

NanoString Technologies Inc  
Form 10-K  
March 13, 2015  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**FORM 10-K**

(Mark One)

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

**For the fiscal year ended December 31, 2014**

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

**20-0094687**  
**(I.R.S. Employer**

**incorporation or organization)**

**Identification Number)**

**530 Fairview Avenue North, Suite 2000**

**Seattle, Washington**  
**(Address of principal executive offices)**

**98109**  
**(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**  
**Common Stock, \$0.0001 par value per share**

**Name of Exchange on Which Registered**  
**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

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

Indicate by check mark 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  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  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.

Edgar Filing: NanoString Technologies Inc - 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  (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

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 \$156.1 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 18,363,898 shares of the Registrant's common stock, \$0.0001 par value per share, outstanding on March 10, 2015.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

**Table of Contents**

**NANOSTRING TECHNOLOGIES, INC.**

**ANNUAL REPORT ON FORM 10-K**

**FOR THE FISCAL YEAR ENDED DECEMBER 31, 2014**

**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I</u></b>	2
Item 1. <u>Business</u>	2
Item 1A. <u>Risk Factors</u>	23
Item 1B. <u>Unresolved Staff Comments</u>	50
Item 2. <u>Properties</u>	50
Item 3. <u>Legal Proceedings</u>	50
Item 4. <u>Mine Safety Disclosures</u>	50
<b><u>PART II</u></b>	51
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	51
Item 6. <u>Selected Financial Data</u>	53
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	54
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	72
Item 8. <u>Financial Statements and Supplementary Data</u>	74
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	101
Item 9A. <u>Controls and Procedures</u>	101
Item 9B. <u>Other Information</u>	102
<b><u>PART III</u></b>	103
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	103
Item 11. <u>Executive Compensation</u>	108
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	116
Item 13. <u>Certain Relationships and Related Transactions and Director Independence</u>	119
Item 14. <u>Principal Accountant Fees and Services</u>	121
<b><u>PART IV</u></b>	123
Item 15. <u>Exhibits, Financial Statement Schedules</u>	123

**Table of Contents**

**Special Note Regarding 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 that are based on our management's beliefs and assumptions and on information currently available. 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, will, may, and other similar expressions. You should read 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, operating expenses and operating and net loss;

our ability to successfully commercialize Prosigna, our first *in vitro* diagnostic product;

the implementation of our business model, strategic plans for our business and future product development plans;

the regulatory regime and our ability to secure regulatory clearance or approval or reimbursement 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, collaboration partners and third parties who conduct our clinical studies;

our intellectual property position;

our expectations regarding the market size and growth potential for our business; 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.

---

**Table of Contents****PART I****Item 1. Business  
Overview**

We develop, manufacture and sell robust, intuitive products that unlock scientifically valuable and clinically actionable genomic information from minute amounts of tissue. Our nCounter Analysis System directly profiles hundreds of molecules simultaneously using a novel barcoding technology that is powerful enough for use in research, yet simple enough for use in clinical laboratories worldwide. We market systems and related consumables to researchers in academic, government, and biopharmaceutical laboratories for use in understanding fundamental biology and the molecular basis of diseases, such as cancer, and to clinical laboratories and medical centers for diagnostic use. As of December 31, 2014, we have an installed base of 264 systems, which our customers have used to publish more than 600 peer-reviewed papers. As researchers using our systems discover how genomic information can be used to improve clinical decision-making, these discoveries can be translated and validated as diagnostic tests, either using our nCounter Elements reagents or, in certain situations, by developing *in vitro* diagnostic assays. For example, our first molecular diagnostic product is the Prosigna Breast Cancer Assay, or Prosigna, which provides an assessment of a patient's risk of recurrence for breast cancer. More recently, we entered into our first companion diagnostic collaboration to develop an *in vitro* diagnostic test for a type of lymphoma, to be used to identify which patients are most likely to respond to a particular drug therapy.

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 or trigger certain diseases, such as cancer. 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. Our technology addresses a fundamental challenge in cancer research. With more cancers being detected earlier, tumor samples are becoming smaller and smaller, while researchers and clinicians have a much greater appetite for genomic information. The sensitivity and precision of our novel barcoding chemistry allows the measurement of subtle changes in genomic activity efficiently from minute samples of tissue. Furthermore, tumor samples are often stored in a format known as formalin-fixed paraffin embedded, or FFPE, which complicates subsequent analysis of genetic material. Our chemistry is particularly compatible with FFPE, increasing its popularity among cancer researchers. The nCounter Analysis System is an easy-to-use and flexible solution that allows researchers to efficiently test hypotheses in a high throughput manner across thousands of different samples. As a result, the nCounter Analysis System is particularly useful for validating networks of genes that characterize and help predict disease states, such as cancer. With the launch of the FLEX configuration of our nCounter Dx Analysis System in late 2013, researchers now have the potential to translate their discoveries to the clinic as diagnostics on a single instrument system after receiving any necessary regulatory authorizations.

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. 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. Physicians use Prosigna to help guide therapeutic decisions so that patients receive a therapeutic intervention only if it is clinically warranted. Prosigna is regulated as an *in vitro* diagnostic test and we distribute it as a kit for



## **Table of Contents**

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.

In March 2014, we initiated our first companion diagnostic collaboration with Celgene Corporation, or Celgene, under which we are developing an *in vitro* diagnostic test to identify a subset of patients with diffuse large B-cell lymphoma, or DLBCL, who are most likely to benefit from treatment with Celgene's drug REVLIMID which is FDA approved for other indications. In the collaboration, our test is being used initially to select patients for a Phase 3 clinical trial. We are eligible to receive payments totaling up to \$45.0 million and, subject to successful completion of the clinical trial and obtaining regulatory approval, we intend to market and sell the test to subtype DLBCL patients as an aid in making treatment decisions. We believe there are many other similar opportunities to collaborate with companies developing cancer drugs and we intend to pursue more of these collaborations.

We generated revenue of \$47.6 million, \$31.4 million and \$23.0 million in 2014, 2013 and 2012, respectively, while incurring net losses of \$50.0 million, \$29.3 million and \$17.7 million in 2014, 2013 and 2012, 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 Element™. Each other trademark, trade name or service mark appearing in this Annual Report on Form 10-K belongs to its holder.

## **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.

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

## **Table of Contents**

widely adopted paradigm that researchers use to understand biological processes and has assisted them in the development of diagnostics and drugs to treat disease. This is particularly important in cancer research and treatment.

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***

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 sequencing, or RNA-Seq has dramatically enhanced researchers' ability to discover patterns of gene expression that have biological meaning. However, researchers are increasingly performing analyses on a larger number of genes and samples and are seeking new methods of interrogation that would allow them to:

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

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

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

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

minimize the computational intensity of complex genomic analysis;

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

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

We believe that the above items create an opportunity for technologies like ours 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***

Growth in the molecular diagnostics market is being 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.

## **Table of Contents**

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.

In contrast to the central laboratory-based first-generation molecular diagnostic tests for various cancers, 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 these factors create an opportunity for technologies like ours that can facilitate the development and use of complex molecular diagnostics with a high level of precision on a decentralized basis.

## **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 reagents and related consumables for the specific experiment or assay they wish to conduct. Our clinical laboratory customers either purchase or lease instruments from us and also purchase our reagents and related consumables, including our Prosigna 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.

## **Table of Contents**

*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.

*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 or Laboratory Developed Tests based on nCounter Elements reagents, and research, by processing translational research experiments and multiplexed assays using our research reagents.

### ***Life Sciences Research***

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.

*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.

*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.

*Gene Fusions.* Researchers can use the nCounter Analysis System to detect gene fusion events that occur when one gene fuses to another gene. A number of design options are available for developing assays for these complex structural variants which have been shown to be important in a number of cancers.

*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.

In 2015, we intend to introduce a new research application for the measurement of protein expression. With the addition of this proteomic application, we believe that our nCounter Analysis System will hold a unique distinction of having capabilities for both genomic and proteomic analysis. Our first product offering in this area is expected to be a version of our Pan Cancer Immune Profiling Panel, measuring the expression of 770 genes involved in the immune system's response to cancer, which will simultaneously measure the expression of up to 30 complementary proteins from a single sample. We expect this initial multi-omic product offering to be particularly attractive to researchers working in the field of immuno-oncology, where an understanding of protein expression in addition to gene expression is critical to the development of new immunotherapies for treating cancer. Over time, we expect to introduce additional multi-omic and protein expression products.



## **Table of Contents**

### ***Molecular Diagnostics***

We believe that the attributes that make the nCounter Analysis System attractive to researchers also 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 reagents and *in vitro* diagnostic kits, initially Prosigna.

### **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.

Maintain a robust level of consumable usage per system through the introduction of new applications and reagent configurations.

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 reagents.

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

Capture capital efficiencies stemming from our unified research and diagnostics business model.

### **Our Products and Technology**

#### ***Instruments and Software***

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. The nCounter Dx Analysis System hardware is identical to the research use only version, and there are two software 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 and nCounter Elements in the other.

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.

## **Table of Contents**

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. When 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.

In mid-year 2015, we intend to introduce a new generation of the nCounter Analysis System that we believe will increase our addressable market by appealing to individual researchers. The new generation system will be a single instrument with a reduced footprint that combines the Prep Station and the Digital Analyzer. We are reducing the cost of the new system by reducing the throughput, and by adopting new, less expensive technologies. The new system will not be approved for diagnostic use, however all other research capabilities are expected to be maintained.

### ***Life Sciences Research Consumables***

Following purchase of an nCounter Analysis System, research customers purchase consumables from us to enable their research experiments. These include custom CodeSets targeted to a specific experiment, panels and nCounter Elements reagents.

#### *Custom CodeSets*

We work with our customers to design and 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.

#### *Panels*

We offer more than 20 panels that are pre-manufactured CodeSets, which include all of the consumables required to perform a specific type of experiment, including the following:

*Pan Cancer Pathways Gene Expression Panel.* A novel set of 770 essential genes representing all known major cancer pathways, including key driver genes, selected using a data-driven approach to identifying the genes most relevant to cancer biology.

*PanCancer Immune Profiling Gene Expression Panel.* A novel set of 770 genes designed in collaboration with cancer immunologists around the globe, combining markers for 24 different immune cell types and populations, 30 common cancer antigens and genes that represent all known categories of immune response including key checkpoint blockade genes.

## Edgar Filing: NanoString Technologies Inc - Form 10-K

*Other Gene Expression Panels.* Allow researchers to conduct a wide variety of gene analysis, including analysis of both human and mouse immunology-related genes and inflammation-related genes.

*miRNA Expression Panels.* 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. Separate panels are available for use with samples from humans, mice, rats, and fruit flies.

*Cancer Copy Number Variation Panel.* Enables copy number quantification for 87 genes commonly amplified or deleted in cancer.

## **Table of Contents**

### *nCounter Elements Reagents*

nCounter Elements are our digital molecular barcoding reagents 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. The highly flexible architecture of nCounter Elements enables a broad range of basic research studies where iterative design and refinement of assays are important.

### *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 Dx 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 Dx Analysis System has the precision, reproducibility, and simple workflow required of technologies used in clinical laboratories. Our clinical laboratory customers will use the nCounter Dx Analysis System, nCounter Elements reagents 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.

### *Laboratory Developed Tests*

Clinical laboratories can use nCounter Elements reagents to create Laboratory Developed Tests, or LDTs, which are diagnostic tests that are developed, validated and performed by a single laboratory and include genetic tests and other tests for rare conditions. nCounter Elements reagents enable assays for gene expression, copy number variation and gene fusions. Many clinical laboratories are currently exploring the use of nCounter Elements reagents to develop assays to replace tests currently performed using fluorescence-based *in situ* hybridization, or FISH. The first commercial use of an nCounter Elements based LDT occurred in 2014.

### *Prosigna*

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. 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 indicates the probability of cancer recurrence over 10 years. Physicians use Prosigna to help guide therapeutic decisions so that patients receive only a therapeutic intervention only if clinically warranted. Prosigna is regulated as an *in vitro* diagnostic test and we distribute it as a kit for use on our nCounter Dx Analysis System in clinical laboratories.

*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

## **Table of Contents**

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.

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.

## **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, 2014, we owned or exclusively licensed nine issued U.S. patents and approximately 27 pending U.S. patent applications, including provisional and non-provisional filings. We also owned or licensed approximately 136 pending and granted counterpart applications worldwide, including 56 country-specific validations of five European patents. The issued U.S. patents that we own or exclusively license are expected to expire between July 3, 2021 and May 27, 2030. 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.

We intend to file additional patent applications in the United States and abroad to strengthen our intellectual property rights; however, our patent applications 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.

### **Collaboration with Celgene Corporation**

In March 2014, we entered into a collaboration with Celgene Corporation, or Celgene, to develop, seek regulatory approval for, and commercialize a companion diagnostic assay using the nCounter Analysis System to



## **Table of Contents**

identify a subset of patients with DLBCL, who are most likely to benefit from treatment with Celgene's drug REVLIMID. Under the terms of the collaboration agreement, we will develop, seek regulatory approval for, and commercialize the diagnostic test and we are eligible to receive payments totaling up to \$45.0 million, of which \$5.8 million was received as an upfront payment, \$17.0 million is for potential success-based developmental and regulatory milestones, and the remainder is for potential commercial payments in the event sales of the test do not exceed certain pre-specified minimum annual revenues during the first three years following regulatory approval.

DLBCL is a heterogeneous group of cancers that represents the most common form of Non-Hodgkin Lymphoma. According to the National Cancer Institute, DLBCL will represent approximately 37% of the estimated 70,000 new cases of Non-Hodgkin Lymphoma in the United States each year. The subtypes of DLBCL have long been known to have varying prognoses. In January 2014, certain of our research customers published a paper in the journal *Blood* describing the development and validation of a biomarker assay based on a 20-gene expression DLBCL subtype classifier using our nCounter Analysis System. We have secured a license to the relevant intellectual property to enable the collaboration.

Under the collaboration agreement with Celgene, we have delivered an *in vitro* companion diagnostic test that will be used to subtype and screen patients who are being enrolled in a pivotal study of REVLIMID for the treatment of DLBCL. The upfront payment and a portion of the success-based milestone payments, totaling \$11.8 million, were received in 2014 and were intended to cover our costs for clinical development of the test. Upon successful completion of the Phase 3 clinical trial of the drug, we intend to pursue regulatory approval of the test in key global markets. Pursuant to the terms of the agreement, we retain the flexibility to independently develop and commercialize additional indications for the test.

## **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. In the future, we may consider these gene signatures for in-licensing. For example, in May 2014, we licensed a gene signature discovered by certain of our customers that could be used, after further development and regulatory authorization as a molecular diagnostic product to subtype patients with a certain form of non-Hodgkin lymphoma. 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. 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. Through December 31, 2014, we have paid aggregate royalties of \$2.6 million under the license agreement. 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.

## **Table of Contents**

### ***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 eight non-provisional patent applications, related to the PAM50 gene signature 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. Pursuant to the 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, 2014, we have paid Bioclassifier \$400,000 of which \$108,000 will be credited against future royalties owed.

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

### **Research and Development**

We have committed, and expect to continue to commit, significant resources to developing new technologies and products, improving product performance and reliability and reducing costs. We have assembled experienced research and development teams at our Seattle, Washington location with the scientific, engineering, software and process talent that we believe is required to successfully grow our business. As of December 31, 2014, including clinical, medical and regulatory affairs, we had 69 employees in research and development, of which 14 hold a Ph.D. degree. Our research and development expenses for the years ended December 31, 2014, 2013 and 2012 were \$21.4 million, \$15.0 million and \$11.6 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 are developing additional application areas to enable researchers to apply the nCounter Analysis System to new experimental paradigms. For example, we are developing an application for the measurement of protein expression using our existing chemistry based on the discoveries of one of our research customers. Ultimately, we believe that research customers will be able to measure multiple nucleic

acids and proteins in a single experiment, which is referred to as multi-omics. We are also continuing to update our panel product line.

*Instruments.* We are developing a new generation of the nCounter Analysis System that we believe will increase our addressable market by appealing to individual researchers. The new generation system will be a single instrument with a reduced footprint that combines the prep station and the digital analyzer. We are reducing the cost of the new system by reducing the throughput and adopting new,

## **Table of Contents**

less expensive technologies. The new system will not be approved for diagnostic use, however all other research capabilities are expected to be maintained. We are targeting release of the new generation system in mid-year 2015.

### ***Companion Diagnostic Development***

In March 2014, we entered into our first companion diagnostic collaboration with Celgene Corporation. Pursuant to the collaboration, we have developed an *in vitro* diagnostic test that is being used to test DLBCL patients to determine the subtype of their cancer (the Lymphoma Subtyping Test, or LST) and whether they will be enrolled in a Phase 3 clinical trial of REVLIMID for the DLBCL indication. We will monitor the testing process during that Phase 3 study and, if the study results are positive, we will submit appropriate filings for regulatory approval of the LST. We will own the commercial rights to the test and would make it commercially available in territories in which REVLIMID is approved for the DLBCL indication and for which we have any necessary regulatory authorizations to approve the test. Celgene has paid us \$11.8 million to date, and may be obligated to pay us up to \$45.0 million in total over the course of the collaboration.

We believe that there are likely to be many similar opportunities to collaborate with drug developers in the future and we intend to secure additional collaborations. These collaborations may be based on Prosigna, the LST, or other tests discovered by our research customers, either in academia or within biopharmaceutical companies themselves.

### ***Prosigna Breast Cancer Assay***

We plan to conduct clinical studies of Prosigna to generate more data regarding utilization of Prosigna in the clinical setting and, potentially, 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.

Our Prosigna 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 may participate in prospective clinical studies that require recruiting new patients. For example, we have been selected to participate in the OPTIMA trial, which is being organized and sponsored by a cooperative group in the United Kingdom. We are not financially responsible for conducting the trial; however, we intend to provide in-kind support through the sale of Prosigna *in vitro* diagnostic kits at a discounted price.

### ***Future Molecular Diagnostics***

We are continuously monitoring molecular signatures which have the potential to become 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

## **Table of Contents**

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.

## **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 18 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, 2014, 2013 or 2012.

## ***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 an nCounter Analysis System 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***

The commercialization of Prosigna kits involves a three-pronged effort. First, we 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 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. As of December 31, 2014, there were 37 laboratories worldwide that had purchased or rented nCounter Analysis Systems with the intent to market and sell Prosigna testing services. In the United States, this includes national diagnostic laboratories ARUP

Laboratories, Laboratory Corporation of America Holdings, Quest Diagnostics and Genoptix. Third, we intend to drive physician demand for clinical testing services enabled by our diagnostic products, and direct test orders toward those laboratories which have adopted our technology.



## **Table of Contents**

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.

### **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. Our next generation nCounter system will be manufactured by a sole source supplier as well.

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 are planning to expand our manufacturing capacity in 2015 by relocating certain research and development functions and converting the space to incremental manufacturing labs and offices. In the future, 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 (part of 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 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 *Oncotype DX*, a service for gene expression analysis performed in its central laboratory in Redwood City, California. We also face

## **Table of Contents**

competition from companies such as Agendia, Clariant (a GE Healthcare company), and bioMérieux, which also offer centralized laboratories that profile gene or protein expression in breast cancer. In Europe, we also face regional competition from Myriad Genetics, which is marketing a product from Sividon Diagnostics called EndoPredict, a distributed test for breast cancer recurrence, and other independent laboratories.

We believe that we have multiple competitive advantages in the research market, including 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. In the diagnostics market, we believe our competitive advantages include 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.

While we believe that we compete favorably based on the factors described above, many of our competitors enjoy other 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.

For additional information, see the section of this report captioned "Risk Factors." The life sciences 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

## **Table of Contents**

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. Placement of a device into Class II generally 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.

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

---

**Table of Contents**

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.

*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.



## **Table of Contents**

*Dual-Use Instruments.* Dual-use instruments are subject to FDA regulation since they are intended, at least in part, for use by customers performing clinical diagnostic testing. In November 2014, FDA issued a guidance that described FDA's approach to regulating molecular diagnostic instruments that combine in a single molecular instrument both approved/cleared device functions and device functions for which approval/clearance is not required.

*Laboratory Developed Tests.* Laboratory Developed Tests, or LDTs, are developed, validated and used within a single lab. Because the LDTs are not distributed as kits, but only used within the laboratory, the FDA has historically exercised enforcement discretion and has not required clearance or approval prior to marketing. However, on October 3, 2014, FDA issued two draft guidances that propose to actively regulate LDTs using a risk-based approach. If the draft guidances go into effect in their current format, all laboratories offering LDTs, except for those offering only LDTs for forensic use and certain transplantation tests, will be subject to certain general device requirements such as MDR reporting. In addition, high and moderate risk devices not subject to an exemption will need to submit a PMA or 510(k) to FDA in a phased-in manner. The comment period for the draft guidances closed February 2. The draft guidances have been the subject of considerable controversy and it is unclear whether the draft guidances will be finalized, and if so, what they will contain.

*Companion Diagnostics.* In August 2014, FDA issued a companion diagnostics final guidance stating that if the device is essential to the safety or efficacy of the drug, FDA will generally require approval or clearance for the device at the time when FDA approves the drug.

### *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 patient's 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.

### *Reimbursement*

Our nCounter Dx Analysis Systems are purchased or leased by clinical laboratories, which 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.

**Table of Contents**

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 dossiers to 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 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 may 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 based on this protocol we have completed one decision impact study to date, and have two other such studies currently underway.

*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 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. 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. A genomic test with an assigned MAAA code must still be vetted and approved by individual payors for coverage and payment 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.

In April 2014, we received an administrative MAAA code (0008M) for use in reimbursement of testing services based on Prosigna. Given the recent commercial launch of Prosigna in the United States, and the lack of utilization data, we expected the issuance of an administrative MAAA initially. We intend to reapply for a Category 1 MAAA at a later date when additional Prosigna utilization data are available.

---

**Table of Contents**

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 three routes to coverage via CMS: National Coverage Determinations, or NCDs, Local Coverage Determinations, or LCDs, or simply payment of claims by a MAC. The NCD applies to Medicare beneficiaries living throughout the United States. Due to cost and CMS bandwidth limitations there are generally few NCDs. 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. Due to the cost of developing an LCD, contractors tend to develop a relatively small number and prefer to tacitly cover services by paying claims. There is also a subset of NCDs known as Coverage with Evidence Development, or CED, 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. Some MACs have developed CED policies, but these are outside the statute that established CED.

