NanoString Technologies Inc
Form 10-K
March 11, 2016
Table of Contents

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, 2015

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	**(I.R.S. Employer**
incorporation or organization)	**Identification Number)**
530 Fairview Avenue North	
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 $212.1 million. Shares of common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the Registrant, have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

There were 19,639,075 shares of the Registrant s common stock, $0.0001 par value per share, outstanding on March 1, 2016.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Table of Contents

NANOSTRING TECHNOLOGIES, INC.

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2015

TABLE OF CONTENTS

Table of Contents

Special Note Regarding Forward-Looking Information

This Annual Report on Form 10-K, including the Management s Discussion and Analysis of Financial Condition and Results of Operation section in Item 7, and other materials accompanying this Annual Report on Form 10-K contain forward-looking statements that are based on our management s beliefs and assumptions and on information currently available. The statements contained in this Annual Report on Form 10-K that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended.

Forward-looking statements are identified by words such as believe, anticipate, expect, intend, plan, will, m other similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other forward-looking information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements include, but are not limited to:

- our expectations regarding our future operating results, including our expectations regarding instrument, consumable and total revenue, operating expenses and operating and net loss;
- 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 ability to successfully commercialize Prosigna, our first *in vitro* diagnostic product;
- our ability to realize the potential payments set forth in our collaboration agreements;
- our strategic relationships, including with patent holders of our technologies, manufacturers and distributors of our products, collaboration partners and third parties who conduct our clinical studies;
- our intellectual property position;
- our expectations regarding the market size and growth potential for our business; and
- our ability to sustain and manage growth, including our ability to develop new products and enter new markets.

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

Table of Contents

PART I

Item 1. Business

Overview

We develop, manufacture and sell robust, intuitive products that unlock scientifically valuable and clinically actionable biologic 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, 2015, we have an installed base of over 350 systems, which our customers have used to publish more than 1,000 peer-reviewed papers. As researchers using our systems discover new biologic insights 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. In addition, we are collaborating with several biopharmaceutical companies to develop companion diagnostics, *in vitro* diagnostic tests, to be used to identify which patients are most likely to respond to a particular drug therapy.

Our nCounter Analysis System enables biologic analysis on a scale appropriate for pathway-based biology, the examination of networks of tens or hundreds of genes and proteins that act in concert to produce biologic functions or trigger certain diseases, by digitally quantifying the activity of up to 800 genes or proteins simultaneously in a single minute tissue sample. We offer a range of instruments to appeal to an array of potential customer types. Our nCounter *SPRINT* Profiler is designed to appeal to individual researchers running relatively smaller experiments. Our nCounter MAX is a higher throughput instrument with features appealing to larger core laboratories serving multiple researchers. Our nCounter Dx FLEX instrument has been FDA 510(k) cleared together with Prosigna and is targeted toward clinical laboratories. All three instruments are capable of running all of our research consumable products and provide comparable, high-quality data. This includes our revolutionary new 3D Biology products, which enable researchers to measure combinations of gene expression, protein expression and gene mutations simultaneously from a single minute tissue sample.

Our technology and products address 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 information regarding the activity of genes and proteins. The sensitivity and precision of our novel barcoding chemistry allows the measurement of subtle changes in genomic and proteomic 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 and proteins that characterize and help predict disease states, such as cancer. Using the FLEX configuration of our nCounter Dx Analysis System, researchers also 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

Table of Contents

warranted. Prosigna is regulated as an *in vitro* diagnostic test and we distribute it as a kit for use on our nCounter Dx FLEX 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 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 believed to be the most likely to benefit from treatment with Celgene s drug REVLIMID which is FDA approved for other indications. In May 2015, we entered into a collaboration with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., or Merck, to develop an assay intended to optimize immune-related gene expression signatures and evaluate its potential to predict benefit to Merck s anti-PD-1 therapy, KEYTRUDA, in multiple tumor types. In January 2016, we entered into a collaboration with Medivation, Inc. and Astellas Pharma Inc. to develop an *in vitro* diagnostic test to identify a subset of patients with triple negative breast cancer who are most likely to benefit from treatment with XTANDI, a drug currently marketed by Medivation and Astellas as a treatment for prostate cancer. In February 2016, we expanded our collaboration with Merck to develop and commercialize a novel diagnostic test to predict response to KEYTRUDA in multiple tumor types. 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 $62.7 million, $47.6 million and $31.4 million in 2015, 2014 and 2013, respectively, while incurring net losses of $45.6 million, $50.0 million and $29.3 million in 2015, 2014 and 2013, respectively.

We were incorporated in Delaware in June 2003. Our principal executive offices are located at 530 Fairview Avenue, N., 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®, nCounter Elements™, nCounter *SPRINT*™, 3D Biology™, and Hyb & Seq™. 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, gene activity, and proteins 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.

Table of Contents

Biological pathways are the networks of tens or hundreds of genes that work in concert to produce a biological function. Understanding the activation state of pathways and disruptions in individual elements of these pathways provides significant insight into the fundamental basis of disease and facilitates data driven treatment decisions. Therapeutic interventions, such as drugs, can be used to treat disease by activating or inactivating biological pathways that are relevant to disease. As a result, pathway-based biology has become a widely adopted paradigm that researchers use to understand biological processes and has assisted them in the development of diagnostics and drugs to treat disease. 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 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. Furthermore, there is an untapped opportunity for technologies capable of simultaneously profiling the activity of genes and related proteins, which ultimately dictate biological activity.

Life Sciences Research

Academic, government, and biopharmaceutical researchers engaged in gene expression or protein 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 gene expression experiments using microarrays or quantitative PCR, and protein expression experiments using flow cytometry, mass spectrometry, immunohistochemistry or enzyme-linked immunosorbent assay, or ELISA, assays. Recently, RNA sequencing, or RNA-Seq, has dramatically enhanced researchers ability to discover patterns of gene expression that have biological meaning. However, related workflows and data analysis can be cumbersome and time consuming, and simultaneous analysis of proteins is not possible. 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 molecular targets 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 biologic information extracted from precious tissue samples;
- minimize the computational intensity of complex genomic and proteomic 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 with the capability to analyze both genomic and proteomic information.

