estimated offering expenses. Similarly, a decrease of 1,000,000 shares in the number of shares offered by us would decrease the pro forma as adjusted net tangible book value by approximately \$13.0 per share, assuming that the assumed initial price to public remains the same, and after deducting the estimated offering expenses. Similarly, a decrease of 1,000,000 shares in the number of shares offered by us would decrease the pro forma as adjusted net tangible book value by approximately \$13.0 million, or \$0.58 per share, and the pro forma dilution per share to investors in this offering would be \$9.50 per share, assuming that the assumed initial price to public remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses. The pro forma as adjusted net tangible book value by approximately \$13.0 million, or \$0.58 per share, and the pro forma dilution per share to investors in this offering would be \$9.50 per share, assuming that the assumed initial price to public remains th

If the underwriters exercise their option in full to purchase 810,000 additional shares of common stock in this offering, the pro forma as adjusted net tangible book value per share after the offering would be \$5.50 per share, the increase in the pro forma net tangible book value per share to existing stockholders would be \$4.97 per share and the pro forma dilution to new investors purchasing common stock in this offering would be \$8.50 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 an assumed initial price to public of \$14.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses (in thousands, except per share amounts):

|  |           |          |            |           | Weighted-<br>Average |
|--|-----------|----------|------------|-----------|----------------------|
|  | Shares Pu | ırchased | Total Cons | ideration | Price                |
|  | Number    | Percent  | Amount     | Percent   | Per Share            |
| Existing stockholders before this offering | 9,195     | 63.0%    | \$ 83,800  | 52.6%     | \$ 9.11              |
| Investors participating in this offering   | 5,400     | 37.0     | 75,600     | 47.4      | 14.00                |
| Total                                      | 14,595    | 100.0%   | \$ 159,400 | 100.0%    |                      |

Each \$1.00 increase (decrease) in the assumed initial price to public of \$14.00 per share would increase (decrease) total consideration paid by new investors by approximately \$5.0 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses. We may also increase or decrease the number of shares we are offering. An increase (decrease) of 1,000,000 in the number of shares offered by us would increase (decrease) total consideration paid by new investors by \$13.0 million, assuming that the assumed initial price to public remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses.

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 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.

#### 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. 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 I<br>2009 | Ended Decemb<br>2010 | er 31,<br>2011 | 2012        | Three I<br>Ended M<br>2012 |            |
|--|-------------|----------------|----------------------|----------------|-------------|----------------------------|------------|
|  |             |                | In thousands,        | except per sha | re amounts) |                            |            |
| Consolidated Statements of Comprehensive<br>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 $(unaudited)^{(1)}$ |             |                |                      |                | \$ (2.16)   |                            | \$ (0.74)  |

| S  | hares used in computing    | pro form   | a net loss p     | er |
|----|----------------------------|------------|------------------|----|
| sl | nare, basic and diluted (u | inaudited) | ) <sup>(1)</sup> |    |

9,168

|  |          |          | As of           |                  |           |                   |
|--|----------|----------|-----------------|------------------|-----------|-------------------|
|  | 2008     | 2009     | 2010<br>(In tho | 2011<br>ousands) | 2012      | March 31,<br>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 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.

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#### 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

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.

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.

|                      |           | Y    | ear Ended Dec | cember 31 | ,              |         | Three    | Months E | nded March | 31,  |
|----------------------|-----------|------|---------------|-----------|----------------|---------|----------|----------|------------|------|
|                      | 2010      |      | 2011          |           | 2012           |         | 2012     | 2        | 2013       | ;    |
|                      |           |      |               | (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 Dece | nber 31,               |          | Months<br>Iarch 31, |
|--|----------|------------|------------------------|----------|---------------------|
|  | 2010     | 2011       | 2012<br>(In thousands) | 2012     | 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 -48-

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.