We are pursuing Medicare coverage for Prosigna and where necessary working with MACs to obtain a favorable LCD. There are two distinct LCD processes for molecular diagnostic tests: the individual MAC LCD process and the Molecular Diagnostics Program, or MoIDX program for Palmetto, a MAC. Pursuing a series of LCDs will require us to engage with each of the seven MACs not currently under the MoIDX program for jurisdictions in which Prosigna testing services are provided. MACs have the option of paying for Prosigna claims without an LCD, and where possible we will pursue this less burdensome option. The MoIDX 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 MoIDX 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 MoIDX program. The MoIDX program requires providers to follow a unique and specific path to obtain an LCD.

The MoIDX 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 MoIDX program, Palmetto and Noridian. Laboratories under the MoIDX 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. We continue to be in dialogue with representatives of MoIDX, regarding our LCD application for reimbursement of Prosigna. In June 2014, MoIDX requested that we modify our application to address new guidelines addressing MoIDX's clinical test evaluation process and to respond to questions raised by MoIDX in its initial review of our application. We recently provided additional information to MoIDX to address this request. Based on our most recent interactions with MoIDX, we believe that MoIDX's coverage determination and what, if any, additional clinical data or other information we will be asked to provide in connection with our application will be strongly influenced by the final update to the National Comprehensive Cancer Network's, or NCCN, treatment guidelines. In mid-February, the NCCN issued a partial revision to the guidelines in which it updated the treatment algorithm section of the guidelines. Prosigna was not included in this partial update. We expect the full guidelines update, including the discussion section of the guidelines, to be published in March of this year. We do not expect MoIDX to make a coverage determination until after the NCCN guideline update. 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. As with other tests that have MAAA CPT codes, we believe that CMS will reimburse Prosigna testing services under the Clinical

Laboratory Fee Schedule.

-21-

## **Table of Contents**

With respect to private insurance coverage, there is significant uncertainty surrounding third-party reimbursement for the use of tests that incorporate new technology, such as Prosigna. For example, in the third quarter of 2014, the Blue Cross and Blue Shield, or BCBS, Association Technology Evaluation Center affirmed their position that Prosigna should be considered investigational. Subsequently, several BCBS entities updated their coverage policies based on this evaluation. In February 2015, Cigna decided that it would not reimburse for Prosigna. However, in August 2014, UnitedHealthcare, the largest private health insurer in the United States, agreed with Laboratory Corporation of America, one of our commercial laboratory customers, to begin paying for Prosigna testing. In addition, we recently received confirmations of coverage for Prosigna from California's Medicaid group, MediCal, and from Providence Health Plan.

### *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*

Our operations 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 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, 2014, we had 276 employees, of which 75 work in manufacturing, 100 in sales, marketing and business development, 54 in research and development, 15 in clinical, medical and regulatory



## **Table of Contents**

affairs, and 32 in general and administrative. None of our U.S. employees is represented by a labor union or is the subject of a collective bargaining agreement. As of December 31, 2014, of our 276 employees, 251 were employed in the United States and 25 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.

## **Where You Can Find Additional Information**

We make available free of charge through our investor relations website, [www.nanostring.com](http://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](mailto: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](http://www.sec.gov).

## **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 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 \$50.0 million and \$29.3 million for the years ended December 31, 2014 and 2013, respectively. As of December 31, 2014, we had an accumulated deficit of \$176.9 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 operating expenses will continue to increase as we grow our business, but

there can be no assurance that our revenues and gross profit will increase sufficiently such that our net losses decline, or we attain profitability, in the future. 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.

**Table of Contents**

***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, and revenue from licensing agreements, including the amount and timing of payments pursuant to collaboration agreements such as our agreement with Celgene Corporation, 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 changes 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 has required us to hire and retain additional sales and marketing, regulatory, manufacturing and quality assurance personnel. If we do not successfully generate 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 or clearance 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 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 than those centralized laboratories. For example, in the third quarter of 2014, we were notified by the Blue Cross Blue Shield Technology Evaluation Center that Prosigna does not currently meet its criteria for inclusion for reimbursement. In

February 2015, Cigna decided that it would not reimburse for Prosigna. In addition, our diagnostic tests are 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

## **Table of Contents**

business model and oncologists regarding the reliability and consistency of results generated locally. Also, we intend to offer Prosigna in other countries outside of the United States, where genomic testing for breast cancer is not widely available 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.

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. In mid-February, the NCCN issued a partial revision to the guidelines in which it updated only the treatment algorithm section of the guidelines. Prosigna was not included in this partial update. We expect the full guidelines update, including the discussion section of the guidelines, to be published in March of this year. 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. In 2013, with the introduction of our first diagnostic products, we began selling into the clinical laboratory market. 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 help 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 a large portion of our revenue will be derived from sales of our nCounter Analysis Systems to academic institutions, governmental laboratories and biopharmaceutical companies worldwide for research and development 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.

## **Table of Contents**

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. Furthermore, we have begun placing instruments under reagent rental agreements, wherein a customer does not purchase an instrument upfront but instead pays a rental fee associated with each purchase of reagents. An increase in instruments placed under these reagent rental agreements may reduce the number of instruments we would otherwise sell in any period. 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, and on clinical laboratories for delivery of Prosigna testing services, could limit or prevent us from selling our products 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.

Similarly, we have entered into agreements with clinical laboratories in the United States, Canada, Europe and Israel to provide Prosigna testing services. We do not provide testing services directly and, thus, we are reliant on these clinical laboratories to actively promote and sell Prosigna testing services. These clinical laboratories may take longer than anticipated to begin offering Prosigna testing services and may not commit the necessary resources to market and sell Prosigna testing services to the level of our expectations. Furthermore, we intend to contract with additional clinical laboratories to offer Prosigna testing services and we may be unsuccessful in attracting and contracting with new clinical laboratory providers. If current or future Prosigna testing service providers do not perform adequately, or we are unable to enter into contracts with additional clinical laboratories to provide Prosigna testing services, we may not be successful selling Prosigna and our future revenue prospects may be adversely affected.





## **Table of Contents**

***Our strategy to seek to enter into strategic collaborations and licensing arrangements with third parties to develop diagnostic tests may not be successful.***

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. Similarly, in connection with our collaboration with Celgene Corporation, we licensed the rights to intellectual property relating to a gene signature for lymphoma subtyping, which was discovered by a consortium of researchers including several of our research customers, from the National Institutes of Health. We intend to enter into more such arrangements with our research customers and other researchers, including biopharmaceutical companies, for development of 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 of Prosigna 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.

In March 2014, we entered into our first companion diagnostic collaboration with Celgene Corporation to develop an *in vitro* diagnostic assay to be used for subtyping certain lymphoma patients and we intend to enter into additional similar collaborations over time. The success of the development programs for such assays will be dependent on the success of the related drug trials conducted by our collaborators. There is no guarantee that those clinical trials will be successful and, as a result, we may expend considerable time and resources developing *in vitro* diagnostic assays that cannot gain regulatory approval. Although we expect such collaborations to provide funding to cover our costs of development, failure of these clinical trials would reduce our prospects for introducing new diagnostic products and would adversely impact our growth prospects and future operating results.

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

Under standard clinical practice, tumor biopsies removed from patients are preserved and stored in formalin-fixed paraffin embedded, or FFPE, format. We rely on our ability to secure access to these archived FFPE tumor biopsy samples, as well as information pertaining to the clinical outcomes of the patients from which they were derived for our clinical development activities. Others compete with us for access to these samples. Additionally, the process of negotiating access to archived samples is lengthy because it typically involves numerous parties and approval levels to

resolve complex issues such as usage rights, institutional review board approval, privacy rights, publication rights, intellectual property ownership and research parameters. If we are not able to negotiate access to archived tumor tissue samples with hospitals, clinical partners, pharmaceutical companies, or companies developing therapeutics on a timely basis, or at all, or if other laboratories or our

## Table of Contents

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 (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 Biosystems.

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, Clariant (a GE Healthcare company), Genoptix (a division of Novartis) and bioMeri  ux, 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 Myriad Genetics, which is marketing a product from Sividon Diagnostics called EndoPredict, a distributed test for breast cancer recurrence, as well as from 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.

**Table of Contents**

We believe that additional competitive factors specific to the diagnostics market include:

availability of reimbursement for testing services;

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

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

inclusion in treatment guidelines; 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 to clinical laboratories, 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 to clinical laboratories. Our nCounter Dx Analysis System 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. Many members of our original sales force were hired and our distributors were selected based on experience selling to research customers and not necessarily to clinical laboratories. If we are unable to market and sell our products effectively to clinical laboratories, our ability to sell diagnostic products, including Prosigna, will be adversely affected.

Our future sales of Prosigna will depend in large part on our ability to successfully maintain an effective oncology sales and marketing organization. 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. In February 2015, we combined our two separate sales teams into a single organization selling our entire suite of products, targeted primarily toward major academic medical centers and biopharmaceutical companies. If we are not able to maintain an efficient and effective sales organization targeting these markets, our business and operating results will be adversely affected.

***We may not be able to develop new products, enhance the capabilities of our systems to keep pace with rapidly changing technology and customer requirements or successfully manage the transition to new product offerings, any of 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, gene fusions and copy number variation, as well as potential markets for our research and diagnostic product candidates, are characterized by rapid technological change and innovation. 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. 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

## Table of Contents

on a timely and cost-effective basis. If we do not successfully innovate and introduce new technology into our product lines, our business and operating results will be adversely impacted.

The development of new products typically requires new scientific discoveries or advancements and complex technology and engineering. Such developments may involve external suppliers and service providers, making the management of development projects complex and subject to risks and uncertainties regarding timing, timely delivery of required components or services and satisfactory technical performance of such components or assembled products. For example, we are developing a new version of our nCounter Analysis System that is expected to be smaller and less expensive than the current version. If we do not achieve the required technical specifications, successfully manage new product development processes, or development work is not performed according to schedule, then such new technologies or products may be adversely impacted and our business and operating results may be harmed.

Additionally, we must carefully manage the introduction of new products. For example, we have begun testing manufacturing prototypes of the new version of our nCounter Analysis System and are targeting commercial launch of the new system mid-year 2015. If customers believe that such products, including the new version of our nCounter system, 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 effectively manage the transitions to new product offerings, our revenues, results of operations and business will be adversely affected.

***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 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 this product 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. In 2015, we plan to commercially launch two major products, a new version of our nCounter Analysis system and a new application that enables customers to measure protein expression using our technology. If the markets for our new products do not develop as we expect, our business may be adversely affected. 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.

***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. In addition, 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.***

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 market Prosigna for diagnostic purposes in any other markets, other than Israel, Canada, Turkey, South Africa, New Zealand, Hong Kong and Australia or to promote Prosigna in the United States for additional indications. Other than with respect to Prosigna in such jurisdictions, and our nCounter Elements reagents, we are limited to marketing our products for research use

only, which means that we cannot make any diagnostic or clinical



## **Table of Contents**

claims. We intend to seek regulatory authorizations to market Prosigna in other jurisdictions, as well as for other indications. We cannot assure investors that we will be successful in obtaining these regulatory clearances or approvals. If we do not obtain additional regulatory clearances or approvals to market future products or future indications for diagnostic purposes, if additional 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.

***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. Our new version of the nCounter system will also be manufactured by a sole supplier. 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, Washington 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 new processes can be very time consuming, and any unexpected difficulty in doing so could delay the introduction of a product.

***If our Seattle facility becomes unavailable or inoperable, we will be unable to continue our research and development, manufacturing our consumables or processing 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 research and development, 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 products 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

**Table of Contents**

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 years ended December 31, 2014 and 2013, approximately 32% and 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, as it did in 2014, 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.

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

As of December 31, 2014, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of approximately \$136.6 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

**Table of Contents**

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 term loan agreement 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;

engage in any new line of business; and

engage in certain transactions with our affiliates.

These restrictions could inhibit our ability to pursue our business strategies. In addition, we are subject to financial covenants based on total revenue and minimum cash balances. If we default under our term loan agreement, and such event of default is not cured or waived, the lenders could terminate commitments to lend and cause all amounts outstanding with respect to the debt to be due and payable immediately, which in turn could result in cross defaults under other debt instruments. Our assets and cash flow may not be sufficient to fully repay borrowings under all of our outstanding debt instruments if some or all of these instruments are accelerated upon a default. We may incur additional indebtedness in the future. The debt instruments governing such indebtedness could contain provisions that are as, or more, restrictive than our existing debt instruments. If we are unable to repay, refinance or restructure our indebtedness when payment is due, the lenders could proceed against the collateral granted to them to secure such indebtedness or force us into bankruptcy or liquidation.

***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, together with funds available under our term loan agreement, 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;

**Table of Contents**

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.

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 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;

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. Additionally, the commercial launch of Prosigna required us to establish an oncology-focused



## **Table of Contents**

commercial organization to fully optimize the breast cancer diagnostic market opportunity. In February 2015, we combined our two separate sales teams into a single organization selling our entire suite of products, targeted primarily toward major academic medical centers and biopharmaceutical companies. 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' businesses 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 adversely impact our business and operating results.

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

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

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

## **Risks Related to Government Regulation and Diagnostic Product Reimbursement**

***Our research use only products for the 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 and government 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



---

**Table of Contents**

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. In November 2014, FDA issued a guidance that described FDA's approach to regulating molecular diagnostic instruments that combine both approved/cleared device functions and device functions for which approval/clearance is not required. There is a risk that the FDA could take enforcement action against a manufacturer for distributing dual-use instruments if the company does not follow the restrictions discussed in the guidance. For example, there could be enforcement action if 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.

***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, in June 2014, the Blue Cross and Blue Shield, or BCBS, Association Technology Evaluation Center affirmed their position that Prosigna should be considered investigational. Subsequently, several BCBS entities updated their coverage policies based on this evaluation. In February 2015, Cigna decided that it would not reimburse for Prosigna. Also, in August 2014, UnitedHealthcare, the largest private health insurer in the United States, agreed with Laboratory Corporation of America, one of our commercial laboratory customers, to begin paying for Prosigna testing. In addition, we recently received confirmations of coverage for Prosigna from California's Medicaid group, MediCal, and from Providence Health Plan.

We continue to be in dialogue with representatives of the Molecular Diagnostic Services Program, or MolDX, regarding our application for Medicare reimbursement of Prosigna. In June 2014, MolDX requested that we modify our application to address new guidelines addressing MolDX's clinical test evaluation process and to respond to questions raised by MolDX in its initial review of our application. We recently provided additional information to MolDX to address this request. Based on our most recent interactions with MolDX, we believe that MolDX's coverage determination and what, if any, additional clinical data or other information we will be asked to provide in connection with our application will be strongly influenced by the update to the National Comprehensive Cancer Network's, or NCCN, treatment guidelines. In mid-February, the NCCN issued a partial revision to the guidelines in which it updated the treatment algorithm section of the guidelines. Prosigna was not included in this partial update. We expect the full guidelines update, including the discussion section of the guidelines, to be published in March of this year. We do not expect MolDX to make a coverage determination until after the NCCN guideline update.



---

**Table of Contents**

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

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

We continue to pursue positive reimbursement coverage decisions from government insurance plans, managed care organizations and private insurance plans. From time to time, if positive reimbursement coverage decisions are obtained, we intend to publicly announce such decisions. In circumstances where coverage is denied or no decision has been rendered, we intend to evaluate the benefit of continued pursuit of a positive reimbursement determination on a case by case basis and in most cases expect to continue to pursue a positive coverage decision with those payors; as a result, we do not intend to publicly announce any denials of coverage or the absence of a coverage determination on a regular basis.

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

In February 2014, we launched nCounter Elements reagents, 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 reagents may be used in conjunction with appropriate analyte specific reagents and other general purpose reagents to create diagnostic test procedures or test systems.

A clinical laboratory can use nCounter Elements reagents to create what is called a Laboratory Developed Test, or LDT. LDTs, according to the FDA, are diagnostic tests that are developed, validated, manufactured and performed by a single laboratory and include genetic tests. Historically LDTs have not been subject to FDA regulation. In October 2014, the FDA issued its draft guidance for LDTs proposing the use of a risk-based approach to regulating LDTs. Any restrictions on LDTs by the FDA could restrict the demand for our products, including nCounter Elements reagents. Additionally, compliance with additional regulatory burdens could be time consuming and costly for our customers. If the FDA issues final guidance for LDTs or limits the acceptability of the raw materials and components used to make LDTs, such regulation could adversely affect our prospects, results of operations and financial condition.

---

**Table of Contents**

***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. We intend to pursue additional intended uses for Prosigna, which may require a PMA approval which is a more burdensome regulatory processes than the 510(k) clearance process. In addition, we are currently collaborating with Celgene on a companion diagnostic. In August 2014, the FDA issued a companion diagnostics final guidance stating that if the device is essential to the safety or efficacy of the drug, the FDA generally will require approval or clearance for the device at the time when the FDA approves the drug. 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, 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 or clearance, and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. Approval or clearance by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval or clearance 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 or clearances could impair our ability to commercialize our diagnostic products outside of the United States.

***We expect to rely on third parties in conducting 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, clinical investigators, consultants, and collaborators 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.

**Table of Contents**

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

Certain of our products are regulated as medical devices, including Prosigna, the nCounter Dx Analysis System and nCounter Elements reagents. Accordingly, we are subject to ongoing International Organization for Standardization, or 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, 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. Other agencies may also issue guidelines and regulations that could impact the development of our products, including companion diagnostic tests. For example, the European Medicines Agency, a European Union agency which is responsible for the scientific evaluation of medicines used in the EU, recently launched an initiative to determine guidelines for the use of genomic biomarkers in the development and life-cycle of drugs. We may also be subject to additional FDA post-marketing obligations or requirements by the FDA to change our current product classifications which would impose additional regulatory obligations on us. 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. If we are not able to maintain regulatory compliance, we may not be permitted to market our medical device 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.

***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.***

Our operations are 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 state and federal marketing expenditure disclosure 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.

---

**Table of Contents**

***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 ACA, enacted in March 2010, made changes that significantly impact the pharmaceutical and medical device industries and clinical laboratories. For example, 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 tax applies to our listed medical device products, which include the nCounter Dx Analysis System, Prosigna *in vitro* diagnostic kits and nCounter Elements reagents. The ACA 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 ACA 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 ACA 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 ACA 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.

In addition to the ACA, 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 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, 2014, we owned or exclusively licensed nine issued U.S. patents and approximately 27 pending U.S. patent applications, including provisional and non-provisional filings. We also owned or licensed approximately 136 pending and granted counterpart applications worldwide, including 56 country-specific

## **Table of Contents**

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

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

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

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

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

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

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

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

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

It is possible that 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.

## **Table of Contents**

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

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

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

We rely on licenses in order to be able to use various proprietary technologies that are material to our business, including our core digital molecular barcoding technology licensed from the Institute for Systems Biology, technology relating to Prosigna licensed from Bioclassifier, LLC and the intellectual property relating to a gene signature for lymphoma subtyping from the National Institutes of Health for use in our collaboration with Celgene Corporation. 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



## Table of Contents

our attorneys, and we did not have control over the drafting and prosecution. The former patent owners and our licensors might not have given the same attention to the drafting and prosecution of these patents and applications as we would have if we had been the owners of the patents and applications and had control over the drafting and prosecution. We cannot be certain that drafting or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

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

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

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

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

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

As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to



extract substantial license and royalty payments from us. Our competitors and others may now and in the future have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product revenue and against whom our own patents may provide little or no deterrence or protection. Therefore,

---

**Table of Contents**

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

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

Many of our employees were previously employed at universities or other life sciences companies, including our competitors or potential competitors. Although no claims against us are currently pending, we or our employees 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.



## **Table of Contents**

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

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

Although we monitor our use of open source software to avoid subjecting our products to conditions we do not intend, the terms of many open source licenses have not been interpreted by U.S. courts, and there is a risk that these licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to commercialize our products. Moreover, we cannot assure investors that our processes for controlling our use of open source software in our products will be effective. If we are held to have breached the terms of an open source software license, we could be required to seek licenses from third parties to continue offering our products on terms that are not economically feasible, to re-engineer our products, to discontinue the sale of our products if re-engineering could not be accomplished on a timely basis, or to make generally available, in source code form, our proprietary code, any of which could adversely affect our business, operating results, and financial condition.

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

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

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

## **Risks Related to 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. 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 stockholders to lose all or part of their investment in our common stock. 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;

-45-

**Table of Contents**

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;

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.

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

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.

**Table of Contents**

Holders of approximately 6.8 million shares (including shares underlying outstanding warrants), or approximately 37%, 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 also register 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 officers and directors, and their respective affiliates, own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.***

Our executive officers and directors together with their respective affiliates, own approximately 31% of our outstanding common stock as of December 31, 2014. Accordingly, our executive officers and directors together with their respective affiliates, will be able to exert significant influence over matters submitted to our stockholders for approval, as well as our management and affairs. 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.

***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);

## **Table of Contents**

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 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 have chosen 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. If some investors find our common stock less attractive as a result of these exemptions, there may be a less active trading market for our common stock and our stock price may be lower and 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 increases 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 incur and will continue to 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 must 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

## **Table of Contents**

Reform and Consumer Protection Act of 2010 may impose on public companies. These requirements have increased and will likely 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, as a public company, it is 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 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 are availing 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.

The SEC adopted its final rule implementing Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act concerning conflict minerals in August 2012. The rule requires us to submit forms and reports to the SEC annually to disclose our determinations and due diligence measures. On June 2, 2014, we filed Form SD for the year ended December 31, 2013 and included a Conflict Minerals Report as an exhibit to this form. We do not directly purchase any conflict minerals. However, tracing these materials back to their country of origin is a complex task that required us to, among other things, survey suppliers in our supply chain to understand what programs they have in place for tracing the source of minerals supplied to us or used in products supplied to us and to ensure that reasonable due diligence has been performed. However, we have not determined how many, or if any, of our supply chain partners use conflict minerals. Moreover, we may face a limited pool of suppliers who can provide us conflict-free components, parts and manufactured products, and we may not be able to obtain conflict-free products or supplies in sufficient quantities or at competitive prices for our operations, and may be required to disclose that our products are not conflict free. This could adversely affect our reputation and may harm relationships with business partners and customers, and our stock price could suffer as a result.



**Table of Contents**

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

We recently entered into a lease agreement, pursuant to which we will lease office, laboratory and storage space in a new building being constructed adjacent to our headquarters in Seattle, Washington. The new lease agreement has a ten-year term and is estimated to commence in April 2016. At the same time, we entered into an amendment to the existing lease on our headquarters, to be coterminous with the new lease. We have an option to extend the term of both leases for two additional periods of five years. The initial base rent on the new lease will be approximately \$88,000 per month, subject to rent abatement during the first three months of the lease, and will increase at a rate of 3% annually. Beginning January 2015, the base rent on the amended lease will be approximately \$150,000 per month, and will increase at a rate of 3% annually.