Molecular Diagnostics

Growth in the molecular diagnostics market is being driven by technological innovations that have enabled unprecedented biological insights that may be used to inform treatment decisions. New and improved technologies have also led to increased test sensitivity, decreased turnaround times, simplified workflow, and lowered costs when compared to previous 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

Table of Contents

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 initially on gene expression analysis, and ultimately based on our 3D Biology capability.

Cancer is a disease generally caused by genetic mutations in cells. The behavior of cancer cells is extremely complex, depending on the activity of many different genes and proteins. It is often impossible for researchers to identify a single gene or protein that adequately predicts a more aggressive or less aggressive type of cancer. In some cases, researchers have been able to identify more aggressive or less aggressive types of cancer through gene expression analysis of biological pathways, enabling oncologists to 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.

Recently, researchers in the field of oncology have begun to demonstrate the potential of harnessing a patient s immune system to fight cancer. A new class of compounds, referred to generally as immuno-oncology drugs, have begun to come to market with the promise of long-term remissions, or even cures, in certain types of cancer. Unlike cancer therapeutics of the past, these compounds do not target genetic abnormalities and there are to date no reliable genetic biomarkers for determining which patients are likely to respond to treatment. The development of diagnostics to inform decisions regarding treatment with immuno-oncology drugs is likely to require analysis of both RNA and proteins.

In addition, the medical community has favored a trend toward 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 advanced molecular diagnostic 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, potentially targeting gene mutations, gene expression and protein expression, 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 is based on 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.

Table of Contents

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 or proteins that mediate biological pathways.

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

Simple Workflow. The nCounter Analysis System s minimal sample preparation and automated workflow enable the simultaneous analysis of hundreds of genes and proteins 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 biologic 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 molecule. Additionally, in September 2015, we launched the first of our 3D Biology applications, which enable the simultaneous analysis of DNA, RNA and proteins in a single sample. 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.

Protein Expression. Today, researchers can use the nCounter Analysis System to measure up to 30 proteins of importance in immuno-oncology. In 2016 and beyond, we expect to expand this capability to additional proteins and may have the potential to simultaneously measure hundreds of proteins, limited only by the number of antibodies that can be sourced and combined without cross-reaction.

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.

Table of Contents

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 2016, as part of our suite of 3D Biology applications, we intend to introduce a new capability for the measurement of single nucleotide variants, also known as DNA or gene mutations. We expect this added capability to further distinguish our nCounter Analysis System, holding a unique distinction of having capabilities for the simultaneous measurement of gene mutations, gene expression and protein expression.

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 Products and Technology

Instruments and Software

The nCounter Analysis System is an automated, multi-application, digital detection and counting system. In 2008, we began marketing a research use only version of the system, and since that time we have expanded our product line to include three instruments, each targeted at a distinct user segment of our target market.

	nCounter *SPRINT*	**nCounter MAX**	**nCounter FLEX**
Target customer	Individual researchers	Core research labs	Clinical labs
Throughput (samples per day)	24	48	48
Expandable with additional prep station[(1)]	No	Yes	Yes
Diagnostic menu	No	No	Yes
U.S. list price	$ 149,000	$ 235,000	$ 265,000

(1) nCounter MAX and FLEX throughput increased to up to 96 samples per day by adding a second prep station.

The nCounter MAX and FLEX systems comprise a Prep Station and a Digital Analyzer. The 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 nCounter *SPRINT* Profiler is a single instrument targeted to individual researchers that provides both the liquid handling steps and the digital analysis through use of a microfluidic cartridge. All of these instruments 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 instrument, the nCounter Analysis

Table of Contents

Dx FLEX System, was FDA 510(k) cleared and CE-marked together with Prosigna. The FLEX System can be enabled with the software that runs Prosigna to generate individualized patient reports, in addition to running any of our research applications.

The nCounter MAX and FLEX Systems employ a simple three-step workflow that 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 48 samples per day by installing one Prep Station with a single Digital Analyzer. One can increase the number of samples analyzed to 96 samples per day on a single Digital Analyzer if it is coupled with two 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. The nCounter *SPRINT* Profiler employs an even more streamlined two-step workflow that requires only 10 minutes of hands-on time by the user and can process up to 24 samples per day.

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, also available in a mouse version.

PanCancer RNA: Protein Immune Profiling Panel. A panel that combines gene expression analysis of the 770 genes contained in the PanCancer Immune Profiling Gene Expression Panel with the analysis of 30 proteins of interest in measuring the immune system s response to cancer.

PanCancer Progression Panel. A novel set of 770 genes addressing the key questions of what happens when cancer metastasizes, including genes for the study of angiogenesis, epithelial mesenchymal transition, extracellular matrix formation, and metastasis.

Table of Contents

PanCancer Profiles. A series of seven 192-gene expression panels each designed to interrogate a focused area of cancer biology: Adaptive Immunity, Cancer Metabolism, Intracellular Signaling, Cellular Profiling, Wnt Pathway, Innate Immunity, and DNA Damage & Repair, any of which may be combined with nCounter 3D Biology protein expression modules.

Other Gene Expression Panels. A series of panels that allow researchers to conduct a wide variety of gene expression 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.

nCounter Elements Reagents

nCounter Elements are our digital molecular barcoding reagents that allow 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 FLEX Configuration has the ability to simultaneously quantify gene expression on tens or hundreds of genes from minimal amounts of FFPE tissue, which makes it well suited for profiling pathway activation in tumor samples. In addition, it has the precision, reproducibility, and simple workflow required of technologies used in clinical laboratories. Our clinical laboratory customers 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.

