NanoString Technologies Inc
Form 10-K
March 27, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2013

Or

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

For the transition period from to

Commission file number: 001-35980

NANOSTRING TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-0094687**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

530 Fairview Avenue North, Suite 2000

Seattle, Washington	**98109**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code: (206) 378-6266

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

Title of Each Class	**Name of Exchange on Which Registered**
Common Stock, $0.0001 par value per share	**The NASDAQ Stock Market LLC (The NASDAQ Global Market)**

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

None

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). (Check one): Yes ¨ No x

The aggregate market value of the voting and non-voting stock held by non-affiliates of the Registrant, based on the closing sale price of the Registrant s common stock on the last business day of its most recently completed second fiscal quarter, as reported on The NASDAQ Global Market, was approximately $53.1 million. Shares of common stock held by each executive officer and director and by each person who owns 5% or more of the outstanding common stock, based on filings with the Securities and Exchange Commission, have been excluded from this computation since such persons may be deemed affiliates of the Registrant. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

There were 18,052,694 shares of the Registrant s common stock, $0.0001 par value per share, outstanding on March 21, 2014.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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NANOSTRING TECHNOLOGIES, INC.

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2013

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PART I

Item 1. Business

Forward-Looking Information

This Annual Report on Form 10-K, including the Management s Discussion and Analysis of Financial Condition and Results of Operation section in Item 7, and other materials accompanying this Annual Report on Form 10-K contain forward-looking statements or incorporate by reference forward-looking statements. The statements contained in this Annual Report on Form 10-K that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are identified by words such as believe, anticipate, expect, intend, plan, may, and other similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other forward-looking information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements include, but are not limited to:

- our expectations regarding our future operating results, including our expectations regarding instrument, consumable and total revenue and operating and net loss;
- our ability to successfully commercialize Prosigna, our first product for which we have obtained a CE mark in the European Union and, in September 2013, received 510(k) clearance from the U.S. Food and Drug Administration, or FDA;
- the implementation of our business model and strategic plans for our business;
- the regulatory regime and our ability to secure regulatory clearance or approval for the clinical use of our products, domestically and internationally;
- our strategic relationships, including with patent holders of our technologies, manufacturers and distributors of our products, and third parties who conduct our clinical studies;
- our intellectual property position;
- our expectations regarding the market size and growth potential for our business;
- 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.

All forward-looking statements are based on information available to us on the date of this Annual Report on Form 10-K and we will not update any of the forward-looking statements after the date of this Annual Report on Form 10-K, except as required by law. Our actual results could differ materially from those discussed in this Annual Report on Form 10-K. The forward-looking statements contained in this Annual Report on Form 10-K, and other written and oral forward-looking statements made by us from time to time, are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in the following discussion and within Part I, Item 1A Risk Factors of this Annual Report on Form 10-K.

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

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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 and to clinical laboratories and medical centers for diagnostic use. We have an installed base of more than 180 systems, which our customers have used to publish more than 360 peer-reviewed papers. As researchers discover how genomic information can be used to improve clinical decision-making, these discoveries can be translated and validated as diagnostic tests based on our nCounter Elements General Purpose Reagents, or GPRs. In certain situations, we intend to translate their discoveries into *in vitro* diagnostic assays. For example, in September 2013, we received 510(k) clearance from the U.S. Food and Drug Administration, or FDA, to market in the United States a version of our first molecular diagnostic product, the Prosigna Breast Cancer Assay, or 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 genomic analysis on a scale appropriate for pathway-based biology by digitally quantifying the activity of up to 800 genes simultaneously in a single minute tissue sample. The sensitivity and precision of our novel barcoding chemistry allows the measurement of subtle changes in genomic activity efficiently, which is essential in both research and diagnostics 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. Researchers may use nCounter to develop their own diagnostic tests based on our nCounter Elements GPRs or we may selectively partner with them to translate their discoveries into *in vitro* diagnostic assays.

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 research 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. We have conducted two large clinical studies, based on tumor samples from over 2,400 patients, validating 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 one of these studies, we compared the risk estimate provided by Prosigna to the risk estimate previously generated using Genomic Health s Onco*type* DX, the historical market leader in breast cancer recurrence testing. Investigators concluded that Prosigna is capable of providing more prognostic information than Onco*type* DX. In September 2013, we received 510(k) clearance from the FDA to market in the United States a version of Prosigna providing an assessment of a patient s risk of recurrence for breast cancer. In December 2013, we commercially launched Prosigna in the United States, and entered into agreements with three national diagnostic reference laboratories and two comprehensive cancer centers to offer the Prosigna assay in the

United States, with the earliest testing beginning

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during the first quarter of 2014. These laboratories collectively serve the pathology testing needs of a substantial portion of breast cancer patients throughout the United States. We expect additional clinical laboratories to adopt Prosigna in the future. In September 2012, we obtained CE Mark designation in the European Union for a version of Prosigna that provides 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 November 2013, we began offering a version of the nCounter Dx Analysis System to high-complexity, CLIA-certified laboratories for research and diagnostics purposes. This FLEX configuration of the nCounter Dx Analysis System provides clinical laboratories a single platform with the flexibility to support both clinical testing, by running Prosigna, and research, by processing translational research experiments using our custom CodeSets and panels. The nCounter Elements GPRs provide further flexibility by allowing laboratories to develop their own Laboratory Developed Tests for gene expression, copy number variation and gene fusion signatures, which can be performed by a laboratory and may include genetic tests and other tests for rare conditions.

Prosigna is regulated as an *in vitro* diagnostic test and we distribute it as a kit for use on our nCounter Analysis System in clinical laboratories. We expect that our future *in vitro* 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 $31.4 million, $23.0 million and $17.8 million in 2013, 2012 and 2011, respectively, while incurring net losses of $29.3 million, $17.7 million and $10.9 million in 2013, 2012 and 2011, respectively.

We were incorporated in Delaware in June 2003. Our principal executive offices are located at 530 Fairview Avenue, N., Suite 2000, Seattle, Washington 98109 and our telephone number is (206) 378-6266. Our common stock trades on The NASDAQ Global Market under the symbol NSTG.

This Annual Report on Form 10-K includes our trademarks and registered trademarks, including NanoString®, NanoString Technologies®, nCounter®, Prosigna™ and nCounter Elements™. Each other trademark, trade name or service mark appearing in this Annual Report on Form 10-K belongs to its holder.

Where You Can Find Additional Information

We make available free of charge through our investor relations website, www.nanostring.com, our annual reports, quarterly reports, current reports, proxy statements and all amendments to those reports as soon as reasonably practicable after such material is electronically filed or furnished with the SEC. These reports may also be obtained without charge by contacting Investor Relations, NanoString Technologies, Inc., 530 Fairview Avenue, N., Suite 2000, Seattle, Washington 98109, e-mail: investorrelations@nanostring.com. Our Internet website and the information contained therein or incorporated therein are not intended to be incorporated into this Annual Report on Form 10-K. In addition, the public may read and copy any materials we file or furnish with the SEC at the SEC s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 or may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Moreover, the SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding reports that we file or furnish

electronically with them at www.sec.gov.

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Our Market Opportunity

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

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

Biological pathways are the networks of tens or hundreds of genes that work in concert to produce a biological function. Understanding the activation state of pathways and disruptions in individual elements of these pathways provides significant insight into the fundamental basis of disease and facilitates data driven treatment decisions. Therapeutic interventions, such as drugs, can be used to treat disease by activating or inactivating biological pathways that are relevant to disease. As a result, pathway-based biology has become a widely adopted paradigm that researchers use to understand biological processes and has assisted them in the development of diagnostics and drugs to treat disease. To be successful in their research, these scientists need the ability to precisely and simultaneously measure the activation state of the tens or hundreds of genes that comprise biological pathways.

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

Life Sciences Research

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

Academic, government, and biopharmaceutical researchers engaged in gene expression analysis typically focus on making biological discoveries that may lead to the development of relevant medical products and better informed treatment decisions for physicians and patients. They have traditionally performed these experiments using microarrays or qPCR. Recently, RNA-Seq has dramatically enhanced researchers ability to discover

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patterns of gene expression that have biological meaning. However, researchers are increasingly performing analyses on a larger number of genes and samples and are seeking new methods of interrogation that would allow them to:

- increase the number of genes that can be analyzed simultaneously in order to understand the complete biological pathway involving multiple genes;
- improve the overall efficiency of their laboratories by simplifying workflow and accelerating the rate of successfully completing their research;
- provide more reliable, precise and reproducible data about targeted genes and biological pathways;
- maximize the amount of genomic information extracted from precious tissue samples;
- minimize the computational intensity of complex genomic analysis;
- process difficult-to-work-with specimens, such as tumor biopsies stored in FFPE format; and
- create more systematic and reliable ways to help transition their research discoveries into future clinical products.

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

Molecular Diagnostics

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

determine which specific treatments are most likely to be effective for an individual patient, monitor a patient s response to those treatments, and determine the likelihood of recurrence.

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.

Multi-gene molecular diagnostic tests for breast cancer are provided by several companies today, including Genomic Health, Agendia and Clarient (a GE Healthcare company). These tests are offered as services with the analysis conducted at company-owned centralized laboratories. When a physician orders the test, the pathologist sends a tumor block or thin sections from the biopsy specimen to the centralized laboratory for analysis. The lab operator then uses a multi-gene panel to determine a risk category for each patient, which predicts that

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individual s likelihood of recurrence. The lab operator typically analyzes the tumor tissue and delivers results to the treating physician within 10 to 14 days of receipt of the tumor sample.

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

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

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

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

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

Our Solution

Our nCounter Analysis System is an automated, multi-application, digital detection and counting system which directly profiles hundreds of molecules simultaneously using a novel barcoding technology that is powerful enough for use in research, yet simple enough for use in clinical laboratories worldwide. Our nCounter Analysis System consists of two automated instruments that prepare and analyze tissue samples using proprietary reagents, which can only be obtained from us. Our research customers purchase instruments from us and then purchase our panels, custom CodeSets, nCounter Elements GPRs and related consumables for the specific experiment or assay they wish to conduct. Our clinical laboratory customers will either purchase or lease instruments from us and also generally purchase nCounter Elements GPRs or our diagnostic kits for tests 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 customers to analyze interactions among hundreds of genes that mediate biological pathways.

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

Simple Workflow. The nCounter Analysis System s minimal sample preparation and automated workflow enable the performance of gene expression analysis across hundreds of genes simultaneously in approximately 24 hours between the time a sample is loaded into the system and results are obtained. Our nCounter Analysis System generates data that customers can evaluate without the use of complex bioinformatics.

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

Versatility. The FLEX configuration of the nCounter Dx Analysis System provides clinical laboratories a single platform with the flexibility to support both clinical testing, by running Prosigna, and research, by processing translational research experiments and multiplexed assays using our custom CodeSets and panels. The nCounter Elements GPRs provide further flexibility by enabling laboratories to develop their own Laboratory Developed Tests for gene expression, copy number variation and gene fusion signatures.

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

Life Sciences Research

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

Research Applications

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

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

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

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

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

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

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Our customers have used the nCounter Analysis System to publish more than 360 peer-reviewed papers. In 2013 alone, our customers published more than 180 peer-reviewed papers incorporating data generated using the nCounter Analysis System. The most frequent topic of nCounter-based peer-reviewed publications is cancer research, including biomarker discovery and validation. Other frequent topics include immunology and inflammation, infectious disease and developmental and cell biology.

Consumables

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

Molecular Diagnostics

We believe that the attributes that make the nCounter Analysis System attractive to researchers also have the potential to make the system attractive to hospitals and clinical laboratories that desire to conduct molecular diagnostic tests. The precision, ease of use and flexibility of the nCounter Analysis System will allow medical technicians in pathology labs to conduct complex molecular diagnostic tests with minimal training. We expect these tests to encompass both Laboratory Developed Tests based on our nCounter Elements GPRs and *in vitro* diagnostic kits, initially Prosigna.

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

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

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

addition, our decentralized model can help address the needs of patients outside of the United States by enabling local laboratories to provide testing.

Potentially More Treatment Decisions. Prosigna measures the expression of up to 50 genes, providing a more detailed profile of the biology of a patient s tumor than the first-generation tests. In addition, Prosigna utilizes the concept of intrinsic subtypes, a fundamental method of classifying breast tumors into the four distinct subtypes of that disease. By providing a more detailed view of tumor biology and

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determining the intrinsic subtype of breast cancer patients, Prosigna has the potential to inform not only the decision of whether to administer adjuvant chemotherapy, but also potentially inform other important treatment decisions. These decisions may include the selection of specific adjuvant chemotherapy for individual patients, the duration of adjuvant endocrine therapy, and the use of adjuvant radiation therapy. We intend to perform clinical studies validating Prosigna s ability to inform additional treatment decisions, and to seek a pre-market approval, or PMA, to enable Prosigna to report these intrinsic subtypes for use in informing clinical decisions within the United States.

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

Our Strategy

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

Our strategy includes the following key elements:

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

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 diagnostic content, in collaboration with researchers and biopharmaceutical companies, comprising both proprietary *in vitro* diagnostic kits and Laboratory Developed Tests based on nCounter Elements GPRs.

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 unified research and diagnostics business model.

Our Products and Technology

The fundamental technology employed in our nCounter Analysis System was conceived at the Institute for Systems Biology in the laboratories of Dr. Leroy Hood, a renowned pioneer in genomics and personalized medicine. Our research customers purchase instruments from us and then purchase our panels or custom CodeSets and related consumables for the specific experiment they wish to conduct. Our clinical laboratory customers will either purchase or lease instruments from us and also generally purchase nCounter Elements GPRs or our diagnostic kits for tests that they intend to run.

nCounter Analysis System

The nCounter Analysis System is an automated, multi-application, digital detection and counting system consisting of one or more nCounter Prep Stations and one nCounter Digital Analyzer. Since 2008, we have marketed a research use only version of the system, and in 2013 we introduced the nCounter Dx Analysis System

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to be marketed to clinical laboratories. The nCounter Dx Analysis System comes in two configurations, one that only runs Prosigna and one that is called the FLEX Configuration, a dual-mode system that runs Prosigna in one mode and our research applications, including nCounter Elements, in the other.

Instruments and Software

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

Simple and Rapid NanoString Workflow

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

- during step 1, up to 12 targeted research tissue samples (or up to 48 samples with sample multiplexing) or up to 10 breast cancer tissue samples in the case of Prosigna, and our reagents or diagnostic kits are injected into strip tubes that we provide and allowed to hybridize overnight;

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

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

When the nCounter Analysis System is run in research mode, a user can process up to approximately 36 samples per day by installing one Prep Station with a single Digital Analyzer. One can increase the number of samples analyzed to 108 samples per day on a single Digital Analyzer if it is coupled with three Prep Stations. This throughput can be quadrupled using sample multiplexing for experiments targeting 200 genes or fewer. For Prosigna, a clinical laboratory can process up to 30 samples per day on an nCounter Dx Analysis System.

Life Sciences Research

Following purchase of our nCounter Analysis System, research customers purchase panels, custom CodeSets targeted to a specific experiment or nCounter Elements GPRs.

Panels

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

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

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

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

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

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

Custom CodeSets

We also work with our customers to develop custom CodeSets to enable them to evaluate specific genes that are the subject of their study. Our customers provide us a list of targets for which we subsequently build a unique CodeSet. Our design process leverages full length sequences for the DNA or RNA molecules that our customers are interested in detecting and prevents cross hybridization to non-target molecules in the sample. The custom CodeSet design process occurs in four distinct steps: (1) the customer selects the genes of interest, (2) we design probes and provide a design report to the customer, (3) the customer reviews and approves the design report, and (4) we manufacture, test and ship the CodeSet to the customer. The manufacturing process typically takes from three to five weeks, depending on the number of genes targeted and samples to be processed by the customer.

nCounter Elements

nCounter Elements is our digital molecular barcoding chemistry that allows users to design their own customized assays using standard sets of barcodes provided by us with the laboratories choice of oligonucleotide probes that they can purchase independently from an oligonucleotide manufacturer. Clinical laboratories can use nCounter Elements to create Laboratory Developed Tests, which are diagnostic tests that are developed and performed by a laboratory and include genetic tests and other tests for rare conditions. In addition, the highly flexible architecture of nCounter Elements enables a broad range of basic research studies where iterative design and refinement of assays are important.

nCounter Elements GPRs have been registered with the FDA as GPRs and are available for use in developing Laboratory Developed Tests, pursuant to a licensing arrangement.

Master Kits

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

Molecular Diagnostics

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

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Following purchase or lease of our nCounter Dx Analysis System, we expect that our clinical laboratory customers will build menus of diagnostic tests comprised of Laboratory Developed Tests, Prosigna and other *in vitro* diagnostic kits we develop and sell in the future. These customers will use the nCounter Dx Analysis System, nCounter Elements GPRs and *in vitro* diagnostic kits to provide clinical diagnostic services. Currently, Prosigna is the only *in vitro* diagnostic kit available for use on our nCounter Dx Analysis System. Over time, we intend to develop, obtain regulatory authorization for, and sell additional *in vitro* diagnostic kits, each of which will enable a unique diagnostic test.

Informing Breast Cancer Treatment using the PAM50 Gene Signature

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

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

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

- providing prognostic information that may help physicians and patients decide whether the addition of adjuvant chemotherapy to hormonal therapy is appropriate;
- providing prognostic information that may help physicians and patients decide whether extended endocrine therapy is appropriate;
- providing information that may help physicians choose which adjuvant chemotherapy regimen to select for an individual patient; and
- providing information that may help physicians and patients decide whether adjuvant radiation therapy is appropriate.

Development and Validation of the Prosigna Breast Cancer Assay

In 2010, we began developing Prosigna based on our in-licensed PAM50 gene signature, simplifying and optimizing the test for use on the nCounter Analysis System. In 2011, we performed the first in a series of clinical studies designed to validate the test s ability to provide prognostic information for postmenopausal women with HR+ early stage breast cancer treated with endocrine therapy alone using material extracted from tumor samples from 1,017 patients from the TransATAC population of which 1,007 samples passed prespecified criteria and yielded evaluable results. TransATAC is a translational study group that has used the tumor tissue and data from a subset of the 9,366 women enrolled (1996-2000) in the ATAC (Arimidex, Tamoxifen, Alone or in Combination) trial to study the molecular characteristics of tumors in postmenopausal women with HR+ early stage breast cancer of pathological grade 1, 2 or 3. The TransATAC population had been previously used in 2008 to clinically validate the current market leader in breast cancer prognosis and prediction, Genomic Health s Onco*type* DX, which is a laboratory-developed test that is administered using a centralized laboratory service

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model. Our study used RNA that had been extracted by Genomic Health from 1,017 tumor samples from patients with postmenopausal HR+ early stage breast cancer during the 2008 study. Because both the Onco*type* DX results and the outcomes of the patients associated with each RNA sample were known, the study provided an opportunity to measure both the ability of Prosigna to provide prognostic information, and how the prognostic information provided by Prosigna compares to data previously collected using Onco*type* DX. Results of our TransATAC study were presented in December 2011 at the CTRC-AACR San Antonio Breast Cancer Symposium. In July 2013 the TransATAC results were published in the Journal of Clinical Oncology.