In December 2014, we entered into an amendment effective as of November 2014 to an existing lease, pursuant to which we will lease additional office space in a building nearby our headquarters. The amendment increases the size of the leased premises from approximately 8,800 square feet to 23,000 square feet effective February 2015 and extends the term of the lease through January 2025. We will also have an option to extend the term of the lease for one additional three year period at the then-current fair market rent for comparable space. The base rent will be approximately \$38,000 per month beginning in February 2015, and \$63,000 per month beginning in February 2016; thereafter, the rent will increase at a rate of approximately 2% annually.

Our landlords hold letters of credit or security deposits equal to a total of approximately \$359,000. 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.

**Item 4. Mine Safety Disclosures**

Not applicable.

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

<b>Year ended December 31, 2013</b>	<b>High</b>	<b>Low</b>
Second quarter (beginning June 26, 2013)	\$ 9.90	\$ 7.81
Third quarter	\$ 14.10	\$ 7.01
Fourth quarter	\$ 18.09	\$ 8.64
<b>Year ended December 31, 2014</b>		
First quarter	\$ 22.44	\$ 16.28
Second quarter	\$ 21.87	\$ 12.03
Third quarter	\$ 15.45	\$ 10.81
Fourth quarter	\$ 15.28	\$ 7.80
<b>Year ending December 31, 2015</b>		
First quarter (through March 10, 2015)	\$ 14.74	\$ 9.95

On March 10, 2015, the last reported sale price of our common stock was \$11.54 per share.

**Holder**s

As of February 28, 2015, there were approximately 60 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 term loan agreement 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.

**Table of Contents**

**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.

**Recent Sales of Unregistered Securities**

In April 2014, we issued 11,176 shares of our common stock upon the cashless exercise of warrants at a price per share of \$8.45. In July 2014, we issued 16,093 shares of our common stock upon the exercise of warrants at a price per share of \$8.45 and received gross proceeds of \$135,954. These issuances were exempt from registration under the Securities Act of 1933, as amended, under Section 4(a)(2) thereof as a transaction by an issuer not involving a public offering. The recipients acquired the securities for investment only and not with a view to or for sale in connection with any distribution of the securities and appropriate legends were affixed thereto.



**Table of Contents****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, 2014, 2013 and 2012 and Consolidated Balance Sheet data as of December 31, 2014 and 2013 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, 2011 and 2010 and Consolidated Balance Sheet data as of December 31, 2012, 2011 and 2010 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.

	<b>Year Ended December 31,</b>				
	<b>2014</b>	<b>2013</b>	<b>2012</b>	<b>2011</b>	<b>2010</b>
	<b>(In thousands, except per share amounts)</b>				
<b>Consolidated Statements of Operations:</b>					
<b>Revenue</b>	\$ 47,593	\$ 31,403	\$ 22,973	\$ 17,800	\$ 11,730
<b>Costs and expenses:</b>					
Cost of revenue	21,149	15,009	12,361	9,777	9,128
Research and development	21,404	14,979	11,635	8,990	7,547
Selling, general and administrative	51,063	29,912	15,486	9,529	8,027
<b>Total costs and expenses</b>	<b>93,616</b>	<b>59,900</b>	<b>39,482</b>	<b>28,296</b>	<b>24,702</b>
Loss from operations	(46,023)	(28,497)	(16,509)	(10,496)	(12,972)
<b>Other income (expense):</b>					
Interest income	272	68	21	10	29
Interest expense	(4,140)	(1,942)	(804)	(599)	(94)
Other income (expense)	(147)	(66)	(29)	80	254
Revaluation of preferred stock warrant liability		1,156	(387)	73	15
<b>Total other income (expense)</b>	<b>(4,015)</b>	<b>(784)</b>	<b>(1,199)</b>	<b>(436)</b>	<b>204</b>
<b>Net loss</b>	<b>\$ (50,038)</b>	<b>\$ (29,281)</b>	<b>\$ (17,708)</b>	<b>\$ (10,932)</b>	<b>\$ (12,768)</b>
Accretion of mandatorily redeemable convertible preferred stock		(4,653)	(7,533)	(5,251)	(4,351)
<b>Net loss attributable to common stockholders</b>	<b>\$ (50,038)</b>	<b>\$ (33,934)</b>	<b>\$ (25,241)</b>	<b>\$ (16,183)</b>	<b>\$ (17,119)</b>
<b>Net loss per share – basic and diluted</b>	<b>\$ (2.80)</b>	<b>\$ (4.44)</b>	<b>\$ (71.10)</b>	<b>\$ (50.10)</b>	<b>\$ (54.17)</b>
<b>Weighted-average shares used in computing basic and diluted net loss per share</b>	<b>17,839</b>	<b>7,643</b>	<b>355</b>	<b>323</b>	<b>316</b>

	<b>As of December 31,</b>				
	<b>2014</b>	<b>2013</b>	<b>2012</b>	<b>2011</b>	<b>2010</b>
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments	\$ 72,225	\$ 42,656	\$ 21,692	\$ 10,868	\$ 4,366
Working capital	76,539	42,106	19,937	12,236	2,944
Total assets	102,748	64,372	37,406	24,584	13,275
Total long-term debt (includes current portion)	30,926	18,293	12,759	1,887	1,829
Mandatorily redeemable convertible preferred stock			103,622	80,957	57,887
Total stockholders equity (deficit)	44,813	31,469	(93,760)	(69,451)	(53,517)

-53-

---

**Table of Contents****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 diseases, such as cancer, and to clinical laboratories and medical centers for diagnostic use. As of December 31, 2014, we have an installed base of 264 systems, which our customers have used to publish more than 600 peer-reviewed papers. As researchers using our systems 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 reagents or, in certain situations, by developing *in vitro* diagnostic assays. For example, our first molecular diagnostic product is the Prosigna Breast Cancer Assay, or Prosigna, which provides an assessment of a patient's risk of recurrence for breast cancer. More recently, we entered into our first companion diagnostic collaboration to develop an *in vitro* diagnostic test for a type of lymphoma, to be used to identify which patients are most likely to respond to a particular drug therapy.

We derive a substantial majority of our revenue from the sale of our products to life science researchers, which consist of our nCounter instruments and related proprietary consumables, which we call CodeSets, nCounter Elements reagents and Master Kits. 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. 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.

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 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 research consumables. The nCounter Elements reagents 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.

In December 2013, we commercially launched Prosigna in the United States. National diagnostic laboratories, including Laboratory Corporation of America Holdings and Quest Diagnostics, as well as laboratories at numerous cancer centers and major hospitals have chosen to add Prosigna to their suites of breast cancer diagnostic tests. 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,

## **Table of Contents**

our first diagnostic product, and, in early 2013 we commercially launched Prosigna in Europe and Israel. To support the commercial launch of Prosigna, we added a team of experienced oncology sales, marketing, market access and medical affairs professionals, resulting in increased operating expenses. In February 2015, we combined our two separate sales teams into a single organization selling our entire suite of products, targeted primarily toward major academic medical centers and biopharmaceutical companies. We expect Prosigna sales growth to be dependent on the installation of more systems, inclusion of Prosigna in important breast cancer treatment guidelines and reimbursement by third-party payors becoming 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 technologies, products and solutions. We invested \$21.4 million, \$15.0 million and \$11.6 million in 2014, 2013 and 2012, respectively, in research and development and intend to continue to make significant investments in research and development.

In March 2014, we entered into a collaboration agreement with Celgene Corporation pursuant to which we are working collaboratively with Celgene to develop, seek regulatory approval for, and commercialize a companion diagnostic assay for use in screening patients with Diffuse Large B-Cell Lymphoma. We received an upfront payment of \$5.8 million in June 2014 upon our delivery of certain information to Celgene. We also achieved and were paid for certain development-related milestones totaling \$6.0 million during 2014 and recognized the related revenue according to the proportional performance model. We are eligible to receive up to \$11.0 million in additional success-based payments related to regulatory milestones. We will retain all commercial rights to the diagnostic test developed under this collaboration and, assuming success in the clinical trial process, and subject to regulatory approval, expect to generate revenues from the sale of the resulting *in vitro* diagnostic kits.

Our total revenue increased to \$47.6 million in 2014 from \$31.4 million in 2013 and \$23.0 million in 2012, which was driven primarily 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, recently, sales revenue has been growing more rapidly outside North America and we believe this trend may continue. We have never been profitable and had net losses of \$50.0 million, \$29.3 million, and \$17.7 million in 2014, 2013 and 2012, respectively. As of December 31, 2014, our accumulated deficit was \$176.9 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 diagnostic testing on the same instrument. We have one sales force that now sells these systems to both research and clinical testing labs, and we launched our first product that can be used for both research and diagnostic testing, nCounter Elements reagents. 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.

## **Table of Contents**

### ***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**.

#### ***Product Revenue***

Our products consist of our nCounter Analysis System and related consumables, including Prosigna *in vitro* diagnostic kits. 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 FLEX is \$265,000. 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) custom CodeSets, which we manufacture to the specific requirements of an individual researcher, (2) panels, which are standard pre-manufactured CodeSets, (3) nCounter Elements reagents, 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. Since 2010, our average consumables revenue per installed system has exceeded \$100,000 per year.

For our clinical laboratory customers, related consumables include Prosigna *in vitro* diagnostic kits and nCounter Elements reagents. 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, the majority of our clinical laboratory customers have elected to purchase instruments.

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, the average selling price per Prosigna test is expected to be lower than list price.

#### ***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.

#### ***Collaboration Revenue***

Collaboration revenue is primarily derived from our companion diagnostic development collaboration with Celgene. As of December 31, 2014, we had received a total of \$11.8 million from Celgene, of which \$2.9 million had been recorded as collaboration revenue, with the remainder recorded as deferred revenue, which will be



**Table of Contents**

recognized as collaboration revenue over our remaining development performance period. Collaboration revenue also includes revenue recognized under a smaller evaluation study being performed for a different biopharmaceutical company.

*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.

The following table reflects total revenue by geography based on the geographic location of our customers, distributors and collaborators. Americas consists of the United States, Canada, Mexico and South America; and Asia Pacific includes Japan, China, South Korea, Singapore, Malaysia, Australia and New Zealand.

	Year Ended December 31,					
	2014	2013		2012		
	(Dollars in thousands)					
Americas	\$ 32,244	68%	\$ 21,855	70%	\$ 15,906	69%
Europe & Middle East	9,174	19	5,775	18	4,167	18
Asia Pacific	6,175	13	3,773	12	2,900	13
Total	\$ 47,593	100%	\$ 31,403	100%	\$ 22,973	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 Product and Service Revenue*

Cost of product and service 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 product and service 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 reagents.

***Operating Expenses***

***Research and Development***

Research and development expenses consist primarily of salaries and benefits, occupancy, laboratory supplies, engineering services, consulting fees, costs associated with licensing molecular diagnostics rights and

**Table of Contents**

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 other than collaborations. Research and development expense by functional area was as follows:

	<b>Year Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
	<b>(In thousands)</b>		
Core nCounter platform technology	\$ 6,975	\$ 4,330	\$ 1,537
Manufacturing process development	2,124	1,588	1,183
Life sciences research products and applications	3,834	2,914	2,183
Diagnostic product development	3,292	1,617	3,343
Clinical, regulatory and medical affairs	3,740	2,988	1,440
Facility allocation	1,439	1,542	1,949
<b>Total</b>	<b>\$ 21,404</b>	<b>\$ 14,979</b>	<b>\$ 11,635</b>

Our Prosigna clinical studies generally 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, potentially, for future diagnostic products.

We expect to license additional rights to technology and potential molecular diagnostics as part of our strategy to capitalize on the discoveries of our customers. For example, in January 2014 we secured an option from a research customer to acquire an exclusive worldwide license for technology used for protein analysis on our nCounter Analysis System. The related option fee was expensed in the first quarter of 2014. Similarly, in May 2014 we licensed rights to the gene signature being developed to subtype DLBCL patients that is the subject of our collaboration with Celgene. The related license fee was expensed in the second quarter of 2014. Such arrangements may include upfront, milestone or annual cash payments and revenue-based royalties.

*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, during 2014, we established a dedicated oncology focused team to support the commercialization of Prosigna, which has contributed to a 90% increase in selling and marketing expenses over 2013. In February 2015, we combined our two separate sales teams into a single organization selling our entire suite of products, targeted primarily toward major academic medical centers and biopharmaceutical companies. Legal, accounting and compliance costs have also increased as a result of our being a public company, and we expect them to continue to increase as our business grows.

## **Table of Contents**

### **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 substantially in 2014 in an effort to increase the rate of sales of our nCounter Analysis Systems. Similarly, as of December 2014, we have contracted with a total of 18 distributors. 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.

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 a new generation of the nCounter Analysis System which 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 and which we expect to offer at a more affordable price. 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 mid-year 2015.

As of December 31, 2014 we had an installed base of 264 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, a large majority of our systems and related consumables have been sold to research customers. Since 2010, our average consumables revenue per system has 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 continue to 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 as we install more diagnostic systems, Prosigna is included in important breast cancer treatment guidelines and reimbursement by third-party payors becomes more broadly available. Furthermore, we intend to launch entirely new applications, such as multi-omics, which will enable researchers to measure gene expression

**Table of Contents**

and protein expression in a single experiment. The introduction of new applications has the potential to further increase our consumables revenue stream. 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 tend to increase our gross margins. In addition, we expect both the average selling price and the manufacturing cost of our instruments to decrease following the introduction of future generations of our nCounter Analysis System. Future instrument selling prices and gross margins may fluctuate as we introduce new products and reduce our product costs and from variability in the timing of new product introductions.

We derive service revenue from extended service contracts, which are purchased by a majority of our customers. Additionally, we selectively provide proof-of-principle studies in connection with prospective sales to customers to demonstrate the performance of our nCounter Analysis System. Collaboration revenue is a new source of revenue primarily from our companion diagnostic development collaboration with Celgene, which may increase over time if we are successful in entering into other similar collaborations.

The following table reflects the breakdown of revenue in absolute dollars and as percentage of total revenue.

	Year Ended December 31,					
	2014	2013		2012		
	(Dollars in thousands)					
Product revenue:						
Instruments	\$ 18,078	38%	\$ 12,995	41%	\$ 8,786	38%
Consumables	23,819	50	16,642	53	13,036	57
<i>In vitro</i> diagnostic kits	668	1	181	1		
Total product revenue	42,565	89	29,818	95	21,822	95
Service revenue	1,932	4	1,585	5	1,151	5
Total product and service revenue	44,497	93	31,403	100	22,973	100
Collaboration revenue	3,096	7				
Total revenue	\$ 47,593	100%	\$ 31,403	100%	\$ 22,973	100%

**Diagnostic Product Development**

During 2013, we 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 reagents or, in certain situations, developed as *in vitro* diagnostic assays. Our first example of this is Prosigna, for which we in-licensed the rights to intellectual property

from Bioclassifier, LLC, a company founded by several of our research customers. More recently, we in-licensed the rights to the gene signature being developed as an *in vitro* diagnostic assay to subtype DLBCL patients that is the subject of our collaboration with Celgene. We intend to enter into similar arrangements with our research customers and other researchers for future diagnostic gene signatures, which may be developed independently as an *in vitro* diagnostic, or become the subject of future companion diagnostic collaborations. For



**Table of Contents**

independent development, our strategy is to target 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.

We believe that there is significant potential to enter into more companion diagnostic collaborations of a similar nature to our collaboration with Celgene. Such collaborations are attractive in that they provide near-term funding of development costs, potential milestone revenues and potential additions to the menu of tests that we can market and sell for use on the nCounter Dx Analysis System. We believe we are well positioned as a desirable development partner to drug developers due to a number of factors, including unique technological capabilities in multiplexed gene expression analysis; prior FDA clearance of our instrument system for use with Prosigna; an expanding installed base of systems in clinical laboratories; and established clinical and regulatory capabilities.

**Results of Operations****Comparison of Years Ended December 31, 2014 and 2013***Revenue*

	Year Ended December 31,		Change 2014 v. 2013	
	2014	2013	Dollars	Percentage
	(Dollars in thousands)			
Product revenue:				
Instruments	\$ 18,078	\$ 12,995	\$ 5,083	39%
Consumables	23,819	16,642	7,177	43
<i>In vitro</i> diagnostic kits	668	181	487	269
Total product revenue	42,565	29,818	12,747	43
Service revenue	1,932	1,585	347	22
Total product and service revenue	44,497	31,403	13,094	42
Collaboration revenue	3,096		3,096	
Total revenue	\$ 47,593	\$ 31,403	\$ 16,190	52

Instruments, consumables and service revenue increased significantly for the year ended December 31, 2014 due to the increased volume of instruments sold. The total growth in the annual installed base in 2014 was 43%. Distributor sales represented 32% and 19% of systems installed in 2014 and 2013, respectively. The average 2014 sales price for direct sales was approximately 6% greater than the average sales price to distributors in the same period. The increase in consumables revenue was primarily driven by growth in our installed base of instruments as the annualized pull-through remained over \$100,000 per installed system in 2014 and 2013. The increase in service revenue was primarily related to an increase in the number of instruments covered by service contracts.

*Cost of Product and Service Revenue; Gross Profit; and Gross Margin*

	Year Ended December 31,		Change 2014 v. 2013	
	2014	2013	Dollars	Percentage
			(Dollars in thousands)	
Cost of product and service revenue	\$ 21,149	\$ 15,009	\$ 6,140	41%
Product and service gross profit	\$ 23,348	\$ 16,394	\$ 6,954	42
Product and service gross margin	52%	52%		

The increase in cost of product and service revenue for 2014 was related to the increased volume of instruments, consumables, *in vitro* diagnostic kits and services sold. Product and service gross margin was

**Table of Contents**

approximately the same for both periods. Although gross margin for instrument revenues in 2014 improved slightly by 1.7 percentage points over 2013, this was largely offset by a 1.0 percentage point reduction in gross margin for consumables, *in vitro* diagnostic kits and service.

*Research and Development Expense*

	Year Ended December 31,		Change 2014 v. 2013	
	2014	2013	Dollars	Percentage
	(Dollars in thousands)			
Research and development expense	\$ 21,404	\$ 14,979	\$ 6,425	43%

The increases in research and development expense in 2014 reflected a \$4.1 million increase in personnel-related expenses primarily to support the advancement of our nCounter technology. In addition, there was a \$1.5 million increase in engineering costs for development of the next generation of our nCounter system and an increase in costs to support the Celgene collaboration agreement. Partially offsetting the increase was a reduction of \$0.4 million in clinical study costs. The remaining \$1.2 million change was due to various other operating expense fluctuations that were individually immaterial.

*Selling, General and Administrative Expense*

	Year Ended December 31,		Change 2014 v. 2013	
	2014	2013	Dollars	Percentage
	(Dollars in thousands)			
Selling, general and administrative expense	\$ 51,063	\$ 29,912	\$ 21,151	71%

The increases in selling, general and administration expense in 2014 were primarily attributable to a \$17.3 million increase in staffing and personnel-related costs to support sales and marketing and administration; and increased external marketing and other consulting costs of \$3.2 million. Partially offsetting the increase was a reduction of \$1.8 million in external legal costs. The remaining \$3.0 million change was due to various other operating expense fluctuations that were individually immaterial.

*Other Income (Expense)*

	Year Ended December 31,		Change 2014 v. 2013	
	2014	2013	Dollars	Percentage
	(Dollars in thousands)			
Interest income	\$ 272	\$ 68	\$ 204	300%
Interest expense	(4,140)	(1,942)	(2,198)	113
Other expense	(147)	(66)	(81)	123
Revaluation of preferred stock warrant liability		1,156	(1,156)	(100)
Total other income (expense)	\$ (4,015)	\$ (784)	\$ (3,231)	412

The increase in interest expense in 2014 was related to the costs incurred to pay off our former credit facility in April 2014 and an overall increase in borrowing. In 2014, we incurred and recorded \$1.4 million of interest expense related to the repayment of our former credit facility, including a loss on extinguishment of debt of \$0.6 million. Long-term debt outstanding increased to \$30.9 million as of December 31, 2014 as compared to \$18.3 million as of December 31, 2013. The average net debt balance was \$22.5 million in 2014 compared to \$16.7 million in 2013.

The revaluation of the preferred stock warrant liability in 2013 resulted from a re-measurement of the fair value of preferred stock warrants using the Black-Scholes option pricing model, which was primarily impacted

**Table of Contents**

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, 2013 and 2012***Revenue*

	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
<i>In vitro</i> diagnostic kits	181		181	
Total product revenue	29,818	21,822	7,996	37
Service revenue	1,585	1,151	434	38
Total product and service revenue	\$ 31,403	\$ 22,973	\$ 8,430	37

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.

*Cost of Product and Service Revenue; Gross Profit; and Gross Margin*

	Year Ended December 31,		Change 2013 v. 2012	
	2013	2012	Dollars	Percentage
	(Dollars in thousands)			
Cost of product and service revenue	15,009	12,361	2,648	21%
Product and service gross profit	\$ 16,394	\$ 10,612	\$ 5,782	54
Product and service gross margin	52%	46%		

The increase in cost of revenue in 2013 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.

**Table of Contents***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%

The increase in 2013 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 in 2013 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.

**Liquidity and Capital Resources**

As of December 31, 2014, we had cash, cash equivalents and short-term investments of \$72.2 million, compared to \$42.7 million as of December 31, 2013. We believe our existing cash, cash equivalents and short-term investments will be sufficient to meet our working capital and capital expenditure 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; the nature and timing of any

additional companion diagnostic development collaborations we may establish; and the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

If we require additional funds in the future, we may not be able to obtain such funds on acceptable terms, or at all. 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



---

**Table of Contents**

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.

***Sources of Funds***

Our cash used in operations for the year ended December 31, 2014 was \$38.1 million and we expect to continue to require cash to fund our operations for at least the next several years.

In January 2014, we completed an underwritten public offering of common stock for total gross proceeds of \$55.0 million. In February 2014, the underwriters partially exercised an overallotment option, purchasing additional shares from us for additional gross proceeds of \$6.4 million. After underwriters' fees and commissions and other expenses of the offering, our aggregate net proceeds were approximately \$57.0 million.