Table of Contents

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 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, which is indicated for postmenopausal women with Stage I/II lymph node-negative or Stage II lymph node-positive (one to three positive nodes) hormone receptor-positive breast cancer who have undergone surgery in conjunction with locoregional treatment consistent with standard of care. For each patient, the Prosigna report includes the Prosigna Score, which is referred to as the ROR Score in the scientific literature and outside the United States, and a risk category based on both the Prosigna Score and nodal status. Node-negative patients are classified as low, intermediate or high risk, while node-positive patients are classified as low or high risk. Prosigna is not intended for diagnosis, to predict or detect response to therapy, or to help select the optimal therapy for patients. Prosigna competes with other tests that are currently available as services from specialized central laboratories.

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, 2015, we owned or exclusively licensed twelve issued U.S. patents and approximately 38 pending U.S. patent applications, including provisional and non-provisional filings. We also owned or licensed approximately 154 pending and granted counterpart applications worldwide, including 60 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 February 6, 2033. 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;

Table of Contents

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.

Collaborations

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 identify a subset of patients with DLBCL, who are believed to be the 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 retain the flexibility to independently develop and commercialize additional indications for the test. 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. In October 2015, the collaboration agreement was amended to include additional countries to conduct clinical trials and in return we received an upfront payment of $1.6 million in December 2015.

DLBCL is a heterogeneous group of cancers that represents the most common form of Non-Hodgkin Lymphoma. According to the National Cancer Institute, there were approximately 70,000 new cases of Non-Hodgkin Lymphoma in the United States in 2015. DLBCL is the most common type of Non-Hodgkin Lymphoma, representing approximately 1 out of every 3 cases. 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, a portion of the success-based milestone payments and the payment related to the 2015 amendment, totaling $13.3 million, have been received from Celgene to date, and we intend to use to cover our costs for clinical development of the test.

Merck & Co., Inc.

In May 2015, we entered into a clinical research collaboration agreement with Merck, to develop an assay intended to optimize immune-related gene expression signatures and evaluate the potential to predict benefit from Merck s anti-PD-1 therapy, KEYTRUDA, in multiple tumor types. Under the terms of the collaboration

Table of Contents

agreement, we are eligible to receive up to $4.0 million in payments, of which we received an upfront payment of $2.0 million in July 2015 and development payments totaling $1.9 million during 2015.

In February 2016, we expanded our collaboration with Merck by entering into a new development collaboration agreement to clinically develop and commercialize a novel diagnostic test, based on an optimized gene expression signature, to predict response to KEYTRUDA in multiple tumor types. In connection with the execution of the development collaboration agreement, we and Merck terminated our May 2015 clinical research collaboration and moved all remaining activities under such clinical research collaboration work plan to the new development collaboration agreement. Under the terms of the new development collaboration agreement, we will receive $12.0 million as an upfront technology access payment and are eligible to receive up to an additional $12.0 million for potential preclinical regulatory milestone payments. We are also eligible to receive additional milestone payments upon achievement of certain regulatory milestones. Merck is responsible for its own costs under the development collaboration agreement and will reimburse us for allowable development costs, including personnel related and overhead costs for our employees assigned to the project, nCounter systems and clinical study reagents, and reimbursement of other out-of-pocket costs. For the first two quarters of the development term, our personnel related and overhead costs for employees assigned to the project are estimated to be up to $1.25 million. Following completion of the first two quarters of the development term, our allowable development costs for a given calendar quarter must be agreed to in advance by a joint steering committee composed of our and Merck s representatives which will oversee and coordinate the parties activities under the development collaboration agreement. Development funding under the agreement also includes up to approximately $3.7 million related to work under an extension of our previous clinical research collaboration.

KEYTRUDA is among a class of promising immuno-oncology drugs called checkpoint inhibitors that target the interaction between the programmed cell death-1 (PD-1) immune checkpoint receptor, which inhibits the T-cell response and plays a key role in modulating T-cell function. Certain tumor cells expressing PD-1 are able to bind to the programmed cell death ligand-1 (PDL-1) expressed on the surface of certain T-cells and neutralize a patient s immune response to the cancer cells. It has been shown that by administering a checkpoint inhibitor to block this interaction, a patient s immune response can be unleashed to attack and kill the tumor cells, resulting in long-term remissions or cures in a meaningful percentage of patients treated.

Medivation, Inc. and Astellas Pharma, Inc.

In January 2016, we entered into a collaboration with Medivation, Inc. and Astellas Pharma Inc. to pursue the translation of a novel gene expression signature algorithm discovered by Medivation into a companion diagnostic assay using the nCounter Analysis System. Under the terms of the collaboration agreement, we will modify our PAM50-based Prosigna Breast Cancer Assay for potential use as a companion diagnostic test for XTANDI (enzalutamide) for triple negative breast cancer. We will be responsible for developing and validating the diagnostic test and, if the parties thereafter determine to proceed, we will also be responsible for seeking regulatory approval for and commercializing the test. We have received a $6.0 million upfront payment for technology access, and are eligible to receive up to $10.0 million in development funding, in addition to other potential downstream milestone payments.

Triple negative breast cancer is a form of breast cancer for which the three most common types of receptors known to fuel breast cancer growth estrogen, progesterone, and the HER-2/neu gene are not present in the cancer tumor. Receptor-targeting therapies have fueled tremendous recent advances in the fight against breast cancer. However, since triple negative breast tumor cells lack the necessary receptors, all such targeted therapies are ineffective. Triple negative breast cancer represents a significant unmet need, as it tends to be more aggressive, more likely to recur, and more difficult to treat due to the lack of targeted treatments. XTANDI is currently approved for the treatment of metastatic castration-resistant prostate cancer. The modified Prosigna test will be based upon data from a

Phase 2 trial conducted by Medivation and Astellas that evaluated enzalutamide in patients with triple negative breast cancer.

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 have licensed technology related to the DLBCL assay from the National Institutes of Health, and 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. Our licensing arrangements with the Institute for Systems Biology and Bioclassifier are discussed below in greater detail.