In 2012, we performed a second clinical validation study to test the ability of Prosigna to estimate the prognosis of postmenopausal women with HR+ early stage breast cancer treated with endocrine therapy alone that evaluated tumor samples from 1,620 patients enrolled in the Austrian Breast & Colorectal Cancer Study Group 8, or ABCSG8, trial, of which 1,478 samples passed prespecified criteria and yielded evaluable results. The ABCSG8 trial enrolled 3,714 women (1996-2003) to compare the safety and efficacy of tamoxifen alone to sequential treatment with tamoxifen followed by anastrozole in postmenopausal women with HR+ early stage breast cancer of pathological grade 1 or 2. Results of our ABCSG8 study were presented in December 2012 at the CTRC-AACR San Antonio Breast Cancer Symposium. In December 2013, the results of the ABCSG8 study were published in the Annals of Oncology, the Journal of the European Society of Medical Oncology.

Beginning in 2012, we planned and executed a series of prospectively defined analyses of the data sets from the ATAC and ABCSG8 trials designed to clinically validate additional features and benefits of Prosigna. Results from three of these analyses have been presented publicly at medical meetings. At the European Society of Medical Oncology meeting in September 2012, the investigators of our TransATAC study presented results indicating that the prognostic risk of recurrence, or ROR, score provided by Prosigna adds significant prognostic information to clinical-pathology variables for recurrence between five and 10 years after diagnosis, which is often referred to as late recurrence. In September 2013, these results were published in the Journal of the National Cancer Institute. At the IMPAKT Breast Cancer Conference in May 2013, the investigators of our TransATAC study and our ABCSG8 study presented additional analyses providing further evidence that Prosigna provides valuable information that could assist with treatment decisions by helping to identify patients at highest risk of this late recurrence. In February 2014, these results from the ABCSG8 study were published in the journal Clinical Cancer Research. In addition, the results of an analysis of the combined data set of the ABCSG8 and ATAC studies was presented during the 2013 Annual American Society of Clinical Oncology, or ASCO, Meeting in June 2013 and demonstrated that Prosigna can identify a clinically significant number of low risk patients with one or two positive nodes. Several additional analyses of the ABCSG8 and ATAC studies are planned or ongoing.

In 2012, we performed a series of multi-site analytical validation studies intended to show that Prosigna provides consistent and reliable results, independent of the specific instrument, laboratory or operator performing the testing. We presented results from these analytical validation studies in March 2013 at the United States & Canadian Academy of Pathology annual meeting. In March 2014, these results were published in the journal BMC Cancer.

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

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

in satisfaction of the primary objective of both studies, the ROR score was significantly related to outcome, and added significant prognostic information about 10 year distant recurrence risk to standard clinical-pathological variables in the study populations as a whole. In satisfaction of a secondary objective of both studies, similar results were achieved in all three prospectively defined clinically important subsets of patients: node-negative, node-positive and HER2-negative;

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

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

When taken together, we believe that our TransATAC and ABCSG8 studies provide strong evidence for Prosigna s clinical validity.

Comparison of Prosigna and Oncotype DX Performance in Our TransATAC Study

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

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

For each test, the low risk group was prospectively defined as patients with less than a 10% estimated risk of recurrence. For each test, the intermediate risk group was prospectively defined as patients with between a 10% and 20% estimated risk of recurrence. For each test, the high risk group was prospectively defined as patients with greater than a 20% estimated risk of recurrence.

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

Prosigna in the United States.

In September 2013, we received 510(k) clearance from the FDA to market in the United States a version of Prosigna providing a prognostic indicator for distant recurrence-free survival at 10 years, and is indicated for postmenopausal women with Stage I/II lymph node-negative or Stage II lymph node-positive (one to three positive nodes) hormone receptor-positive breast cancer who have undergone surgery in conjunction with locoregional treatment consistent with standard of care. For each patient, the Prosigna report includes the Prosigna Score, which is referred to as the ROR Score in the scientific literature and outside the United States, and a risk category based on both the Prosigna

Score and nodal status. Node-negative patients are classified as low, intermediate or high risk, while node-positive patients are classified as low or high risk. Prosigna is not intended for diagnosis, to predict or detect response to therapy, or to help select the optimal therapy for patients. We expect Prosigna to be competitive with other products that are currently available in the United States given the advantages demonstrated by our published clinical studies. In the future, we plan to submit a separate

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application for approval to report intrinsic subtype. If we obtain approval to report intrinsic subtyping from the FDA, we expect our competitive position in the United States will be enhanced. We expect that this future application will require a PMA supported by additional clinical studies.

We sell Prosigna kits to our lab customers on a fixed dollars-per-kit basis. These customers are responsible for providing the testing service and contracting and billing payors. Accordingly, we are not directly exposed to third-party payor reimbursement risk.

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

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

Intellectual Property

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

As of December 31, 2013, we owned or exclusively licensed seven issued U.S. patents and approximately 23 pending U.S. patent applications, including provisional and non-provisional filings. We also owned or licensed approximately 73 pending and granted counterpart applications worldwide, including 22 country-specific validations of four European patents. The issued U.S. patents that we own or exclusively license are expected to expire between July 3, 2021 and March 28, 2029. We have either sole or joint ownership positions in all of our pending U.S. patent applications. Where we jointly own cases, we have negotiated license or assignment provisions for exclusive rights. For our material nCounter Analysis System and Prosigna product rights, we are the exclusive licensee. We also generally protect our newly developed intellectual property by entering into confidentiality agreements that include intellectual property assignment clauses with our employees, consultants and collaborators.

Our patent applications relate to the following three main areas:

- our nCounter Analysis System biology, chemistry, software and hardware;
- specific applications for our nCounter Analysis System technology; and
- our gene expression markers, methods and algorithms for recurrence and drug response in certain forms of cancer.

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

Patent and Patent Application Numbers	Form of Ownership	Expected Expiration Date	Description
US 7,473,767, US 7,919,237, US 8,148,512, EP Patent No. 1448581, AU Patent No. 2002327202, CA Patent No. 2452712, JP Patent No. 4343682, USSN 13/794,299, US 8,492,094 and foreign applications in certain jurisdictions claiming priority to PCT/ US2002/021278	In-licensed from the Institute for Systems Biology	7/3/2021	Directed to compositions and methods of immobilization and detection
EP Patent No. 1963531, AU Patent No. 2006330830, USSN 13/794,424 and foreign applications in certain jurisdictions claiming priority to PCT/US2006/049274	Co-owned with the Institute for Systems Biology	12/22/2026	Directed to compositions and methods of immobilization and detection
EP Patent No. 1963500, USSN 11/645,270 and foreign applications in certain jurisdictions claiming priority to PCT/ US2006/049279	Owned	12/22/2026	Directed to methods of immobilization and detection
US 7,941,279, AU Patent No. 2007268027, CA Patent No. 2653095, JP Patent No. 5081232 and foreign applications in certain jurisdictions claiming priority to PCT/US2007/012130	Owned	5/21/2027	Directed to compositions
US 8,415,102, USSN 13/788,133 and foreign applications in certain jurisdictions claiming priority to PCT/US2008/059959	Owned	4/10/2028	Directed to methods of manufacture
US 8,519,115, USSN 13/957,029 and foreign applications in certain jurisdictions claiming priority to PCT/ US2009/053790	Owned	8/13/2029	Directed to compositions and methods of detections

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

Patent Application Numbers	Form of Ownership	Expected Expiration Date	Description
USSN 12/904,078 and foreign applications in certain jurisdictions claiming priority to PCT/ US2010/052556	Owned	10/13/2030	Directed to compositions and methods of detection
USSN 13/025,458 and foreign applications in certain jurisdictions claiming priority to PCT/ US2011/024519	Owned	2/11/2031	Directed to compositions and methods of detection
USSN 13/049,682 and foreign applications in certain jurisdictions claiming priority to PCT/ US2011/028657	Owned	3/16/2031	Directed to methods of detection
USSN 14/007,586	Owned	3/28/2032	Directed to compositions and methods of diagnosis
USSN 13/530,848 and foreign applications in certain jurisdictions claiming priority to PCT/ US2012/043799	Owned	6/22/2032	Directed to compositions and methods of detection
USSN 14/078,009 and PCT/US2013/069665	Owned	11/12/2033	Directed to compositions and methods of diagnosis
Additional pending provisional patent applications	Owned	2033	Directed to nCounter Analysis System methods of use

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

Patent Application Numbers	Form of Ownership	Expected Expiration Date	Description
USSN 13/959,575 and foreign applications in certain jurisdictions claiming priority to PCT/US2006/044737	In-licensed from Bioclassifier, LLC	11/17/2026	Directed to methods of prognosis
EP Patent No. 2297359, USSN 12/995,450 and foreign applications in certain jurisdictions claiming priority to PCT/ US2009/045820	In-licensed from Bioclassifier, LLC	6/1/2029	Directed to methods of prognosis
USSN 13/421,367 and foreign applications in certain jurisdictions claiming priority to PCT/ US2012/029226	In-licensed from Bioclassifier, LLC	3/15/2032	Directed to methods of treatment and determining drug response
USSN 13/690,891 and PCT/ US2012/067317	In-licensed from Bioclassifier, LLC	11/30/2032	Directed to methods of treatment and determining drug response
USSN 13/899,656 and PCT/US2013/042157	Owned	5/22/2033	Directed to compositions and methods of using gene expression markers
USSN 13/930,249 and PCT/US2013/048551	In-licensed from Bioclassifier, LLC	6/28/2033	Directed to methods of treatment and determining drug response
Additional pending provisional patent applications	Owned or In-licensed from Bioclassifier, LLC	2033	Directed to compositions and methods of using gene expression markers, some of which are owned by NanoString Technologies, Inc. and some of which are encompassed by our license agreement with Bioclassifier, LLC

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

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

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Collaborations; License Agreements

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

Institute for Systems Biology

In 2004, we entered into an agreement with the Institute for Systems Biology pursuant to which the Institute granted to us an exclusive, subject to certain government rights, worldwide license, including the right to sublicense, to the digital molecular barcoding technology on which our nCounter Analysis System is based, including 13 patents and patent applications. We issued 15,625 shares of our common stock to the Institute for Systems Biology as partial consideration for entry into the license agreement. Pursuant to the terms of the amended license agreement, we are required to pay the Institute for Systems Biology royalties on net sales of products sold by us, or our sublicensees, at a low single digit percentage rate. Royalties owed to the Institute for Systems Biology had been subject to annual minimums, which have expired. Through December 31, 2013, we have paid aggregate royalties of $1.7 million to the Institute for Systems Biology. Unless earlier terminated in accordance with the terms of the amended license agreement, the agreement will terminate upon the expiration of the last to expire patent licensed to us. The Institute for Systems Biology has the right to terminate the agreement under certain situations, including our failure to meet certain diligence requirements or our uncured material breach of the agreement.

Bioclassifier, LLC

In July 2010, we entered into an exclusive license agreement with Bioclassifier, LLC, pursuant to which Bioclassifier granted to us an exclusive, subject to certain government rights, worldwide license, with the right to sublicense, to certain intellectual property rights and technology, including intellectual property rights that comprise eight non-provisional patent applications as of December 31, 2013, in the field of research products and prognostic and/or diagnostic tests for cancer, including Prosigna. Bioclassifier has licensed these rights from the academic institutions that employed the cancer researchers that discovered or were involved in the initial development of PAM50. This license agreement was amended and restated in February 2012, with the changes retroactively effective to the July 2010 date of the original agreement. Pursuant to the terms of the amended and restated license agreement, we are required to pay Bioclassifier the greater of certain minimum royalty amounts and mid-single digit to low double digit percentage royalties on net sales of products and/or methods sold by us that are covered by patent rights or include, use or are technology licensed to us. Our obligation to pay royalties to Bioclassifier expires on a country-by-country basis upon the expiration of the last patent licensed or, if a product or method includes, uses or is technology licensed to us but is not covered by a patent licensed to us, ten years after the first commercial sale of the product or method in such country. We are also required to pay Bioclassifier low to mid double digit percentage of any income received by us from the grant of a sublicense by use to the patents or technology licensed us under the agreement. We are also

required to meet certain development and commercialization milestones extending to 2015. Through December 31, 2013, we have paid Bioclassifier $365,000 of which $175,000 will be credited against future royalties owed.

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

Research and Development

We have committed, and expect to continue to commit, significant resources to developing new technologies and products, improving product performance and reliability and reducing costs. We have assembled experienced research and development teams at our Seattle, Washington location with the scientific, engineering, software and process talent that we believe is required to successfully grow our business. As of December 31, 2013, we had 38 employees in research and development, of which 17 hold a Ph.D. degree and five hold a M.S. degree. We are currently focused on several products and enhancements in both our future diagnostic products and current research offerings. Our research and development expenses for the years ended December 31, 2013, 2012 and 2011 were $15.0 million, $11.6 million and $9.0 million, respectively.

nCounter Technology

We are continuously seeking to improve the nCounter Analysis System, including improvements to the technology and accessibility. As we make improvements, we anticipate that we will make available new and improved generations of the nCounter Analysis System.

Our technology development efforts are focused on:

Applications. We plan to develop additional application areas to enable researchers to apply the nCounter Analysis System to new experimental paradigms. Currently, we are updating our panel product line with panels focused on cancer pathways and the immune response to cancer. We are also focused on improving and expanding the ability of our technology to detect gene fusions. Finally, we are exploring the application of the nCounter Analysis System for the digital multiplexed quantitation of proteins, which may allow researchers to measure multiple nucleic acids and proteins with a single instrument using small amounts of precious sample. In January 2014, we announced that we had secured an exclusive option from Massachusetts General Hospital to license intellectual property related to a novel approach for multiplexed protein analysis using our nCounter Analysis System.

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

Expanding Clinical Utility of the Prosigna Breast Cancer Assay

We plan to extend the clinical utility of Prosigna to inform other major treatment decisions in breast cancer, after appropriate regulatory authorization. The decisions about receiving extended adjuvant endocrine therapy, adjuvant chemotherapy or adjuvant radiation therapy have significant objective quality of life implications because of the acute

and long term risk of side effects, some of them severe (including death), that are caused by these treatments. In addition, there are significant health economic consequences to decisions regarding these therapies based both on the cost of the treatments themselves and of treating their side effects. Therefore, a pressing issue is to identify the individual patients who need or are likely to benefit from extended adjuvant endocrine therapy, adjuvant radiation therapy and adjuvant chemotherapy so that the rest of the patients can be spared these treatments without affecting their long term outcome.

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

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

Future Molecular Diagnostics

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

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

In the future, we intend to collaborate with biopharmaceutical companies to develop companion diagnostic assays that may be used to select patients for specific drug therapies. Under such collaborations, we would expect to develop, seek regulatory approval for, and commercialize the diagnostic assay. We would also expect to receive development funding and potential milestone payments from our collaborators. Upon approval of the diagnostic assay, we would expect to generate revenues from the sale of the resulting *in vitro* diagnostic kits.

Sales and Marketing

We began selling nCounter Analysis Systems to researchers in 2008 and began sales efforts in the clinical laboratory market in Europe and Israel in early 2013, and in the United States in November 2013. We sell our instruments and related products primarily through our own sales force in North America and through a combination of direct and distributor channels in Europe, the Middle East, Asia Pacific and South America. We have agreements with 15 distributors, each of which is exclusive within a certain territory. In the event the distributor does not meet minimum performance requirements, we may terminate the distribution agreement or convert from an exclusive to non-exclusive arrangement within the territory, allowing us to enter into arrangements with other distributors for the territory. None of our customers represented more than 10% of our revenue for the years ended December 31, 2013,

2012 or 2011.

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Instrumentation and Research

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

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

Molecular Diagnostics

We intend to sell Prosigna kits via a three-pronged effort. First, we will seek to establish third-party reimbursement and patient access for clinical testing services that our clinical laboratory customers will provide based upon our products by educating third-party payors regarding the clinical utility and health economic value of the clinical tests enabled by our technology. Second, we will seek to establish an installed base of nCounter Analysis Systems by selling or leasing instruments to select clinical laboratories, with initial sales efforts directed at large commercial laboratories and academic medical centers that treat a high volume of breast cancer patients. In December 2013, we announced that national diagnostic laboratories ARUP Laboratories, Laboratory Corporation of America Holdings and Quest Diagnostics have chosen to add Prosigna to their suites of breast cancer diagnostic tests, and the laboratories at the University of Alabama at Birmingham Comprehensive Cancer Center and University of North Carolina Lineberger Comprehensive Cancer Center will be among the initial facilities to offer the Prosigna assay in the United States, with the earliest testing beginning during the first quarter of 2014. Third, we will drive physician demand for clinical testing services enabled by our diagnostic products, and direct test orders toward those laboratories which have adopted our technology.

We intend to have a direct sales model in the United States, Canada, Israel and certain European countries. In other countries, we intend to have distributor relationships or a mix of both. Because oncology and pathology are relatively concentrated medical specialties, we believe that a focused marketing organization and specialized sales force with regional and local experience can effectively build interest within clinical laboratories and generate physician demand for Prosigna. Where appropriate, we intend to coordinate commercial efforts with the sales and marketing personnel of the clinical laboratories offering clinical testing services based on our diagnostic products. We believe that these clinical laboratories will be motivated to coordinate commercial efforts by the potential to improve patient care, broaden patient access and profit from testing services based on Prosigna and other potential nCounter-based diagnostics. We believe this direct sales approach, coupled with our multiple publications of clinical data in peer-reviewed journals, provides the best opportunity to increase patient and physician demand.

In connection with the U.S. launch of Prosigna, we have been actively recruiting sales professionals to build a dedicated sales force to educate medical oncologists about Prosigna. We intend to use a phased approach to

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build our sales force, initially hiring approximately 15 field based oncology-focused sales representatives during the first quarter of 2014, with the expectation that the sales force will grow once internal milestones related to treatment guideline inclusion and third-party payor reimbursement have been achieved. We also intend to build a small team of medical science liaisons to complement the sales force and expect to continue to rely on our existing sales professionals to place nCounter Dx Analysis Systems in clinical labs.

Manufacturing; Suppliers

We use third-party contract manufacturers to produce our instruments and raw materials for our consumables, and we build the CodeSets and reagent packages at our Seattle, Washington facility.

Instruments

We outsource manufacturing of our nCounter Prep Stations and nCounter Digital Analyzers. Precision System Science, Co., Ltd. of Chiba, Japan, or PSS, is our sole source supplier for the nCounter Prep Station. Korvis Automation Inc., or Korvis, is our sole source supplier for our nCounter Digital Analyzers at its facility in Corvallis, Oregon.

The facilities at which our instruments are built have been certified to ISO 13485:2003 standards. Our contracts with these instrument suppliers do not commit them to carry inventory or make available any particular quantities. Under the terms of the two instrument supply agreements, we are required to place binding purchase orders for instruments that will be delivered to us by the supplier three to six months from the date of placement of the purchase order. Although qualifying alternative third-party manufacturers could be time consuming and expensive, our instruments design is similar to other instruments and we believe that alternatives would be available if necessary. However, if our instrument suppliers terminate our relationship with them or if they give other customers needs higher priority than ours, then we may not be able to obtain adequate supplies in a timely manner or on commercially reasonable terms.