In April 2014, we entered into a term loan agreement under which we may borrow up to \$45.0 million, or up to an aggregate of approximately \$51.0 million if we elect to exercise in full an option to defer payment of a portion of the interest that would accrue on the borrowing under the term loan agreement. Upon initial closing, we borrowed \$20.0 million, the proceeds of which were primarily used to repay the outstanding balance under our former credit facility plus a related \$1.0 million end of term payment, a \$0.3 million make-whole premium, and interest accrued. We incurred and recorded a total charge to interest expense of \$1.4 million related to the repayment of our former credit facility, including a loss on extinguishment of debt of \$0.6 million. In October 2014, we borrowed an additional \$10.0 million under the term loan agreement. Up to an additional \$15.0 million, in increments of \$5.0 million, may be borrowed under the agreement no later than May 2015, subject to a revenue requirement, which was met as of December 31, 2014. All borrowings under the new term loan agreement accrue interest at 12.5% annually, payable quarterly, of which 3.5% can be deferred during the first four years of the term at our option and paid together with the principal. We exercised our option to defer payment of the 3.5% accrued interest for the six months ended December 31, 2014. We are required to pay only interest for the first five years of the term. Principal payments are due in four equal installments during the sixth year of the term. We have the option to prepay the term loans, in whole or in part, at any time subject to payment of a redemption fee of up to 4%, which declines over the term. The term loan agreement contains 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; buy, sell or transfer assets; engage in any new line of business; and enter into certain transactions with affiliates. The new term loan agreement also includes a \$2.0 million minimum liquidity covenant and minimum annual revenue requirements, which shall initially be \$40.0 million for 2014 with annual increases of \$15.0 million for each subsequent fiscal year thereafter. If our actual revenues are below the minimum annual revenue requirement for any given year, we may avoid a related default by generating proceeds from an equity or subordinated debt issuance equal to the shortfall between our actual revenues and the minimum revenue requirement. We were in compliance with our covenants as of December 31, 2014. Our obligations under the new term loan agreement are collateralized by substantially all of our assets.

In July 2013, we raised \$54.0 million, before offering expenses, in our initial public offering. Net of offering expenses, our initial public offering generated approximately \$47.4 million. In April 2013, we incurred \$5.0 million of the remaining term loan borrowings under our previous credit facility.

*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

**Table of Contents**

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, developing and commercializing Prosigna, and supporting our companion diagnostic collaboration with Celgene. As a result, our cash used in operating activities has increased. Our operating cash requirements may 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, and continue to promote consumable usage, including Prosigna, (2) commercialize, and conduct studies to expand the clinical utility of Prosigna and develop new diagnostic tests, such as LST for DLBCL, and (3) develop new applications, chemistry and instruments for our nCounter platform, as we cannot be certain our revenues will grow sufficiently to offset our operating expense increases.

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:

	<b>Year Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
	<b>(In thousands)</b>		
Cash used in operating activities	\$ (38,061)	\$ (31,346)	\$ (14,808)
Cash used in investing activities	(24,275)	(32,955)	(428)
Cash provided by financing activities	69,566	52,550	26,060

***Operating Cash Flows***

We derive operating cash flows from cash collected from the sale of our products and services and, beginning in 2014, from collaborations. 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 and this will likely continue for the foreseeable future.

Net cash used in operating activities for 2014 consisted of our net loss of \$50.0 million partially offset by \$4.7 million of changes in our operating assets and liabilities, including \$8.8 million of deferred revenue from the Celgene collaboration, and \$7.3 million of net non-cash income and expense items, such as depreciation and amortization, amortization of debt discount, amortization of premium on short-term investments, loss on extinguishment of debt, accrued interest converted to principal balance of term loan and stock-based compensation.

Net cash used in operating activities for 2013 consisted of our net loss of \$29.3 million and \$3.8 million of changes in our operating assets and liabilities. 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.

**Table of Contents***Investing Cash Flows*

Our most significant investing activities for the years ended December 31, 2014 and 2013 were related to the purchase and sale of 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.

In the years ended December 31, 2014, 2013 and 2012, we purchased \$1.9 million, \$0.8 million, and \$0.4 million respectively, 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 2014 consisted of net proceeds of \$57.0 million from our public offering of common stock, proceeds of \$30.0 million from our new term loan agreement, Employee Stock Purchase Plan proceeds of \$1.0 million, \$0.4 million of proceeds from the exercise of stock options, and net proceeds of \$0.2 million from the exercise of common stock warrants. These proceeds were partially offset by the repayment of the outstanding balance under our former credit facility in the amount of \$18.2 million, payment of deferred costs related to our new term loan agreement in the amount of \$0.8 million, and repurchase of shares related to common stock warrant exercise of \$0.1 million.

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.

**Contractual Obligations**

The following table reflects a summary of our contractual obligations as of December 31, 2014.

Contractual Obligations(1)	Total	Payments due by period			More than 5 Years
		Less than 1 Year	1-3 Years	3-5 Years	
			(In thousands)		
Lease obligations(2)	\$ 43,959	\$ 2,784	\$ 7,023	\$ 7,814	\$ 26,338
Long-term debt obligations(3)	30,926	251	255	22,815	7,605
Inventory purchase obligations(4)	6,749	6,749			
Total	\$ 81,634	\$ 9,784	\$ 7,278	\$ 30,629	\$ 33,943

- (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) 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.

-67-

## **Table of Contents**

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

Revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the price to the customer is fixed or determinable; and (4) collectability is reasonably assured. The evaluation of these revenue recognition criteria requires significant management judgment. For instance, we use judgment to assess collectability based on factors such as the customer's creditworthiness and past collection history, if applicable. If we determine that collection of a payment is not reasonably assured, revenue recognition is deferred until receipt of payment. We also use judgment to assess whether a price is fixed or determinable including but not limited to, reviewing contractual terms and conditions related to payment terms.

Instruments, consumables and *in vitro* diagnostic kits are considered to be separate units of accounting as they are sold separately and revenue is recognized upon transfer of ownership, which is generally upon shipment. Instrument revenue related to installation and calibration services is recognized when services are rendered. For instruments sold

for use primarily to run Prosigna assays, training must be provided prior to instrument revenue recognition. Instrument revenue from leased instruments is recognized ratably over the lease term.

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



## **Table of Contents**

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

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

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

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

We enter into collaborative agreements that may generate upfront fees with subsequent milestone payments that may be earned upon the completion of development-related milestones. We are able to estimate the total cost of services to be provided under the arrangement and recognize collaboration revenue using a proportional performance model. Costs incurred to date compared to total expected costs are used to determine proportional performance, as this is considered to be representative of the delivery of outputs under the arrangements. Revenue recognized at any point in time is limited to cash received and amounts contractually due. Changes in estimates of total expected costs are accounted for prospectively as a change in estimate. From period to period, collaboration revenue can fluctuate substantially based on the achievement of development-related milestones.

### ***Stock-based Compensation***

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.

## **Table of Contents**

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.

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.

### ***Inventory Valuation***

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

### ***Fair Value Measurements***

We 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.

---

**Table of Contents*****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, 2014, we had federal net operating loss carryforwards, or NOLs, of approximately \$136.6 million and federal research and experimentation credit carryforwards of approximately \$2.3 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.

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**

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.

In May 2014, the Financial Accounting Standards Board ( FASB ) issued an accounting standards update entitled ASU 2014-09, Revenue from Contracts with Customers. The standard requires entities to recognize

## **Table of Contents**

revenue through the application of a five step model, which includes identification of the contract, identification of the performance obligations, determination of the transaction price, allocation of the transaction price to the performance obligations, and recognition of revenue as the entity satisfies the performance obligations. The standard will become effective for us beginning January 1, 2017. We are currently evaluating the guidance to determine the potential impact on our consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

In June 2014, FASB issued an accounting standards update entitled ASU 2014-12, Compensation – Stock Compensation. The standard requires entities that grant their employees share-based payments in which the terms of the award provide that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. The standard will become effective for us beginning January 1, 2016. We are currently evaluating the guidance to determine the potential impact on our consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

In August 2014, FASB issued an accounting standards update entitled ASU 2014-15, Presentation of Financial Statements – Going Concern. The standard requires entities to evaluate for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). The standard will become effective for us beginning January 1, 2017.

## **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. 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, asset-backed securities, and money market funds. Declines in interest rates, however, would reduce future investment income. A 10% decline in interest

rates, occurring on January 1, 2015 and sustained throughout the period ending December 31, 2015, would not be material.



**Table of Contents**

As of December 31, 2014, the principal and accrued interest outstanding under our term borrowings was \$30.9 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 continue to 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 directly in certain markets outside of the United States denominated in local currency, 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 potentially greater 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.

**Table of Contents**

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

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

**NANOSTRING TECHNOLOGIES, INC.**

	<b>Page(s)</b>
<b>Financial Statements:</b>	
<u>Report of Independent Registered Public Accounting Firm</u>	75
<u>Consolidated Balance Sheets</u>	76
<u>Consolidated Statements of Operations</u>	77
<u>Consolidated Statements of Comprehensive Loss</u>	78
<u>Consolidated Statements of Changes in Mandatorily Redeemable Convertible Preferred Stock and Stockholders' (Deficit) Equity</u>	79
<u>Consolidated Statements of Cash Flows</u>	80
<u>Notes to Consolidated Financial Statements</u>	81

**Table of Contents**

**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. (the Company) at December 31, 2014 and 2013, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014 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 13, 2015

**Table of Contents****NanoString Technologies, Inc.****Consolidated Balance Sheets**

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
	<b>(In thousands, except par value amounts)</b>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 17,223	\$ 9,941
Short-term investments	55,002	32,715
Accounts receivable, net	12,436	8,331
Inventory	5,444	6,750
Prepaid expenses and other	5,242	2,999
<b>Total current assets</b>	<b>95,347</b>	<b>60,736</b>
Restricted cash	143	201
Deferred offering costs		29
Property and equipment, net	6,366	3,065
Other assets	892	341
<b>Total assets</b>	<b>\$ 102,748</b>	<b>\$ 64,372</b>
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 3,380	\$ 3,354
Accrued liabilities	10,403	7,088
Deferred revenue, current portion	4,627	1,462
Deferred rent, current portion	147	590
Long-term debt, current portion	251	6,136
<b>Total current liabilities</b>	<b>18,808</b>	<b>18,630</b>
Deferred revenue, net of current portion	7,135	803
Deferred rent, net of current portion	1,317	1,313
Long-term debt, net of current portion	30,675	12,157
<b>Total liabilities</b>	<b>57,935</b>	<b>32,903</b>
Commitments and contingencies (Note 15)		
Stockholders equity		
Preferred stock, \$0.0001 par value, 15,000 shares authorized; none issued		
Common stock, \$0.0001 par value, 150,000 shares authorized; 18,272 and 14,620 shares issued and outstanding at December 31, 2014 and 2013, respectively	2	1
Additional paid-in-capital	221,724	158,278

Edgar Filing: NanoString Technologies Inc - Form 10-K

Other comprehensive income (loss)	(43)	22
Accumulated deficit	(176,870)	(126,832)
Total stockholders' equity	44,813	31,469
Total liabilities and stockholders' equity	\$ 102,748	\$ 64,372

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

**Table of Contents****NanoString Technologies, Inc.****Consolidated Statements of Operations**

	<b>Years Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
	<b>(In thousands, except per share amounts)</b>		
<b>Revenue:</b>			
Product and service	\$ 44,497	\$ 31,403	\$ 22,973
Collaboration	3,096		
<b>Total revenue</b>	<b>47,593</b>	<b>31,403</b>	<b>22,973</b>
<b>Costs and expenses:</b>			
Cost of product and service revenue	21,149	15,009	12,361
Research and development	21,404	14,979	11,635
Selling, general and administrative	51,063	29,912	15,486
<b>Total costs and expenses</b>	<b>93,616</b>	<b>59,900</b>	<b>39,482</b>
<b>Loss from operations</b>	<b>(46,023)</b>	<b>(28,497)</b>	<b>(16,509)</b>
<b>Other income (expense):</b>			
Interest income	272	68	21
Interest expense	(4,140)	(1,942)	(804)
Other expense	(147)	(66)	(29)
Revaluation of preferred stock warrant liability		1,156	(387)
<b>Total other income (expense)</b>	<b>(4,015)</b>	<b>(784)</b>	<b>(1,199)</b>
<b>Net loss</b>	<b>(50,038)</b>	<b>(29,281)</b>	<b>(17,708)</b>
Accretion of mandatorily redeemable convertible preferred stock		(4,653)	(7,533)
<b>Net loss attributable to common stockholders</b>	<b>\$ (50,038)</b>	<b>\$ (33,934)</b>	<b>\$ (25,241)</b>
<b>Net loss per share basic and diluted</b>	<b>\$ (2.80)</b>	<b>\$ (4.44)</b>	<b>\$ (71.10)</b>
<b>Weighted average shares used in computing basic and diluted net loss per share</b>	<b>17,839</b>	<b>7,643</b>	<b>355</b>

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



**Table of Contents****NanoString Technologies, Inc.****Consolidated Statements of Comprehensive Loss**

	<b>Years Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
	<b>(In thousands)</b>		
Net loss	\$ (50,038)	\$ (29,281)	\$ (17,708)
Other comprehensive loss:			
Unrealized gain (loss) on short-term investments	(65)	22	
Comprehensive loss	\$ (50,103)	\$ (29,259)	\$ (17,708)

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



Table of Contents

## NanoString Technologies, Inc.

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

Period From December 31, 2011 Through December 31, 2014

	Series B Preferred Stock		Series C Preferred Stock		Series D Preferred Stock		Series E Preferred Stock		Common Stock		Additional Paid-in Capital
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	
	(In thousands, except share amounts)										
33	515,836	\$ 12,793	3,551,060	\$ 35,614	2,430,054	\$ 18,167		\$	324,529	\$	\$
							1,063,951	15,132			
2		1,072		2,978		2,156		105		85,135	(9)
										1,562	1
											7
5	515,836	13,865	3,551,060	38,592	2,430,054	20,323	1,063,951	15,237	411,226		
33		577		1,604		1,140		649			(8)
8)	(515,836)	(14,442)	(3,551,060)	(40,196)	(2,430,054)	(21,463)	(1,063,951)	(15,886)	5,400,000	8,631,427	46,8
									1	108,2	

							2,5
						177,165	3
							1,1
						14,619,818	1 158,2
						3,318,917	1 56,9
						27,269	1
						141,386	9
						164,394	4
							4,9
\$	\$	\$	\$	\$		18,271,784	\$ 2 \$ 221,7

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

**Table of Contents****NanoString Technologies, Inc.****Consolidated Statements of Cash Flows**

	<b>Years Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
	<b>(In thousands)</b>		
<b>Operating activities:</b>			
Net loss	\$ (50,038)	\$ (29,281)	\$ (17,708)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	1,539	1,777	1,947
Amortization of debt discount	51	213	136
Stock-based compensation	4,926	1,145	745
Revaluation of preferred stock warrant liability		(1,156)	387
Loss on extinguishment of debt	581		
Amortization of premium on short-term investments	86	(518)	
Interest accrued on long-term debt	(348)	259	90
Conversion of accrued interest to long-term debt	420		
Loss on disposal of property and equipment		1	3
Gain on sale of investments	(5)		
Changes in operating assets and liabilities			
Accounts receivable, net	(4,109)	(5,009)	(210)
Inventory	(1,252)	(1,370)	(1,884)
Prepaid expenses and other	(2,132)	(1,679)	221
Other	(70)	(268)	118
Accounts payable	21	1,601	103
Accrued liabilities	3,379	2,678	1,830
Deferred revenue	9,497	1,025	146
Deferred rent	(607)	(764)	(732)
<b>Net cash used in operating activities</b>	<b>(38,061)</b>	<b>(31,346)</b>	<b>(14,808)</b>
<b>Investing activities:</b>			
Purchases of property and equipment	(1,900)	(759)	(428)
Proceeds from sale of short-term investments	4,500		
Proceeds from maturity of short-term investments	35,977		
Purchases of short-term investments	(62,911)	(32,175)	
Decrease (increase) in restricted cash	59	(21)	
<b>Net cash used in investing activities</b>	<b>(24,275)</b>	<b>(32,955)</b>	<b>(428)</b>
<b>Financing activities:</b>			
Proceeds from long-term debt	30,000	5,000	13,000
Deferred costs related to long-term debt	(770)		
Repayment of long-term debt	(18,214)	(211)	(1,706)
Proceeds from public offering	57,015	47,374	

Edgar Filing: NanoString Technologies Inc - Form 10-K

Proceeds from exercise of common stock warrants	230		
Proceeds from issuance of common stock for employee stock purchase plan	988		
Proceeds from issuance of preferred stock and warrants			15,132
Repurchase of shares related to common stock warrant exercise	(94)		
Deferred offering costs			(553)
Proceeds from exercise of stock options	411	387	187
Net cash provided by financing activities	69,566	52,550	26,060
Net increase (decrease) in cash and cash equivalents	7,230	(11,751)	10,824
Effect of exchange rate changes on cash and cash equivalents	52		
Cash and cash equivalents:			
Beginning of year	9,941	21,692	10,868
End of year	\$ 17,223	\$ 9,941	\$ 21,692
Supplemental disclosures:			
Accretion of preferred stock	\$	\$ 4,653	\$ 7,533
Accrual of offering costs		29	1,212
Cash paid for interest	3,479	1,474	563
Rental instruments reclassified from inventory	2,541		
Issuance of preferred stock warrants with debt		138	648
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	262	410	

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

**Table of Contents**

**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 laboratory customers.

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.

*Public Offerings*

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.

In January 2014, the Company completed an underwritten public offering of 2,972,972 shares of common stock for total gross proceeds of \$55.0 million. In February 2014, the underwriters partially exercised an overallotment option, purchasing 345,945 additional shares from the Company for additional gross proceeds of \$6.4 million. After underwriters' fees and commissions and other expenses of the offering, the Company's aggregate net proceeds were approximately \$57.0 million.

**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. Each of the 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

---

**Table of Contents**

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, the calculation of stock-based compensation and the estimated future cost of ongoing collaboration agreements, for which revenues are recognized on a proportional performance basis.

*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 (loss) 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 by analyzing the status of significant past due receivables. The allowance for doubtful accounts was \$63,000 and \$0 as of December 31, 2014 and 2013, respectively. Additions to the allowance were \$63,000 for the year ended December 31, 2014 and none for the years ended December 31, 2013 and 2012, respectively. There were no deductions during the years ended December 31, 2014, 2013, and 2012.

*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



## **Table of Contents**

receivable. The Company performs initial and ongoing evaluations of its customers' financial position and generally extends credit on account without collateral.

The Company had no customers that individually represented more than 10% of total revenue during the years ended December 31, 2014, 2013 and 2012. The Company had one customer that represented more than 10% of total accounts receivable at December 31, 2014 and none at December 31, 2013.

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, 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 depreciated over five years, prototype systems are depreciated over two years, computer equipment is generally depreciated over three years, lease and loaner instruments are depreciated over one to five 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.



## **Table of Contents**

### *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.

### *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 had no such deferred costs recorded as of December 31, 2014 and had recorded approximately \$29,000 of deferred offering costs as a non-current asset as of December 31, 2013.

### *Segments*

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 diagnostic testing on the same instrument. The Company has one sales force that now sells these systems to both research and clinical testing labs, and has launched its first product, nCounter Elements reagents, 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.

Instruments, consumables and *in vitro* diagnostic kits are considered to be separate units of accounting as they are sold separately and revenue is recognized upon transfer of ownership, which is generally upon shipment. Instrument revenue related to installation and calibration services is recognized when services are rendered by

---

**Table of Contents**

the Company. Such services can also be provided by the Company's distribution partners. For instruments sold for use primarily to run Prosigna assays, training must be provided prior to instrument revenue recognition. Instrument revenue from leased instruments is recognized ratably over the lease term.

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

For arrangements with multiple deliverables, the Company allocates the agreement consideration at the inception of the agreement 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.

The Company enters into collaborative agreements that may generate upfront fees with subsequent milestone payments that may be earned upon completion of development-related milestones. The Company is able to estimate the total cost of services under the arrangements and recognizes collaboration revenue using a proportional performance model. Costs incurred to date compared to total expected costs are used to determine proportional performance, as this is considered to be representative of the delivery of outputs under the arrangements. Revenue recognized at any point in time is limited to cash received and amounts contractually due. Changes in estimates of total expected costs are accounted for prospectively as a change in estimate. From period to period, collaboration revenue can fluctuate substantially based on the achievement of development-related milestones.

*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.

**Table of Contents**

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

	<b>(In thousands)</b>
<b>Warranty reserve, December 31, 2011</b>	<b>\$ 167</b>
Cost of warranty claims	(244)
Warranty accrual	325
<b>Warranty reserve, December 31, 2012</b>	<b>248</b>
Cost of warranty claims	(191)
Warranty accrual	301
<b>Warranty reserve, December 31, 2013</b>	<b>358</b>
Cost of warranty claims	(213)
Warranty accrual	358
<b>Warranty reserve, December 31, 2014</b>	<b>\$ 503</b>

*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 \$5.1 million, \$3.3 million and \$590,000 during the years ended December 31, 2014, 2013 and 2012, respectively.

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.

---

**Table of Contents**

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, 2014 and 2013.

*Comprehensive Loss*

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 loss.

*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.

In May 2014, the Financial Accounting Standards Board ( FASB ) issued an accounting standards update entitled ASU 2014-09, Revenue from Contracts with Customers. The standard requires entities to recognize revenue through the application of a five step model, which includes identification of the contract, identification of the performance obligations, determination of the transaction price, allocation of the transaction price to the performance obligations, and recognition of revenue as the entity satisfies the performance obligations. The standard will become effective for the Company beginning January 1, 2017. The Company is currently evaluating the guidance to determine the potential impact on its consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

In June 2014, FASB issued an accounting standards update entitled ASU 2014-12, Compensation - Stock Compensation. The standard requires entities that grant their employees share-based payments in which the terms of the award provide that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. The standard will become effective for the Company beginning January 1, 2016. The Company is currently evaluating the guidance to determine the potential impact on its consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

In August 2014, FASB issued an accounting standards update entitled ASU 2014-15, Presentation of Financial Statements - Going Concern. The standard requires entities to evaluate for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). The standard will



become effective for the Company beginning January 1, 2017.

**Table of Contents****3. Short-term Investments**

Short-term investments consisted of available-for-sale securities as follows:

<b>Type of security as of December 31, 2014</b>	<b>Amortized cost</b>	<b>Gross unrealized gains (In thousands)</b>	<b>Gross unrealized losses (In thousands)</b>	<b>Fair value</b>
U.S. government-related debt securities	\$ 4,502	\$	\$ (4)	\$ 4,498
Corporate debt securities	47,345	2	(40)	47,307
Asset-backed securities	3,198		(1)	3,197
Total available-for-sale securities	\$ 55,045	\$ 2	\$ (45)	\$ 55,002

<b>Type of security as of December 31, 2013</b>	<b>Amortized cost</b>	<b>Gross unrealized gains (In thousands)</b>	<b>Gross unrealized losses (In thousands)</b>	<b>Fair value</b>
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 fair values of available-for-sale securities by contractual maturity at December 31 were as follows:

	<b>2014 (In thousands)</b>	<b>2013 (In thousands)</b>
Maturing in one year or less	\$ 51,235	\$ 26,725
Maturing in one to three years	3,767	5,990
Total available-for-sale securities	\$ 55,002	\$ 32,715

The following table summarizes investments that have been in a continuous unrealized loss position for less than 12 months and none have been in a continuous unrealized loss position for more than 12 months as of December 31, 2014:

<b>Less Than 12 Months Fair value (In thousands)</b>	<b>Gross unrealized losses</b>
--	--

Edgar Filing: NanoString Technologies Inc - Form 10-K

U.S. government-related debt securities	\$ 2,996	\$ (4)
Corporate debt securities	30,372	(40)
Asset-backed securities	2,259	(1)
Total	\$ 35,627	\$ (45)

The Company invests in securities that are rated investment grade or better. The unrealized losses on investments as of December 31, 2014 were primarily caused by interest rate increases.