Table of Contents

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, 2015, we have paid aggregate royalties of $3.5 million under the license agreement. Unless terminated earlier in accordance with the terms of the amended license agreement, the agreement will terminate upon the expiration of the last to expire patent licensed to us. The Institute for Systems Biology has the right to terminate the agreement under certain situations, including our failure to meet certain diligence requirements or our uncured material breach of the agreement.

Bioclassifier, LLC

In July 2010, we entered into an exclusive license agreement with Bioclassifier, LLC, pursuant to which Bioclassifier granted to us an exclusive, subject to certain government rights, worldwide license, with the right to sublicense, to certain intellectual property rights and technology, including 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. 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. Through December 31, 2015, we have paid Bioclassifier $468,000 of which $26,000 will be credited against future royalties owed.

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, 2015, including clinical, medical and regulatory affairs, we had 87 employees in research and development, of which 27 hold a Ph.D. degree and 2 hold an M.D. degree. Our research and development expenses for the years ended December 31, 2015, 2014 and 2013 were $24.6 million, $21.4 million and $15.0 million, respectively.

nCounter Technology

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

Table of Contents

Our current 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, as part of our new suite of applications for 3D Biology, we added protein expression capability in 2015 and we plan to introduce a new capability for measurement of DNA mutations in 2016. With 3D Biology, research customers will be able to measure combinations of DNA, RNA and proteins in a single experiment. Consistent with our 3D Biology initiative, we are also continuing to update our panel product line.

Instruments. In July 2015, we launched the nCounter *SPRINT* Profiler, a new generation of the nCounter Analysis System that increases our addressable market by appealing to individual researchers. In early 2016, we announced our intention to develop a novel DNA sequencing chemistry called Hyb & Seq and a novel approach to digital, multiplexed measurement of protein expression with spatial resolution, both of which are based on our optical barcoding technology and will require development of new instruments.

Companion Diagnostic Development

In 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 $13.3 million to date, and may be obligated to pay us up to $45.0 million in total over the course of the collaboration.

In May 2015, we entered into a clinical research collaboration agreement with Merck, to develop an assay intended to optimize immune-related gene expression signatures and evaluate the potential to predict benefit from Merck s anti-PD-1 therapy, KEYTRUDA, in multiple tumor types. Under the terms of the collaboration agreement, we are eligible to receive up to $4.0 million in payments, of which we received an upfront payment of $2.0 million in July 2015 and development payments totaling $1.9 million during 2015. In February 2016, we expanded our collaboration with Merck by entering into a new development collaboration agreement to clinically develop and commercialize a novel diagnostic test, based on an optimized gene expression signature, to predict response to KEYTRUDA in multiple tumor types. For additional information regarding the development collaboration agreement, see the section of this report captioned Collaborations Merck & Co., Inc.

In January 2016, we entered into a collaboration with Medivation, Inc. and Astellas Pharma Inc. to pursue the translation of a novel gene expression signature algorithm discovered by Medivation into a companion diagnostic assay using the nCounter Analysis System. Under the terms of the collaboration agreement, we will modify our PAM50-based Prosigna Breast Cancer Assay for potential use as a companion diagnostic test for XTANDI for triple negative breast cancer. XTANDI is currently approved for the treatment of metastatic castration-resistant prostate cancer. We will be responsible for developing and validating the diagnostic test and, if the parties thereafter determine to proceed, we will also be responsible for seeking regulatory approval for and commercializing the test. We received $6.0 million upfront for technology access, and are eligible to receive up to $6.0 million in preclinical stage

milestones and up to $10.0 million in development funding, in addition to other potential downstream milestone payments.

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 as the primary means to expanding our menu of diagnostic tests. 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.

Table of Contents

Prosigna Breast Cancer Assay

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

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 any additional clinical studies we may conduct for Prosigna.

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 may in-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.

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 22 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, 2015, 2014 or 2013.

Instrumentation and Research

Our sales and marketing efforts for instrumentation and in the life sciences 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 lease or reagent rental agreement. Our sales process involves numerous interactions with multiple people within an organization, and often includes

Table of Contents

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.

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 laboratories, hospitals, networks or practices that test or treat a high volume of breast cancer patients. As of December 31, 2015, there were approximately 50 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. 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 and 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 Analysis System instruments. 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. Paramit Corporation, or Paramit, is our sole source supplier for our nCounter *SPRINT* Profiler at its facility in Morgan Hill, California.

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 three 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 expanded 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.

Table of Contents

We rely on a limited number of suppliers for certain components and materials used in the manufacture of our consumables. Some of these components are sourced from a single supplier. For example, Cidra Precision Services, LLC, of Wallingford, Connecticut, is the sole supplier of the microfluidic cartridge for our nCounter *SPRINT* Profiler. For some components, 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, Becton-Dickinson, Bio-Rad, Bio-Techne, Exiqon, Fluidigm, HTG Molecular Diagnostics, Illumina, Luminex, Merck Millipore, O-Link, Perkin Elmer, Qiagen, RainDance Technologies, Roche Applied Science, Thermo Fisher Scientific, and WaferGen Biosystems, some of which also offer diagnostic applications of their technologies. These competitors and others have products for gene and protein 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.

In the breast cancer diagnostics market, we compete with Genomic Health s Onco*type* Dx, a service for gene expression analysis performed in its central laboratory in Redwood City, California. We also face competition from companies such as Agendia, bioTheranostics, and NeoGenomics, which also offer centralized laboratories that profile gene or protein expression in breast cancer. Outside the United States, 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; the ability to analyze combinations of DNA, RNA and proteins simultaneously in a single experiment; 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;

Table of Contents

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 laboratories or other health professional settings and other tests are for consumers to use at home.

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 of a premarket approval application, or PMA, pursuant to the FDC Act prior to marketing, unless subject to an exemption. Devices deemed to pose relatively low 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) seeking clearance for commercial distribution; this is known as the 510(k) clearance process. Most Class I 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 and some diagnostic tests, 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 in many cases required for a 510(k) application. All clinical studies of investigational devices must be conducted in compliance with applicable FDA or Institutional Review Board, or IRB, regulations.