Consumables

We manufacture our consumables in our Seattle, Washington facility which has been certified to ISO 13485:2003 standards. We expect that our existing manufacturing capacity is sufficient to meet our needs at least through 2014. Should additional space become necessary, we believe that there will be space available near our existing facility that we believe we can secure; however, we cannot predict that this space will be available if and when it is needed.

We rely on a limited number of suppliers for certain components and materials used in the manufacture of our consumables. While some of these components are sourced from a single supplier, we have qualified second sources for several of our critical reagents, including oligonucleotides, adhesives and dyes. We believe that having dual sources for our components helps reduce the risk of a production delay caused by a disruption in the supply of a critical component. We continue to pursue qualifying additional suppliers, but cannot predict how expensive, time-consuming or successful these efforts will be. If we were to lose one or more of our suppliers, it may take significant time and effort to qualify alternative suppliers.

Competition

In the life sciences research market, we compete with companies such as Affymetrix, Agilent Technologies, Bio-Rad, Exiqon, Fluidigm, HTG Molecular Diagnostics, Illumina, Life Technologies (recently acquired by Thermo Fisher Scientific), Luminex, Perkin Elmer, Qiagen and Roche Applied Science, some of which also offer diagnostic applications of their technologies. These competitors and others have products for gene expression analysis that

compete in certain segments of the market in which we sell our products. In addition, there are a

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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.

In the breast cancer diagnostics market, we compete with Genomic Health s Onco*type* DX, a service for gene expression analysis performed in its central laboratory in Redwood City, California. We also face competition from companies such as Agendia, Clarient (a GE Healthcare company), Genoptix (a division of Novartis), and bioMeriéux, which also offer centralized laboratories that profile gene or protein expression in breast cancer. In Europe, we 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.

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 diagnostic products;
- 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 believe that the automated nature of our nCounter Analysis System with its simple, rapid and efficient workflow that requires very limited human intervention or labor; the multiplexing capability of our technology to analyze significantly more target molecules in a single tube without amplification, representing multiple biological pathways; compatibility with many sample types, including difficult samples such as FFPE; and the ability to analyze small sample inputs, in some cases down to a single cell, from a wide variety of sample types gives us numerous competitive advantages in the research market. In the diagnostics market, we believe the compelling evidence of Prosigna s ability to inform major medical treatment decisions, including results from our studies; the quality of our nCounter Analysis System, which enables consistent and reproducible results in decentralized laboratories; and the improved convenience for physicians and patients, including more rapid test result turnaround time gives us numerous competitive advantages in the diagnostic market.

While we believe that we compete favorably based on the factors described above, many of our competitors are either publicly traded, or are divisions of publicly-traded companies, and enjoy several 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;

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larger and more established customer bases and relationships; and

better established, larger scale and lower cost manufacturing capabilities.

For additional information, see the section of this report captioned Risk Factors The research and diagnostics markets are highly competitive. If we fail to compete effectively, our business and operating results will suffer.

Government Regulation

Medical Device Regulation

United States

In the United States, medical devices, including *in vitro* diagnostics, are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, under the Federal Food, Drug, and Cosmetic Act, or FDC Act, and its implementing regulations, and other federal and state statutes and regulations. The laws and regulations govern, among other things, medical device development, testing, labeling, storage, premarket clearance or approval, advertising and promotion and product sales and distribution.

A medical device is an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component part or accessory which is (1) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (2) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. *In vitro* diagnostics are a type of medical device and are tests that can be used in the diagnosis and/or detection of diseases, conditions or infections, including, without limitation, the presence of certain chemicals, genetic or other biomarkers. Some tests are used in laboratory or other health professional settings and other tests are for consumers to use at home.

Since the definition of a medical device depends on the intended use of the product, a single product can potentially be regulated multiple ways by the FDA, including no FDA oversight, depending on the intended use of the product. Intended use is governed by the objective intent of the manufacturer, which includes all words and images communicated by a company and its employees.

Medical devices to be commercially distributed in the United States must receive from the FDA either clearance of a premarket notification, or 510(k), or premarket approval, or PMA, pursuant to the FDC Act prior to marketing, unless subject to an exemption. Devices deemed to pose relatively less risk are placed in either Class I or II, which requires the manufacturer to submit to the FDA a 510(k) requesting permission for commercial distribution; this is known as the 510(k) clearance process. Some low risk devices are exempted from this premarket requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k) cleared device or a preamendment Class III device for which PMA applications have not been called, are placed in Class III requiring PMA approval. A clinical trial is almost always required to support a PMA application and is sometimes required for a 510(k) application. All clinical studies of investigational devices must be conducted in compliance with any applicable FDA or Institutional Review Board, or IRB, requirements.

510(k) Clearance Pathway. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating to the FDA s satisfaction that the proposed device is substantially equivalent in intended use and in

safety and effectiveness to a previously 510(k) cleared device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for submission of PMA applications. The previously cleared device is known as a predicate. The FDA s 510(k) clearance pathway usually takes from four to 12 months, but it can last longer, particularly for a novel type of product.

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After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer s decision not to seek a new 510(k) clearance, the agency may require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained.

PMA Approval Pathway. The PMA approval pathway requires proof of the safety and effectiveness of the device to the FDA s satisfaction. The PMA approval pathway is costly, lengthy and uncertain.

A PMA application must provide extensive preclinical and clinical trial data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. As part of the PMA review, the FDA will typically inspect the manufacturer s facilities for compliance with Quality System Regulation, or QSR, requirements, which impose elaborate testing, control, documentation and other quality assurance procedures.

Upon submission, the FDA determines if the PMA application is sufficiently complete to permit a substantive review, and, if so, the application is accepted for filing. The FDA then commences an in-depth review of the PMA application, which typically takes one to three years, but may last longer. The review time is often significantly extended as a result of the FDA asking for more information or clarification of information already provided. The FDA also may respond with a not approvable determination based on deficiencies in the application and require additional clinical studies that are often expensive and time consuming and can delay approval for months or even years. During the review period, an FDA advisory committee, typically a panel of clinicians, likely will be convened to review the application and recommend to the FDA whether, or upon what conditions, the device should be approved. Although the FDA is not bound by the advisory panel decision, the panel s recommendation is important to the FDA s overall decision making process.

If the FDA s evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant s agreement to specific conditions, such as changes in labeling, or specific additional information such as submission of final labeling, in order to secure final approval of the PMA application. Once the approvable letter is satisfied, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the manufacturer. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval or placement of restrictions on the sale of the device until the conditions are satisfied.

Even after approval of a PMA, a new PMA or PMA supplement may be required in the event of a modification to the device, its labeling or its manufacturing process. Supplements to a PMA may require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

De Novo Pathway. If no predicate can be identified, the product is automatically classified as Class III, requiring a PMA. However, the FDA can reclassify, or use de novo classification for, a device for which there was no predicate device if the device is low or moderate risk. The FDA will identify special controls that the manufacturer must implement, which often includes labeling restrictions. Subsequent applicants can rely upon the de novo product as a predicate for a 510(k) clearance. The de novo route is less burdensome than the PMA process; it is essentially the same as a 510(k). A device company can ask the FDA at the outset if the de novo route is available. The de novo route

has been used for many *in vitro* diagnostic products.

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Postmarket. After a device is placed on the market, numerous regulatory requirements apply. These include: the QSR, labeling regulations, the FDA s general prohibition against promoting products for unapproved or off label uses, registration and listing, the Medical Device Reporting regulation (which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and the Reports of Corrections and Removals regulation (which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDC Act).

The FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as fines, injunctions, and civil penalties; recall or seizure of products; operating restrictions, partial suspension or total shutdown of production; refusing requests for 510(k) clearance or PMA approval of new products; withdrawing 510(k) clearance or PMA approvals already granted; and criminal prosecution. For additional information, see the section of this report captioned *Risk Factors Risks Related to Government Regulation and Diagnostic Product Reimbursement.*

Research Use Only. Research Use Only, or RUO, products belong to a separate regulatory classification under long-standing FDA regulation. In essence, RUO products are not regulated as medical devices and are therefore not subject to the regulatory requirements discussed above. The products must bear the statement: For Research Use Only. Not for Use in Diagnostic Procedures. RUO products cannot make any claims related to safety, effectiveness or diagnostic utility, and they cannot be intended for human clinical diagnostic or prognostic use. In November 2013, the FDA issued a final guidance on RUO products, which, among other things, reaffirmed that a company may not make clinical or diagnostic claims about an RUO product.

Laboratory Developed Tests. Laboratory Developed Tests are developed and used within a single lab. Because the Laboratory Developed Tests are not marketed, but only used within the laboratory, the FDA has historically exercised enforcement discretion and has not required clearance or approval prior to marketing. The FDA has publicly stated that it intends to issue a policy under which it will require clearance or approval prior to marketing with respect to certain Laboratory Developed Tests. The FDA has stated that it will announce the details of this policy in a proposed guidance document, which will be subject to public comment. The FDA must also submit any draft proposal to Congress at least 60 days before issuing the draft guidance. To date, the FDA has not forwarded any draft guidance to Congress.

International

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The European Commission is the legislative body responsible for directives under which manufacturers selling medical products in the EU, and the European Economic Area, or EEA, must comply. The EU includes most of the major countries in Europe, while other countries, such as Switzerland, are part of the EEA and have voluntarily adopted laws and regulations that mirror those of the EU with respect to medical devices. The EU has adopted directives that address regulation of the design, manufacture, labeling, clinical studies and post-market vigilance for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be marketed throughout the EU and EEA.

In September 2012, Prosigna was CE-marked to IVDD 98/79/EC for use in conjunction with a diagnostic version of our nCounter Analysis System in the EU to assess a patients risk and or distant recurrence.

Outside of the EU, regulatory approval needs to be sought on a country-by-country basis in order to market medical devices. Although there is a trend towards harmonization of quality system standards, regulations in each country may vary substantially, which can affect timelines of introduction.

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Reimbursement

Our nCounter Dx Analysis Systems will be purchased or leased by clinical laboratories, which will use our diagnostic products as the basis for testing patients samples. These customers can use our products to enable commercial testing services, and generate revenue for their laboratories for this service. In order to collect payment for testing services based upon our diagnostic products, our clinical laboratory customers may bill third parties, including public and private payors. The demand for our diagnostic products will depend indirectly upon the ability for our customers to successfully bill for and receive reimbursement from third-party payors for the clinical testing services based on our products. Therefore, we intend to work with third-party payors in markets where we intend to sell our diagnostic products to ensure that testing services based on our products are covered and paid.

The decision of payors to cover and pay for a specific testing service is driven by many factors, including:

- strong clinical validation data;
- acceptance into major clinical guidelines, including NCCN, ASCO, and the St. Gallen Consensus guidelines;
- health economic studies that may indicate that the test improves quality-adjusted survival and leads to reduced costs; and
- decision impact studies that show the test leads to better treatment decisions.

We are generating and intend to generate dossiers that will be submitted to payors in support of reimbursement for testing services based upon our diagnostic products, beginning with Prosigna. In March 2013, we submitted the first of these dossiers to a government health ministry. The dossiers typically will contain data from studies supporting the analytical and clinical validity of Prosigna, as well as health economic analyses that examine whether the clinical information supplied by Prosigna changes medical practice in a way that leads to benefit for both the patients and the payors. In some cases, these health economic analyses will be supported by the results of clinical studies of Prosigna s impact on adjuvant treatment decisions in early stage breast cancer called decision impact studies. We developed a clinical protocol for Prosigna decision impact studies in collaboration with two European cooperative groups, and entered into agreements with those groups to initiate two decision impact studies during 2013. These studies are being conducted by performing Prosigna testing using nCounter Analysis Systems placed at several European medical centers, including at the Vall d Hebron Institute of Oncology in Barcelona, Spain and at the Ludwig Maximilians University of Munich in Munich, Germany.

United States

In the United States, clinical laboratory revenue is derived from various third-party payors, including insurance companies, health maintenance organizations, or HMOs, and government healthcare programs, such as Medicare and Medicaid. Clinical laboratory testing services are paid through various methodologies when covered by third-party payors, such as prospective payment systems and fee schedules. For any new clinical test, payment for the clinical laboratory service requires a decision by the third-party payor to cover the particular test, the establishment of a reimbursement rate for the test and the identification of one or more Current Procedural Terminology, or CPT, codes that accurately describes the test methodology and the analyte to be used in claims processing.

The most commonly used first-generation genomic test for breast cancer, Genomic Health s Onco*type* DX, is covered and reimbursed by most national and regional third-party payors in the United States, along with the local Medicare Administrative Contractor, or MAC, for California with jurisdiction for claims submitted by Genomic Health for Medicare patients. We believe that U.S. payors on average reimburse Onco*type* DX testing services at approximately $3,000 or more per test. The Onco*type* DX breast cancer test is usually billed and reimbursed using a miscellaneous chemistry CPT code (84999).

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Based on market research that we have conducted with U.S. private payors, we believe that the combination of clinical data that we have generated to date and FDA clearance would lead multiple private payors to cover Prosigna testing services. We believe that the reimbursement rate for Prosigna testing services will be similar to that provided for Onco*type* DX testing services.

The American Medical Association, or AMA, has issued a new set of CPT codes for billing and reimbursement of complex genomic tests that are based on information from multiple analytes or genes. These new MAAA, or Multianalyte Assays with Algorithmic Analyses, codes are intended to capture tests such as Prosigna and are divided into two categories of unique codes. Category 1 MAAA codes are intended for tests that AMA s CPT Editorial Panel has vetted and found to meet a certain set of criteria, such as demonstrated clinical validity and utility, as well as current national utilization thresholds. MAAAs issued to complex genomic tests that have not met all Category 1 coding criteria are referred to as administrative MAAA codes. Currently, there are no requirements to achieve an administrative MAAA code. Assignment of either unique reimbursement code to a particular test may facilitate claims processing by payors; however, assignment of a unique reimbursement code alone does not guarantee favorable reimbursement decisions by payors and a genomic test with an assigned MAAA code must still be vetted and approved by individual payors before reimbursement is achieved. Given the more stringent requirements for receipt of a Category 1 MAAA, including demonstrated clinical validity and utility and satisfaction of national utilization thresholds, we believe that certain payors may more readily render favorable reimbursement decisions for genomic tests with a Category 1 MAAA rather than an administrative MAAA.

We applied for a Category 1 MAAA code for use in reimbursement of testing services based on Prosigna. We anticipate that we will receive the CPT Editorial Panel s decision on our application no later than April 2014. While the CPT Editorial Panel is not required to issue any MAAA code, we believe that testing services enabled by Prosigna will be classified as MAAA, and ultimately will be reimbursed using either a Category 1 or administrative MAAA code. Given the recent commercial launch of Prosigna in the United States, and the lack of utilization data, we expect the issuance of an administrative MAAA. If an administrative MAAA is issued, we would anticipate reapplying for a Category 1 MAAA at a later date when additional Prosigna utilization data are available. During the period following commercial launch and prior to the receipt of a MAAA code, we intend to recommend our clinical laboratory customers seek reimbursement for Prosigna using the CPT code designated for Unlisted Multianalyte Assay with Algorithmic Analysis (81599).

Centers for Medicare & Medicaid Services, or CMS, administers the Medicare and Medicaid programs, which provide health care to almost one in every three Americans. For any particular geographic region, Medicare claims are processed on behalf of CMS by private companies called Medicare Administrative Contractors, or MACs. New diagnostic tests typically follow one of two routes to coverage via CMS: National Coverage Determinations, or NCDs, or Local Coverage Determinations, or LCDs. The NCD applies to Medicare beneficiaries living throughout the United States. The LCD process applies to only beneficiaries in the coverage area of a single MAC, requiring multiple LCDs to cover the testing throughout the United States. There is also a subset of NCDs known as Coverage with Evidence Development that allow a technology (service or procedure) to be covered while evidence is collected through a registry or a study to answer outstanding questions on outcomes.

We plan to pursue Medicare coverage for Prosigna using a series of LCDs. There are two distinct LCD processes for molecular diagnostic tests: the individual MAC LCD process and the MolDx program. Pursuing a series of LCDs will require us to engage the MAC for each jurisdiction in which Prosigna testing services are provided. We believe that the LCD approach has potential advantages, including more rapid establishment of Medicare reimbursement and mitigation of the risk of an adverse national decision. The individual MAC process requires requesting an LCD from each of the seven MACs not currently under the MolDx program. The MolDx program, which only applies to the MACs Palmetto and Noridian, requires providers to follow a unique and specific path to obtain an LCD.

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The Palmetto MolDx program has contracted with McKesson to create unique identifiers or codes for unique lab tests. A McKesson Z-Code Identifier is a unique code associated with a specific advanced diagnostic test. Z-codes are reported to the payor along with the appropriate CPT codes, which potentially improves the efficiencies in the reimbursement process. Z-code identifiers are currently only required by the MACs associated with the MolDx program, Palmetto and Noridian, The MolDx program is the technology assessment and medical policy review process currently employed by Palmetto for North Carolina, South Carolina, Virginia, and West Virginia and by Noridian for California, Nevada, and Hawaii (Noridian has not published a MolDx decision for the other states under their Medicare contract: Washington, Oregon, Idaho, Utah, Arizona, Montana, Wyoming, North Dakota, and South Dakota). Determination of the Medicare contractor responsible for a laboratory claim is based on the location of the laboratory (not patient location). The laboratories performing Prosigna testing for Quest Diagnostics and Laboratory Corporation of America are within the jurisdiction of the MolDx program. Laboratories under the MolDx program cannot submit claims for Prosigna until a Z-code is available and a Medicare LCD has been published. A Z-code Identifier was issued for Prosigna in February 2014. Accordingly, in collaboration with our lab partners, we are preparing to submit our clinical evidence dossier to the MolDx program for technology assessment, establishment of medical policy and pricing. We expect to receive a LCD for Prosigna testing as early as the third quarter of 2014, although if requests for additional data are made, this timeline could be extended.

For Medicare, the reimbursement rates for individual tests are established under the Clinical Laboratory Fee Schedule (local fee schedules for outpatient clinical laboratory services) or the Physician Fee Schedule, depending on the amount of physician work involved in the test. Molecular diagnostic tests that require little physician work are generally paid under the Clinical Laboratory Fee Schedule. We believe that CMS will reimburse Prosigna testing services under the Clinical Laboratory Fee Schedule.

Outside the United States

In Europe, governments are primarily responsible for reimbursing diagnostic testing services. A relatively small portion of the market is made up of private payors and cash-pay patients.