The Company reviews the individual securities in its portfolio to determine whether a decline in a security's fair value below the amortized cost basis is other-than-temporary. The Company determined that as of December 31, 2014, there were no investments in its portfolio that were other-than-temporarily impaired.

#### 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

**Table of Contents**

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.

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

As of December 31, 2014	Fair value measurement using:			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Cash equivalents:				
Money market fund	\$ 13,426	\$	\$	\$ 13,426
Short-term investments:				
U.S. government-related debt securities		4,498		4,498
Corporate debt securities		47,307		47,307
Asset-backed securities		3,197		3,197
<b>Total</b>	<b>\$ 13,426</b>	<b>\$ 55,002</b>	<b>\$</b>	<b>\$ 68,428</b>

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
<b>Total</b>	<b>\$ 8,454</b>	<b>\$ 32,715</b>	<b>\$</b>	<b>\$ 41,169</b>

**5. Inventory**

Inventory consisted of the following at December 31:

**2014**      **2013**  
(In thousands)

Edgar Filing: NanoString Technologies Inc - Form 10-K

Raw materials	\$ 1,299	\$ 2,164
Work in process	2,157	2,198
Finished goods	1,988	2,388
	\$ 5,444	\$ 6,750

In 2014, \$2.5 million of inventory leased, loaned, or assigned for internal use in the Company's facilities were transferred into property, plant and equipment.

**Table of Contents****6. Prepaid Expenses and Other**

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

	2014	2013
	(In thousands)	
Prepaid expenses	\$ 955	\$ 416
Subsidiary bank trust deposits	626	192
Deposits for inventory	2,207	1,577
Other	1,454	814
	\$ 5,242	\$ 2,999

**7. Property and Equipment**

Property and equipment consisted of the following at December 31:

	Useful Life (Years)	2014	2013
		(In thousands)	
Manufacturing equipment	5	\$ 3,654	\$ 3,333
Lease and loaner instruments	1 5	2,629	
Prototype instruments	2	2,157	1,893
Computer equipment	3	1,430	1,325
Furniture and fixtures	5	831	543
Leasehold improvements	Various	4,888	4,713
Construction in progress		1,058	
		16,647	11,807
Less: Accumulated depreciation and amortization		(10,281)	(8,742)
		\$ 6,366	\$ 3,065

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

Accumulated depreciation on lease and loaner instruments was \$128,000 and \$0 at December 31, 2014 and 2013, respectively.

Depreciation and amortization expense for the years ended December 31, 2014, 2013 and 2012 totaled approximately \$1.5 million, \$1.8 million and \$1.9 million, respectively.

**8. Accrued Liabilities**

Accrued liabilities consisted of the following at December 31:

	<b>2014</b>	<b>2013</b>
	<b>(In thousands)</b>	
Employee compensation	\$ 6,838	\$ 4,701
Clinical study costs	461	539
Royalties payable	632	448
Warranty reserves	503	357
Accounting and legal	297	272
Other accrued liabilities	1,672	771
	<b>\$ 10,403</b>	<b>\$ 7,088</b>

---

**Table of Contents****9. Long-Term Debt****Term Loans***2014 Term Loan Agreement*

In April 2014, the Company entered into a term loan agreement under which it may borrow up to \$45.0 million, or up to an aggregate of approximately \$51.0 million if the Company elects to exercise in full an option to defer payment of a portion of the interest that would accrue on the borrowing under the term loan agreement. Upon initial closing, the Company borrowed \$20.0 million, the proceeds of which were primarily used to repay the outstanding balance under a previous credit facility plus a related \$1.0 million end of term payment, a \$0.3 million make-whole premium, and interest accrued. The Company incurred and recorded a total charge to interest expense of \$1.4 million related to the repayment of the former credit facility including a loss on extinguishment of debt of \$0.6 million.

In October 2014, the Company borrowed an additional \$10.0 million under the term loan agreement. The Company may borrow up to an additional \$15.0 million under the agreement no later than May 2015, subject to a revenue requirement. All borrowings under the term loan agreement accrue interest at 12.5% annually, payable quarterly, of which 3.5% can be deferred during the first four years of the term at the Company's option and paid together with the principal. The Company exercised its option to defer payment of the 3.5% accrued interest for the six months ended December 31, 2014. The Company is required to pay only interest for the first five years of the term. Principal payments are due in four equal installments during the sixth year of the term. The Company has the option to prepay the term loans, in whole or in part, at any time subject to payment of a redemption fee of up to 4%, which declines over the term. The term loan agreement contains customary conditions to borrowings, events of default and negative covenants, including covenants that could limit the Company's ability to, among other things, incur additional indebtedness, liens or other encumbrances, make dividends or other distributions; buy, sell or transfer assets; engage in any new line of business; and enter into certain transactions with affiliates. The term loan agreement also includes a \$2.0 million minimum liquidity covenant and revenue-based financial covenants, which shall initially be \$40.0 million for 2014 with annual increases of \$15.0 million for each subsequent fiscal year thereafter. If the Company's actual revenues are below the minimum annual revenue requirement for any given year, the Company may avoid a related default by generating proceeds from an equity or subordinated debt issuance equal to the shortfall between its actual revenues and the minimum revenue requirement. The Company was in compliance with its covenants as of December 31, 2014. The Company's obligations under the term loan agreement are collateralized by substantially all of its assets.

*2012 Credit Facility*

In 2012, the Company entered into a credit facility and incurred \$13.0 million and \$5.0 million in term loan borrowings during the years ended December 31, 2012 and 2013, respectively. In connection with the term loan borrowings during 2012, the Company issued warrants to purchase an aggregate of 76,940 shares of Series D and 20,837 shares of Series E preferred stock at exercise prices of \$8.45 and \$14.40 per share, respectively. In connection with the term loan borrowings during 2013, the Company issued warrants to purchase an aggregate of 10,418 shares of Series E preferred stock. The issued 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 57.0 to 61.0% and a risk free interest rate of 1.63 to 2.20%. The warrants were treated as debt discount and were 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.

**Capital Leases**



In July 2014, the Company entered into an equipment lease of hardware, software and capitalized installation costs over a lease term of three years expiring June 2017. The amount financed totaled approximately \$260,000 and is being repaid in 36 equal monthly installments. Ownership of the property transfers to the Company at the end of the term.

**Table of Contents**

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 in 36 equal monthly installments. Ownership of the property transfers to the Company at the end of the term.

Depreciation expense was recorded for each of these leases.

Borrowings consisted of the following at December 31:

	<b>2014</b>	<b>2013</b>
	<b>(In thousands)</b>	
Term loans payable	\$ 30,420	\$ 18,348
Capital leases	506	410
Landlord payable		49
	30,926	18,807
Less: Unamortized debt discount		(514)
Current portion	(251)	(6,136)
Non-current portion	\$ 30,675	\$ 12,157

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

	<b>2014</b>	
	<b>(In thousands)</b>	
2015	\$	251
2016		207
2017		48
2018		
2019		22,815
Thereafter		7,605
	\$	30,926

**10. Collaboration Agreement**

In March 2014, the Company entered into a collaboration agreement with Celgene Corporation ( Celgene ) to develop, seek regulatory approval for, and commercialize a companion diagnostic assay for use in screening patients with Diffuse Large B-Cell Lymphoma. The Company received an upfront payment of \$5.8 million upon its delivery of certain information to Celgene, and is eligible to receive up to \$17.0 million in success-based payments related to development and regulatory milestones. The Company will retain all commercial rights to the diagnostic test developed under this collaboration. Assuming success in the clinical trial process, and subject to regulatory approval, the Company will market and sell the diagnostic assay and Celgene has agreed to make certain potential commercial payments to the Company in the event sales of the assay do not exceed certain pre-specified minimum annual revenues during the first three years following regulatory approval.

The Company achieved and was paid for milestones totaling \$6.0 million during 2014. The process of successfully developing a product candidate, obtaining regulatory approval and ultimately commercializing a product candidate is highly uncertain and the attainment of any additional milestones is therefore uncertain and difficult to predict. In addition, certain milestones are outside the Company's control and are dependent on the performance of Celgene and the outcome of a clinical trial and related regulatory processes. Accordingly, the Company is not able to reasonably estimate when, or if at all, any additional milestone payments may be receivable by the Company from Celgene.

The Company uses a proportional performance model to recognize revenue over the Company's performance period for the related agreement. Costs incurred to date compared to total expected costs are used to

---

**Table of Contents**

determine proportional performance, as this is considered to be representative of the delivery of outputs under the arrangement. Revenue recognized at any point in time is limited to cash received and amounts contractually due, such as the \$11.8 million of upfront and milestone payments received during 2014. Changes in estimates of total expected costs are accounted for prospectively as a change in estimate. All amounts received or due are classified as collaboration revenue as they are earned.

For the year ended December 31, 2014, the Company recognized collaboration revenue related to the Celgene agreement of \$2.9 million. No such amounts were recognized in 2013 or 2012. At December 31, 2014, the Company had recorded \$8.9 million of deferred revenue related to the collaboration, of which \$2.6 million is estimated to be recognized as revenue within one year.

**11. 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 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, 2014, 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.

**Table of Contents**

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 and \$7.5 million for the years ended December 31, 2013 and 2012, respectively. The Company also accreted any related issuance costs or discounts.

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

<b>Mandatorily Redeemable Convertible Preferred Stock</b>	<b>Shares Authorized</b>	<b>Shares Outstanding</b>	<b>Liquidation Preference</b>	<b>Book Value</b>
			<b>(Amounts in thousands)</b>	
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.

*Warrants*

Prior to the Company's initial public offering, warrants to purchase preferred stock were issued related to certain financing transactions. Such warrants were recorded as liabilities and measured at fair value at each reporting date. 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, 2014 there were 572,496 common stock warrants outstanding with a weighted average exercise price of \$8.77 per common stock warrant.

**12. 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 4,533,326 shares of the Company's common stock as of December 31, 2014. 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.



**Table of Contents**

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, 2013	2,112,632	\$ 4.47	8.12	\$ 26,968
Granted	1,553,581	17.12		
Canceled	(206,997)	13.40		
Exercised	(164,394)	2.41		
Outstanding at December 31, 2014	3,294,822	\$ 9.98	8.08	\$ 17,985

December 31, 2014:

Options vested and expected to vest	3,288,066	\$ 9.79	7.93	\$ 18,286
Options exercisable	1,423,760	\$ 5.34	7.11	\$ 12,974

The total fair value of stock options vested during the year ended December 31, 2014 was \$3.5 million.

The following table summarizes information about the Company's options outstanding at December 31, 2014:

Exercise Price	Options Outstanding		Options Exercisable	
	Number of Shares	Weighted-Average Remaining Contractual Life in Years	Number of Shares	Weighted-Average Remaining Contractual Life in Years
\$0.32 - 1.92	787,662	7.09	570,418	7.04
2.24 - 3.84	359,622	5.34	358,138	5.34
5.12 - 6.72	389,070	7.85	200,015	7.81
8.96 - 12.50	493,918	9.08	120,841	8.71
13.93 - 20.65	1,264,550	9.16	174,348	9.08
	3,294,822		1,423,760	

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:

	2014		2013		2012	
Risk-free interest rates	1.74%	2.15%	1.05%	1.95%	0.85%	1.44%
Expected term (years)	6.25		6.25		6.25	



Expected dividend yield					
Volatility	57.0%	57.0%	58.0%	54.0%	61.0%

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 three years ended December 31, 2014 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

**Table of Contents**

value of its common stock for financial reporting purposes. 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 on 101,487 and 988,268 shares, 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, 2014, 2013 and 2012 was \$9.45, \$5.30 and \$1.59, respectively.

The aggregate intrinsic value for options exercised during the years ended December 31, 2014, 2013 and 2012 was \$2.2 million, \$681,000 and \$161,000, respectively, determined as of the date of option exercise.

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

	2014	2013	2012
	(In thousands)		
Cost of revenue	\$ 281	\$ 49	\$ 71
Research and development	1,018	273	204
Selling, general and administrative	3,234	823	470
Total stock compensation expense	\$ 4,533	\$ 1,145	\$ 745

At December 31, 2014, the total unrecognized compensation cost was approximately \$12.8 million and will be recognized on a straight-line basis over the weighted-average remaining service period of approximately three years. Compensation expense of \$0.4 million related to the 2013 Employee Stock Purchase Plan is not included in the table.

**Employee Stock Purchase Plan**

In July 2013, the Company's stockholders approved the Company's 2013 Employee Stock Purchase Plan (ESPP). The ESPP provides eligible employees with an opportunity to purchase common stock from the Company and to pay for their purchases through payroll deductions. The Purchase Plan has overlapping offering periods of approximately 12 months in length. The offering periods generally start with the first trading day on or after March 1 and September 1 of each year and end on the first trading day on or after March 1 and September 1 of the following year, approximately 12 months later. Within each offering period, shares will be purchased each 6 months on an exercise date. The first offering period began in August 2013.

An employee electing to participate in the Purchase Plan (a Participant) will be granted an option at the start of the offering period to purchase shares with contributions in any whole percentage ranging from zero percent to ten percent (or greater or lesser percentages or dollar amounts that the Administrator determines) of the participant's eligible compensation. The participant's contributions will be accumulated and then used to purchase the Company's shares on each exercise date. The purchase price will be the lesser of (i) 85% of the fair market value of the Company's shares on the first trading day of the offering period or (ii) 85% of the fair market value of the Company's shares on the exercise date.

During 2014, 141,386 shares were issued under the ESPP. A total of 427,448 shares of common stock have been reserved for issuance under the ESPP, of which 286,062 shares were available for issuance as of December 31, 2014.

No shares were issued under the ESPP during 2013 or 2012.

**Table of Contents****13. Defined Contribution Retirement Plan**

The Company maintains a 401(k) defined contribution retirement plan covering substantially all of its employees. The plan provides for matching and discretionary contributions by the Company. Contributions were \$0.4 million, \$0 and \$0 for the years ended December 31, 2014, 2013 and 2012, respectively.

**14. Income Taxes**

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

	2014	2013	2012
	(In thousands)		
Domestic	\$ (50,455)	\$ (28,746)	\$ (17,618)
Foreign	417	(535)	(90)
Loss before income taxes	\$ (50,038)	\$ (29,281)	\$ (17,708)

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:

	2014	2013	2012
	(In thousands)		
Income tax provision at statutory rate	\$ (17,013)	\$ (9,955)	\$ (6,021)
Nondeductible items	456	(32)	349
Change in tax credits	(678)	(893)	39
Change in valuation allowance	17,911	10,965	5,894
Other	(676)	(85)	(261)
	\$	\$	\$

Net operating loss ( NOL ) carryforwards created by excess tax benefits from the exercise of non-qualified stock options are not recorded as deferred income tax assets. To the extent such NOL carryforwards are utilized, the benefit realized will increase stockholders' equity. At December 31, 2014, for income tax return purposes the Company has gross federal and state NOL carryforwards totaling \$136.6 million and tax credit carryforwards of \$2.3 million. These carryforwards may be subject to limitations under the Internal Revenue Code and applicable state tax law. If not utilized, a portion of the carryforwards will begin to expire in 2023 through 2033.

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.

Edgar Filing: NanoString Technologies Inc - Form 10-K

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

	<b>2014</b>	<b>2013</b>
	<b>(In thousands)</b>	
Net operating loss carryforwards	\$ 47,444	\$ 31,989
Research and development tax credit carryforwards	2,332	1,654
Other	4,147	2,369
Total deferred tax assets	53,923	36,012
Less: Valuation allowance	(53,923)	(36,012)
Net deferred tax assets	\$	\$

-97-

**Table of Contents**

The Company has recorded a full valuation allowance related to its deferred tax assets due to the uncertainty of the ultimate realization of the future benefits from those assets.

The table below summarizes changes in the deferred tax asset valuation allowance:

	<b>Balance at Beginning of Year</b>	<b>Changed to Costs and Expenses</b>	<b>Write-offs</b>	<b>Balance at End of Year</b>
	(In thousands)			
Deferred tax valuation allowance:				
For year ended December 31, 2012	\$ 19,153	\$ 5,894	\$	\$ 25,047
For year ended December 31, 2013	25,047	10,965		36,012
For year ended December 31, 2014	36,012	17,911		53,923

The total balance of unrecognized gross tax benefits for the years ended December 31, resulting from R&D credits claimed on the Company's annual tax return was as follows:

	<b>2014</b>	<b>2013</b>	<b>2012</b>
	(In thousands)		
Unrecognized tax benefits at beginning of year	\$ 551	\$ 253	\$ 267
Additions (reductions) based on current year tax positions	226	298	(14)
Unrecognized tax benefits at end of year	\$ 777	\$ 551	\$ 253

The Company classifies applicable interest and penalties on amounts due to tax authorities as a component of the provision for income taxes. The amount of accrued interest and penalties recorded in 2014, 2013 or 2012 was not material. The Company does not anticipate that the amount of its existing unrecognized tax benefits will significantly increase or decrease within the next 12 months. Due to the presence of net operating loss carryforwards in most jurisdictions, the Company's tax years remain open for examination by U.S. taxing authorities back to 2004.

**15. Commitments and Contingencies**

In December 2014, the Company entered into a lease agreement, pursuant to which the Company will lease office, laboratory and storage space in a new building being constructed adjacent to the Company's headquarters. The new lease agreement has a ten-year term and is estimated to commence in April 2016. At the same time, the Company entered into an amendment to the existing lease on its headquarters, to be coterminous with the new lease. The Company has an option to extend the term of both leases for two additional periods of five years. The initial base rent on the new lease will be approximately \$88,356 per month, subject to rent abatement during the first three months of the lease. Beginning January 1, 2015, the base rent on the amended lease will be approximately \$150,361 per month. Base rents under both leases will increase at a rate of 3% annually. In addition, the leases require the Company to pay a property management fee equal to 3% of the base rent. The leases also obligate the landlord to fund tenant improvements, grant the Company a right of first refusal and right of first offer with respect to portions of the buildings, require the Company to reimburse the landlord for certain operating expenses, and include terms related to parking.

In December 2014, the Company entered into a one-year lease agreement, pursuant to which the Company will rent temporary office and laboratory space commencing in March 2015. The base rent on the new lease will be \$52,537 per month. In addition, the lease requires the Company to pay a property management fee equal to 3% of the base rent.

In December 2014, the Company entered into an amendment effective as of November 2014 to an existing lease, pursuant to which the Company leases office space in a building nearby its headquarters. The amendment increases the size of the leased premises effective February 2015 and extends the term of the lease through January 2025. The Company also has an option to extend the term of

**Table of Contents**

the lease for one additional three year period at the then-current fair market rent for comparable space. The base rent will be \$38,205 per month beginning in February 2015, and \$63,473 per month beginning in February 2016; thereafter, the rent will increase at a rate of approximately 2% annually. The amendment obligates the landlord to fund a substantial portion of tenant improvements, and includes terms related to parking and a right of first offer and right of first refusal with respect to a portion of the building.

Rent expense totaled approximately \$1.4 million, \$1.2 million and \$856,000 for the years ended December 31, 2014, 2013 and 2012, respectively.

Future minimum lease payments under noncancelable capital and operating leases as of December 31, 2014 were as follows:

	<b>(In thousands)</b>
2015	\$ 3,034
2016	3,483
2017	3,794
2018	3,852
2019	3,962
Thereafter	26,340
	<b>\$ 44,465</b>

The Company has purchase obligations totaling \$6.7 million at December 31, 2014 related to binding commitments to purchase inventory.

From time to time, the Company may become involved in litigation relating to claims arising from the ordinary course of business. Management believes that there are no claims or actions pending against the Company currently, the ultimate disposition of which would have a material adverse effect on the Company's consolidated results of operation, financial condition or cash flows.

**16. Net Loss Per Share**

Net loss attributable to common stockholders per share is computed by dividing the net loss allocable to common stockholders by the weighted average number of shares of common stock outstanding. Outstanding stock options, warrants and preferred stock, have not been included in the calculation of diluted net loss attributable to common stockholders per share because to do so would be anti-dilutive. Accordingly, the numerator and the denominator used in computing both basic and diluted net loss per share for each period are the same.

The following table provides a reconciliation of the numerator and denominator used in computing basic and diluted net loss per share for the years ended December 31:

	<b>2014</b>	<b>2013</b>	<b>2012</b>
	<b>(In thousands)</b>		
Numerator:			



Edgar Filing: NanoString Technologies Inc - Form 10-K

Net loss	\$ (50,038)	\$ (29,281)	\$ (17,708)
Accretion of mandatorily redeemable convertible preferred stock		(4,653)	(7,533)
Net loss attributable to common stockholders	\$ (50,038)	\$ (33,934)	\$ (25,241)
Denominator:			
Weighted-average common shares outstanding-basic and diluted	17,839	7,643	355

-99-

**Table of Contents**

The following outstanding options, warrants and preferred stock as of December 31 were excluded from the computation of diluted net loss per share for the periods presented because their effect would have been anti-dilutive:

	2014	2013	2012
	(In thousands)		
Options to purchase common stock	3,295	2,113	1,686
Convertible preferred stock (as converted)			8,631
Convertible preferred stock warrants (as converted)			607
Common stock warrants	572	618	

**17. Information about Geographic Areas**

The following table is based on the geographic location of distributors or end users who purchased products and services and collaborators. For sales to distributors, their geographic location may be different from the geographic locations of the ultimate end user. Revenue by geography as of December 31 was as follows:

	2014	2013	2012
	(In thousands)		
North America	\$ 32,244	\$ 21,855	\$ 15,906
Europe & Middle East	9,174	5,775	4,167
Asia Pacific	6,175	3,773	2,900
Total revenue	\$ 47,593	\$ 31,403	\$ 22,973

Total revenue in the United States was \$29.0 million, \$19.3 million and \$14.9 million for the years ended December 31, 2014, 2013 and 2012, respectively.

The Company's assets are primarily located in the United States and not allocated to any specific geographic region. Substantially all of the Company's long-lived assets are located in the United States.