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 technological characteristics to a previously 510(k) cleared device or a device that was in

Table of Contents

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 significantly 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 reasonable scientific evidence 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. The PMA approval process 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 for a new type of device, an FDA advisory committee, a panel of external experts, 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, post-approval studies and 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 establish special controls that other applicants for the same device type must implement, which often includes labeling restrictions and data requirements. Subsequent applicants can rely upon the de novo product as a predicate for a 510(k) clearance. The

Table of Contents

de novo route is less burdensome than the PMA process; it is similar in many respects to a 510(k), but generally takes much longer for clearance than the 510(k) process. A device company can ask the FDA at the outset if the de novo route is available for its particular product. 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, or MDR, 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, market surveillance, and other means. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from an untitled letter or 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 a 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 use. In November 2013, the FDA issued a final guidance on RUO products, which, among other things, reaffirmed that a company may not make any clinical or diagnostic claims about an RUO product. The FDA will also evaluate the totality of the evidence to determine if the product is intended for diagnostic purposes, including how a customer uses the product. We cannot assure you that the FDA will not determine, based on the totality of circumstances, that our products marketed for RUO are not medical devices that will require clearance or approval.

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. In the past, the FDA generally exercised its enforcement discretion for LDTs and did not require 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 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. Congress has also been considering legislation to regulate LDTs. It is unclear that any LDT-related legislation will be enacted.

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. Most companion diagnostics will require PMA approval.

Table of Contents

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 for compliance with 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.

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 the National Comprehensive Cancer Network, or NCCN, the American Society of Clinical Oncologists, or 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. 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.

Table of Contents

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.

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

Table of Contents

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). Prosigna was successfully covered and assigned a payment amount by the MolDx program in 2015. In late 2015 Prosigna was also covered by First Coast, the Florida MAC, and priced in early January 2016. Noridian has issued a draft LCD, which is expected to become final in 2016.

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. 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.

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.

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.

Table of Contents

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, 2015, we had 307 employees, of which 87 work in manufacturing, 92 in sales, marketing and business development, 72 in research and development, 15 in clinical, medical and regulatory affairs, and 41 in general and administrative. None of our U.S. employees are represented by a labor union or is the subject of a collective bargaining agreement. As of December 31, 2015, of our 307 employees, 280 were employed in the United States and 27 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., 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.

Table of Contents

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this report, including the section of this report captioned Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, our business, operating results and financial condition could be seriously harmed. This report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report.

Risks Related to our Business and Strategy

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

We have incurred losses since we were formed and expect to incur losses in the future. We incurred net losses of $45.6 million and $50.0 million for the years ended December 31, 2015 and 2014, respectively. As of December 31, 2015, we had an accumulated deficit of $222.5 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.

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.

Table of Contents

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, development and commercialization of the Prosigna Breast Cancer Assay, or Prosigna, and other future diagnostic products worldwide are key elements of our growth strategy and have 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.

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 and government research laboratories, biopharmaceutical companies and clinical laboratories that perform analyses using our nCounter Analysis Systems. Our success will depend, in part, upon our ability to increase our market penetration among all of these customers and to expand our market by developing and marketing new research applications, new instruments, and new diagnostic products. 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. Moreover, 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 Systems could enable an equivalent or superior approach that lessens reliance on centralized laboratories. 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 and government research 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 (such as the National Institutes of Health) 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.

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.

Table of Contents

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, from time-to-time, we may lease instruments or place 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 lease or 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 continue to use 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 Systems and related consumable products within parts of Europe, the Middle East, Africa, 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 or our distributors have entered into agreements with clinical laboratories globally 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.

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. 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 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

Table of Contents

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. 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 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. In May 2015, we entered into a clinical research collaboration agreement with Merck to develop an assay that could become the subject of an additional companion diagnostic collaboration. In February 2016, we expanded our collaboration with Merck by entering into a new development collaboration agreement to clinically develop and commercialize a novel diagnostic test, based on an optimized gene expression signature, to

predict response to KEYTRUDA in multiple tumor types. In January 2016, we announced a companion diagnostic collaboration with Medivation Inc. and Astellas Pharma Inc. to modify our Prosigna Breast Cancer Assay for potential use as a companion diagnostic test for enzalutamide for triple negative breast cancer. 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

Table of Contents

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 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;
- revenue and cash flow derived from existing or future collaborations;
- the cost of our research and development activities;
- the cost and timing of regulatory clearances or approvals;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including new licensing arrangements for new products.

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. For example, as of December 31, 2015, we have issued an aggregate of 960,400 shares of our common stock under a sales agreement with Cowen and Company, LLC, or Cowen, for total gross proceeds of $13.0 million. We have a sales agreement in place with Cowen to sell up to $40.0 million worth of shares of our common stock, from time to time,

through an at the market equity offering program under which Cowen will act as sales agent. As of December 31, 2015, approximately $27.0 million worth of shares of our common stock remained available for sale under the at the market equity offering program. 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.

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

Table of Contents

approval, privacy rights, publication rights, intellectual property ownership and research parameters. On September 8, 2015, the Department of Health and Human Services, or HHS, issued a proposed rule that would modify informed consent requirements. This proposed rule, if finalized as drafted, could make it more expensive and difficult to obtain banked specimens. 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 on commercially reasonable terms, or at all, or if other laboratories or our competitors secure access to these samples before us, our ability to research, develop and commercialize future products will be limited or delayed.

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

We face significant competition in the life sciences research and diagnostics markets. We currently compete with both established and early stage life sciences research companies that design, manufacture and market instruments and consumables for gene expression analysis, single-cell analysis, polymerase chain reaction, or PCR, digital PCR, other nucleic acid detection and additional applications. These companies use well-established laboratory techniques such as microarrays or quantitative PCR, or qPCR, as well as newer technologies such as next generation sequencing. We believe our principal competitors in the life sciences research market are Affymetrix, Agilent Technologies, Becton-Dickinson, Bio-Rad, Bio-Techne, Exiqon, Fluidigm, HTG Molecular Diagnostics, Illumina, Luminex, Merck Millipore, O-Link, Perkin Elmer, Qiagen, RainDance Technologies, Roche Applied Science, Thermo Fisher Scientific, and WaferGen Biosystems. In addition, there are a number of new market entrants in the process of developing novel technologies for the life sciences market.