The primary barrier of adoption of a new *in vitro* diagnostic test is often reimbursement, and public reimbursement can take several years to achieve, depending on the country. Public reimbursement for genomic testing for breast cancer is available in Canada, Ireland, Greece and the United Kingdom. Selected private coverage for testing is available in the United Kingdom, Germany, Spain, France, the UAE and Hungary. The public reimbursement pathway may be more favorable in Germany and France given their willingness to accept additional costs in return for improved outcomes, their centralized review process, and the role of key opinion leaders. Reimbursement approval in some countries, such as Spain and Italy, is managed at the regional level. Israel is a market in which genomic testing for breast cancer is widely reimbursed by all four major Sick Funds, the third-party payors that cover a substantial majority of the population.

Our market preparation in Europe will be similar to that in the United States and involve data driving clinical and economic publications to support guideline inclusion. Initially, we will target the private and cash pay market in Europe. In parallel, we will seek to establish public reimbursement of Prosigna by national and regional governments in Europe.

Other Regulations

Products that have obtained FDA approval in the United States are subject to various federal and state fraud and abuse laws, including, without limitation, the federal anti-kickback statute and state and federal marketing compliance laws. These laws may impact our operations directly, or indirectly through our customers, and may impact, among other

things, our proposed sales, marketing and education programs. In addition, we may be

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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 following federal laws and their counterparts at the state level:

- the Federal Anti-kickback Law and state anti-kickback prohibitions;
- the Federal physician self-referral prohibition, commonly known as the Stark Law, and state equivalents;
- the Federal Health Insurance Portability and Accountability Act of 1996, as amended;
- the Medicare civil money penalty and exclusion requirements;
- the Federal False Claims Act civil and criminal penalties and state equivalents;
- the Foreign Corrupt Practices Act, which applies to our international activities; and
- the Physician Payment Sunshine Act.

Employees

As of December 31, 2013, we had 174 employees, of which 58 work in manufacturing, 51 in sales, marketing and business development, 38 in research and development, 20 in general and administrative, and seven in medical and regulatory affairs. 34 of our employees hold Ph.D. degrees. None of our United States employees is represented by a labor union or is the subject of a collective bargaining agreement. As of December 31, 2013, of our 174 employees, 160 were employed in the United States and 14 were employed outside the United States.

Environmental Matters

Our operations require the use of hazardous materials (including biological materials) which subject us to a variety of federal, state and local environmental and safety laws and regulations. Some of the regulations under the current regulatory structure provide for strict liability, holding a party potentially liable without regard to fault or negligence. We could be held liable for damages and fines as a result of our, or others , business operations should contamination of the environment or individual exposure to hazardous substances occur. We cannot predict how changes in laws or development of new regulations will affect our business operations or the cost of compliance.

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this report, including the section of this report captioned Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes. If any of the events described in the following

risk factors and the risks described elsewhere in this report occurs, our business, operating results and financial condition could be seriously harmed. This report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report.

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 $29.3 million and $17.7 million for the years ended December 31, 2013 and 2012, respectively. As of

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December 31, 2013, we had an accumulated deficit of $126.8 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 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 the United States 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 in additional jurisdictions and subsequent demand for our diagnostic products or manage our anticipated expenses accordingly, our operating results will be harmed.

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

Commercialization of Prosigna in Europe, the United States and the other jurisdictions in which we intend to pursue regulatory approval is a key element of our strategy. Currently, most oncologists seeking sophisticated gene expression analysis for diagnosing and profiling breast cancer in their patients, ship tissue samples to a

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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 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 requires us to educate pathologists regarding the benefits of this business model and oncologists regarding the reliability and consistency of results generated locally.

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. Furthermore, we may encounter significant difficulty in gaining inclusion in breast cancer treatment guidelines, obtaining patient reimbursement from public and private payors, and gaining broad market acceptance of Prosigna. If we fail to successfully commercialize Prosigna, we may never receive a return on the significant investments in sales and marketing, regulatory, manufacturing and quality assurance personnel we have made, and further investments we intend to make, which would adversely affect our growth prospects, operating results and financial condition.

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 research 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 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.

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

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

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

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

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

We have established exclusive distribution agreements for our nCounter Analysis System and related consumable products 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 and retain existing distributors to maximize the commercial opportunity for our products. There is no guarantee that we will be successful in attracting or retaining 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 additional regulatory clearances or approvals to market products other than Prosigna for diagnostic purposes, we will be limited to marketing such products for research use only. In addition, if we are unable to obtain additional regulatory clearances or approvals to market Prosigna in additional countries or if regulatory limitations are placed on our diagnostic products our business and growth will be harmed.

We have received regulatory clearance in the United States under a 510(k) for a version of our first diagnostic product, Prosigna, providing an assessment of a patient s risk of recurrence for breast cancer, and we have obtained a CE mark for Prosigna which permits us to market that assay for diagnostic purposes in Europe. We do not have regulatory

clearance or approval to market any other product for diagnostic purposes or to

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market Prosigna for diagnostic purposes in any other market, other than Israel. 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. Similarly, if we do not obtain additional regulatory clearances or approvals to market future products or future indications for diagnostic purposes, 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.

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 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 further development, as a Laboratory Developed Test, or, 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 research customers and other researchers, including biopharmaceutical companies, for future diagnostic products. However, there is no assurance that we will be successful in doing so. In particular, our 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 Arimidex, Tamoxifen, Alone or in Combination, or ATAC, study and the Austrian Breast & Colorectal Cancer Study Group 8, or ABCSG8, study of postmenopausal women with HR+ early stage breast cancer were favorable, there is no guarantee that any future studies will be successful. 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

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board approval, privacy rights, publication rights, intellectual property ownership and research parameters. If we are not able to negotiate access to archived tumor tissue samples with hospitals, clinical partners, pharmaceutical companies, or companies developing therapeutics on a timely basis, or at all, or if other laboratories or our competitors secure access to these samples before us, our ability to research, develop and commercialize future products will be limited or delayed.

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

We face significant competition in the life sciences research and diagnostics markets. We currently compete with both established and early stage life sciences research companies that design, manufacture and market instruments and consumables for gene expression analysis, single-cell analysis, polymerase chain reaction, or PCR, digital PCR, other nucleic acid detection and additional applications. These companies use well established laboratory techniques such as microarrays or quantitative PCR, or qPCR, as well as newer technologies such as next generation sequencing. We believe our principal competitors in the life sciences research market are Affymetrix, Agilent Technologies, Bio-Rad, Exiqon, Fluidigm, HTG Molecular Diagnostics, Illumina, Life Technologies (recently acquired by Thermo Fisher Scientific), 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 also compete with commercial diagnostics companies. We believe our principal competitor in the breast cancer diagnostics market is 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 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 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.

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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 research market in 2008, and was introduced for sale in the clinical laboratory market in Europe and Israel in February 2013, and in the United States in November 2013. 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, Middle East, 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, including Prosigna, will depend in large part on our ability to successfully establish an oncology sales force and to increase the scope of our marketing efforts. Because we have limited 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.

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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, and in July 2013, we launched nCounter Elements, a new digital molecular barcoding chemistry that allows users to design their own customized assays using standard sets of barcodes provided by us. The future growth of the market for these products 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 nCounter Elements, single cell analysis or others do not develop as we expect, our business may be adversely affected. In addition, we commercially launched Prosigna in Europe and Israel in February 2013 and we intend to offer Prosigna in other countries outside of the United States. Genomic testing for breast cancer is not widely available outside of the United States and the market for such tests is new. The future growth of the market for genomic breast cancer testing will depend on physicians acceptance of such testing and the availability of reimbursement for such tests. Our success in these new markets will depend to a large extent on our ability to successfully market, sell and establish reimbursement for products using our technologies. If we are not able to successfully market and sell our products or to achieve the revenue or margins we expect, our operating results may be harmed and we may not recover our product development and marketing expenditures.

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

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

We may experience manufacturing problems or delays that could limit our growth or adversely affect our operating results

Our consumable products are manufactured at our Seattle facility using complex processes, sophisticated equipment and strict adherence to specifications and quality systems procedures. Any unforeseen manufacturing problems, such as contamination of our facility, equipment malfunction, or failure to strictly follow procedures or meet specifications, could result in delays or shortfalls in production of our consumable products. Identifying and resolving the cause of any such manufacturing issues could require substantial time and resources. If we are unable to keep up with demand for our products by successfully manufacturing and shipping our products in a timely manner, our revenue could be impaired, market acceptance for our products could be adversely affected and our customers might instead purchase our competitors products.

In addition, the introduction of new products may require the development of new manufacturing processes and procedures. While all of our codesets are produced using the same basic processes, significant variations may be required to meet product specifications. Developing such a process can be very time consuming, and any unexpected difficulty in doing so could delay the introduction of a product.

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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, and in particular earthquake insurance, which is limited, 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.

For the year ended December 31, 2013, approximately 30% 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.

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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, 2013, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of approximately $92.6 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 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;

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 total 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. For example, in January 2014, we entered into a non-binding letter of intent for a term loan agreement with a lender which would allow us to refinance our existing credit facility and potentially incur up to an aggregate of $45 million in term loan borrowings or up to an aggregate of approximately $52 million if we elect to exercise in full an option to pay in kind a portion of the interest that would accrue on the borrowings under the term loan agreement. The debt instruments governing such

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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.

Our future capital needs are uncertain and we may need to raise additional funds in the future.

We believe that our existing cash and cash equivalents, including the funds raised in our January 2014 public offering, together with funds available under our credit facility, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. However, we may need to raise substantial additional capital to:

- expand the commercialization of our products;
- fund our operations; and
- further our research and development.

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

- market acceptance of our products;
- the cost and timing of establishing additional sales, marketing and distribution capabilities;
- the cost of our research and development activities;
- the cost and timing of regulatory clearances or approvals;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including new licensing arrangements for new products, although we currently have no commitments or agreements to complete any such transactions.

We cannot assure you that we will be able to obtain additional funds on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Additional debt financing, if available, may involve additional covenants restricting our operations or our ability to incur additional debt. Any debt or additional equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets, or delay,

reduce the scope of or eliminate some or all of our development programs.

If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could harm our operating results.

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;

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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.

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 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. 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

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

Risks Related to Government Regulation and Diagnostic Product Reimbursement

Our research use only products for the research 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 business and results of operations.

In the United States, most of 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 research 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. In November 2013, the FDA issued a final guidance on RUO products, which, among other things, reaffirmed that a company may not make clinical or diagnostic claims about an RUO product. Although not suggested in the final RUO guidance, 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.

In addition, we sell dual-use instruments with software that have both FDA-cleared functions and research functions, for which FDA approval or clearance is not required. Dual-use instruments are subject to FDA regulation since they are intended, at least in part, for use by customers performing clinical diagnostic testing. There is a risk that the FDA could take enforcement action against a manufacturer for distributing dual-use instruments if the FDA determines that approval or clearance was required for those functions for which FDA approval or clearance has not been obtained, and the instruments are being sold off-label. There is also a risk that the FDA could broaden its current regulatory enforcement of dual-use instruments through additional FDA oversight.

Our GPRs may be used by clinical laboratories to create Laboratory Developed Tests, which could in the future be subject to regulation as medical devices, which could materially and adversely affect our business and results of operations.

Recently, we launched nCounter Elements, a new digital molecular barcoding chemistry that allows users to design their own customized assays using standard sets of barcodes provided by us with the laboratories choice of oligonucleotide probes. nCounter Elements are considered GPRs by the FDA, that are Class I medical devices, and we listed nCounter Elements with the FDA as GPRs in July 2013.

A clinical laboratory can use nCounter Elements to create what is called a Laboratory Developed Test. Laboratory Developed Tests are diagnostic tests that are developed and performed by a laboratory and include genetic tests and other tests for rare conditions. In June 2013, the Commissioner of the FDA stated that the FDA intends to further

regulate Laboratory Developed Tests; however, it is unclear whether, when and to what extent the FDA will do so. Restrictions on Laboratory Developed Tests by the FDA could restrict the demand for our products, including nCounter Elements. Additionally, compliance with additional regulatory burdens could be time consuming and costly. If the FDA regulates Laboratory Developed Tests, such regulation could adversely affect our prospects, results of operations and financial condition.

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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 are required to obtain either prior 510(k) clearance or prior pre-market approval, or PMA, from the FDA. In September 2013, we received FDA 510(k) clearance for Prosigna as a prognostic indicator for distant recurrence-free survival at 10 years in post-menopausal women with Stage I/II lymph node-negative or Stage II lymph node-positive (1 3 positive nodes) hormone receptor-positive breast cancer who have undergone surgery in conjunction with locoregional treatment and consistent with standard of care. In the future we plan to submit a separate application for approval of Prosigna to report intrinsic subtype and we expect that this application will require a PMA supported by additional clinical studies. We intend to pursue additional intended uses for Prosigna, which may require more burdensome regulatory processes than the 510(k) clearance process, including PMAs. Even if granted, a 510(k) clearance or PMA approval for any future product would likely place substantial restrictions on how our device is marketed or sold, and the FDA will continue to place considerable restrictions on our products, including, but not limited to, quality system regulations, or QSR, registering manufacturing facilities, listing the products with the FDA, and complying with labeling, marketing, complaint handling, adverse event and medical device reporting requirements and corrections and removals. Obtaining FDA clearance or approval for diagnostics can be expensive and uncertain, and generally takes from several months to several years, and generally requires detailed and comprehensive scientific and clinical data. Notwithstanding the expense, these efforts may never result in FDA approval or clearance. Even if we were to obtain regulatory approval or clearance, it may not be for the uses we believe are important or commercially attractive, in which case we would not be permitted to market our product for those uses.

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

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We are subject to ongoing and extensive regulatory requirements, and our failure to comply with these requirements could substantially harm our business.

Following our obtaining CE Mark in the EU and receipt of FDA 510(k) clearance in September 2013 for Prosigna, we are subject to ongoing ISO and FDA obligations and continued regulatory oversight and review, including routine inspections by EU Notified Bodies and by the FDA of our manufacturing facilities and compliance with requirements such as ISO 13485 and quality system regulations, or QSRs, which establish extensive requirements for quality assurance and control as well as manufacturing procedures; requirements pertaining to the registration of our manufacturing facilities and the listing of our devices with the FDA; continued complaint, adverse event and malfunction reporting; corrections and removals reporting; and labeling and promotional requirements. The promotional claims we can make for Prosigna are limited to the cleared indication. For instance, in the United States the following special conditions for use are listed in the intended use: Prosigna is not intended for diagnosis, to predict or detect response to therapy or to help select the optimal therapy for patients. 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 enforcement by EU Competent Authorities and the FDA such as the issuance of warning or untitled letters, 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 as we continue to commercialize our products in new markets. Adverse Notified Body, EU Competent Authority or FDA action in any of these areas could significantly increase our expenses and limit our revenue and profitability.

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. For example, the American Medical Association, or AMA, has issued a new set of CPT codes for billing and reimbursement of complex genomic tests that are intended to capture tests such as Prosigna and are divided into two categories of unique codes, with the assignment of one category possibly leading to more rapid, and perhaps broader, acceptance of Prosigna than the other. There can be no assurance which code Prosigna will receive, or if it receives a code at all. 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.

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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.

As we begin commercializing Prosigna and any other potential diagnostic 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 and gift bans. These laws may impact, among other things, our proposed sales and marketing and education programs and require us to implement additional internal systems for tracking certain marketing expenditures and reporting them to government authorities. 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;
- the federal False Claims Act civil and criminal penalties and state equivalents; and
- state physician gift bans and marketing expenditure laws.

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 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 must pay a sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. The new tax applies to our listed medical device products, which include the nCounter Dx Analysis System, Prosigna *in vitro* diagnostic kits and nCounter Elements GPRs. 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

customers use our technology to deliver to Medicare beneficiaries, and may indirectly reduce demand for our 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 customers use our technology to deliver beginning in 2016 and for hospital services beginning in 2020, and may indirectly reduce demand for our products.

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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 December 31, 2013, we owned or exclusively licensed seven issued U.S. patents and approximately 23 pending U.S. patent applications, including provisional and non-provisional filings. We also owned or licensed approximately 73 pending and granted counterpart applications worldwide, including 22 country-specific validations of four 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

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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 our pending patent applications will not 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.
- 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

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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

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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 patents and pending patent applications in the United States, Europe and other jurisdictions that claim methods of using certain genes that are included in Prosigna. We believe that Prosigna does not infringe any valid issued claim. Numerous significant intellectual property issues have been litigated, and will likely continue to be litigated, between existing and new participants in our existing and targeted markets and competitors may assert that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into those markets. Third parties may assert that we are employing their proprietary technology without authorization. In addition, our competitors and others may have patents or may in the future obtain patents and claim that use of our products infringes these patents. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and obtain one or more licenses from third parties, or be prohibited from selling certain products. We may not be able to obtain these licenses at a reasonable cost, if at all. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. In addition, we could encounter delays in product introductions while we attempt to develop alternative methods or products to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing products, and the prohibition of sale of any of our products could materially affect our ability to grow and gain market acceptance for our products.

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

In addition, our agreements with some of our suppliers, distributors, customers and other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in

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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.

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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 Our Common Stock

The price of our common stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock has fluctuated and may continue to fluctuate substantially. Since shares of our common stock were sold in our initial public offering in June 2013 at a price of $10.00 per share, the reported high and low sales prices of our common stock ranged from $22.44 to $7.01 through March 15, 2014. The trading price of our common stock depends on a number of factors, including those described in this Risk Factors section, many of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose all or part of your investment in our common stock since you might be unable to sell your shares at or above the price you paid. Factors that could cause fluctuations in the trading price of our common stock include the following:

- 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 research and 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 Risk Factors section.

The stock market in general, and market prices for the securities of life sciences and diagnostic 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.

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An active trading market for our common stock may not be sustained.

Until recently, there has been no public market for our common stock. Although our common stock is listed on The NASDAQ Global Market, the market for our shares has demonstrated varying levels of trading activity. Furthermore, the current level of trading may not be sustained in the future. The lack of an active market for our common stock 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.

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 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.

Holders of approximately 7.4 million shares (including shares underlying outstanding warrants), or approximately 41%, of our outstanding shares, 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 have also registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans.

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 48.3% of our outstanding common stock as of March 15, 2014. Accordingly, our executive officers, directors and principal stockholders will effectively be able to determine the composition of the board of directors, 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.

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Our management team has broad discretion to use the net proceeds from our initial public offering and our January 2014 public offering and its investment of these proceeds may not yield a favorable return. We may invest the proceeds of these offerings in ways with which investors disagree.

We have broad discretion as to how to spend and invest the proceeds from our initial public offering and our January 2014 public offering, and we may spend or invest these proceeds in a way with which our stockholders disagree. Accordingly, investors will need to rely on our judgment with respect to the use of these proceeds and these uses may not yield a favorable return to our stockholders. In addition, 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 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:

- 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);

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 are 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.

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

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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.