**18. Condensed Quarterly Financial Data (unaudited)**

The following table contains selected unaudited financial data for each quarter of 2014 and 2013. The unaudited information should be read in conjunction with the Company's financial statements and related notes included elsewhere in this report. The Company believes that the following unaudited information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

	Three months ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share data)			
<b>2014</b>				
Total revenue	\$ 8,751	\$ 10,881	\$ 12,343	\$ 15,618

Edgar Filing: NanoString Technologies Inc - Form 10-K

Net loss attributable to common stockholders	\$ (11,422)	\$ (14,088)	\$ (12,148)	\$ (12,380)
Net loss per share basic and diluted	\$ (0.68)	\$ (0.78)	\$ (0.67)	\$ (0.68)
<b>2013</b>				
Total revenue	\$ 5,676	\$ 7,218	\$ 8,389	\$ 10,120
Net loss attributable to common stockholders	\$ (9,601)	\$ (7,806)	\$ (7,700)	\$ (8,827)
Net loss per share basic and diluted	\$ (17.88)	\$ (13.69)	\$ (0.53)	\$ (0.60)

-100-

---

**Table of Contents**

**Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**Item 9A. CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2014. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the U.S. Securities and Exchange Commission's, or SEC's, rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2014, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

**Management's Annual Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) and Rule 15d-15(f) of the Exchange Act. Our internal control over financial reporting is a process to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

- (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute, assurances. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that

controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate. Our management assessed the effectiveness of NanoString's internal control over financial reporting as of December 31, 2014. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated 1992 Framework. Based on our assessment using those criteria, our management has concluded that, as of December 31, 2014, NanoString's internal control over financial reporting was effective.

**Table of Contents**

**Changes in Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended December 31, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

None.

**Table of Contents****PART III****Item 10. Directors, Executive Officers and Corporate Governance****Executive Officers and Directors**

The following table sets forth the names, ages and positions of our executive officers and directors as of March 2, 2015:

<b>Name</b>	<b>Age</b>	<b>Position</b>
<b>Executive Officers</b>		
R. Bradley Gray	38	President, Chief Executive Officer and Director
Joseph M. Beechem, Ph.D.	57	Senior Vice President of Research and Development
Wayne Burns	58	Senior Vice President, Operations and Administration
David W. Ghesquiere	48	Senior Vice President, Corporate & Business Development
James A. Johnson	58	Chief Financial Officer
Barney Saunders, Ph.D.	52	Senior Vice President of Sales & Marketing
<b>Non-Employee Directors</b>		
William D. Young <sup>(1)(3)</sup>	70	Chairman of the Board
Nicholas Galakatos, Ph.D. <sup>(2)(3)</sup>	57	Director
Robert M. Hershberg, M.D., Ph.D. <sup>(3)</sup>	51	Director
Gregory Norden <sup>(1)</sup>	57	Director
Charles P. Waite <sup>(1)(2)(3)</sup>	59	Director

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Nominating and Corporate Governance Committee.

There are no family relationships among any of the directors or executive officers.

**Executive Officers**

*R. Bradley Gray* has served as a member of the board of directors and as President and Chief Executive Officer since June 2010. Prior to joining our company, Mr. Gray held various positions at Genzyme, a biotechnology company acquired by Sanofi in 2011. He served as Vice President of Product & Business Development for Genzyme Genetics, the diagnostic services division of Genzyme, from June 2008 to May 2010, leading the development of molecular diagnostics and partnering activities. From September 2006 to June 2008, he served as Vice President of Business & Strategic Development for Genzyme Genetics, leading growth efforts through partnerships and licensing. Mr. Gray joined Genzyme in October 2004 as Director of Corporate Development, supporting business development and leading Genzyme Ventures, the corporate venture capital fund of Genzyme. Prior to joining Genzyme, Mr. Gray was a management consultant in the healthcare practice of McKinsey & Company, a global management consulting firm, from September 2000 to October 2004, where he worked with senior healthcare executives in the United States and Europe on a broad range of issues including pharmaceutical and diagnostic product strategy, post-merger integration, organization design, and operational turnarounds. Mr. Gray received a B.A. in Economics and Management from Oxford University, where he studied as a British Marshall Scholar, and an S.B. in Chemical Engineering from the

Massachusetts Institute of Technology. We believe that Mr. Gray possesses specific attributes that qualify him to serve as a director, including the perspective and experience he brings as Chief Executive Officer and his knowledge of molecular diagnostic development and commercialization.

*Joseph M. Beechem, Ph.D.* has served as Senior Vice President of Research and Development since April 2012. Prior to joining our company, Dr. Beechem held various positions at Life Technologies, a publicly-traded biotechnology tools company, most recently as Vice President, Head of Advanced Sequencing and Head of



---

**Table of Contents**

Global Sequencing Chemistry, Biochemistry and Biophysics from January 2010 to April 2012. From December 2007 to December 2012, he served as Chief Technology Officer of Life Technologies. During his career at Life Technologies, he led the design and development of multiple genetic analysis technologies, the latest advanced SOLiD sequencing technology and the single molecule nano-DNA sequencing technology. Prior to joining Life Technologies, Dr. Beechem was Chief Scientific Officer at Invitrogen, a publicly-traded biotechnology company that acquired Applied Biosystems in November 2008 to form Life Technologies, from August 2003 to December 2007 and Director of Biosciences at Molecular Probes, a biotechnology company acquired by Invitrogen in 2003, from August 2000 to August 2003. Prior to his industry experience, Dr. Beechem led an NIH-funded research laboratory for 11 years as a tenured associate professor at Vanderbilt University. He has authored or co-authored more than 100 peer-reviewed papers in diverse fields such as biomathematics, physics, chemistry, physiology, spectroscopy, diagnostics and biology. Dr. Beechem is also named on nearly 30 U.S. patents or patent applications and has served on a number of editorial and scientific advisory boards. He received a B.S. in Chemistry and Biology from Northern Kentucky University and a Ph.D. in Biophysics from The Johns Hopkins University.

*Wayne Burns* has served as Senior Vice President, Operations and Administration since October 2012 and served as Chief Financial Officer from April 2007 to September 2012. During the period from March 2009 through June 2010, Mr. Burns served as Acting Chief Executive Officer as well as Chief Financial Officer. Prior to joining our company, Mr. Burns served as Chief Operating Officer and Chief Financial Officer at Action Engine, a developer of a mobile application platform, from 2001 to 2006. From 2000 to 2001, Mr. Burns was a founder and the Chief Executive Officer of SafariDog, a developer of a search engine optimization platform. Mr. Burns also served as Vice President Operations and Chief Financial Officer of NetPodium during 1999 prior to its acquisition by InterVU, where from 1999 to 2000 Mr. Burns served as Vice President of Business Development. During the period from 1990 to 1996, Mr. Burns served as Chief Financial Officer and Vice President of Finance for three venture-backed companies, all of which were acquired by public companies. Mr. Burns spent five years with PricewaterhouseCoopers in the United States and Italy. Mr. Burns received a B.A. in Business Administration with a concentration in Accounting from the University of Washington.

*David W. Ghesquiere* has served as Senior Vice President, Corporate & Business Development since November 2013. Prior to joining our company, Mr. Ghesquiere was the founder and managing director of Adrenaline Venture & Advisory LLC, an international advisory firm, from August 2012 to November 2013. Prior to founding Adrenaline Venture & Advisory, Mr. Ghesquiere served as Senior Vice President, Corporate & Business Development at Dendreon Corporation, a biotechnology company, from 2011 to 2012. From 2005 to 2010, Mr. Ghesquiere held a variety of executive positions at OSI Pharmaceuticals, acquired by Astellas Pharma in 2010, including Senior Vice-President of Corporate & Business Development and Managing Director of OSI Investment Holdings GmbH and OSI Investment Management GmbH, OSI's wholly owned, Switzerland-based subsidiaries, where he played a key role in establishing OSI's venture capital arm. Earlier in his career, Mr. Ghesquiere served as Director of Global Business Development for Aventis Pharmaceuticals, which merged with Sanofi in 2004, and worked in product marketing at Johnson & Johnson. Mr. Ghesquiere received an M.B.A. from The University of Western Ontario's Ivey School of Business and a B.A. in economics from The University of Western Ontario.

*James A. Johnson* has served as Chief Financial Officer since October 2012. Prior to joining our company, Mr. Johnson was Chief Financial Officer of Relypsa, Inc., a clinical-stage biopharmaceutical company, from May 2011 to September 2012. From September 2009 to October 2010, Mr. Johnson served as Executive Vice President, Chief Financial Officer, Treasurer and Secretary of ZymoGenetics, Inc., a biopharmaceutical company acquired by Bristol-Myers Squibb in October 2010. Mr. Johnson served as ZymoGenetics' Executive Vice President, Chief Financial Officer and Treasurer from July 2007 to September 2009 and as ZymoGenetics' Senior Vice President, Chief Financial Officer and Treasurer from February 2001 to July 2007. Mr. Johnson served as Chief Financial Officer, Treasurer and Secretary of Targeted Genetics Corporation, a biotechnology company, from 1994 to February 2001, as

its Senior Vice President, Finance and Administration, from January 1999 to February 2001, and as its Vice President, Finance, from 1994 to January 1999. From 1990 to 1994,

---

**Table of Contents**

Mr. Johnson served as Vice President, Finance, and, from 1988 to 1990, as Director of Finance, at Immunex Corporation, a biopharmaceutical company. Mr. Johnson received a B.A. in Business Administration from the University of Washington.

*Barney Saunders, Ph.D.* has served as Senior Vice President of Sales & Marketing since March 2015, and previously served as our Senior Vice President & General Manager, Life Sciences, from September 2012 to March 2015 and our Chief Commercial Officer from September 2010 to September 2012. Prior to joining our company, Dr. Saunders served as Chief Commercial Officer of Microchip Biotechnologies (now IntegenX), a manufacturer of automation systems enabling microsample preparation and analysis for the life sciences, from September 2005 to June 2010. Prior to joining Microchip Biotechnologies, Dr. Saunders served as General Manager at Agilent Technologies, a publicly-traded measurement company providing core bio-analytical and electronic measurement solutions, from 2000 to 2004, where he led the team that launched the first commercially-available, complete genome arrays for human, rat and mouse and also entered the array CGH (comparative genomic hybridization) market. Dr. Saunders began his career with Amersham International, a pharmaceutical company specializing in Diagnostics and Life Sciences which was acquired by General Electric in 2004, where he held a variety of commercial positions, of increasing responsibility, in the United States and Europe from 1988 to 2000. Dr. Saunders received a B.Sc. Hons in Biological Sciences and Ph.D. in Rice Resistance Gene Expression from Birmingham University, England.

**Our Directors***Directors Continuing in Office Until the 2015 Annual Meeting of Stockholders*

*Gregory Norden* has served as a member of the board of directors and as chairman of the audit committee since July 2012. From 1989 to 2010, Mr. Norden held various senior positions with Wyeth/American Home Products, most recently as Wyeth's Senior Vice President and Chief Financial Officer. Prior to this role, Mr. Norden was Executive Vice President and Chief Financial Officer of Wyeth Pharmaceuticals. Prior to his affiliation with Wyeth, Mr. Norden served as Audit Manager at Arthur Andersen & Company. Mr. Norden also serves on the boards of directors of WelchAllyn, a leading global provider of medical diagnostic equipment, Zoetis Inc., a global leader in discovering, developing, manufacturing and commercializing animal health medicines and vaccines, and Royalty Pharma, an industry leader in the acquisition of revenue-producing intellectual property. He is a former director of Human Genome Sciences (acquired by GlaxoSmithKline in August 2012) and Lumara Health (acquired by AMAG Pharmaceuticals in November 2014). Mr. Norden received a M.S. in Accounting from Long Island University - C.W. Post and a B.S. in Management/Economics from the State University of New York - Plattsburgh. We believe that Mr. Norden's qualifications to serve on the board of directors include his extensive financial and accounting expertise and experience at Wyeth and at Arthur Andersen & Company and his significant experience in the biopharmaceutical industry.

*Charles P. Waite* has served as a member of the board of directors since July 2004 and as a member of the audit committee, compensation committee and nominating and corporate governance committee since June 2009; he currently serves as chairman of the nominating and corporate governance committee. He has been a General Partner of OVP Venture Partners II and a Vice President of Northwest Venture Services Corp. since 1987, a General Partner of OVP Venture Partners III since 1994, a General Partner of OVP Venture Partners IV since 1997, a General Partner of OVP Venture Partners V since 2000, a General Partner of OVP Venture Partners VI since 2001, and a General Partner of OVP Venture Partners VII since 2007, all of which are venture capital firms. Prior to joining OVP, Mr. Waite was a General Partner at Hambrecht & Quist Venture Partners from 1984 to 1988, where he focused on investments in information technology and life sciences. He is a former director of Complete Genomics, a publicly-traded DNA sequencing platform developer (acquired by BGI-Shenzen in March 2013), and currently serves on the board of directors of eight private companies. Mr. Waite received an A.B. in history from Kenyon College and an M.B.A. from

Harvard University. We believe that Mr. Waite's significant operational and leadership experience as a venture capital investor who sits on a number of boards qualify him to serve as a director. Mr. Waite's investment focus on life sciences companies also provides substantial expertise in our industry.

**Table of Contents***Directors Continuing in Office Until the 2016 Annual Meeting of Stockholders*

*William D. Young* has served as the chairman of the board of directors since January 2010 and as a member of the audit committee since November 2011 and nominating and corporate governance committee since September 2013. Mr. Young is a Venture Partner at Clarus Ventures, a health care and life sciences venture capital firm, which he joined in March 2010. Prior to joining Clarus Ventures, Mr. Young served from 1999 until June 2009 as Chairman of the board of directors and Chief Executive Officer of Monogram Biosciences, a biotechnology company acquired by Laboratory Corporation of America in June 2009. From 1980 to 1999, Mr. Young was employed at Genentech, a biotechnology company acquired by Roche in March 2009, most recently as Chief Operating Officer from 1997 to 1999, where he was responsible for all Product Development, Manufacturing and Commercial functions. Mr. Young joined Genentech in 1980 as Director of Manufacturing and Process Sciences and became Vice President in 1983. Prior to joining Genentech, Mr. Young worked at Eli Lilly & Co. for 14 years and held various positions in production and process engineering, antibiotic process development and production management. Mr. Young is retired Chairman of the board of directors of Biogen Idec Inc. and a member of the boards of directors of BioMarin Pharmaceutical Inc., Theravance Biopharma and Vertex Pharmaceuticals. Mr. Young received his M.B.A. from Indiana University and his B.S. in chemical engineering from Purdue University, and an honorary doctorate of engineering from Purdue University. Mr. Young was elected to The National Academy of Engineering in 1993 for his contributions to biotechnology. We believe that Mr. Young's demonstrated leadership in his field, his understanding of the industry and his senior management experience in several companies in our industry qualify him to serve as the chairman of the board of directors.

*Nicholas Galakatos, Ph.D.* has served as a member of the board of directors, as the chairman of the compensation committee and as a member of the nominating and corporate governance committee since June 2009. Dr. Galakatos is a Managing Director of Clarus Ventures, a health care and life sciences venture capital firm, which he co-founded in 2005. Dr. Galakatos has been a venture capital investor since 1992, initially at Venrock Associates from 1992 to 1997 and then at MPM Capital since 2000 where he was General Partner of the Bioventures II and Bioventures III funds. From 1997 to 2000, he was Vice President, New Business, and a member of the management team at Millennium Pharmaceuticals, a biopharmaceutical company acquired by Takeda Pharmaceutical in May 2008. He was a founder of Millennium Predictive Medicine and TransForm Pharmaceuticals, where he also was the Chairman and founding Chief Executive Officer. Dr. Galakatos is a Director of Portola Pharmaceuticals, Inc. and Ophthotech Corporation, and has been the Lead Director at Affymax Inc., and a Director of Critical Therapeutics Inc., and Aveo Pharmaceuticals, Inc. Dr. Galakatos received a B.A. degree in Chemistry from Reed College, a Ph.D. degree in Organic Chemistry from the Massachusetts Institute of Technology, and performed postdoctoral studies in molecular biology at Harvard Medical School. We believe that Dr. Galakatos is qualified to serve as a director of NanoString because of his operating experience in the biopharmaceutical industry and his extensive experience as a venture capital investor and a director of several public companies. Dr. Galakatos's investment focus on life sciences companies also provides substantial expertise in our industry.

*Directors Continuing in Office Until the 2017 Annual Meeting of Stockholders*

*R. Bradley Gray.* See Directors, Executive Officers and Corporate Governance Executive Officers included elsewhere in this Annual Report on Form 10-K for Mr. Gray's biographical information.

*Robert M. Hershberg, M.D., Ph.D.* has served as a member of the board of directors and as a member of a nominating and corporate governance committee since March 2015. Since July 2014, Dr. Hershberg has served as Senior Vice-President of Immuno-Oncology at Celgene Corporation, a publicly-traded biopharmaceutical company, where he leads the company's research and early development efforts across its immuno-oncology portfolio. Dr. Hershberg is also the President and Chief Executive Officer of VentiRx Pharmaceuticals, a clinical stage biopharmaceutical

company, which he co-founded in 2006. Prior to co-founding VentiRx, Dr. Hershberg served as Senior Vice President and Chief Medical Officer at Dendreon Corporation, a biotechnology company, where he led the clinical, regulatory and biometrics groups, focusing on the development of Provenge® in

## **Table of Contents**

metastatic prostate cancer. From 2001 to 2003, Dr. Hershberg was the Vice President of Medical Genetics at Corixa, a pharmaceutical company (acquired by GlaxoSmithKline in 2005). Earlier in his career, Dr. Hershberg served as an Assistant Professor at Harvard Medical School and an Associate Physician at the Brigham and Women's Hospital in Boston, Massachusetts. Dr. Hershberg holds clinical and research faculty positions at the University of Washington School of Medicine and is a member of the board of directors of Adaptive Biotechnologies Corp., a clinical stage diagnostics company. He completed his undergraduate degree in molecular biology and M.D. at UCLA, and his Ph.D. in biology at the Salk Institute. We believe Dr. Hershberg is qualified to serve as a director of NanoString because of his extensive experience as a senior executive officer at multiple biotechnology companies.

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than ten percent of a registered class of our equity securities, to file reports of ownership of, and transactions in, our securities with the SEC and NASDAQ. Such directors, executive officers, and ten percent stockholders are also required to furnish us with copies of all Section 16(a) forms that they file.

Based solely on a review of the copies of such forms received by us, or written representations from certain reporting persons, we believe that during 2014, our directors, executive officers, and 10% stockholders complied with all Section 16(a) filing requirements applicable to them.

### **Code of Business Conduct and Ethics**

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the code is posted on the investor section of our website, [www.nanostring.com](http://www.nanostring.com).

### **Audit Committee**

The members of our audit committee are Messrs. Norden, Waite and Young, each of whom satisfies the independence standards for audit committee members established by applicable SEC and The NASDAQ Global Market rules. Our audit committee chairman, Mr. Norden, is our audit committee financial expert, as that term is defined under the SEC rules implementing Section 407 of the Sarbanes-Oxley Act of 2002, and possesses financial sophistication, as defined under the rules of The NASDAQ Global Market. Our audit committee oversees our corporate accounting and financial reporting process and assists the board of directors in monitoring our financial systems. Our audit committee also:

approves the hiring, discharging and compensation of our independent auditors;

oversees the work of our independent auditors;

approves engagements of the independent auditors to render any audit or permissible non-audit services;

reviews the qualifications, independence and performance of the independent auditors;

reviews financial statements, critical accounting policies and estimates;

reviews the adequacy and effectiveness of our internal controls; and

reviews and discusses with management and the independent auditors the results of our annual audit, our quarterly financial statements and our publicly filed reports.

-107-



**Table of Contents****Item 11. Executive Compensation**  
**Summary Compensation Table**

The following table provides information regarding the compensation of our named executive officers during 2014, 2013 and 2012.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option	Non-Equity	All	Total (\$)
				Awards	Incentive	Other	
				(\$)(2)	Plan	Compensation	
R. Bradley Gray	2014	441,750		902,430	243,054		1,587,234
	2013	384,214		252,986	228,000		865,200
President and Chief Executive Officer	2012	333,802	104,000 <sup>(1)</sup>	242,246	120,802		800,850
James A. Johnson(4)	2014	349,167		451,215	130,240		930,622
	2013	324,167		114,996	128,975		568,138
Chief Financial Officer	2012	75,000	30,000 <sup>(5)</sup>	219,036	21,878		345,914
Wayne Burns	2014	325,000		451,215	133,650		909,865
Senior Vice President, Operations and Administration							

(1) This amount represents a special bonus accelerated and paid in 2012.

(2) The dollar amounts in this column represent the aggregate grant date fair value of stock option awards granted in 2014, 2013 and 2012, respectively. These amounts have been computed in accordance with FASB ASC Topic 718, using the Black-Scholes option pricing model. Pursuant to SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. For a discussion of valuation assumptions, see the notes to our financial statements included elsewhere in this report.

(3) The amounts in this column represent the amounts earned and payable each year under the bonus plan for such year, all of which were paid in the subsequent year.

(4) Mr. Johnson was hired in October 2012.

(5) This amount represents a signing bonus.

**Non-Equity Incentive Plan Compensation & Bonus****2014 Non-Equity Incentive Plan Payments**

For 2014, the target incentive amounts and the aggregate annual payments earned by our named executive officers were the following:

Name Executive Officer	Target Award Opportunity	Actual Award
R. Bradley Gray	\$ 270,000	\$ 243,054

Edgar Filing: NanoString Technologies Inc - Form 10-K

James A. Johnson	140,800	130,240
Wayne Burns	148,500	133,650

Our 2014 incentive compensation plan provides our named executive officers with an annual incentive compensation payment, subject to our achievement of our corporate performance goals and individual achievement. For 2014, our corporate-level goals included continued revenue growth, execution of the U.S. commercial launch of Prosigna and continued international commercialization of Prosigna, continued development of our next-generation nCounter Analysis System, an enhanced diagnostic pipeline, effective management of organizational growth, achievement of cash position goals and other financial targets and additional stretch targets. The Actual Award amounts are calculated by weighing corporate goal attainment and individual goal attainment for each named executive officer as follows: Mr. Gray, 100% corporate goal; Mr. Johnson, 75% corporate goal/25% individual goal and Mr. Burns, 75% corporate goal/25% individual goal.

## **Table of Contents**

For 2014, we achieved corporate attainment of our goals at 90%. The following was our determination of individual goal attainment in 2014: Mr. Gray, N/A; Mr. Johnson, 100%; and Mr. Burns, 90%. For 2015, the compensation committee has approved corporate-level goals, including continued revenue growth, expansion of our cancer focus and development of related products, enablement and initiation of additional cancer-focused diagnostic collaborations, further establishing Prosigna clinical utility, expanded installed base and increased reimbursement, expansion of addressable market through the development and introduction of new products, achievement of cash position goals and other financial targets and additional stretch targets.