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, bioTheranostics, and NeoGenomics, 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.

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

- greater name and brand recognition, financial and human resources;
- broader product lines;
- larger sales forces and more established distributor networks;
- substantial intellectual property portfolios;
- larger and more established customer bases and relationships; and

better established, larger scale, and lower cost manufacturing capabilities.

We believe that the principal competitive factors in all of our target markets include:

cost of capital equipment;

cost of consumables and supplies;

reputation among customers;

innovation in product offerings;

flexibility and ease-of-use;

accuracy and reproducibility of results; and

compatibility with existing laboratory processes, tools and methods.

Table of Contents

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

- availability of reimbursement for testing services;
- breadth of clinical decisions that can be influenced by information generated by tests;
- volume, quality, and strength of clinical and analytical validation data;
- inclusion in treatment guidelines; and
- economic benefit accrued to customers based on testing services enabled by products.

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

We have limited experience in marketing and selling our diagnostic 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 diagnostic products to clinical laboratories. Our sales of Prosigna will depend in large part on our ability to successfully market to oncologists and other healthcare providers. 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. 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.

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 new markets, such as protein expression and gene mutations, and 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 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,

Table of Contents

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. 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. If customers believe that such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. In July 2015 we commercially launched a new version of our nCounter Analysis System, the nCounter *SPRINT* Profiler, that is smaller and less expensive than the previous version. If customers conclude that such new products offer better value as compared to our existing products, we may suffer from reduced sales of our existing products and our overall revenues may decline. 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 September 2015, we launched our first 3D Biology application, a new product that allows users to simultaneously measure gene and protein expression from a single sample. We plan to launch additional 3D Biology applications in the future that will also include measurement of DNA mutations. The future growth of the market for these new products depends on many factors beyond our control, including recognition and acceptance of our applications by the scientific community and the growth, prevalence and costs of competing methods of genomic analysis. Also, in 2015, we commercially launched a new version of our nCounter Analysis system for research, the nCounter *SPRINT* Profiler. 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.

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 necessary 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 the European Union. We do not have regulatory clearance or approval to market in any additional 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, we are limited to marketing our products for research use only, which means that we cannot make diagnostic or clinical claims. We intend to seek regulatory authorizations to market Prosigna in other jurisdictions, as well as for other indications. In addition, pursuant to our collaborations with pharmaceutical companies for the development of companion diagnostic tests for use with their drugs, we are responsible for obtaining regulatory authorizations needed to use the companion diagnostic tests in clinical trials as well as the regulatory approvals to sell the companion diagnostic tests following completion of such trials.

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.

Table of Contents

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

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

Our consumable products are manufactured at our Seattle, 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. For example, our new 3D Biology applications for the simultaneous measurement of gene and protein expression involve a new process for attaching antibodies to our molecular barcodes. 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 facilities become 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 headquarters facilities in Seattle, Washington. In addition, Seattle is the center for research and development, order processing, receipt of our instruments manufactured by third-party contract manufacturers and shipping products to customers. Our facilities 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. These facilities 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 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.

Table of Contents

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

For the year ended December 31, 2015 and 2014, approximately 34% and 32%, respectively, of our revenue was generated from sales to customers located outside of North America. We believe that a significant percentage of our future revenue will come from international sources as we expand our overseas operations and develop opportunities in additional areas. Engaging in international business involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign regulatory requirements and laws;
- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act and U.K. Bribery Act, data privacy requirements, labor laws and anti-competition regulations;
- export or import restrictions;
- various reimbursement and insurance regimes;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;
- difficulties and costs of staffing and managing foreign operations; and
- difficulties protecting or procuring intellectual property rights.

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

currencies, 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. Similarly, a strong U.S. dollar relative to the local currencies of our international customers can potentially reduce demand for our products, which may compound the adverse effect of foreign exchange translation on our revenue. 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, 2015, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of approximately $165.4 million, which expire in various years beginning in 2025, if not utilized. A lack of future taxable income would adversely affect our ability to utilize these NOLs. In addition, under Section 382 of the Internal Revenue Code, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We may have already experienced one or more ownership changes. Depending on the timing of any future utilization of our carryforwards, we may be limited as to the amount that can be utilized each year as a result of such previous ownership changes. However, we do not believe such limitations will cause our NOL and credit carryforwards to expire unutilized. In addition, future changes in our stock ownership as well as other changes that may be outside of our control, could result in

Table of Contents

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.

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.

Table of Contents

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. 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.

Table of Contents

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 or directions or support to use as diagnostic products, they are not subject to regulation by the Food and Drug Administration, or 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 final guidance on RUO products, which, among other things, reaffirmed that a company may not make clinical or diagnostic claims about an RUO product or provide directions or support services to customers who are using RUO products for diagnostic purposes. If the FDA were to modify 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 has 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 the FDA determines that approval or clearance was required for those functions for which FDA approval or clearance has not been obtained, and the instruments are being promoted off-label. There is also a risk that the FDA could broaden its current regulatory enforcement of dual-use instruments through additional FDA oversight of such products or impose additional requirements upon such products.

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, and other private payers have adopted similar policies. By contrast, 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 have received confirmations of coverage for Prosigna from California s Medicaid group, MediCal, and from Providence Health Plan and several other private payers, although they have not

issued Prosigna-specific policies.