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 Act, or the 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 until December 31, 2018, although, if we have more than $1.0 billion in annual revenue, if the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30 of any year, or we issue more than $1.0 billion of non-convertible debt over a three-year period before the end of that five-year period, we would cease to be an emerging growth company as of the following December 31. We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

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 burdens may increase as new legislation is passed and implemented, including any new requirements that the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 may impose on public companies. 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 in the future 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, requires us to perform system and process evaluation and testing of our internal control over financial reporting

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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 control over financial reporting from our independent registered public accounting firm.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We lease approximately 42,000 square feet of office and laboratory space in two separate buildings in Seattle, Washington, under leases that expire in August 2016, subject to five-year options to renew. We currently pay a total of approximately $187,000 per month in base rent, and the landlords hold letters of credit or security deposits equal to a total of approximately $188,000. We believe that our existing facilities are adequate to meet our business requirements for the near-term and that additional space will be available on commercially reasonable terms, if required.

Item 3. Legal Proceedings

We are not engaged in any material legal proceedings. From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business.

On September 30, 2013, we settled lawsuits filed by Fluidigm Corporation and its subsidiary Fluidigm Singapore Pte Ltd filed in the U.S. District Court for the Northern District of California and in the High Court of Singapore alleging substantially similar claims relating to false advertising, unfair competition and unlawful trade practices. As part of the settlement agreement, we agreed to remove references to a comparative study of our nCounter Single Cell Assay with Fluidigm s BioMark system from our marketing materials, website, and promotional activities and to stop using

those materials. On October 22, 2013, the case in the U.S. District Court of the Northern District of California was dismissed with prejudice, and on October 29, 2013, the case in the High Court of Singapore was dismissed with prejudice.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on The NASDAQ Global Market under the symbol NSTG. Trading of our common stock commenced on June 26, 2013 in connection with our initial public offering. The following table sets forth, for the periods indicated, the high and low sales prices for our common stock as reported on The NASDAQ Global Market.

Year ended December 31, 2013	High	Low
Second quarter (beginning June 26, 2013)	$ 9.90	$ 7.81
Third quarter	$ 14.10	$ 7.01
Fourth quarter	$ 18.09	$ 8.64

Holders

As of March 15, 2014, there were approximately 70 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Dividends

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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Performance Graph

The following graph compares the performance of our common stock for the periods indicated with the performance of the NASDAQ Composite Index and the NASDAQ Medical Equipment Index. This graph assumes an investment of $100 on June 26, 2013 in each of our common stock, the NASDAQ Composite Index and the NASDAQ Medical Equipment Index, and assumes reinvestment of dividends, if any. The stock price performance shown on the graph below is not necessarily indicative of future stock price performance.

Use of Proceeds

On June 25, 2013, our registration statement on Form S-1 (No. 333-188704) was declared effective for our initial public offering, and on July 1, 2013 we consummated the initial public offering consisting of 5,400,000 shares of our common stock for $10.00 per share. As a result of the offering, we received total net proceeds of approximately $46.8 million, after deducting total expenses of $7.2 million, consisting of underwriting discounts and commissions of $3.8 million and offering-related expenses of approximately $3.4 million. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates. There has been no material change in the planned use of proceeds from our initial public offering from that described in the final Prospectus dated June 25, 2013 filed with the SEC pursuant to Rule 424(b)(4).

Recent Sales of Unregistered Securities

In 2013, we granted stock options under our 2004 Plan to purchase 314,524 shares of our common stock to certain of our employees and a director at exercise prices ranging from $6.72 to $8.96 per share. In addition, in 2013, we granted stock options under our 2013 Plan to purchase 11,686 shares of our common stock to a director at an exercise price of $10.00 per share. During 2013, we issued an aggregate of 171,302 shares of common stock to our employees and a director pursuant to the exercise of stock options for cash consideration with aggregate exercise proceeds of approximately $372,567. These issuances were undertaken in reliance upon the exemption from registration requirements available under Rule 701 of the Securities Act.

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Item 6. Selected Financial Data

The following selected financial data is derived from our audited financial statements and should be read in conjunction with, and is qualified in its entirety by, Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations, and Item 8, Financial Statements and Supplementary Data. contained elsewhere in this Annual Report on Form 10-K. The selected Consolidated Statements of Operations data for the years ended December 31, 2013, 2012 and 2011 and Consolidated Balance Sheet data as of December 31, 2013 and 2012 have been derived from our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. The selected Consolidated Statements of Operations data for the years ended December 31, 2010 and 2009 and Consolidated Balance Sheet data as of December 31, 2011, 2010 and 2009 have been derived from our audited consolidated financial statements that are not included in this Annual Report on Form 10-K. Historical results are not necessarily indicative of future results.

	Year Ended December 31,				
	2013	2012	2011	2010	2009
	(In thousands, except per share amounts)				
Consolidated Statements of Operations:					
Revenue	$ 31,403	$ 22,973	$ 17,800	$ 11,730	$ 7,288
Costs and expenses:					
Cost of revenue	15,009	12,361	9,777	9,128	5,874
Research and development	14,979	11,635	8,990	7,547	4,550
Selling, general and administrative	29,912	15,486	9,529	8,027	5,464
Total costs and expenses	59,900	39,482	28,296	24,702	15,888
Loss from operations	(28,497)	(16,509)	(10,496)	(12,972)	(8,600)
Other income (expense):					
Interest income	68	21	10	29	64
Interest expense	(1,942)	(804)	(599)	(94)	(320)
Other income (expense)	(66)	(29)	80	254	
Revaluation of preferred stock warrant liability	1,156	(387)	73	15	19
Total other income (expense)	(784)	(1,199)	(436)	204	(237)
Net loss	$ (29,281)	$ (17,708)	$ (10,932)	$ (12,768)	$ (8,837)
Accretion of mandatorily redeemable convertible preferred stock	(4,653)	(7,533)	(5,251)	(4,351)	(2,551)
Net loss attributable to common stockholders	$ (33,934)	$ (25,241)	$ (16,183)	$ (17,119)	$ (11,388)
Net loss per share basic and diluted	$ (4.44)	$ (71.10)	$ (50.10)	$ (54.17)	$ (36.62)
Weighted-average shares used in computing basic and diluted net loss per share	7,643	355	323	316	311

	As of December 31,				
	2013	**2012**	**2011**	**2010**	**2009**
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 42,656	$ 21,692	$ 10,868	$ 4,366	$ 1,739
Working capital	42,106	19,937	12,236	2,944	1,385
Total assets	64,372	37,406	24,584	13,275	9,367
Total long-term debt	18,293	12,759	1,887	1,829	1,274
Mandatorily redeemable convertible preferred stock		103,622	80,957	57,887	38,551
Total stockholders equity (deficit)	31,469	(93,760)	(69,451)	(53,517)	(36,565)

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Item 7. 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 report. 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 this report captioned Risk Factors and elsewhere in this report, our actual results may differ materially from those anticipated in these forward-looking statements. Throughout this discussion, unless the context specifies or implies otherwise, the terms NanoString , we , us and our refer to NanoString Technologies, Inc. and its subsidiaries.

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 and to clinical laboratories and medical centers for diagnostic use. We have an installed base of more than 180 systems, which our customers have used to publish more than 360 peer-reviewed papers. As researchers discover how genomic information can be used to improve clinical decision-making, these discoveries can be translated and validated as diagnostic tests based on our nCounter Elements General Purpose Reagents, or GPRs. In certain situations, we intend to translate their discoveries into *in vitro* diagnostic assays.

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, nCounter Elements GPRs 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, research 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.

In 2013, we began offering instruments and consumables for use in diagnostic testing. In September 2013, we received 510(k) clearance from the FDA to market in the United States a version of Prosigna providing an assessment of a patient s risk of recurrence for breast cancer. In December 2013, we commercially launched Prosigna in the United States. National diagnostic laboratories ARUP Laboratories, Laboratory Corporation of America Holdings and Quest Diagnostics have chosen to add Prosigna to their suites of breast cancer diagnostic tests, and the laboratories at the University of Alabama at Birmingham Comprehensive Cancer Center and University of North Carolina Lineberger Comprehensive Cancer Center will be among the initial facilities to offer the Prosigna assay in the United States, with the earliest testing beginning during the first quarter of 2014. These laboratories collectively serve the pathology testing needs of a substantial portion of breast cancer patients throughout the United States. In September 2012, we obtained a CE mark for Prosigna, our first diagnostic product, and, in early 2013 we commercially launched Prosigna in Europe and Israel.

In November 2013, we began offering a version of the nCounter Dx Analysis System to high-complexity, CLIA-certified laboratories for research and diagnostics purposes. This FLEX configuration of the nCounter Dx Analysis System provides clinical laboratories a single platform with the flexibility to support both clinical testing, by running Prosigna, and research, by processing translational research experiments using our custom CodeSets and

panels. The nCounter Elements GPRs provide further flexibility by allowing laboratories to

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develop their own Laboratory Developed Tests for gene expression, copy number variation and gene fusion signatures, which can be performed by a laboratory and may include genetic tests and other tests for rare conditions.

To support the commercial launch of Prosigna, we are establishing a dedicated oncology sales force. As a result, we expect sales and marketing expenses and operating losses to increase as we market the product. In addition, we expect sales to grow gradually as more systems are installed, Prosigna gains inclusion in important breast cancer treatment guidelines and to the extent reimbursement by third-party payors becomes more broadly available.

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 $15.0 million, $11.6 million and $9.0 million in 2013, 2012 and 2011, respectively, in research and development and intend to continue to make significant investments in research and development.

In the future, we intend to collaborate with biopharmaceutical companies to develop companion diagnostic assays that may be used to select patients for specific drug therapies. Under such collaborations, we would expect to develop, seek regulatory approval for, and commercialize the diagnostic assay. We would also expect to receive development funding and potential milestone payments from our collaborators. Upon approval of the diagnostic assay, we would expect to generate revenues from the sale of the resulting *in vitro* diagnostic kits.

Our total revenue increased to $31.4 million in 2013 from $23.0 million in 2012 and $17.8 million in 2011, 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 $29.3 million, $17.7 million, and $10.9 million in 2013, 2012 and 2011, respectively. As of December 31, 2013, our accumulated deficit was $126.8 million.

Key Financial Metrics

We are organized as, and operate in, one reportable segment, which is the development, manufacture and commercialization of instruments, consumables and services for efficiently profiling the activity of hundreds of genes simultaneously from a single tissue sample.

Our chief operating decision maker is the chief executive officer, who manages our operations and evaluates our financial performance on a total company basis. Our principal operations and decision-making functions are located at our corporate headquarters in the United States.

Until the fourth quarter of 2013, we operated in two reportable segments, our life sciences business and our diagnostics business. In November 2013, our nCounter Dx Analysis System with FLEX Configuration was launched, enabling customers to perform both research and clinical testing on the same instrument. We have one sales force that now sells these systems to both research and diagnostic testing labs, and we launched our first product that can be used for both research and diagnostic testing, nCounter Elements GPRs. As a result of these fundamental changes to our business, we began operating the Company as a single reportable segment during the fourth quarter of 2013.

Revenue

We generate revenue from the sale of our products and related services. For a description of our revenue recognition policies, see the section of this report captioned Critical Accounting Policies and Significant Estimates Revenue Recognition.

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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 research use only nCounter Analysis System is $235,000. Outside the United States, depending on the country, the list price is generally higher. The U.S. list price of one nCounter Dx Analysis System is $285,000. Systems are sold to distributors at a discount to list price. Our customer base is primarily composed of academic institutions, government laboratories, biopharmaceutical companies and clinical laboratories that perform analyses or testing using our nCounter Analysis System and purchase related consumables, potentially including Prosigna kits.

For our research customers, related consumables include (1) panels, which are standard pre-manufactured CodeSets, (2) custom CodeSets, which we manufacture to the specific requirements of an individual researcher, (3) nCounter Elements GPRs, and (4) 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. In 2013, 2012 and 2011, our average consumables revenue per system exceeded $100,000 per year.

For our clinical laboratory customers, related consumables include Prosigna in vitro diagnostic kits and nCounter Elements GPRs. We sell our nCounter Dx Analysis Systems to clinical laboratory customers or offer to 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 products over a period of time. To date, all clinical laboratory customers have elected to purchase instruments; however, we expect that in the future, certain customers will elect to lease them.

The list price of a Prosigna test in the United States and Europe is $2,080 and 1,550 per patient, respectively. 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 research consumables. We sell Prosigna kits to our lab customers, who will be responsible for providing the testing service and contracting and billing payors. Prosigna kits are sold to clinical laboratories on a fixed dollars-per-kit basis, which does not expose us to direct third-party payor reimbursement risk. However, we provide customary volume discounts, and in some cases, introductory pricing during the period in which third-party payor reimbursement is being established. As a result, we expect the average selling price per Prosigna test to be between $1,500 and $2,000.

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 products through our own sales forces in the United States, Canada, Singapore, Israel and certain European countries. We sell through distributors in other parts of the world. As we have expanded our European direct sales force and entered into agreements with distributors of our products in Europe, the Middle East, Asia Pacific and South America, the amount of revenue generated outside of North America has generally increased, although there have been significant quarter-to-quarter fluctuations. 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, Malaysia and Australia.

	Year Ended December 31,					
	2013		2012		2011	
	(Dollars in thousands)					
North America	$ 21,855	70%	$ 15,906	69%	$ 14,044	79%
Europe & Middle East	5,775	18	4,167	18	2,918	16
Asia Pacific	3,773	12	2,900	13	838	5
Total	$ 31,403	100%	$ 22,973	100%	$ 17,800	100%

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 research 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, *in vitro* diagnostic kits and nCounter Elements GPRs.

Operating Expenses

Research and Development

Research and development expenses consist primarily of salaries and benefits, occupancy, laboratory supplies, contract services, 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. 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.

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.

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	Year Ended December 31,		
	2013	2012	2011
	(In thousands)		
Core nCounter platform technology and diagnostic product development	$	$	$ 4,359
Core nCounter platform technology	4,330	1,537	
Manufacturing process development	1,588	1,183	969
Research products and applications	2,914	2,183	1,875
Diagnostic product development	4,605	4,783	
Facility allocation	1,542	1,949	1,787
Total	$ 14,979	$ 11,635	$ 8,990

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 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, potentially, to develop a molecular diagnostic product or a Laboratory Developed Test 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, legal 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 continued commercialization of Prosigna requires us to establish a dedicated oncology focused sales force which will increase selling and marketing expenses significantly. Our legal, accounting and compliance costs have also increased as a result of our becoming a public company, and we expect them to continue to increase as our business grows.

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 research 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 strategies, including expanding our sales efforts outside of the United States and continuing to enhance the underlying technology and applications for both research and clinical diagnostics use. As part of this strategy, we increased our existing sales and marketing headcount by over 30% in 2013 in an

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effort to increase the rate of sales of our nCounter Analysis Systems. Similarly, since January 2013, we have contracted with ten additional distributors bringing our total to 16. 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 research customers. The new generation system will be a single instrument with a reduced footprint that combines the prep station and the digital analyzer. We expect 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 late 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 research customers as well as increase our addressable market.

We have sold more than 180 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 Consumables 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. Historically, nearly all of our systems and related consumables have been sold to research customers. In 2013, 2012 and 2011, our average consumables 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. Additionally, we expect Prosigna *in vitro* diagnostic kit revenue to contribute an increasing amount of recurring 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, including Prosigna *in vitro* diagnostic kits. Generally, our consumables have higher gross margins than our instruments. There will be fluctuations in mix between instruments and consumables from period to period. Although results may vary 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.

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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 the breakdown of revenue in absolute dollars and as percentage of total revenue.

	Year Ended December 31,					
	2013		2012		2011	
	(Dollars in thousands)					
Product revenue:						
Instruments	$ 12,995	41%	$ 8,786	38%	$ 7,112	40%
Consumables	16,642	53	13,036	57	9,997	56
In vitro diagnostic kits	181	1				
Service revenue	1,585	5	1,151	5	691	4
Total	$ 31,403	100%	$ 22,973	100%	$ 17,800	100%

Impact of Our Diagnostic Products Strategy

We have only recently commercially launched the nCounter Dx Analysis System and Prosigna. 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, these discoveries can be translated and validated as diagnostic tests based on our nCounter Elements GPRs. In certain situations, we intend to translate their discoveries into *in vitro* diagnostic assays. We in-licensed the rights to intellectual property that forms the basis of Prosigna from Bioclassifier, LLC, which was founded by several of our research customers. We intend to enter into similar arrangements with our research customers and other researchers for future diagnostic gene signatures. Our strategy is to target intellectual property rights to potential gene signatures 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, potentially, to develop a molecular diagnostic product or Laboratory Developed Test 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 model is more capital efficient than the clinical laboratory services model. Our diagnostic products leverage our existing technology platform and instrument sales, 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 clinical laboratory 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.

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Results of Operations

Comparison of Years Ended December 31, 2013 and 2012

Revenue; Cost of Revenue; Gross Profit

	Year Ended December 31,		Change 2013 v. 2012	
	2013	2012	Dollars	Percentage
	(Dollars in thousands)			
Product revenue:				
Instruments	12,995	8,786	4,209	48%
Consumables	16,642	13,036	3,606	28
In vitro diagnostic kits	181		181	
Service revenue	1,585	1,151	434	38
Total revenue	31,403	22,973	8,430	37
Cost of revenue	15,009	12,361	2,648	21
Gross profit	$ 16,394	$ 10,612	$ 5,782	54
Gross margin	52%	46%		

Instrument revenue increased significantly for the year ended December 31, 2013 due to an increase in the number of instruments sold, including from the launch of our nCounter Dx Analysis System. This increase was partially offset by a reduction in average selling price attributable to increased sales to distributors, which are priced lower than direct sales, and increased customer incentives. The increase in consumables revenue was driven by growth in our installed base of instruments. The increase in service revenue was primarily related to an increase in the number of instruments covered by service contracts.

The increase in cost of revenue was related to the increased volume of both instruments and consumables sold. Gross margin improved due to cost efficiencies associated with increased consumables production volume and several large custom consumable orders with unusually low per unit manufacturing costs. These improvements were partially offset by a shift in product mix toward instruments.

Research and Development Expense

	Year Ended December 31,		Change 2013 v. 2012	
	2013	2012	Dollars	Percentage
	(Dollars in thousands)			
Research and development expense	$ 14,979	$ 11,635	$ 3,344	29%

The increase reflected a $2.9 million increase in personnel-related expenses to support the advancement of our nCounter technology and clinical development of Prosigna and a $1.5 million increase in engineering costs for the development of the next generation of our nCounter system. Decreases in Prosigna clinical study costs of $1.0 million, after completion of the ABCSG8 study in late 2012, partially offset the increases.

Selling, General and Administrative Expense

	Year Ended December 31,		Change 2013 v. 2012	
	2013	2012	Dollars	Percentage
	(Dollars in thousands)			
Selling, general and administrative expense	$ 29,912	$ 15,486	$ 14,426	93%

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The increase for the year was primarily attributable to $6.8 million of increased staffing and personnel-related costs to support sales and marketing and administration; $2.8 million of increased external marketing and other consulting costs related to the commercial launch of Prosigna; $2.5 million of increased legal costs, $0.5 million of increased facility-related costs, and $1.1 million of increased corporate professional fees and other public company costs.