## **Executive Employment Arrangements**

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

We entered into an employment agreement in May 2010 with Mr. Gray, our President and Chief Executive Officer. The employment agreement has no specific term and constitutes at-will employment. For 2015, Mr. Gray's annual base salary is \$475,000, and he is eligible for an annual incentive payment equal to 70% of his base salary, subject to achievement of performance metrics.

Previously, Mr. Gray was eligible for a special annual retention bonus equal to \$52,000 per year, subject to continued employment with us on January 1 of each year through 2014. In 2012, the compensation committee approved a payment of \$104,000 for the acceleration of the unpaid portion of Mr. Gray's annual retention bonus.

In connection with Mr. Gray's commencement of employment, we granted him stock options, or sign-on stock options, covering an aggregate of (1) 241,905 shares subject to time-based vesting and (2) 15,125 shares subject to performance-based vesting. The stock options were granted pursuant to our 2004 Stock Option Plan with an exercise price equal to the per share fair market value of our common stock on the date of grant. All of Mr. Gray's sign-on stock options (other than 89,285 shares subject to time-based vesting) were early-exercisable as to unvested shares, subject to our right to repurchase any unvested shares upon termination of employment for any reason at a repurchase price per share equal to the original purchase price per share. Twenty five percent of Mr. Gray's sign-on time-based stock options vested in June 2011, with the remaining 75% vesting in equal monthly installments over the following three years, until the option fully vested in June 2014. Fifty percent of Mr. Gray's performance-based sign-on stock options vested upon the FDA's final approval of Prosigna in September 2013 and the remaining 50% are scheduled to vest upon the portion of our business achieving profitability, subject to Mr. Gray's continuing service through such vesting date.

If Mr. Gray's employment is terminated other than for cause (as defined in his employment agreement and summarized below), death or disability or he resigns for good reason (as defined in his employment agreement and summarized below), in each case, upon or within 12 months following such change in control, then 100% of the then-unvested portion of the sign-on stock options will vest.

Also, if we terminate his employment other than for cause, death or disability or he resigns for good reason, then subject to his execution of a release of claims and his continued adherence to certain restrictive covenants, he will receive continuing base salary payments for a period of twelve months.

As an incentive to induce Mr. Gray to join us, we provided him an allowance for relocation expenses of up to \$100,000. To the extent that any of the relocation expenses were deemed taxable, we provided a gross-up benefit.

Additionally, in connection with his hiring, we extended to Mr. Gray a full recourse loan of \$115,000 at an annual interest rate equal to 2.72%. The loan was repaid in 2012.

***James A. Johnson***

We entered into an employment agreement in September 2012 with Mr. Johnson, our Chief Financial Officer. The employment agreement has no specific term and constitutes at-will employment. For 2015,

## **Table of Contents**

Mr. Johnson's annual base salary is \$362,000, and he is eligible for an annual incentive payment equal to 50% of his base salary, subject to achievement of performance metrics.

In connection with Mr. Johnson's commencement of employment, we granted him stock options, or sign-on stock options, covering an aggregate of 82,968 shares. The stock options were granted pursuant to our 2004 Stock Option Plan with an exercise price equal to the per share fair market value of our common stock on the date of grant. All of Mr. Johnson's sign-on stock options were early-exercisable as to unvested shares, subject to our right to repurchase any unvested shares upon termination of employment for any reason at a repurchase price per share equal to the original purchase price per share. Twenty-five percent of Mr. Johnson's sign-on stock options vested in September 2013, and the remaining 75% vest in equal monthly installments, until the option is fully vested in September 2016, the fourth anniversary of the vesting commencement date.

In addition and supplementing the vesting schedule described above, in the event that Mr. Johnson's employment is terminated other than for cause (as defined in his employment agreement and summarized below), death or disability or Mr. Johnson resigns for good reason (as defined in his employment agreement and summarized below), in each case, upon or within 12 months following such change in control, then 100% of the then-unvested portion of the sign-on stock options will vest.

Also, if we terminate his employment other than for cause, death or disability or he resigns for good reason, then subject to his execution of a release of claims and his continued adherence to certain restrictive covenants, he will receive continuing base salary payments for a period of six months.

### ***Wayne Burns***

We entered into an employment agreement in June 2009 with Mr. Burns, our Senior Vice President, Operations and Administration. The employment agreement has no specific term and constitutes at-will employment. For 2015, Mr. Burns' annual base salary is \$360,000 and he is eligible for an annual incentive payment equal to 45% of his base salary, subject to achievement of performance metrics.

In connection with Mr. Burns' commencement of employment, we granted him stock options, or sign-on stock options, covering an aggregate of 39,062 shares. The stock options were granted pursuant to our 2004 Stock Option Plan with an exercise price equal to the per share fair market value of our common stock on the date of grant. Twenty five percent of these stock options vested in June 2010, with the remaining 75% vesting in equal monthly installments over the following three years, until the option fully vested in June 2013.

If we terminate his employment other than for cause (as defined in his employment agreement and summarized below), death or disability or he resigns for good reason (as defined in his employment agreement and summarized below), then subject to his execution of a release of claims and his continued adherence to certain restrictive covenants, he will receive continuing base salary payments for a period of twelve months.

### ***Definition of Terms***

For purposes of the 2004 Stock Option Plan, change in control means generally a:

sale of all or substantially all of our assets;

our merger, consolidation or other business combination transaction with or into another corporation, entity or person, other than certain transactions in which a majority of the voting power of our stock continues to hold a majority of the voting power of our stock; or

the direct or indirect acquisition (including by way of a tender or exchange offer) by any person, or persons acting as a group, of beneficial ownership or a right to acquire beneficial ownership of shares representing a majority of the voting power of the then outstanding shares of our capital stock.

**Table of Contents**

For purposes of each of the named executive officers' employment agreements, "cause" means generally:

a violation of one of our material written policies that continues uncured for 30 days;

an act of dishonesty in connection with an executive's responsibilities as our employee;

such executive's conviction of, or plea of nolo contendere to, a felony;

such executive's gross misconduct;

such executive's failure or refusal to follow the lawful and proper directives of the board of directors which are within his duties; or

such executive's material breach of his proprietary information agreement or the non-disparagement provision of his employment agreement.

For purposes of the named executive officers' employment agreements, "good reason" means generally any of the following without such executive's written consent:

a material and permanent diminution in such executive's duties, authority or responsibilities;

a reduction in base salary then in effect by more than 5% (or, for Mr. Gray, more than 10%);

our material breach of such executive's employment agreement; or

a refusal by such executive to relocate to a facility or location more than 40 miles (or, for Mr. Gray, more than 50 miles) from our current location.

To qualify as a resignation for good reason, an executive must provide notice to us within 90 days (or, for Mr. Burns, 30 days) of the initial existence of the condition or event described above and allow us to cure the condition or event within 30 days following our receipt of the notice.

For purposes of Mr. Johnson's sign-on stock option agreement, "cause" means generally:

an executive's failure to substantially perform his duties or responsibilities (other than a failure resulting from his disability) after receiving notice of failure and 10 days to cure;

an executive's commission of any act of fraud, embezzlement, dishonesty or misrepresentation;

an executive's violation of any federal or state law or regulation applicable to our business;

an executive's breach of any confidentiality or invention assignment agreement with us; or

an executive being convicted of, or entering a plea of nolo contendere to, a felony or committing any act of moral turpitude, dishonesty or fraud against us, or the misappropriation of our material property.

The cause determination is made by the board of directors in good faith.

For purposes of Mr. Johnson's sign-on stock option agreement, "good reason" means generally:

the material diminution of an executive's duties; provided that diminution following a change in control solely by virtue of duties occurring at a subsidiary or division level rather than at the parent will not be deemed good reason;

a material reduction in base salary;

a material change in geographic location of where an executive must perform services; or

our material breach of the option agreement.

To qualify as a resignation for good reason, the executive must provide notice to us within 90 days of the initial existence of the condition or event described above and allow us to cure the condition or event within 30 days following our receipt of notice.



**Table of Contents****Outstanding Equity Awards at Fiscal Year-End**

The following table presents information concerning equity awards held by our named executive officers at the end of 2014.

Name	Vesting Commencement Date	Option Awards Number of Securities Underlying Option (#)		Option Exercise Price (\$)	Option Expiration Date
		Exercisable	Unexercisable		
R. Bradley Gray	6/25/2010	130,299(1)(2)		2.24	6/29/2020
	6/25/2010	33,481(2)		2.24	6/29/2020
	6/25/2010	8,370(1)(2)		2.24	6/29/2020
	6/25/2010	15,125(1)(3)		2.24	6/29/2020
	3/01/2012	35,047(1)(5)		1.92	2/28/2022
	3/01/2012	100,541(1)(5)		1.92	2/28/2022
	1/10/2013	68,749(1)(6)		6.72	1/09/2023
James A. Johnson	1/31/2014	26,256(6)	63,744(6)	18.18	1/30/2024
	10/01/2012	82,968(1)(4)		5.12	10/15/2022
	1/10/2013	31,249(1)(6)		6.72	1/09/2023
Wayne Burns	1/31/2014	13,132(6)	31,868(6)	18.18	1/30/2024
	10/15/2009	7,812(4)		1.92	10/14/2019
	3/02/2010	16,093(1)(4)		2.24	3/01/2020
	3/19/2012	34,375(1)(4)		1.92	2/28/2022
	1/10/2013	10,000(1)(6)		6.72	1/09/2023
	1/31/2014	13,132(6)	31,868(6)	18.18	1/30/2023

- (1) The options listed are subject to an early exercise right and may be exercised in full prior to vesting of the shares underlying the option. Vesting of all options is subject to continued service on the applicable vesting date.
- (2) Options vest over four years as follows: 25% of the shares vest one year following the vesting commencement date, with the remaining 75% vesting in equal monthly installments over the following years. Notwithstanding the foregoing, if the named executive officer's employment is terminated other than for cause, death or disability or such named executive officer resigns for good reason, in each case, during the period on, and 12 months after, a change in control, then 100% of the then-unvested shares vest.
- (3) The option vested as to 50% upon the FDA's final approval of Prosigna in September 2013 and the remaining 50% will vest upon the tools portion of our business becoming profitable.
- (4) Options vest over four years as follows: 25% of the shares vest one year following the vesting commencement date, with the remaining 75% vesting in equal monthly installments over the following years. Notwithstanding the foregoing, if the named executive officer is terminated without cause or resigns for good reason, in each case following a change in control, then 100% of the then-unvested shares vest.
- (5) Options vest over four years as follows: 15% of the shares vest on the vesting commencement date, with the remaining 85% vesting in equal monthly installments over the following four years. Notwithstanding the foregoing, if the named executive officer is terminated without cause or resigns for good reason, in each case, following a change in control, then 100% of the then-unvested shares vest.
- (6)

Options vest in equal monthly installments from the vesting commencement date over four years.

Notwithstanding the foregoing, if the named executive officer is terminated without cause or resigns for good reason, in each case, following a change in control, then 100% of the then-unvested shares vest.

**401(k) Plan**

We maintain a tax-qualified retirement plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. All participants' interests in their deferrals are 100% vested when contributed. In 2014, we contributed \$0.4 million into the 401(k) plan as matching contributions. In 2012 and

## **Table of Contents**

2013 we made no matching contributions into the 401(k) plan. Pre-tax contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participant's directions. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Internal Revenue Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan, and all contributions are deductible by us when made.

## **Director Compensation**

### ***Director Compensation Policy***

The compensation committee retained Arnosti Consulting, Inc., a compensation advisory firm, to provide recommendations on director compensation following our initial public offering based on an analysis of market data compiled from certain public technology companies. Based on the recommendation of Arnosti Consulting, Inc., in June 2013, our board of directors approved a director compensation policy for our non-employee directors that became effective following our initial public offering. For purposes of the policy, or the Post-IPO Director Compensation Policy, the board of directors classified each director into one of the two following categories: (1) an employee director, is a director who is employed by us; and (2) a non-employee director, is a director who is not an employee director. Only non-employee directors will receive compensation under the Post-IPO Director Compensation Policy. All directors will be reimbursed for expenses in their capacities as directors in accordance with our standard expense reimbursement policy. Non-employee directors will receive compensation in the form of equity and cash under the Post-IPO Director Compensation Policy, as described below. Certain of our non-employee directors are employees, officers, directors, managers, managing members or general partners of a stockholder of our company or an entity that is an affiliate of such stockholder (excluding our company), and as a result of the internal policies of such stockholder or its affiliates, these directors may be required to hold any compensation received for their service on our board of directors for the benefit of such stockholder or its affiliates.

### ***Equity Compensation***

Upon joining our board of directors, each non-employee director receives an option to purchase 0.08% of our outstanding shares on the date of grant. The exercise price of the initial grant is the fair market value, as determined in accordance with our 2013 Equity Incentive Plan, on the date of the grant. The shares underlying the initial grant vest as to 50% of the total shares subject to such award on the one year anniversary of the date the director commenced services, and the remaining 50% of the total shares vest in 12 equal monthly installments thereafter, in each case, subject to continued service as a director through each vesting date.

At the beginning of each fiscal year, each non-employee director is granted an option to purchase 0.04% of our outstanding shares on the date of grant. The exercise price of this annual grant is the fair market value, as determined in accordance with our 2013 Equity Incentive Plan, on the date of the grant. All of the shares underlying the annual grant vest on the one year anniversary of the date of grant, subject to continued service as a director through the vesting date.

In addition, on July 10, 2013 (the 10th trading day following our initial public offering on June 25, 2013) each non-employee director then serving on the board of directors received an option to purchase 0.06% of our outstanding shares on the date of grant. As an exception to the terms of our 2013 Equity Incentive Plan, the exercise price of this grant was the average closing price of our stock for the 10 trading day period following June 25, 2013. The shares underlying the post-offering grant vested as to 50% of the total shares subject to such award on June 25, 2014, and the remaining 50% of the total shares vest in 12 equal monthly installments thereafter, in each case, subject to continued service as a director through each vesting date.

Also, the chairman of the board of directors received, in addition to the grant discussed in the immediately preceding paragraph, an additional option to purchase 0.05% of our outstanding shares. This additional grant was granted at the same time as and had the same terms and conditions as the post-offering grant.

**Table of Contents**

The vesting of each grant described above accelerates in full upon a change in control as defined in our 2013 Equity Incentive Plan.

*Cash Compensation*

For each fiscal year, each non-employee director receives an annual cash retainer of \$35,000 for serving on the board of directors. In addition to the annual retainer, the chairperson of the board of directors is entitled to an additional cash retainer of \$40,000 per year, and the chairperson of each of the board's three standing committees are entitled to an additional cash retainer of \$10,000 per year.

All cash payments are payable in four equal installments at the end of each calendar quarter during which such individual served as a director (such payments to be prorated for service during a portion of such quarter).

Subsequent to our initial public offering, our board of directors determined that oversight of non-employee director compensation should be a responsibility of its nominating and corporate governance committee. Our board of directors, acting pursuant to the recommendation of its nominating and corporate governance committee, revised cash compensation levels for non-employee directors serving as chairman of each of the board of directors' audit committee, compensation committee and nominating and corporate governance committee, and established cash compensation levels for non-employee directors serving on such committees. The changes will become effective as of the date of our 2015 annual meeting of stockholders.

The following table summarizes the revised non-employee director cash compensation levels approved by our board of directors:

<b>Position</b>	<b>Compensation</b>
Audit Committee, Chairman	\$ 15,000
Audit Committee, Member	7,500
Compensation Committee, Chairman	12,000
Compensation Committee, Member	6,000
Nominating and Corporate Governance Committee, Chairman	10,000
Nominating and Corporate Governance Committee, Member	5,000

The following table sets forth information concerning the compensation paid or accrued for services rendered to us by members of the board of directors for the year ended December 31, 2014. Compensation paid or accrued for services rendered to us by Mr. Gray in his role as chief executive officer is included in our disclosures related to executive compensation in the section of this report captioned Executive Compensation.

<b>Name</b>	<b>Fees Earned or paid in Cash (\$)</b>	<b>Option Awards (\$)(1)</b>	<b>Total (\$)</b>
William D. Young	75,000	55,973	130,973
Bradford Crutchfield(2)	29,008	55,973	84,981
Jennifer Scott Fonstad(3)	17,500	55,973	73,473
Nicholas Galakatos	45,000	55,973	100,973
Finny Kuruvilla(4)	17,500	55,973	73,473
Gregory Norden	45,000	55,973	100,973

Edgar Filing: NanoString Technologies Inc - Form 10-K

Tina Nova(5)	7,104	132,257	139,361
Charles P. Waite	45,000	55,973	100,973

- (1) Represents the aggregate grant date fair value of stock option awards granted in 2014. These amounts have been computed in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718, using the Black-Scholes option pricing model without regard to estimated forfeitures. For a discussion of valuation assumptions, see the notes to our financial statements included elsewhere in this report.

-114-

**Table of Contents**

- (2) Mr. Crutchfield resigned from the board of directors in October 2014.
- (3) Ms. Fonstad did not stand for reelection to the board of directors at our 2014 annual meeting of stockholders and ceased to be a member of the board of directors in July 2014.
- (4) Dr. Kuruvilla did not stand for reelection to the board of directors at our 2014 annual meeting of stockholders and ceased to be a member of the board of directors in July 2014.
- (5) Dr. Nova was appointed to the board of directors in April 2014 and resigned from the board of directors in July 2014.

For further information regarding the equity compensation of our non-employee directors, see the section titled Executive Compensation Employee Benefit and Stock Plans.

**Compensation Committee Interlocks and Insider Participation**

During 2014, the members of our compensation committee included Dr. Galakatos, Ms. Fonstad, Dr. Nova and Mr. Waite. The current members of our compensation committee are Dr. Galakatos and Mr. Waite. None of the members of our compensation committee is or has been an officer or employee of us. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee (or other board committee performing equivalent functions or, in the absence of any such committee, the entire board of directors) of any entity that has one or more executive officers serving on our board of directors or compensation committee. We are a party to certain transactions with significant stockholders affiliated with Dr. Galakatos and Mr. Waite as described in the section of this report captioned Certain Relationships and Related Party Transactions and Director Independence.

**Compensation Committee Report**

The compensation committee has reviewed and discussed the section captioned Executive Compensation, included in this Annual Report on Form 10-K, with management and, based on such review and discussion, the compensation committee has recommended to our board of directors that this Executive Compensation section be included in this Annual Report on Form 10-K.

Respectfully submitted by the members of the compensation committee of the board of directors:

Dr. Nicholas Galakatos, Chairman

Charles P. Waite

**Table of Contents****Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters****Securities Authorized for Issuance Under Equity Compensation Plans**

The following table summarizes information about our equity compensation plans as of December 31, 2014. All outstanding awards relate to our common stock.

<b>Plan Category</b>	<b>(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</b>	<b>(b) Weighted Average Exercise Price of Outstanding Options, Warrants and Rights</b>	<b>(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))<sup>1</sup></b>
Equity compensation plans approved by security holders:			
2004 Stock Option Plan	1,551,354	3.147	
2013 Equity Incentive Plan	1,743,468	16.055	543,816
2013 Employee Stock Purchase Plan		N.A.	286,062
Equity compensation plans not approved by security holders:			
		N.A.	
<b>Total</b>	<b>3,294,822</b>	<b>N.A.</b>	<b>829,878</b>

- (1) Our 2013 Equity Incentive Plan includes provisions providing for an annual increase in the number of securities available for future issuance on the first day of each fiscal year, equal to the least of: (a) 1,406,250 shares; (b) 5% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; and (c) such other amount as the board of directors may determine. Our 2013 Employee Stock Purchase Plan includes provisions providing for an annual increase in the number of securities available for future issuance on the first day of each fiscal year, equal to the least of: (a) 1% of the outstanding shares of common stock on the first day of such fiscal year; (b) 281,250 shares; and (c) such other amount as the board of directors, or a committee appointed by the board of directors, may determine.

**Principal Stockholders**

The following table sets forth certain information with respect to the beneficial ownership of our common stock at March 2, 2015 for:

each person who we know beneficially owns more than 5% of our common stock;



each of our directors;

each of our named executive officers; and

all of our directors and executive officers as a group.

The percentage of beneficial ownership shown in the table is based upon 18,360,219 shares outstanding as of March 2, 2015.

Information with respect to beneficial ownership has been furnished by each director, executive officer or beneficial owner of more than 5% of our common stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules take into account shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before the 60th day after March 2, 2015. Certain of the options granted to our named executive officers may be exercised prior to the vesting of the

**Table of Contents**

underlying shares. We refer to such options as being early exercisable. Shares of common stock issued upon early exercise are subject to our right to repurchase such shares until such shares have vested. These shares are deemed to be outstanding and beneficially owned by the person holding those options or a warrant for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for each person or entity listed in the table is c/o NanoString Technologies, Inc., 530 Fairview Avenue, N., Suite 2000, Seattle, Washington 98109.

Name of Beneficial Owner	Common Stock Beneficially Owned	
	Shares	Percentage
<b>5% Stockholders:</b>		
Entities affiliated with Clarus Funds(1)	4,121,848	22.3
Entities affiliated with DFJ Funds(2)	1,864,010	10.1
Entities affiliated with OVP Funds(3)	1,640,884	8.9
Entities affiliated with Redmile Group, LLC(4)	1,266,538	6.9
Entities affiliated with Deerfield Management Company, L.P.(5)	923,378	5.0
<b>Directors and Named Executive Officers:</b>		
R. Bradley Gray(6)	517,211	2.8
Wayne Burns(7)	116,107	*
James A. Johnson(8)	133,061	*
William D. Young(9)	86,352	*
Nicholas Galakatos, Ph.D.(10)	4,135,732	22.3
Robert M. Hershberg, M.D., Ph.D.(11)		*
Gregory Norden(12)	20,821	*
Charles P. Waite(13)	1,654,768	9.0
All directors and executive officers as a group (12 persons)(14)	6,874,746	35.1

(\*) Less than one percent.

(1) Includes 3,959,440 shares held and 162,408 shares that may be acquired pursuant to the exercise of warrants held of record by Clarus Lifesciences II, L.P. ( Clarus ). Clarus Ventures II GP, L.P. (the GPLP ), as the sole general partner of Clarus, may be deemed to beneficially own certain of the shares held of record by Clarus. The GPLP disclaims beneficial ownership of all shares held of record by Clarus in which the GPLP does not have an actual pecuniary interest. Clarus Ventures II, LLC (the GPLLC ), as the sole general partner of the GPLP, may be deemed to beneficially own certain of the shares held of record by Clarus. The GPLLC disclaims beneficial ownership of all shares held of record by Clarus in which it does not have an actual pecuniary interest. Each of Nicholas Galakatos, a member of the board of directors, and Messrs. Henner, Liptak, Simon, Steinmetz and Wheeler, as individual Managing Directors of the GPLLC, may be deemed to beneficially own certain of the shares held of record by Clarus. Each of Messrs. Galakatos, Henner, Liptak, Simon, Steinmetz and Wheeler disclaims beneficial ownership of all shares held of record by Clarus in which he does not have an actual

pecuniary interest. The address of Clarus Lifesciences is 101 Main Street, Suite 1210, Cambridge, Massachusetts 02142.