In May 2015, Palmetto GBA, a Medicare Administrative Contractor that assesses molecular diagnostic technologies through its Molecular Diagnostic Services Program, or MolDX, issued a favorable local coverage determination for Prosigna which became effective on October 1, 2015. The coverage policy applies to the

Table of Contents

Palmetto jurisdiction, comprising North Carolina, South Carolina, Virginia and West Virginia, but other Medicare jurisdictions participating in the MolDX program may choose to adopt the same policy and other MACs have confirmed coverage but have not issued Prosigna-specific policies. For example, CGS, another MAC whose jurisdiction covers Kentucky and Ohio, issued a local coverage determination identical to Palmetto s which also became effective October 1 and CAHABA, the MAC that covers Alabama, Georgia and Tennessee, has confirmed coverage through its news bulletins. In late 2015 Prosigna was also covered by First Coast, the Florida MAC, and priced in early January 2016. Despite such positive developments, other Medicare contractors covering other jurisdictions (such as Novitas) have initially declined to cover Prosigna.

If we are unable to obtain positive policy decisions from third-party payors approving reimbursement for our tests at adequate levels, the commercial success of our products would be compromised and our revenue would be significantly limited. Even if we do obtain reimbursement for our tests, Medicare, Medicaid and private and other payors may withdraw their coverage policies, cancel their contracts with us at any time, review and adjust the rate of reimbursement, require co-payments from patients or stop paying for our tests, which would reduce revenue for testing services based on our technology, and indirectly, demand for diagnostic products. In addition, insurers, including managed care organizations as well as government payors such as Medicare and Medicaid, have increased their efforts to control the cost, utilization and delivery of healthcare services, which may include decreased coverage or reduced reimbursement. From time to time, Congress has considered and implemented changes to the Medicare fee schedules in conjunction with budgetary legislation, and pricing and payment terms, including the possible requirement of a patient co-payment for Medicare beneficiaries for tests covered by Medicare, and are subject to change at any time. Most recently the Protecting Access to Medicare Act (PAMA) of 2014 revises the Medicare Clinical Laboratory Fee Schedule (CLFS) to base prices on commercial payer rates that are reported to the Centers for Medicare and Medicaid Services (CMS). In September 2015, CMS released the much anticipated Clinical Diagnostic Tests Laboratory Payment System regulations, in response to PAMA. The statute applies different reporting and payment requirements to Advanced Diagnostic Laboratory Tests (ADLTs) and to Clinical Diagnostic Laboratory Tests (CDLTs). Under the definitions in the proposed rules, Prosigna would be defined as a CDLT and would be repriced every three years based on a weighted median of commercial payments submitted by labs. As a result, if commercial payment amounts decline, there is a risk that Medicare prices will fall as well. Reductions in the reimbursement rate of third-party payors have also 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. Recently, positive reimbursement decisions for Prosigna have occurred in certain regions of Spain and Israel. Despite these positive developments, we continue to expect that it will take several years to establish broad coverage and reimbursement for testing services based on our products with most 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 most cases where coverage is denied by a third-party payor, there will be subsequent opportunities to submit additional information or clinical evidence and have such decision reconsidered. 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 based on additional information or subsequent clinical developments; 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.

Table of Contents

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 by laboratories in conjunction with appropriate analyte specific reagents and 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 and performed by a single laboratory and include genetic tests. Historically, LDTs generally have not been subject to FDA regulation. In October 2014, the FDA issued its draft guidance documents 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 documents for LDTs, such regulation could adversely affect our prospects, results of operations and financial condition. Similarly, there have been proposals that Congress enact legislation that could result in FDA regulation of some LDTs. If legislation were enacted, it could adversely affect demand for our products, including nCounter Elements reagents.

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 the standard of care. We intend to pursue additional intended uses for Prosigna that may require a PMA approval, which is a more burdensome regulatory process than the 510(k) clearance process. In addition, we are currently collaborating with Celgene, Merck and Medivation and Astellas on companion diagnostics. 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. The FDA stated in the companion diagnostics final guidance that while in some instances a companion diagnostic could come to market through a 510(k), the Agency expects that companion diagnostics usually will require a PMA.

Any 510(k) clearance or PMA approval we obtain for any future product would likely place substantial restrictions on how our device is marketed or sold. The FDA will continue to place considerable restrictions on our products, including, but not limited to, the Quality System Regulation, or QSR, registering manufacturing facilities, listing the products with the FDA, and complying with labeling, marketing, complaint handling, medical device reporting requirements, and reporting certain 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 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, regulatory inspections, 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

Table of Contents

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 beyond what the FDA requires. 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 additional indications for 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 develop, 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.

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 and certain of our contract manufacturers are subject to ongoing International Organization for Standardization, or ISO, and FDA obligations and continued regulatory oversight and review. These include routine inspections by EU Notified Bodies and by the FDA of our manufacturing facilities and our records for compliance with requirements such as ISO 13485 and the QSR, which establish extensive requirements for quality assurance and control as well as manufacturing and change control procedures. We are also subject to other regulatory obligations, such as 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. It is expected that in 2016 the European Union will adopt the IVD Directive Regulation, currently in draft form, which would increase the regulatory requirements applicable to some in vitro diagnostics in the EU and may require that we re-classify and obtain pre-approval for our existing CE-marked IVD products after a 5-year grace period. We may also be subject to additional FDA or global regulatory authority post-marketing obligations or requirements by the FDA or global regulatory authority 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 (or equivalent) indication. 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 and other global regulatory authority 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 outside of the U.S. and Europe. Adverse Notified Body, EU Competent Authority or FDA or global regulatory authority action in any of these areas could significantly increase our expenses and limit our revenue and profitability.

Table of Contents

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.

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. In December 2015, Congress passed a two-year suspension of the medical device tax from January 1, 2016 to December 31, 2017. Absent further legislative action, the medical device tax would be reinstated January 1, 2018. 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

Table of Contents

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, 2015, we owned or exclusively licensed twelve issued U.S. patents and approximately 38 pending U.S. patent applications, including provisional and non-provisional filings. We also owned or licensed approximately 154 pending and granted counterpart applications worldwide, including 60 country-specific 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.