Other Income (Expense)

	Year Ended December 31,		Change 2013 v. 2012	
	2013	2012	Dollars	Percentage
	(Dollars in thousands)			
Interest income	$ 68	$ 21	$ 47	224%
Interest expense	(1,942)	(804)	(1,138)	142
Other expense	(66)	(29)	(37)	128
Revaluation of preferred stock warrant liability	1,156	(387)	1,543	(399)
Total other income (expense)	$ (784)	$ (1,199)	$ 415	(35)

The increase in interest expense was driven by increased borrowing under our credit facility during 2012 and 2013, from $1.5 million as of December 31, 2011 to $13.0 million as of December 31, 2012 and to $18.0 million as of December 31, 2013.

The increase in other income from the revaluation of the preferred stock warrant liability resulted from a re-measurement of the fair value of preferred stock warrants using the Black-Scholes option pricing model, which was primarily impacted by a decrease in the valuation of the underlying stock. Upon closing of our initial public offering in July 2013, all outstanding warrants to purchase preferred stock converted into warrants to purchase common stock. As a result, the preferred stock warrant liability was reclassified to stockholders equity.

Comparison of Years Ended December 31, 2012 and 2011

Revenue; Cost of Revenue; Gross Profit

	Year Ended December 31,		Change 2012 v. 2011	
	2012	2011	Dollars	Percentage
	(Dollars in thousands)			
Revenue:				
Product revenue:				
Instruments	$ 8,786	$ 7,112	$ 1,674	24%
Consumables	13,036	9,997	3,039	30
Service revenue	1,151	691	460	67
Total revenue	22,973	17,800	5,173	29
Cost of revenue	12,361	9,777	2,584	26

Gross profit	$ 10,612	$ 8,023	$ 2,589	32
Gross margin	46%	45%		

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

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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 Ended December 31,		Change 2012 v. 2011	
	2012	2011	Dollars	Percentage
	(Dollars in thousands)			
Research and development expense	$ 11,635	$ 8,990	$ 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 December 31,		Change 2012 v. 2011	
	2012	2011	Dollars	Percentage
	(Dollars in thousands)			
Selling, general and administrative expense	$ 15,486	$ 9,529	$ 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)

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

Liquidity and Capital Resources

As of December 31, 2013, we had cash, cash equivalents and short-term investments of $42.7 million, compared to $21.7 million as of December 31, 2012. Since inception, we have financed our operations primarily through the sale of equity securities and, to a lesser extent, from borrowings. Our principal uses of cash are funding our operations, debt service payments as described below, and capital expenditures.

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Sources of Funds

Our cash used in operations for the year ended December 31, 2013 was $31.3 million. During 2013, we raised $54.0 million, before offering expenses, in our initial public offering, which closed in July 2013. Net of offering expenses, our initial public offering generated approximately $46.8 million. In April 2013, we incurred $5.0 million of the remaining term loan borrowings under our credit facility. Our cash, cash equivalents and short-term investments, together with the net proceeds from our follow-on offering in January 2014 of approximately $57 million, are sufficient to meet our anticipated cash needs for at least the next 12 months. However, we may need to raise additional capital to expand the commercialization of our products, fund our operations and further our research and development activities. Our future funding requirements will depend on many factors, including: market acceptance of our products; the cost and timing of establishing additional sales, marketing and distribution capabilities; the cost of our research and development activities; the cost and timing of regulatory clearances or approvals; the effect of competing technological and market developments; and the extent to which we acquire or invest in businesses, products and technologies, including new licensing arrangements for new products, although we currently have no commitments or agreements to complete any such transactions.

From time to time, we may explore additional financing sources and means to lower our cost of capital, which could include equity, equity-linked and debt financing. There can be no assurance that any additional financing will be available to us on acceptable terms. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or additional equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets, or delay, reduce the scope of or eliminate some or all of our development programs. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations.

In January 2014, we entered into a non-binding letter of intent for a term loan agreement with a lender which would allow us to refinance our existing credit facility and potentially incur up to an aggregate of $45 million in term loan borrowings or up to an aggregate of approximately $52 million if we elect to exercise in full an option to pay in kind a portion of the interest that would accrue on the borrowings under the term loan agreement. We expect this term loan agreement will contain customary conditions to borrowings, events of default and negative covenants, including covenants that could limit our ability to, among other things, incur additional indebtedness, liens or other encumbrances, make dividends or other distributions, and buy, sell or transfer assets. We also expect that the term loan agreement will include liquidity and revenue-based financial covenants. Our obligations under the term loan agreement will be secured by substantially all of our assets. However, there can be no assurance that we will successfully enter into this term loan agreement.

Credit Facility

In 2012, we entered into a credit facility, as amended, that consists of up to $23.0 million in term loan borrowings and a $2.0 million accounts receivable revolving line of credit. All borrowings under the credit facility have a maturity date of July 2016. The term loans bear interest at fixed rates based on the three-month LIBOR rate plus 8.39% (subject to a LIBOR floor of 0.50%) at the time of borrowing and borrowings under the revolving line of credit bear interest at the Prime Rate plus 3.70% (subject to a floor of 6.95%). At December 31, 2013, the Prime Rate was equal

to 3.25%. We are also required to pay a fee of 0.075% per month on the unused portion of the revolver borrowings. Through January 2014, we are required to only pay interest on all outstanding term borrowings. Following the expiration of the interest only payment period, we are required to pay principal

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and interest in 30 equal monthly payments, plus an end of term payment equal to 5.5% of the amount borrowed. We may at our option prepay all of the term loan borrowings by paying the lender, among other things, all principal and accrued interest, the end of term payment plus a make-whole premium.

During 2012, we incurred $13.0 million in term loan borrowings at an interest rate of 8.89%. In connection with the credit facility, we issued warrants to purchase an aggregate of 76,940 shares of Series D preferred stock at an exercise price of $8.45 per share and 20,837 shares of Series E preferred stock at an exercise price of $14.40 per share. The warrants have a ten-year term and an aggregate fair value at issuance of $648,000. The warrants were valued at the date of issuance using the Black-Scholes option pricing model with the following assumptions: fair value of preferred stock equal to exercise price of warrant, volatility of 58.0 to 61.0% and a risk free interest rates of 1.63 to 2.20%. The warrants were treated as debt discount and are being amortized over the term of the debt. In connection with our initial public offering, these warrants became exercisable for shares of common stock.

In April 2013, we incurred an additional $5.0 million in term loan borrowings under the credit facility at an interest rate of 8.89%. In connection with this borrowing, we issued warrants to purchase an aggregate of 10,418 shares of Series E preferred stock, which were valued at the date of issuance at $137,000 using the Black-Scholes option pricing model with the following assumptions: fair value of preferred stock equal to the exercise price of the warrants, volatility of 57.0% and a risk-free interest rate of 1.7%. In connection with ou initial public offering, these warrants became exercisable for shares of common stock.

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

Convertible Promissory Notes

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

2010 Loan and Security Agreement

In November 2010, we amended our then-existing loan and security agreement to provide for up to $2.0 million of equipment term borrowings and, subject to certain conditions, up to $3.0 million in revolver borrowings. Under the agreement, we incurred $1.9 million of equipment term borrowings, which were payable over periods of up to 36 months in equal monthly installments of principal and interest. In addition, we incurred maximum borrowings under the revolver of $2.7 million. All of the indebtedness incurred under the 2010 loan and security agreement was repaid in 2012 in connection with the entry into our existing credit facility.

We also issued the lender warrants to purchase 4,691 shares of our Series B preferred stock at an exercise price of $17.47 per share. After giving effect to the anti-dilution provisions of such warrant, in connection with our initial public offering, these warrants became exercisable for 7,315 shares of our common stock. These warrants will expire in October 2014.

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Use of Funds

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

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

Historical Cash Flow Trends

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

	Year Ended December 31,		
	2013	2012	2011
	(In thousands)		
Cash used in operating activities	$ (31,346)	$ (14,808)	$ (10,692)
Cash used in investing activities	(32,955)	(428)	(2,800)
Cash provided by financing activities	52,550	26,060	19,994

Operating Cash Flows

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

Net cash used in operating activities for 2013 consisted of our net loss of $29.3 million and $3.8 million of cash used for working capital purposes. These uses were partially offset by $1.8 million of net non-cash income and expense items, such as depreciation and amortization, stock-based compensation and change in the fair value of preferred stock warrants.

Net cash used in operating activities for 2012 consisted of our net loss of $17.7 million and changes in our operating assets and liabilities of $0.4 million, which were partially offset by $3.3 million of non-cash expense items such as depreciation and amortization, stock-based compensation, revaluation of preferred stock warrant liability and amortization of debt discounts and issuance cost.

Net cash used in operating activities for 2011 consisted of our net loss of $10.9 million and changes in our operating assets and liabilities of $1.8 million, which were partially offset by $2.0 million of net non-cash income and expense items including depreciation and amortization, amortization of debt discounts and issuance costs and stock-based compensation.

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Investing Cash Flows

Our most significant cash flows used in investing activities for 2013 are for the purchase of short-term investments. These amounts primarily relate to shifts between cash and cash equivalents and short-term investments. Because we manage our cash usage with respect to our total cash, cash equivalents and short-term investments, we do not consider these cash flows to be important to an understanding of our liquidity and capital resources.

Excluding the purchase of short-term investments, net cash used in investing activities for each of the periods presented was primarily for the purchase of laboratory, manufacturing and computer equipment and software to support our expanding infrastructure. In 2011, we leased additional laboratory and office space and incurred $1.8 million in expenses related to leasehold improvements and our restricted cash related to this leased space increased by $0.1 million. In 2012 and 2013, we purchased lesser amounts of property and equipment required to support the growth and expansion of our operations.

Financing Cash Flows

Historically, we have funded our operations through the issuance of equity securities and the incurrence of indebtedness.

Net cash provided by financing activities for 2013 consisted of net proceeds of $47.4 million from our initial public offering, proceeds from term loan borrowings of $5.0 million and proceeds from exercise of stock options of $0.4 million. These proceeds were partially offset by repayments of borrowings of $0.2 million.

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

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

Contractual Obligations

The following table reflects a summary of our contractual obligations as of December 31, 2013.

		Payments due by period			
Contractual Obligations(1)	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
			(In thousands)		
Operating lease obligations(2)	$ 5,982	$ 2,167	$ 3,815	$	$
Long-term debt obligations(3)	18,807	6,342	12,465		
Inventory purchase obligations(4)	2,998	2,998			
Total	$ 27,787	$ 11,507	$ 16,280	$	$

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

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Critical Accounting Policies and Significant Estimates

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

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

- revenue recognition;
- stock-based compensation;
- inventory valuation;
- fair value measurements; and
- income taxes.

Revenue Recognition

We recognize revenue when: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the price to the customer is fixed or determinable; and (4) collectability is reasonably assured. We generate revenue from the sale of products and services. Our products consist of our proprietary nCounter Analysis System and related consumables, including Prosigna *in vitro* diagnostic kits. Services consist of extended warranties and service fees for assay processing. A delivered product or service is considered to be a separate unit of accounting when it has value to the customer on a stand-alone basis. Products or services have value on a stand-alone basis if they are sold separately by any vendor or if the customer could resell the delivered product.

Systems product revenue is recognized upon installation and calibration in geographic regions where such services are only available from our specialized technicians. In these regions, systems and related installation and calibration are considered to be one unit of accounting, as systems are required to be professionally installed and calibrated before use. In certain geographic regions, installation and calibration services are available from other vendors, and in such regions they are considered separate revenue elements. For systems sold for use solely to run Prosigna assays, training must be provided prior to system revenue recognition. Consumables, including *in vitro* diagnostic kits, are considered to be separate units of accounting as they are sold separately. Consumables product revenue is recognized upon shipment.

Service revenue is recognized when earned, which is generally upon the rendering of the related services. Service contracts and service fees for assay processing are each considered separate units of accounting as they are sold separately. We offer service contracts on our nCounter Analysis System for periods ranging from 12 to 36 months after the end of the standard 12-month warranty period. Service contracts are generally separately priced. Revenue from service contracts are deferred and recognized in income on a straight-line basis over the service period.

For arrangements with multiple deliverables, we allocate the contract consideration at the inception of the contract to the deliverables based upon their relative selling prices. To date, selling prices have been established by reference to vendor specific objective evidence based on stand-alone sales transactions for each deliverable.

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Vendor specific objective evidence is considered to have been established when a substantial majority of individual sales transactions within the previous 12 month period fall within a reasonably narrow range, which we have defined to be plus or minus 15% of the median sales price of actual stand-alone sales transactions. We use our best estimate of selling price for individual deliverables when vendor specific objective evidence or third-party evidence is unavailable. Allocated revenue is only recognized for each deliverable when the revenue recognition criteria have been met.

Stock-based Compensation

Prior to the closing of our initial public offering, we granted stock options at exercise prices believed to be equal to the fair value of the common stock underlying such options as determined by the board of directors, with input from management, on the date of grant. Because such grants occurred prior to the public trading of our common stock, the board of directors exercised significant judgment in determining the fair market value of our common stock. The valuations were consistent with the guidance and methods outlined in the AICPA Practice Aid Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or AICPA Practice Aid, for all option grant dates. After the closing of the initial public offering, we granted stock options with exercise prices based on market prices.

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

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

The expected term of options granted is based on historical experience of similar awards and expectations of future employee behavior. The risk-free interest rate for the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of grant. We have not paid and do not anticipate paying cash dividends on our common stock; therefore, the expected dividend yield is assumed to be zero. We based our estimate of volatility on the estimated volatility of similar companies whose share prices are publicly available.

Inventory Valuation

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

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Fair Value Measurements

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

Level 1 Quoted prices in active markets for identical assets and liabilities.

Level 2 Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.

Level 3 Valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

Prior to the closing of our initial public offering, we recorded preferred stock warrant liability at fair value. Preferred stock warrant liability was categorized as Level 3 because it was valued based on unobservable inputs and our judgment due to the absence of quoted market prices, inherent lack of liquidity and the long-term nature of such financial instruments. We performed a fair value assessment of the preferred stock warrant inputs on a quarterly basis using the Black-Scholes option pricing model. The assumptions used in the Black-Scholes option pricing model are inherently subjective and involve significant judgment. Changes in our judgments could have had a material impact on our results of operations and financial position. Any change in fair value was recognized as a component of other income (expense) on the consolidated statements of operations.

Income Taxes

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

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

At December 31, 2013, we had federal net operating loss carryforwards, or NOLs, of approximately $92.6 million and federal research and experimentation credit carryforwards of approximately $2.2 million, which may be used to reduce future taxable income or offset income taxes due. These NOLs and credit carryforwards expire beginning in

2023 through 2033.

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Our realization of the benefits of the NOLs and credit carryforwards is dependent on sufficient taxable income in future fiscal years. We have established a valuation allowance against the carrying value of our deferred tax assets, as it is not currently more likely than not that we will be able to realize these deferred tax assets. In addition, utilization of NOLs and credits to offset future income subject to taxes may be subject to substantial annual limitations due to the change in ownership provisions of the Internal Revenue Code of 1986, or the Code, and similar state provisions. We may have already experienced one or more ownership changes. Depending on the timing of any future utilization of our carryforwards, we may be limited as to the amount that can be utilized each year as a result of such previous ownership changes. However, we do not believe such limitations will cause our NOL and credit carryforwards to expire unutilized. Future changes in our stock ownership as well as other changes that may be outside our control could potentially result in further limitations on our ability to utilize our net operating loss and tax credit carryforwards.

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

Recent Accounting Pronouncements

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

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

Off-Balance Sheet Arrangements

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

Inflation

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Interest Rate Risk

Generally, our exposure to market risk has been primarily limited to interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term debt securities. We do not enter into investments for trading or speculative

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purposes. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. To minimize risk, we maintain our portfolio of cash, cash equivalents and short-term investments in a variety of interest-bearing instruments, which have included U.S. government and agency securities, high-grade U.S. corporate bonds and money market funds. Declines in interest rates, however, would reduce future investment income. A 1% decline in interest rates, occurring on January 1, 2014 and sustained throughout the period ended December 31, 2014, would not be material.

As of December 31, 2013, the principal and accrued interest outstanding under our term borrowings was $18.3 million. The interest rates on our term borrowings under our credit facility are fixed. If overall interest rates had increased by 10% during the periods presented, our interest expense would not have been affected.

Foreign Currency Exchange Risk

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

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Item 8. Financial Statements and Supplementary Data

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NANOSTRING TECHNOLOGIES, INC.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of NanoString Technologies, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of comprehensive loss, of changes in mandatorily redeemable convertible preferred stock and stockholders equity (deficit) and of cash flows present fairly, in all material respects, the financial position of NanoString Technologies, Inc. and its subsidiaries (the Company) at December 31, 2013 and 2012, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2013 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Seattle, Washington

March 27, 2014

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NanoString Technologies, Inc.

Consolidated Balance Sheets

	December 31,	
	2013	2012
	(In thousands, except par value amounts)	
Assets		
Current assets:		
Cash and cash equivalents	$ 9,941	$ 21,692
Short-term investments	32,715	
Accounts receivable, net	8,331	3,322
Inventory	6,750	5,380
Prepaid expenses and other	2,999	1,320
Total current assets	60,736	31,714
Restricted cash	201	180
Deferred offering costs	29	1,765
Property and equipment, net	3,065	3,674
Other assets	341	73
Total assets	$ 64,372	$ 37,406
Liabilities, Mandatorily Redeemable Convertible Preferred Stock and Stockholders Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,354	$ 2,865
Accrued liabilities	7,088	4,481
Deferred revenue, current portion	1,462	878
Deferred rent, current portion	590	764
Long-term debt, current portion	6,136	2,789
Total current liabilities	18,630	11,777
Deferred revenue, net of current portion	803	362
Deferred rent, net of current portion	1,313	1,903
Long-term debt, net of current portion	12,157	9,970
Preferred stock warrant liability		3,532
Total liabilities	32,903	27,544
Commitments and contingencies (Note 13)		
Mandatorily redeemable convertible preferred stock, $0.0001 par value, 8,979 shares authorized; no shares outstanding at December 31, 2013; 8,118 shares issued and outstanding at December 31, 2012		103,622
Stockholders equity (deficit):		

Preferred stock, $0.0001 par value, 15,000 shares authorized, no shares issued or outstanding at December 31, 2013; no shares authorized at December 31, 2012		
Common stock, $0.0001 par value, 150,000 shares authorized; 14,620 and 411 shares issued and outstanding at December 31, 2013 and 2012, respectively	1	
Additional paid in capital	158,278	
Other comprehensive income	22	
Accumulated deficit	(126,832)	(93,760)
Total stockholders equity (deficit)	31,469	(93,760)
Total liabilities, mandatorily redeemable convertible preferred stock and stockholders equity (deficit)	$ 64,372	$ 37,406

The accompanying notes are an integral part of these consolidated financial statements.

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NanoString Technologies, Inc.