- (2) Includes (a) 1,703,722 shares held and 85,728 shares that may be acquired pursuant to the exercise of warrants held of record by Draper Fisher Jurvetson Fund VII, L.P., (b) 32,154 shares held of record by Draper Associates, L.P., (c) 24,847 shares held and 1,249 shares that may be acquired pursuant to the exercise of warrants held of record by Draper Fisher Jurvetson Partners VII, LLC, (d) 12,002 shares held and 1,923 shares that may be acquired pursuant to the exercise of warrants held of record by Draper Associates Riskmasters Fund II, LLC and (e) 1,989 shares held and 396 shares that may be acquired

**Table of Contents**

- pursuant to the exercise of warrants held of record by Draper Associates Riskmasters Fund, LLC. Timothy C. Draper, John H.N. Fisher and Steven T. Jurvetson are Managing Directors of the general partner entities of Draper Fisher Jurvetson Fund VII, L.P. ( Fund VII ) that directly hold shares and as such, they may be deemed to have voting and investment power with respect to such shares. Draper Fisher Jurvetson Partners VII, LLC ( Partners VII ) invests lockstep alongside Fund VII. The Managing Members of Partners VII are Timothy C. Draper, John H.N. Fisher and Steven T. Jurvetson. Draper Associates, L.P. ( DALP ) invests lockstep alongside Fund VII. The General Partners of DALP is Draper Associates, Inc. which is controlled by its President and majority shareholder, Timothy C. Draper. Draper Associates Riskmasters Fund, LLC ( DARF ) and Draper Associates Riskmasters Fund II, LLC ( DARF II ) invest lockstep alongside Fund VII, instead and in place of DALP beginning June 2010. The Managing Member of DARF and DARF II is Timothy C. Draper. These individuals disclaim beneficial ownership with respect to such shares except to the extent of their pecuniary interest therein. The address of each of the entities affiliated with Draper Fisher Jurvetson is 2882 Sand Hill Road, Suite 150, Menlo Park, California 94025.
- (3) Includes (a) 1,063,775 shares held by OVP Venture Partners VI, L.P. ( OVP VI ), (b) 472,221 shares held and 103,404 shares that may be acquired pursuant to the exercise of warrants held of record by OVP Venture Partners VII, L.P. ( OVP VII ) and (c) 1,484 shares held by OVP VII Entrepreneurs Fund, L.P. ( OVP VII Entrepreneurs Fund, and together with OVP VI and OVP VII, OVP Venture Partners ). Charles P. Waite, a member of the board of directors, is a managing member of OVMC VI, LLC, the general partner of each of OVP VI and OVP VI Entrepreneurs Fund, and a managing member of OVMC VII, LLC, the general partner of each of OVP VII and OVP VII Entrepreneurs Fund. Mr. Waite, together with the other managing members of OVMC VI, LLC and OVMC VII, LLC are deemed to have shared voting and dispositive power over the shares held by OVP VI, OVP VII, OVP VI Entrepreneurs Fund and OVP VII Entrepreneurs Fund. These individuals disclaim beneficial ownership with respect to such shares except to the extent of their pecuniary interest therein. The address of each of the entities affiliated with OVP Venture Partners is C/O OVP Venture Partners 11023 NE 116th St., Kirkland, WA 98034.
- (4) Based solely on the most recently available Schedule 13G filed with the SEC on February 18, 2015, consists of shares held by certain investment limited partnerships, pooled investment vehicles, etc. for which Redmile Group, LLC, ( Redmile ) serves as the general partner and/or investment manager. Redmile, as the general partner and/or investment manager, and Jeremy Green, as the majority managing member and owner of Redmile, may be deemed to beneficially own such shares insofar as they may be deemed to have the power to direct the voting or disposition of the shares. Each of Redmile and Jeremy Green disclaims beneficial ownership of such shares, except to the extent of his or its pecuniary interests therein. The address of Redmile is One Letterman Drive, Building D, Suite D3-300, San Francisco, CA 94111.
- (5) Based solely on the most recently available Schedule 13G/A filed with the SEC on February 17, 2015, consists of shares held by Deerfield Special Situations Fund, L.P. and Deerfield Special Situations International Master Fund, L.P. Deerfield Management Company, L.P. is the investment advisor and Deerfield Mgmt, L.P. is the general partner of each of Deerfield Special Situations Fund, L.P. and Deerfield Special Situations International Master Fund, L.P. Deerfield Management Company, L.P., Deerfield Mgmt, L.P., and James E. Flynn may be deemed to beneficially own such shares insofar as they may be deemed to have the power to direct the voting or disposition of the shares. The address of each of the foregoing entities is 780 Third Avenue, 37<sup>th</sup> Floor, New York, NY 10017.
- (6) Includes 93,301 shares held and options to purchase 423,910 shares of common stock that are exercisable within 60 days of March 2, 2015, of which 373,642 shares are vested as of such date.
- (7) Includes 33,027 shares held and options to purchase 83,080 shares of common stock that are exercisable within 60 days of March 2, 2015, of which 74,616 shares are vested as of such date.
- (8) Includes 2,898 shares held and options to purchase 130,163 shares of common stock that are exercisable within 60 days of March 2, 2015, of which 85,378 shares are vested as of such date.
- (9)

Edgar Filing: NanoString Technologies Inc - Form 10-K

Consists of options to purchase 86,352 shares of common stock that are exercisable within 60 days of March 2, 2015, all of which are vested as of such date.

- (10) Includes the shares held of record by Clarus described in footnote 1 and options to purchase 13,884 shares of common stock that are exercisable within 60 days of March 2, 2015, all of which are vested as of such date.

---

**Table of Contents**

- (11) Dr. Hershberg joined the board in March 2015. He received an option to purchase 14,688 shares of common stock on March 2, 2015 at an exercise price of \$11.20 per share, none of which are exercisable within 60 days of March 2, 2015.
- (12) Consists of options to purchase 20,821 shares of common stock that are exercisable within 60 days of March 2, 2015, all of which are vested as of such date.
- (13) Includes the shares held of record by OVP Venture Partners described in footnote 3 and options to purchase 13,884 shares of common stock that are exercisable within 60 days of March 2, 2015, all of which are vested as of such date.
- (14) Includes 5,633,542 shares held, 265,812 shares that may be acquired pursuant to the exercise of warrants held of record and options to purchase 975,392 shares of common stock that are exercisable within 60 days of March 2, 2015, of which 837,584 shares are vested as of such date.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

In addition to the arrangements described below, we have also entered into the arrangements which are described where required in the section of this report captioned Part III Item 11 Executive Compensation Executive Employment Arrangements .

***Related Party Transaction Policy***

We have adopted a formal, written policy that our executive officers, directors (including director nominees), holders of more than 5% of any class of our voting securities, and any member of the immediate family of or any entities affiliated with any of the foregoing persons, are not permitted to enter into a related party transaction with us without the prior approval or, in the case of pending or ongoing related party transactions, ratification of our audit committee. For purposes of our policy, a related party transaction is a transaction, arrangement or relationship where we were, are or will be involved and in which a related party had, has or will have a direct or indirect material interest, other than transactions available to all of our United States employees.

Certain transactions with related parties, however, are excluded from the definition of a related party transaction including, but not limited to: (1) transaction with another company at which a related party's only relationship is as an employee (excluding as an executive officer or a director) or beneficial owner of less than 5% of that company's shares; (2) transaction where the related party's interest arises solely from the ownership of our equity securities and all holders of our common stock received the same benefit on a pro rata basis (e.g. dividends); (3) transactions available to all employees generally; (4) transactions involving the purchase or sale of products or services in the ordinary course of business, not exceeding \$20,000; and (5) transactions in which the related party's interest derives solely from his or her service as a director, trustee or officer (or similar position) of a not-for-profit organization or charity that receives donations from the Company.

No member of the audit committee may participate in any review, consideration or approval of any related party transaction where such member or any of his or her immediate family members is the related party. In approving or rejecting the proposed agreement, our audit committee shall consider the relevant facts and circumstances available and deemed relevant to the audit committee, including, but not limited to: (1) the benefits and perceived benefits, or lack thereof, to our company; (2) the impact on a director's independence in the event the related party is a director, an immediate family member of a director or an entity in which a director is a partner, stockholder or executive officer; (3) the materiality and character of the related party's direct and indirect interest; (4) the actual or apparent conflict of interest of the related party; (5) the availability of other sources for comparable products or services; (6) the opportunity costs of alternative transactions; (7) the terms of the transaction; (8) the commercial reasonableness of the terms of the proposed transaction; and (9) terms available to unrelated third parties or to employees under the same or

similar circumstances. In reviewing proposed related party transactions, the audit committee will only approve or ratify related party transactions that are in, or not inconsistent with, the best interests of our company and stockholders, as the audit committee determines in good faith.

**Table of Contents**

Except for the purchase of shares of our common stock in connection with our initial public offering by certain of our directors and 5% stockholders, the transactions described below were consummated prior to our adoption of the formal, written policy described above and therefore the foregoing policies and procedures were not followed with respect to the transactions. However, we believe that the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described were comparable to terms available or the amounts that would be paid or received, as applicable, in arm's-length transactions.

***Sales of Securities***

The following table sets forth a summary of the sale and issuance of our securities to related persons since January 1, 2014, other than compensation arrangements which are described under the section of this report captioned "Executive Compensation," in which the amount involved exceeded \$120,000. For a description of beneficial ownership see the section of this report captioned "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters - Principal Stockholders."

<b>Purchaser</b>	<b>Common Stock</b>
<b>Executive Officers, Directors and Promoters:</b>	
Barney Saunders, Ph.D.(1)	59,190

- (1) Consists of (a) 30,000 shares of common stock upon exercise of stock options in December 2014 at a price of \$2.24 per share; (b) 17,764 shares of common stock upon exercise of stock options in June 2014 at a price of \$1.92 per share; (c) 10,236 shares of common stock upon exercise of stock options in June 2014 at a price of \$2.24 per share; and (d) 1,190 shares of common stock upon an ESPP distribution in September 2014 at a price of \$6.6215 per share.

***Investors' Rights Agreement***

We have entered into an investors' rights agreement with certain holders of our common stock and warrants to purchase our common stock, including entities affiliated with Clarus Ventures, entities affiliated with OVP Venture Partners and entities affiliated with Draper Fisher Jurvetson. As of March 2, 2015, the holders of approximately 6.8 million shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act.

***Indebtedness of Directors and Officers***

None of our current or former directors or executive officers is indebted to us, nor are any of these individuals indebted to another entity which indebtedness is the subject of a guarantee, support agreement, letter of credit or other similar arrangement or understanding provided by us.

***Other Transactions***

We have entered into separate indemnification agreements with each of our directors and certain of our officers.

We have granted stock options and other equity awards pursuant to our 2013 Equity Incentive Plan to our named executive officers, other executive officers and certain of our directors.



Certain of our executive officers are participants in our 2013 Employee Stock Purchase Plan.

**Director Independence**

Under the rules of The NASDAQ Global Market, independent directors must comprise a majority of a listed company's board of directors. In addition, the rules of The NASDAQ Global Market require that, subject to

**Table of Contents**

specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent within 12 months following completion of a listed company's initial public offering. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended. Under the rules of The NASDAQ Global Market, a director will only qualify as an independent director if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

To be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries.

Our board of directors has undertaken a review of its composition, the composition of its committees and the independence of directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, the board of directors has determined that none of Messrs. Young, Waite and Norden and Drs. Galakatos and Hershberg, representing five of our six directors, has a relationship which would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is an independent director as defined under the rules of The NASDAQ Global Market. The board of directors also determined that Messrs. Norden (chairman), Waite and Young, who comprise our audit committee, Dr. Galakatos (chairman) and Mr. Waite, who comprise our compensation committee, and Messrs. Waite (chairman), Young and Drs. Galakatos and Hershberg, who comprise our nominating and corporate governance committee, satisfy the independence standards for those committees established by applicable SEC rules and the rules of The NASDAQ Global Market.

In making this determination, the board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances the board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

**Item 14. Principal Accountant Fees and Services**

The following table summarizes the fees of PricewaterhouseCoopers LLP, our independent registered public accounting firm, for 2014 and 2013.

Fee Category	Year Ended December 31,	
	2014	2013
Audit fees (1)	\$ 610,074	\$ 747,055
Audit-related fees		
Tax fees	19,700	24,449
All other fees (2)	6,200	1,800
<b>Total fees</b>	<b>\$ 635,974</b>	<b>\$ 773,304</b>

- (1) Audit fees consist of fees for professional services provided in connection with the audit of our annual consolidated financial statements, review of our quarterly consolidated financial statements and our initial public and follow-on offerings.
- (2) All other fees include any fees billed that are not audit, audit related, or tax fees. In 2014 and 2013, these fees related to accounting research software.

**Table of Contents**

**Pre-Approval Policies and Procedures**

Pursuant to its charter, the audit committee must review and approve, in advance, the scope and plans for the audits and the audit fees and approve in advance (or, where permitted under the rules and regulations of the SEC, subsequently) all non-audit services to be performed by the independent auditor that are not otherwise prohibited by law and any associated fees. The audit committee may delegate to one or more members of the committee the authority to pre-approve audit and permissible non-audit services, as long as this pre-approval is presented to the full committee at scheduled meetings. In accordance with the foregoing, the committee has delegated to the chair of the audit committee the authority to pre-approve services to be performed by our independent registered public accounting firm and associated fees, provided that the chair is required to report any decision to pre-approve such audit-related or non-audit services and fees to the full audit committee for ratification at its next regular meeting.

**Table of Contents**

**PART IV**

**Item 15. Exhibits, Financial Statement Schedules**

(a)(1) Financial Statements The financial statements filed as part of this Annual Report on Form 10-K are listed on the Index to Consolidated Financial Statements in Item 8.

(a)(2) Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or the notes thereto.

(a)(3) Exhibits

The exhibits required by Item 601 of Regulation S-K are listed in paragraph (b) below.

(b) Exhibits.

The exhibits listed on the Exhibit Index (following the Signatures section of this report) are filed herewith or are incorporated by reference to exhibits previously filed with the SEC.

Table of Contents**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 13, 2015

**NANOSTRING TECHNOLOGIES, INC.**

By: /s/ R. Bradley Gray  
R. Bradley Gray  
President and Chief Executive Officer

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints R. Bradley Gray and James A. Johnson, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file, any and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their and his or her substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1934, this Annual Report on Form 10-K has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ R. Bradley Gray R. Bradley Gray	President, Chief Executive Officer and Director (Principal Executive Officer)	March 13, 2015
/s/ James A. Johnson James A. Johnson	Chief Financial Officer (Principal Accounting and Financial Officer)	March 13, 2015
/s/ William D. Young William D. Young	Chairman of the Board of Directors	March 13, 2015
/s/ Nicholas Galakatos Nicholas Galakatos	Director	March 13, 2015
/s/ Robert M. Hershberg Robert M. Hershberg	Director	March 13, 2015

/s/ Gregory Norden

Director

March 13, 2015

Gregory Norden

/s/ Charles P. Waite

Director

March 13, 2015

Charles P. Waite

-124-

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>	<b>Incorporated by Reference</b>			
		<b>Form</b>	<b>File No.</b>	<b>Exhibit</b>	<b>Filing Date</b>
3.1	Amended and Restated Certificate of Incorporation of the Registrant	10-Q	001-35980	3.1	August 8, 2013
3.2	Amended and Restated Bylaws of the Registrant	10-Q	001-35980	3.2	August 8, 2013
4.1	Specimen Common Stock Certificate of the Registrant.	S-1/A	333-188704	4.1	June 13, 2013
4.2	Amended and Restated Investors Rights Agreement, dated November 29, 2012, by and among the Registrant and the investors named therein.	S-1	333-188704	4.2	May 20, 2013
4.3	Amendment to Amended and Restated Investors Rights Agreement, dated December 20, 2012, by and among the Registrant and the investors named therein.	S-1	333-188704	4.3	May 20, 2013
4.4	Warrant to purchase Series B Preferred Stock, issued to lender under Registrant's prior credit facility on October 1, 2007.	S-1	333-188704	4.4	May 20, 2013
4.5	Warrant to purchase Series C Preferred Stock, issued to lender under Registrant's prior credit facility on November 8, 2010.	S-1	333-188704	4.5	May 20, 2013
4.6	Form of amended and restated warrant to purchase shares of Series D Preferred Stock, issued to investors on June 23, 2011 and September 26, 2011 in connection with the Registrant's 2011 bridge financing.	S-1	333-188704	4.6	May 20, 2013
4.7	Form of warrant to purchase shares of Series D Preferred Stock, issued to the investors on November 1, 2011 and December 28, 2011 in connection with the Registrant's preferred stock and warrant financing.	S-1	333-188704	4.7	May 20, 2013
4.8	Form of warrant to purchase Series D Preferred Stock, issued to lenders on March 30, 2012 and December 10, 2012 under Registrant's March 2012 credit facility.	S-1	333-188704	4.8	May 20, 2013
4.9	Form of warrant to purchase Series E Preferred Stock, issued to lenders on December 31, 2012 and April 30, 2013 in connection with the amendments of the Registrant's March 2012 credit facility.	S-1	333-188704	4.9	May 20, 2013



Edgar Filing: NanoString Technologies Inc - Form 10-K

10.1	Form of Director and Executive Officer Indemnification Agreement.	S-1/A	333-188704	10.1	June 13, 2013
10.2	2004 Stock Option Plan, as amended.	S-1	333-188704	10.2	May 20, 2013
10.3	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2004 Stock Option Plan, as amended.	S-1	333-188704	10.3	May 20, 2013

**Table of Contents**

<b>Exhibit</b>	<b>Description</b>	<b>Incorporated by Reference</b>			
		<b>Form</b>	<b>File No.</b>	<b>Exhibit</b>	<b>Filing Date</b>
10.4	Form of Notice of Stock Option Grant and Stock Option Agreement permitting early exercise under the 2004 Stock Option Plan, as amended.	S-1	333-188704	10.4	May 20, 2013
10.5	2013 Equity Incentive Plan.	S-1/A	333-188704	10.5	June 13, 2013
10.6	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2013 Equity Incentive Plan.	S-1/A	333-188704	10.6	June 13, 2013
10.7	Form of Notice of Restricted Stock Grant and Restricted Stock Agreement under the 2013 Equity Incentive Plan.	S-1/A	333-188704	10.7	June 13, 2013
10.8	Form of Notice of Restricted Stock Unit Grant and Restricted Stock Unit Agreement under the 2013 Equity Incentive Plan.	S-1/A	333-188704	10.8	June 13, 2013
10.9	2013 Employee Stock Purchase Plan.	S-1/A	333-188704	10.9	June 13, 2013
10.10+	Employment Agreement, dated May 24, 2010, between the Registrant and R. Bradley Gray.	S-1	333-188704	10.8	May 20, 2013
10.11+	Employment Agreement, dated September 7, 2012, between the Registrant and Jim Johnson.	S-1	333-193322	10.11	January 13, 2014
10.12+	Employment Agreement, dated March 31, 2012, between the Registrant and Joseph Beechem, as amended on December 27, 2012.	S-1	333-193322	10.12	January 13, 2014
10.13*+	Employment Agreement, dated June 8, 2009, between the Registrant and Wayne Burns, as amended on February 5, 2010 and December 28, 2012.				
10.14*	Lease between the Registrant and BMR-530 Fairview Avenue LLC, dated October 19, 2007, as amended through December 22, 2014.				
10.15*	Lease between the Registrant and BMR-500 Fairview Avenue LLC, dated December 22, 2014.				
10.16*	Lease between the Registrant and Blume Roy Building LLC, dated December 26, 2013, as amended on December 22, 2014.				
10.17	Term Loan Agreement dated April 1, 2014 among the Registrant and certain of the Registrant's subsidiaries and Capital Royalty Partners II L.P., Capital Royalty Partners II Parallel Fund A L.P. and Parallel Investment Opportunities Partners II L.P. and forms	10-Q	001-35980	10.1	August 8, 2014

of promissory note and PIK loan note to be issued thereunder.

**Table of Contents**

<b>Exhibit</b>	<b>Description</b>	<b>Incorporated by Reference</b>			
		<b>Form</b>	<b>File No.</b>	<b>Exhibit</b>	<b>Filing Date</b>
10.18	Security Agreement dated April 17, 2014 among the Registrant and certain of the Registrant's subsidiaries and Capital Royalty Partners II L.P., Capital Royalty Partners II Parallel Fund A L.P. and Parallel Investment Opportunities Partners II L.P. and form of joinder agreement to be issued thereunder.	10-Q	001-35980	10.2	August 8, 2014
10.19	Exclusive License Agreement, dated February 4, 2004, between the Registrant and The Institute for Systems Biology.	S-1	333-188704	10.19	May 20, 2013
10.20	Amendment No. 1 to Exclusive License Agreement, dated February 5, 2007, between the Registrant and The Institute for Systems Biology.	S-1	333-188704	10.20	May 20, 2013
10.21	Amendment No. 2 to Exclusive License Agreement, dated May 17, 2007, between the Registrant and The Institute for Systems Biology.	S-1	333-188704	10.21	May 20, 2013
10.22	Amended and Restated Exclusive License Agreement, effective July 7, 2010, between the Registrant and Bioclassifier, LLC.	S-1	333-188704	10.22	May 20, 2013
21.1	List of subsidiaries of the Registrant.	10-K	001-35980	21.1	March 27, 2014
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.				
24.1*	Powers of Attorney (contained on signature page).				
31.1*	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.				
31.2*	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.				
32.1*	Certification of Principal Executive Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.				
32.2*	Certification of Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.				
101.INS**	XBRL Instance Document.				
101.SCH**	XBRL Taxonomy Extension Schema Document.				
101.CAL**					

XBRL Taxonomy Extension Calculation Linkbase  
Document.

**Table of Contents**

<b>Exhibit</b>	<b>Description</b>	<b>Incorporated by Reference</b>			
		<b>Form</b>	<b>File No.</b>	<b>Exhibit</b>	<b>Filing Date</b>
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document.				

\* Filed herewith.

\*\* XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not otherwise subject to liability under these Sections.

+ Indicates a management contract or compensatory plan.

Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.