|                  | 2010      | Y    | ear Ended Dec<br>2011 |      | ,<br>2012<br>Dollars in tho |      | Three 2012 |      | nded March<br>2013 | ,    |
|------------------|-----------|------|-----------------------|------|-----------------------------|------|------------|------|--------------------|------|
| 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 Months<br>Ended March 31, |                       | 2012 v. 2013 |  |
|------------------|----------|---------------------------------|-----------------------|--------------|--|
|                  | 2012     | 2013                            | Dollars<br>thousands) | 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           |  |
| r                | \$ 1,010 | + =,/ > .                       | + 710                 | 01           |  |
| 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

|                                  | Three M<br>Ended M |             | Change     | 2012 v. 2013 |
|----------------------------------|--------------------|-------------|------------|--------------|
|                                  | 2012               | 2013        | Dollars    | Percentage   |
|                                  |                    | (Dollars in | 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

increase in diagnostic external development costs.

Selling, General and Administrative Expense

|   |       | Three Months    |                 |              |
|---|-------|-----------------|-----------------|--------------|
|   | E     | Inded March 31, | Change          | 2012 v. 2013 |
|   | 20    | 12 2013         | Dollars         | Percentage   |
|   |       | (Dollar         | s in 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 M<br>Ended M |            | Change 2     | 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

|                  |          | ar Ended<br>æmber 31, | Change 2                | 2011 v. 2012 |
|------------------|----------|-----------------------|-------------------------|--------------|
|                  | 2011     | 2012<br>(Dollars i    | Dollars<br>n thousands) | Percentage   |
| 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   | f systems sold, prin | marily related to a | n increase in sales outside |
| of the United States. The net selling price of our instruments was relatively flat. T | ne increase in const | umable revenue wa   | as related to our increased |
| instrument installed base. Overall, we derived \$3.3 million in incremental reven     | e from customers     | outside of North A  | America as a result of the  |
| expansion of our overseas sales and marketing efforts.                                |                      |                     |                             |

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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     | Year Ended  |            |              |  |  |  |
|----------------------------------|----------|-------------|------------|--------------|--|--|--|
|                                  | Decem    | ıber 31,    | Change 2   | 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

|   | Year     | Ended     |                     |            |  |
|---|----------|-----------|---------------------|------------|--|
|   | Decen    | 1ber 31,  | Change 2011 v. 2012 |            |  |
|   | 2011     | 2012      | Dollars             | Percentage |  |
|   |          | , 8       |                     |            |  |
| 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       |                     |            |  |
|--|----------|-------------|---------------------|------------|--|
|  | Decen    | nber 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

|                  |          | Ended<br>nber 31,     | Change 2010 v. 2011 |            |  |
|------------------|----------|-----------------------|---------------------|------------|--|
|                  | 2010     | 2011<br>(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     | Ended    |                     |            |  |
|----------------------------------|----------|----------|---------------------|------------|--|
|                                  | Decem    | ber 31,  | Change 2010 v. 2011 |            |  |
|                                  | 2010     | 2011     | Dollars             | Percentage |  |
|                                  |          | ,        |                     |            |  |
| 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 F<br>Deceml |                        | Change 2010 v. 2011 |            |  |  |
|---|------------------|------------------------|---------------------|------------|--|--|
|   | 2010             | 2011                   | Dollars             | Percentage |  |  |
|   |                  | (Dollars in 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

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

Other Income (Expense), Net

|  |        | Ended<br>ber 31, | Change 2                 | 2010 v. 2011 |
|--|--------|------------------|--------------------------|--------------|
|  | 2010   | 2011<br>(Dollars | Dollars<br>in thousands) | Percentage   |
| 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 | ember 30, | Dece | ember 31, | M     | arch 31,   | June 30, | Sept | ember 30, | Dece | ember 31, | March 31, |
|                          | 2011               | 2011     |      | 2011      |      | 2011      |       | 2012       | 2012     |      | 2012      |      | 2012      | 2013      |
|                          |                    |          |      |           |      | (Dol      | llars | s in thous | ands)    |      |           |      |           |           |
| Revenue:                 |                    |          |      |           |      |           |       |            |          |      |           |      |           |           |
| 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     |      |           |       |            |          |      |           |      |           |           |