Consolidated Statements of Operations

	Years Ended December 31,		
	2013	2012	2011
	(In thousands, except per share amounts)		
Revenue	$ 31,403	$ 22,973	$ 17,800
Costs and expenses:			
Cost of revenue	15,009	12,361	9,777
Research and development	14,979	11,635	8,990
Selling, general and administrative	29,912	15,486	9,529
Total costs and expenses	59,900	39,482	28,296
Loss from operations	(28,497)	(16,509)	(10,496)
Other income (expense):			
Interest income	68	21	10
Interest expense	(1,942)	(804)	(599)
Other income (expense)	(66)	(29)	80
Revaluation of preferred stock warrant liability	1,156	(387)	73
Total other income (expense)	(784)	(1,199)	(436)
Net loss	(29,281)	(17,708)	(10,932)
Accretion of mandatorily redeemable convertible preferred stock	(4,653)	(7,533)	(5,251)
Net loss attributable to common stockholders	$ (33,934)	$ (25,241)	$ (16,183)
Net loss per share basic and diluted	$ (4.44)	$ (71.10)	$ (50.10)
Weighted average shares used in computing basic and diluted net loss per share	7,643	355	323

The accompanying notes are an integral part of these consolidated financial statements.

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NanoString Technologies, Inc.

Consolidated Statements of Comprehensive Loss

	Years Ended December 31,		
	2013	2012	2011
	(In thousands)		
Net loss	$ (29,281)	$ (17,708)	$ (10,932)
Other comprehensive income:			
Unrealized gain on short-term investments	22		
Comprehensive loss	$ (29,259)	$ (17,708)	$ (10,932)

The accompanying notes are an integral part of these consolidated financial statements.

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NanoString Technologies, Inc.

Consolidated Statements of Changes in Mandatorily Redeemable Convertible Preferred Stock and Stockholders Equity (Deficit)

Period From December 31, 2010 Through December 31, 2013

d	Series B Preferred Stock		Series C Preferred Stock		Series D Preferred Stock		Series E Preferred Stock		Common Stock		Additio Paid-C
nt	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capit
					(In thousands, except share amounts)						
50	515,836	$ 11,800	3,551,060	$ 32,837		$		$	322,325	$	$
					2,430,054	17,819					
33		993		2,777		348					(2
									2,204		
											2
83	515,836	12,793	3,551,060	35,614	2,430,054	18,167			324,529		
							1,063,951	15,132			
22		1,072		2,978		2,156		105			(9
									85,135		1
									1,562		
											7

05	515,836	13,865	3,551,060	38,592	2,430,054	20,323	1,063,951	15,237	411,226		
83		577		1,604		1,140		649			(8
									5,400,000		46,8
88)	(515,836)	(14,442)	(3,551,060)	(40,196)	(2,430,054)	(21,463)	(1,063,951)	(15,886)	8,631,427	1	108,2
											2,5
									177,165		3
											1,1
		$		$		$		$	14,619,818	$ 1	$ 158,2

The accompanying notes are an integral part of these consolidated financial statements.

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NanoString Technologies, Inc.

Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2013	2012	2011
	(In thousands)		
Operating activities:			
Net loss	$ (29,281)	$ (17,708)	$ (10,932)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	1,777	1,947	1,454
Amortization of debt discount	213	136	330
Stock-based compensation	1,145	745	243
Revaluation of preferred stock warrant liability	(1,156)	387	(73)
Amortization of premium on short-term investments	(518)		
Interest accrued on convertible promissory notes			87
Interest accrued on long-term note loan	259	90	
Loss on disposal of property and equipment	1	3	
Changes in operating assets and liabilities			
Accounts receivable	(5,009)	(210)	(965)
Inventory	(1,370)	(1,884)	(1,338)
Prepaid expenses and other	(1,679)	221	(1,100)
Related party loans and other assets	(268)	118	(58)
Accounts payable	1,601	103	(1,231)
Accrued liabilities	2,678	1,830	781
Deferred revenue	1,025	146	624
Deferred rent	(764)	(732)	1,486
Net cash used in operating activities	(31,346)	(14,808)	(10,692)
Investing activities:			
Purchases of property and equipment	(759)	(428)	(2,688)
Purchases of short-term investments	(32,175)		
Increase in restricted cash	(21)		(112)
Net cash used in investing activities	(32,955)	(428)	(2,800)
Financing activities:			
Proceeds from issuance of preferred stock and warrants		15,132	14,883
Proceeds from initial public offering	47,374		
Proceeds from issuance of convertible promissory notes and warrants			5,000
Proceeds from issuance of long-term debt	5,000	13,000	5,004
Repayment of long-term debt	(211)	(1,706)	(4,899)
Deferred offering costs		(553)	
Proceeds from exercise of stock options and warrants	387	187	6

Net cash provided by financing activities	52,550	26,060	19,994
Net increase (decrease) in cash and cash equivalents	(11,751)	10,824	6,502
Cash and cash equivalents:			
Beginning of year	21,692	10,868	4,366
End of year	$ 9,941	$ 21,692	$ 10,868
Supplemental disclosures:			
Accretion of preferred stock	$ 4,653	$ 7,533	$ 5,251
Accrual of offering costs	29	1,212	
Cash paid for interest	1,474	563	167
Issuance of preferred stock warrants with debt	138	648	661
Issuance of preferred stock warrants with equity			1,867
Conversion of convertible promissory notes and accrued interest into Series D preferred stock			5,087
Conversion of convertible preferred stock to common stock	108,275		
Conversion of convertible preferred stock warrants to common stock warrants	2,514		
Non-cash capital lease	410		

The accompanying notes are an integral part of these consolidated financial statements.

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NanoString Technologies, Inc.

Notes to Consolidated Financial Statements

1. Description of the Business

NanoString Technologies, Inc. (the Company) was incorporated in the state of Delaware on June 20, 2003. The Company s headquarters is located in Seattle, Washington. The Company s technology enables direct detection, identification and quantification of individual target molecules in a biological sample by attaching a unique color coded fluorescent reporter to each target molecule of interest. The Company markets its proprietary nCounter Analysis System, consisting of instruments and consumables, including its Prosigna Breast Cancer Assay, to academic, government and biopharmaceutical and clinical laboratories.

The Company has incurred losses to date and expects to incur additional losses in the foreseeable future. The Company continues to devote the majority of its resources to the growth of its business in accordance with its business plan. The Company s activities have been financed primarily through the sale of equity securities and incurrence of indebtedness, and to a lesser extent, capital leases and other borrowings.

Reverse Stock Split

On June 12, 2013, the Company effected a 1-for-32 reverse stock split of its common stock and preferred stock. All share and per share information has been retroactively adjusted to reflect this reverse stock split.

Initial Public Offering

On June 25, 2013, the Company s registration statement on Form S-1 was declared effective. This registration statement related to its initial public offering, in which the Company sold 5,400,000 shares of common stock at a price of $10.00 per share. The shares began trading on the NASDAQ Global Market on June 26, 2013. All outstanding shares of the Company s mandatorily redeemable convertible preferred stock converted into shares of common stock in connection with the initial public offering. Following the initial public offering, there were no shares of preferred stock outstanding.

2. Significant Accounting Policies

Accounting Principles

The consolidated financial statements and accompanying notes were prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP).

Principles of Consolidation

The accompanying consolidated financial statements reflect the accounts of the Company and its wholly-owned subsidiaries, NanoString Technologies International, Inc., NanoString Technologies Asia Pacific Limited, NanoString Technologies Europe Limited, Nanostring Technologies Germany GmbH, Nanostring Technologies Singapore Pte Limited and NanoString Technologies SAS. Each of these subsidiaries operates as a sales and support office. The functional currency of each subsidiary is the U.S. dollar. All significant intercompany balances and transactions have been eliminated.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and that affect the reported amounts of revenue and expenditures during the reporting period. Actual results could differ from those estimates. Significant estimates inherent in the preparation of the accompanying consolidated financial statements include the estimation of the fair value of the Company s equity securities and the calculation of stock-based compensation.

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Cash and Cash Equivalents

The Company considers all highly-liquid investments with purchased maturities of three months or less to be cash equivalents. The Company s cash equivalents consist principally of funds maintained in depository accounts. The Company invests its cash and cash equivalents with major financial institutions; at times these investments exceed federally insured limits.

Investments

The Company classifies its securities as available-for-sale, which are reported at estimated fair value with unrealized gains and losses included in accumulated other comprehensive income in stockholders equity. Realized gains, realized losses and declines in the value of securities judged to be other-than-temporary, are included in other income (expense). The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Amortization of premiums and accretion of discounts are included in other income (expense). Interest and dividends earned on all securities are included in other income (expense). Investments in securities with maturities of less than one year, or where management s intent is to use the investments to fund current operations, or to make them available for current operations, are classified as short-term investments.

If the estimated fair value of a security is below its carrying value, the Company evaluates whether it is more likely than not that it will sell the security before its anticipated recovery in market value and whether evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. The Company also evaluates whether or not it intends to sell the investment. If the impairment is considered to be other-than-temporary, the security is written down to its estimated fair value. In addition, the Company considers whether credit losses exist for any securities. A credit loss exists if the present value of cash flows expected to be collected is less than the amortized cost basis of the security. Other-than-temporary declines in estimated fair value and credit losses are charged against other income (expense).

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are stated at the amount management expects to collect from customers based on their outstanding invoices. Management reviews accounts receivable regularly to determine if any receivable will potentially be uncollectible and to estimate the amount of allowance for doubtful accounts necessary to reduce accounts receivable to its estimated net realizable value. This estimate was made by analyzing the status of significant past due receivables and by establishing provisions for estimated losses by analyzing current and historical bad debt trends. At December 31, 2013 and 2012, no allowance for doubtful accounts was recorded.

Concentration of Credit Risks

Cash, cash equivalents and short-term investments are invested in accordance with the Company s investment policy. The policy includes guidelines for the investment of cash reserves and is reviewed periodically to minimize credit risk. The Company also has credit risk related to the collectability of its accounts receivable. The Company performs initial and ongoing evaluations of its customers financial position and generally extends credit on account without collateral.

The Company did not have any customers that individually represented more than 10% of total revenue during the years ended December 31, 2013, 2012 and 2011.

The Company had no customers that represented more than 10% of total accounts receivable at December 31, 2013 and 2012.

The Company is also subject to supply chain risks related to the outsourcing of the manufacturing of its instruments to sole suppliers. Although there are a limited number of manufacturers for instruments of this type,

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the Company believes that other suppliers could provide similar products on comparable terms. A change in suppliers, however, could cause a delay in manufacturing and a possible loss of sales, which would adversely affect operating results.

Fair value of financial instruments

The recorded amounts of certain financial instruments, including cash and cash equivalents, accounts receivable, prepaid expenses and other assets, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities. Investments that are classified as available-for-sale are recorded at fair value. The fair value for securities held is determined using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The recorded amount of the Company s long-term debt approximates fair value because the related interest rates approximate rates currently available to the Company.

Inventory

Inventory consists of finished goods, work in process, raw materials and certain component parts to be used in manufacturing the Company s products. Inventory is stated at the lower of cost or market. Cost is determined using a standard cost system, whereby the standard costs are updated periodically to reflect current costs and market represents the lower of replacement cost or estimated net realizable value. The Company records adjustments to inventory for potentially excess, obsolete, slow-moving or impaired items.

The Company outsources the manufacturing of its instruments to third-party contract manufacturers who manufacture them to certain specifications and source certain raw materials from sole source providers. Major delays in shipments, inferior quality, insufficient quantity or any combination of these or other factors may harm the Company s business and results of operations. In addition, the inability of one or more of these suppliers to provide the Company with an adequate supply of its products or raw materials or the loss of one or more of these suppliers may cause a delay in the Company s ability to fulfill orders while it obtains a replacement supplier and may harm the Company s business and results of operations.

Property and Equipment

Property and equipment are recorded at cost, net of accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets. Manufacturing equipment is amortized over five years, computer equipment is generally depreciated over three years, furniture and fixtures are depreciated over five years and leasehold improvements are amortized over the life of the related assets or the term of the lease, whichever is less. Expenditures for additions are capitalized and expenditures for maintenance and repairs are expensed as incurred. Gains and losses from the disposal of property and equipment are reflected in the consolidated statements of operations in the year of disposition.

Leases and Leasehold Improvements

Rent expense for leases that provide for scheduled rent increases during the lease term is recognized on a straight-line basis over the term of the related lease. Leasehold improvements that are funded by landlord incentives or allowances are recorded in property and equipment and as a component of deferred rent and are amortized as a reduction of rent expense over the term of the related lease.

Impairment of Long-Lived Assets

The Company recognizes impairment losses on long-lived assets when indicators of impairment are present and the anticipated undiscounted cash flows to be generated by those assets are less than the asset s carrying values. The Company has not experienced any impairment losses on its long-lived assets during the periods presented.

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Deferred Offering Costs

Deferred offering costs represent legal, accounting and other direct costs related to the Company s efforts to raise capital through public offerings of the Company s common stock. Costs are deferred until the completion of the applicable offering, at which time they are reclassified to additional paid-in capital as a reduction of the proceeds. The Company accrued approximately $29,000 and $1.8 million of deferred offering costs as a non-current asset in the consolidated balance sheet as of December 31, 2013 and 2012, respectively.

Segments

The Company follows the authoritative literature that established annual and interim reporting standards for enterprises operating segments and related disclosures about its products and services, geographic regions and major customers. Operating segments are defined as components of an entity for which separate financial information is available and evaluated regularly by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company s chief operating decision maker is the chief executive officer, who manages the operations and evaluates the financial performance on a total Company basis. The Company s principal operations and decision-making functions are located at its corporate headquarters in the United States.

Until the fourth quarter of 2013, the Company operated in two reportable segments, its life sciences business and its diagnostics business. In November 2013, the Company s nCounter Dx Analysis System FLEX Configuration was launched, enabling customers to perform both research and clinical testing on the same instrument. The Company has one sales force that now sells these systems to both research and diagnostic testing labs, and has launched its first product, nCounter Elements GPRs, that can be used for both research and diagnostic testing. As a result of these fundamental changes to its business, the Company began operating as a single reportable segment during the fourth quarter of 2013.

Revenue Recognition

The Company recognizes revenue when (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price to the customer is fixed or determinable and (4) collectability is reasonably assured. The Company generates revenue from the sale of products and services. The Company s products consist of its proprietary nCounter Analysis System and related consumables. Services consist of extended warranties and service fees for assay processing. A delivered product or service is considered to be a separate unit of accounting when it has value to the customer on a stand-alone basis. Products or services have value on a stand-alone basis if they are sold separately by any vendor or the customer could resell the delivered product.

Systems product revenue is recognized upon installation and calibration in geographic regions where such services are only available from the Company s specialized technicians. In these regions, systems and related installation and calibration are considered to be one unit of accounting, as systems are required to be professionally installed and calibrated before use. In certain geographic regions, installation and calibration services are available from other vendors, and in such regions they are considered separate revenue elements. Consumables are considered to be separate units of accounting as they are sold separately. Consumables product revenue is recognized upon shipment.

Service revenue is recognized when earned, which is generally upon the rendering of the related services. Service contracts and service fees for assay processing are each considered separate units of accounting as they are sold separately. The Company offers service contracts on its nCounter Analysis System for periods ranging from 12 to 36 months after the end of the standard 12-month warranty period. Service contracts are generally separately priced. Revenue from service contracts is deferred and recognized in income on a straight-line basis over the service period.

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For arrangements with multiple deliverables, the Company allocates the contract consideration at the inception of the contract to the deliverables based upon their relative selling prices. To date, selling prices have been established by reference to vendor specific objective evidence based on stand-alone sales transactions for each deliverable. Vendor specific objective evidence is considered to have been established when a substantial majority of individual sales transactions within the previous 12 month period fall within a reasonably narrow range, which the Company has defined to be plus or minus 15% of the median sales price of actual stand-alone sales transactions. The Company uses its best estimate of selling price for individual deliverables when vendor specific objective evidence or third-party evidence is unavailable. Allocated revenue is only recognized for each deliverable when the revenue recognition criteria have been met.

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 the Company s products, provisions for slow-moving and obsolete inventory and stock-based compensation expense. Cost of revenue for instruments and consumables is recognized in the period the related revenue is recognized. Shipping and handling costs incurred for product shipments are included in cost of revenue in the consolidated statements of operations.

Reserve for Product Warranties

The Company generally provides a one-year warranty on its nCounter Analysis Systems and establishes an accrual based on historical product failure rates and actual warranty costs incurred. Warranty expense is recorded as a component of cost of revenue in the consolidated statements of operations.

Changes in the Company s warranty reserve and related costs were as follows:

	(In thousands)
Warranty reserve, December 31, 2010	$ 63
Cost of warranty claims	(518)
Warranty accrual	622
Warranty reserve, December 31, 2011	167
Cost of warranty claims	(244)
Warranty accrual	325
Warranty reserve, December 31, 2012	248
Cost of warranty claims	(191)
Warranty accrual	301
Warranty reserve, December 31, 2013	$ 358

Research and Development

Research and development expenses, consisting primarily of salaries and benefits, occupancy costs, laboratory supplies, clinical study costs, contracted services, consulting fees and related costs, are expensed as incurred.

Selling, General and Administrative

Selling expenses consist primarily of personnel related costs for sales and marketing, contracted services, and service fees and are expensed as the related costs are incurred. Advertising costs are charged to operations as incurred and are included in sales and marketing expenses. Advertising costs totaled approximately $3.3 million, $590,000 and $417,000 during the years ended December 31, 2013, 2012 and 2011, respectively.

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General and administrative expenses consist primarily of personnel related costs for the Company s finance, human resources, business development, legal and general management, as well as professional fees for services such as legal and accounting services. General and administrative expenses are expensed as they are incurred.

Income Taxes

The Company accounts for income taxes under the liability method. Under the liability method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and income tax bases of assets and liabilities and are measured using the tax rates that will be in effect when the differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that some of the deferred tax assets will not be realized.

The Company determines whether a tax position is more likely than not to be sustained upon examination based on the technical merits of the position. For tax positions meeting the more-likely-than-not threshold, the tax amount recognized in the financial statements is reduced by the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the relevant tax authority.

Stock-Based Compensation

The Company accounts for stock-based compensation under the fair value method. Stock-based compensation costs are based on option awards granted and vested based on their grant-date fair value, estimated using the Black-Scholes option pricing model. The Company uses the straight-line attribution method for recognizing compensation expense.

The Company recognizes compensation expense for only the portion of options expected to vest. Therefore, management applied an estimated forfeiture rate that was derived from historical employee termination behavior. If the actual number of forfeitures differs from these estimates, adjustments to compensation expense may be required in future periods.

Guarantees and Indemnifications

In the normal course of business, the Company guarantees and/or indemnifies other parties, including vendors, lessors and parties to transactions with the Company, with respect to certain matters. The Company has agreed to hold the other parties harmless against losses arising from breach of representations or covenants, or out of intellectual property infringement or other claims made against certain parties. It is not possible to determine the maximum potential amount the Company could be required to pay under these indemnification agreements, since the Company has not had any prior indemnification claims, and each claim would be based upon the unique facts and circumstances of the claim and the particular provisions of each agreement. In the opinion of management, any such claims would not be expected to have a material adverse effect on the Company s consolidated results of operations, financial condition or cash flows. The Company did not have any related liabilities recorded at December 31, 2013 and 2012.

