NanoString Technologies Inc
Form 10-K
March 13, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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	**20-0094687**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
530 Fairview Avenue North, Suite 2000	
Seattle, Washington	**98109**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

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

None

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

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

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

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

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

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 x
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 x

The aggregate market value of the voting and non-voting stock held by non-affiliates of the Registrant, based on the closing sale price of the Registrant s common stock on the last business day of its most recently completed second fiscal quarter, as reported on The NASDAQ Global Market, was approximately $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.

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NANOSTRING TECHNOLOGIES, INC.

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2014

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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.

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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

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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 Elements™. 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

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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.

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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.

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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.

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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.

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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.

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.

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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

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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

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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.

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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,

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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

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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.

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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 Onco*type* DX, a service for gene expression analysis performed in its central laboratory in Redwood City, California. We also face

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competition from companies such as Agendia, Clarient (a GE Healthcare company), and bioMeriéux, 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

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

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.

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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 patients risk and or distant recurrence.

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

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.

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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.

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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 MolDX 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 MolDX 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 MolDX program is the technology assessment and medical policy review process currently employed by Palmetto for North Carolina, South Carolina, Virginia, and West Virginia and by Noridian for California, Nevada, and Hawaii (Noridian has not published a MolDX decision for the other states under their Medicare contract: Washington, Oregon, Idaho, Utah, Arizona, Montana, Wyoming, North Dakota, and South Dakota). Determination of the Medicare contractor responsible for a laboratory claim is based on the location of the laboratory (not patient location). The laboratories performing Prosigna testing for Quest Diagnostics and Laboratory Corporation of America are within the jurisdiction of the MolDX program. The MolDX program requires providers to follow a unique and specific path to obtain an LCD.

The MolDX program has contracted with McKesson to create unique identifiers or codes for unique lab tests. A McKesson Z-Code Identifier is a unique code associated with a specific advanced diagnostic test. Z-codes are reported to the payor along with the appropriate CPT codes, which potentially improves the efficiencies in the reimbursement process. Z-code identifiers are currently only required by the MACs associated with the MolDX program, Palmetto and Noridian. Laboratories under the MolDX program cannot submit claims for Prosigna until a Z-code is available and a Medicare LCD has been published. A Z-code Identifier was issued for Prosigna in February 2014. We continue to be in dialogue with representatives of MolDX, regarding our LCD application for 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 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 MolDX 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.

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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

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

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.

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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

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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.

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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.

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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

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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, Clarient (a GE Healthcare company), Genoptix (a division of Novartis) and bioMeriéux, which also offer services by means of centralized laboratories that profile gene or protein expression in breast cancer. In Europe, we also face regional competition from 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.

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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

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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

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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

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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

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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;

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- 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

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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

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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.

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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.

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

Before we begin to label and market our products for use as clinical diagnostics in the United States, thereby subjecting them to FDA regulation as medical devices, unless an exemption applies, we are required to obtain either prior 510(k) clearance or prior pre-market approval, or PMA, from the FDA. In September 2013, we received FDA 510(k) clearance for Prosigna as a prognostic indicator for distant recurrence-free survival at 10 years in post-menopausal women with Stage I/II lymph node-negative or Stage II lymph node-positive (1 3 positive nodes) hormone receptor-positive breast cancer who have undergone surgery in conjunction with locoregional treatment and consistent with standard of care. 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.

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

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.

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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

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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.

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

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

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

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

We have not yet registered certain of our trademarks 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

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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,

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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.

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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;

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failure to obtain or delays in obtaining product approvals or clearances from the FDA or foreign regulators;

adverse regulatory or reimbursement announcements;

issuance of new or changed securities analysts reports or recommendations for our stock;

developments or disputes concerning our intellectual property or other proprietary rights;

commencement of, or our involvement in, litigation;

market conditions in the 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.

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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);

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

provide that stockholders 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

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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.

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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.

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PART II

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

Market Information

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

Year ended December 31, 2013	High	Low
Second quarter (beginning June 26, 2013)	$ 9.90	$ 7.81
Third quarter	$ 14.10	$ 7.01
Fourth quarter	$ 18.09	$ 8.64
Year ended December 31, 2014		
First quarter	$ 22.44	$ 16.28
Second quarter	$ 21.87	$ 12.03
Third quarter	$ 15.45	$ 10.81
Fourth quarter	$ 15.28	$ 7.80
Year ending December 31, 2015		
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.

Holders

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.

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Performance Graph

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

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.

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Item 6. Selected Financial Data

The following selected financial data is derived from our audited financial statements and should be read in conjunction with, and is qualified in its entirety by, Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations, and Item 8, Financial Statements and Supplementary Data. contained elsewhere in this Annual Report on Form 10-K. The selected Consolidated Statements of Operations data for the years ended December 31, 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.

	Year Ended December 31,				
	2014	2013	2012	2011	2010
	(In thousands, except per share amounts)				
Consolidated Statements of Operations:					
Revenue	$ 47,593	$ 31,403	$ 22,973	$ 17,800	$ 11,730
Costs and expenses:					
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
Total costs and expenses	93,616	59,900	39,482	28,296	24,702
Loss from operations	(46,023)	(28,497)	(16,509)	(10,496)	(12,972)
Other income (expense):					
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