Comprehensive Income

Comprehensive loss includes certain changes in equity that are excluded from net loss. Specifically, unrealized gains and losses on short-term investments are included in comprehensive income.

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Recent Accounting Pronouncements

As an emerging growth company, the Jumpstart Our Business Startups Act allows the Company to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies.

3. Short-term Investments

Short-term investments consisted of available-for-sale securities at December 31, 2013 as follows:

Type of security	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
		(In thousands)		
U.S. government-related debt securities	$ 1,565	$ 1	$	$ 1,566
Corporate debt securities	31,128	24	(3)	31,149
Total available-for-sale securities	$ 32,693	$ 25	$ (3)	$ 32,715

The Company did not have available-for-sale securities at December 31, 2012.

The fair values of available-for-sale securities by contractual maturity at December 31, 2013 were as follows (in thousands):

Maturing in one year or less	$ 26,725
Maturing after one year through three years	5,990
Total available-for-sale securities	$ 32,715

4. Fair Value Measurements

The Company establishes the fair value of its assets and liabilities using the price that would be received to sell an asset or paid to transfer a financial liability in an orderly transaction between market participants at the measurement date. A fair value hierarchy is used to measure fair value. The three levels of the fair value hierarchy are as follows:

Level 1 Quoted prices in active markets for identical assets and liabilities.

Level 2 Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.

Level 3 Valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

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The Company s available-for-sale securities by level within the fair value hierarchy were as follows:

As of December 31, 2013	Fair value measurement using: Level 1	Level 2	Level 3	Total
	(In thousands)			
Cash equivalents:				
Money market fund	$ 8,454	$	$	$ 8,454
Short-term investments:				
U.S. government-related debt securities		1,566		1,566
Corporate debt securities		31,149		31,149
Total	$ 8,454	$ 32,715	$	$ 41,169

As of December 31, 2012	Fair value measurement using: Level 1	Level 2	Level 3	Total
	(In thousands)			
Cash equivalents:				
Money market fund	$ 20,510	$	$	$ 20,510

Prior to the Company s initial public offering, the Company had mandatorily redeemable convertible preferred stock which contained certain redemption provisions that precluded equity classification. Accordingly, warrants to purchase this mandatorily redeemable convertible preferred stock were classified as liabilities for the periods presented. These preferred stock warrants were subject to re-measurement at each balance sheet date and any change in fair value was recognized as a component of other income (expense).

The Company s preferred stock warrants were categorized as Level 3 because they were valued based on unobservable inputs and management judgment due to the absence of quoted market prices, inherent lack of liquidity and the long-term nature of such financial instruments. The Company performed a fair value assessment of the preferred stock warrant inputs on a quarterly basis using the Black-Scholes option pricing model. The assumptions used in the Black-Scholes option pricing model are inherently subjective and involve significant judgment. Any change in fair value was recognized as a component of other income (expense) in the consolidated statements of operations. Upon the closing of the Company s initial public offering, all warrants to purchase preferred stock were converted to warrants to purchase common stock and these warrants are no longer re-measured to fair value at each reporting date.

The Company s preferred stock warrant liabilities by level within the fair value hierarchy were as follows:

As of December 31, 2012	Fair value measurement using: Level 1	Level 2	Level 3	Total
	(In thousands)			
Preferred stock warrant liability	$	$	$ 3,532	$ 3,532

The Company may elect to apply fair value to its financial assets and liabilities on an instrument-by-instrument basis. The Company has not elected to apply the fair value option to any eligible financial assets or liabilities in 2013, 2012 or 2011.

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5. Inventory

Inventory consisted of the following at December 31:

	2013	2012
	(In thousands)	
Raw materials	$ 2,164	$ 2,120
Work in process	2,198	962
Finished goods	2,388	2,298
	$ 6,750	$ 5,380

6. Prepaid Expenses and Other

Prepaid expenses and other consisted of the following at December 31:

	2013	2012
	(In thousands)	
Prepaid royalties	$ 163	$ 175
Deposits for inventory	1,577	883
Other	1,259	262
	$ 2,999	$ 1,320

7. Property and Equipment

Property and equipment consisted of the following at December 31:

	Useful Life (Years)	2013	2012
		(In thousands)	
Manufacturing equipment	5	$ 3,333	$ 2,854
Prototype systems	2	1,893	1,893
Computer equipment	3	1,325	651
Furniture and fixtures	5	543	517
Leasehold improvements	Various	4,713	4,713
Construction in progress			14
		11,807	10,642
Less: Accumulated depreciation and amortization		(8,742)	(6,968)
		$ 3,065	$ 3,674

Prototype systems consist of digital imagers and liquid handling robots used in internal testing and other development activities.

Depreciation and amortization expense for the years ended December 31, 2013, 2012 and 2011 totaled approximately $1.8 million, $1.9 million and $1.5 million, respectively.

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8. Accrued Liabilities

Accrued liabilities consisted of the following at December 31:

	2013	2012
	(In thousands)	
Salaries and bonuses	$ 4,701	$ 2,071
Clinical study costs	539	847
Accounting and legal	272	491
Other accrued liabilities	1,576	1,072
	$ 7,088	$ 4,481

9. Long-Term Debt

In 2012, the Company entered into a credit facility, as amended, that consists of up to $23.0 million in term loan borrowings and a $2.0 million accounts receivable revolving line of credit. All borrowings under the credit facility have a maturity date of July 2016. The term loans bear interest at fixed rates based on the three-month LIBOR rate plus 8.39% (subject to a LIBOR floor of 0.50%) at the time of borrowing and borrowings under the revolving line of credit bear interest at the Prime Rate plus 3.70% (subject to a floor of 6.95%). At December 31, 2013, the Prime Rate was equal to 3.25%. We are also required to pay a fee of 0.075% per month on the unused portion of the revolver borrowings. Through January 2014, the Company is required to only pay interest on all outstanding term borrowings. Following the expiration of the interest only payment period, the Company is required to pay principal and interest in 30 equal monthly payments, plus an end of term payment equal to 5.5% of the amount borrowed. The Company may at its option prepay all of the term loan borrowings by paying the lender, among other things, all principal and accrued interest, the end of term payment plus a make-whole premium.

During 2012, the Company incurred $13.0 million in term loan borrowings at an interest rate of 8.89%. In connection with the credit facility, the Company issued warrants to purchase an aggregate of 76,940 shares of Series D preferred stock at an exercise price of $8.45 per share and 20,837 shares of Series E preferred stock at an exercise price of $14.40 per share. The warrants have a ten-year term and an aggregate fair value at issuance of $648,000. The warrants were valued at the date of issuance using the Black-Scholes option pricing model with the following assumptions: fair value of preferred stock equal to exercise price of warrant, volatility of 58.0 to 61.0% and a risk free interest rates of 1.63 to 2.20%. The warrants were treated as debt discount and are being amortized over the term of the debt. In connection with the Company s initial public offering, these warrants became exercisable for shares of the Company s common stock.

In April 2013, the Company incurred an additional $5.0 million in term loan borrowings under the credit facility at an interest rate of 8.89%. In connection with this borrowing, the Company issued warrants to purchase an aggregate of 10,418 shares of Series E preferred stock, which were valued at the date of issuance at $138,000 using the Black-Scholes option pricing model with the following assumptions: fair value of preferred stock equal to the exercise price of the warrants, volatility of 57.0% and a risk-free interest rate of 1.7%. In connection with the Company s initial public offering, these warrants became exercisable for shares of the Company s common stock.

The credit facility contains customary conditions to borrowing, events of default and covenants, including covenants that restrict the Company s ability to dispose of assets, merge with or acquire other entities, incur indebtedness, incur

encumbrances, make distributions to holders of the Company s capital stock, make investments or engage in transactions with its affiliates. In addition, the Company must comply with a financial covenant based on non-Prosigna revenue. This financial covenant is measured monthly on a trailing three month basis. The Company was in compliance with all covenants as of December 31, 2013. The Company s obligations under the credit facility are collateralized by substantially all of its assets other than intellectual property.

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In August 2013, the Company entered into an equipment lease of hardware, software and capitalized installation costs over a lease term of three years expiring July 2016. The amount financed totaled approximately $410,000 and is being repaid over the term of the lease. The lease is interest free and ownership of the property transfers to the Company at the end of the term.

Pursuant to an office building lease, the owner of the building financed a portion of tenant improvements under an arrangement in which the Company is obligated to pay the amount financed over the term of the lease. The amount financed totaled $843,000 and is being repaid over the original five-year term of the lease. Interest accrues on the unpaid balance at a rate of 10% per annum.

Borrowings, including current portion, consisted of the following at December 31:

	2013	2012
	(In thousands)	
Landlord payable	$ 49	$ 235
Capital lease	410	
Term loans payable	18,348	13,115
	18,807	13,350
Less: Unamortized debt discount	(514)	(591)
Current portion	(6,136)	(2,789)
Non-current portion	$ 12,157	$ 9,970

Scheduled future payments for principal obligations under outstanding debt facilities were as follows at December 31:

	2013
	(In thousands)
2014	$ 6,342
2015	7,458
2016	5,007
2017	
2018	
	$ 18,807

10. Common Stock and Preferred Stock

Prior to the completion of its initial public offering in July 2013, the Company was authorized to issue common stock and Series A, Series B, Series C, Series D and Series E convertible preferred stock. Immediately prior to the completion of the Company s initial public offering, all of the outstanding shares of convertible preferred stock automatically converted into 8,631,427 shares of common stock.

Common Stock

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of other classes of stock outstanding.

Preferred Stock

Pursuant to the amended and restated certificate of incorporation filed by the Company immediately prior to the completion of its initial public offering, the Company s board of directors is authorized to issue up to 15,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and

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restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, redemption rights, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing change in the Company s control or other corporate action. As of December 31, 2013, no shares of preferred stock were issued or outstanding, and the board of directors has not authorized or designated any rights, preferences, privileges and restrictions for any class of preferred stock.

Mandatorily Redeemable Convertible Preferred Stock

Prior to the completion of the Company s initial public offering, the Company issued Series A, Series B, Series C, Series D and Series E convertible preferred stock (collectively, the Preferred Stock).

The convertible preferred stock contained a provision that at any time after November 29, 2017 and upon 30 day notice from the holders of 65% of the outstanding Preferred Stock, such holders could compel the Company to redeem, from any funds legally available, all or part of the Preferred Stock and any accumulated or declared but unpaid dividends thereon. The Company accordingly recorded the Preferred Stock as mandatorily redeemable securities.

The redemption value of the Preferred Stock was equal to the original issue price with interest compounded from the original issuance date to the first installment redemption date at a rate of 8% compounded quarterly. The Company recorded accretion related to issue costs and dividends of Series A, Series B, Series C, Series D and Series E preferred stock totaling approximately $4.7 million, $7.5 million and $5.3 million for the years ended December 31, 2013 and 2012 and 2011, respectively. The Company also accreted any related issuance costs or discounts.

Mandatorily redeemable convertible preferred stock at December 31, 2012 was as follows:

Mandatorily Redeemable Convertible Preferred Stock	Shares Authorized	Shares Outstanding	Liquidation Preference	Book Value
			(Amounts in thousands)	
Series A	564,083	557,339	$ 15,628	$ 15,605
Series B	520,839	515,836	14,045	13,865
Series C	3,659,375	3,551,060	38,709	38,592
Series D	3,125,000	2,430,054	22,510	20,323
Series E	1,109,375	1,063,951	23,078	15,237
	8,978,672	8,118,240	$ 113,970	$ 103,622

Immediately prior to the completion of the Company s initial public offering, each share of Series A preferred stock was converted into common stock on a 1.403030-for-one basis, each share of Series B preferred stock was converted into common stock on a 1.559429-for-one basis and each share of Series C, D and E preferred stock was converted into common stock on a one-for-one basis. The aggregate outstanding shares of convertible preferred stock automatically converted into 8,631,427 shares of common stock.

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Warrants

As of December 31, 2012, there were a total of 604,563 warrants to purchase preferred stock outstanding. In April 2013, the Company issued warrants to purchase an aggregate of 10,418 shares of its Series E preferred stock with a term of 10 years. Prior to the completion of the initial public offering, the warrants to purchase preferred stock were recorded as liabilities and measured at fair value at each reporting date. The following information summarizes the carrying value of the warrants to purchase shares of the Company s preferred stock:

	(In thousands)
Balance at December 31, 2010	$ 42
Issuance of preferred stock warrants	2,528
Warrant revaluation	(73)
Balance at December 31, 2011	2,497
Issuance of preferred stock warrants	648
Warrant revaluation	387
Balance at December 31, 2012	3,532
Issuance of preferred stock warrants	138
Warrant revaluation	(1,156)
Reclassification to common stock warrants	(2,514)
Balance at December 31, 2013	$

All preferred stock warrants were converted into warrants to purchase common stock upon the effectiveness of the initial public offering. The preferred stock warrant liability was reclassified to stockholders equity and recorded as common stock warrants upon the closing of the Company s initial public offering. These warrants are no longer re-measured to fair value at each reporting date. As of December 31, 2013 there were 617,605 common stock warrants outstanding with a weighted average exercise price of $8.78 per common stock warrant.

11. Stock Based Compensation

Stock Option Plans

The Company s 2004 Stock Option Plan and 2013 Equity Incentive Plan authorize the grant of options to employees and consultants for up to 3,948,533 shares of the Company s common stock as of December 31, 2013. All options granted have a ten-year term and generally vest and become exercisable over four years of continued employment or service as defined in each option agreement. The Board of Directors determines the option exercise price and may designate stock options granted as either incentive or nonstatutory stock options. The Company generally grants stock options to employees with exercise prices equal to the estimated fair value of the Company s common stock on the date of grant.

A summary of the Company s employee stock option activity and related information follows:

	Shares	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2012	1,686,179	$ 2.28	8.59	$ 7,486
Granted	669,030	9.17		
Canceled	(65,410)	2.24		
Exercised	(177,165)	2.16		
Outstanding at December 31, 2013	2,112,632	$ 4.47	8.12	$ 26,968
December 31, 2013:				
Options vested and expected to vest	2,087,810	$ 4.46	8.11	$ 26,687
Options exercisable	872,414	$ 2.48	7.39	$ 12,875

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The total fair value of stock options vested during the year ended December 31, 2013 was $920,000.

The following table summarizes information about the Company s options outstanding at December 31, 2013:

	Options Outstanding			Options Exercisable	
Exercise Price	Number of Shares	Weighted-Average Remaining Contractual Life in Years		Number of Shares	Weighted-Average Remaining Contractual Life in Years
$0.32 1.92	862,856	8.18		416,309	8.13
2.24 3.84	457,740	6.48		369,142	6.41
5.12 6.72	418,030	8.35		85,309	7.92
8.96 12.50	374,006	9.73		1,654	9.79
	2,112,632			872,414	

The fair value of each employee option grant as of December 31 was estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

	2013		2012		2011	
Risk-free interest rates	1.05%	1.95%	0.85%	1.44%	2.2%	3.14%
Expected term (years)	6.25		6.25		6.25	
Expected dividend yield						
Volatility	57.0%	58.0%	54.0%	61.0%	73.0%	

The risk-free interest rates are based on the implied yield currently available in U.S. Treasury securities at maturity with an equivalent term. For purposes of determining the expected term of the awards in the absence of sufficient historical data relating to stock-option exercises, the Company applies a simplified approach in which the expected term of an award is presumed to be the mid-point between the vesting date and the expiration date of the award. The Company has not declared or paid any dividends and does not currently expect to do so in the foreseeable future. The Company based its expected volatility on the estimated volatility of similar companies whose share prices are publicly available.

Options granted during the years ended December 31, 2013, 2012, 2011 were granted at exercise prices that the Company s board of directors believed to be equal to the fair value of the common stock underlying such options on the date of grant. Prior to completion of its initial public offering, the Company assessed its estimate of fair value of its common stock for financial reporting purposes given the Company s improving financial performance and prospects, evolving belief that an initial public offering was increasingly viable and the generally improving conditions in the capital markets. Following this assessment, it was determined that for financial reporting purposes the fair value of the Company s common stock was higher than the board of directors fair market value estimate for certain options previously granted. In 2013 and 2012, the Company granted options of 101,487 and 988,268, respectively, that were subsequently determined to be granted at exercise prices that were less than the estimated per share value of the underlying common stock on the date of grant. The valuations of these stock options were adjusted to reflect the increase in estimated fair value of the underlying stock options. The weighted-average grant date fair

value of options granted during the years ended December 31, 2013, 2012 and 2011 was $5.30, $1.59 and $1.83, respectively.

The aggregate intrinsic value for options exercised during the years ended December 31, 2013, 2012 and 2011 was $681,000, $161,000 and $0, respectively, determined as of the date of option exercise.

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Stock compensation expense for the years ended December 31 was as follows:

	2013	2012	2011
		(In thousands)	
Cost of revenue	$ 49	$ 71	$ 4
Research and development	273	204	26
Selling, general and administrative	823	470	213
Total stock-based compensation expense	$ 1,145	$ 745	$ 243

At December 31, 2013, the total unrecognized compensation cost was approximately $4.1 million and will be recognized on a straight-line basis over the weighted-average remaining service period of approximately three years.

12. Income Taxes

Loss before income taxes for the years ended December 31 consisted of the following:

	2013	2012	2011
		(In thousands)	
Domestic	$ (28,746)	$ (17,618)	$ (10,966)
Foreign	(535)	(90)	34
Loss before income taxes	$ (29,281)	$ (17,708)	$ (10,932)

Income tax expense (benefit) differed from the amounts computed by applying the statutory federal income tax rate of 34% to pretax loss as a result of the following for the years ended December 31:

	2013	2012	2011
		(In thousands)	
Income tax provision at statutory rate	$ (9,955)	$ (6,021)	$ (3,717)
Nondeductible items	(32)	349	25
Change in tax credits	(893)	39	(202)
Change in valuation allowance	10,965	5,894	3,963
Other	(85)	(261)	(69)
	$	$	$

At December 31, 2013, the Company had net operating loss carryforwards of approximately $92.6 million which will begin to expire in 2023 through 2033. In addition, at December 31, 2013, the Company had research and development tax credit carryforwards of approximately $2.2 million.

The Company does not expect to utilize any of its net operating loss and tax credit carryforwards in the near term. The Company may have already experienced one or more ownership changes. Depending on the timing of any future utilization of its carryforwards, the Company may be limited as to the amount that can be utilized each year as a result of such previous ownership changes. However, the Company does not believe such limitations will cause its carryforwards to expire unutilized. Future changes in the Company s stock ownership as well as other changes that may be outside the Company s control could potentially result in further limitations on the Company s ability to utilize its net operating loss and tax credit carryforwards.

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The effect of temporary differences and carryforwards that give rise to deferred tax assets for the years ended December 31 were as follows:

	2013	2012
	(In thousands)	
Net operating loss carryforwards	$ 31,989	$ 21,569
Research and development tax credit carryforwards	1,654	761
Other	2,369	2,717
Total deferred tax assets	36,012	25,047
Less: Valuation allowance	(36,012)	(25,047)
Net deferred tax assets	$	$

The Company has recorded a