Table of Contents

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

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

- We might not have been the first to make the inventions covered by each of our pending patent applications.
- We might not have been the first to file patent applications for these inventions.
- Others may independently develop similar or alternative products and technologies or duplicate any of our products and technologies.
- It is possible that our pending patent applications will not result in issued patents, and even if they issue as patents, they may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties.
- We may not develop additional proprietary products and technologies that are patentable.
- The patents of others may have an adverse effect on our business.
- We apply for patents covering our products and technologies and uses thereof, as we deem appropriate. However, we may fail to apply for patents on important products and technologies in a timely fashion or at all.

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

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

We have not yet registered certain of our trademarks 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.

Table of Contents

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 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.

Table of Contents

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

As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. Our competitors and others may now and in the future have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product revenue and against whom our own patents may provide little or no deterrence or protection. Therefore, our commercial success may depend in part on our non-infringement of the patents or proprietary rights of third parties. We are aware of a third party, Genomic Health, Inc., that has issued patents and pending patent applications in the United States, Europe and other jurisdictions that claim methods of using certain genes that are included in Prosigna. We believe that Prosigna does not infringe any valid issued claim. Numerous significant intellectual property issues have been litigated, and will likely continue to be litigated, between existing and new participants in our existing and targeted markets and competitors may assert that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into those markets. Third parties may assert that we are employing their proprietary technology without authorization. In addition, our competitors and others may have patents or may in the future obtain patents and claim that use of our products infringes these patents. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and obtain one or more licenses from third parties, or be prohibited from selling certain products. We may not be able to obtain these licenses at a reasonable cost, if at all. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. In addition, we could encounter delays in product introductions while we attempt to develop alternative methods or products to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing products, and the prohibition of sale of any of our products could materially affect our ability to grow and gain market acceptance for our products.

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

In addition, our agreements with some of our suppliers, distributors, customers, 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.

Table of Contents

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.

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.

Table of Contents

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;
- 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.

Table of Contents

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 and the current level of trading may not be sustained in the future. Purchases or sales of large blocks of our shares relative to the trading volume on a given day can have a disproportionate effect on the price of our common stock. The lack of an active market for our common stock or significant and rapid changes in the price of our common stock may impair investors ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable, may reduce the fair market value of their shares and may impair our ability to raise capital.

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

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

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

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

Holders of approximately 5.0 million shares (including shares underlying outstanding warrants), or approximately 25%, 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 future issuance, including any issuances pursuant to our at the market equity offering program under our sales agreement with Cowen, could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

We will have broad discretion over the use of the proceeds to us from our at the market equity offering program and may apply the proceeds to uses that do not improve our operating results or the value of your securities.

We will have broad discretion to use the net proceeds to us from our at the market equity offering program, and investors will be relying solely on the judgment of our board of directors and management regarding the application of these proceeds. Although we expect to use the net proceeds from our at the market equity offering program for general corporate purposes, we have not allocated these net proceeds for specific purposes. Investors will not have the opportunity, as part of their investment decision, to assess whether the proceeds are being used appropriately. Our use of the proceeds may not improve our operating results or increase the value of the securities offered pursuant to the at the market equity offering program.

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 29% of our outstanding common stock as of December 31, 2015. 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

Table of Contents

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);

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.

Table of Contents

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 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, 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

Table of Contents

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. We have filed Form SD for the two years ended December 31, 2014 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently have three long-term operating lease agreements for 86,877 square feet of space used for general office, laboratory, manufacturing, operations, and research and development purposes in Seattle, Washington. This includes an amendment to one of our lease agreements entered into February 2016, which added an additional 6,604 square feet and extended the original lease term for an additional year. The long-term operating leases, including the amended lease agreement, expire in 2026 and include options to renew at the then fair market rental for each of the facilities. The lease agreements contain rent abatement periods, scheduled rent increases and provide for tenant improvement allowances.

Our landlords hold security deposits 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. We believe that there are no claims or actions pending against us currently, the ultimate disposition of which would have a material adverse effect on our consolidated results of operation, financial condition or cash flows.

Table of Contents

Item 4. Mine Safety Disclosures

Not applicable.

Table of Contents

PART II

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

Market Information

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

Year ended December 31, 2014	High	Low
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 ended December 31, 2015		
First quarter	$ 14.74	$ 9.95
Second quarter	$ 16.40	$ 10.21
Third quarter	$ 19.81	$ 13.16
Fourth quarter	$ 16.23	$ 12.94

Holders

As of March 1, 2016, there were approximately 51 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Dividends

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

Table of Contents

Securities Authorized for Issuance under Equity Compensation Plans

See Part III, Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters of this Annual Report on Form 10-K for more information regarding securities authorized for issuance.

Performance Graph

This performance graph shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or incorporated by reference into any filing of NanoString Technologies, Inc. under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

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 August 2015, we issued 250 shares of our common stock upon the exercise of warrants at a price of $8.45 and received gross proceeds of $2,112. These issuances were exempt from registration under the Securities Act of 1933, as amended, under Section 4(a)(2) thereof as a transaction by an issuer not involving a public offering. The recipients acquired the securities for investment only and not with a view to or for sale in connection with any distribution of the securities and appropriate legends were affixed thereto.

Table of Contents

Item 6. Selected Financial Data

The following selected financial data is derived from our audited financial statements and should be read in conjunction with, and is qualified in its entirety by, Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations, and Item 8, Financial Statements and Supplementary Data. contained elsewhere in this Annual Report on Form 10-K. The selected Consolidated Statements of Operations data for the years ended December 31, 2015, 2014 and 2013 and Consolidated Balance Sheet data as of December 31, 2015 and 2014 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, 2012 and 2011 and Consolidated Balance Sheet data as of December 31, 2013, 2012 and 2011 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,				
	2015	2014	2013	2012	2011
	(In thousands, except per share amounts)				
Consolidated Statements of Operations:					
Revenue	$ 62,667	$ 47,593	$ 31,403	$ 22,973	$ 17,800
Costs and expenses:					
Cost of revenue	26,126	21,149	15,009	12,361	9,777
Research and development	24,597	21,404	14,979	11,635	8,990
Selling, general and administrative	53,186	51,063	29,912	15,486	9,529
Total costs and expenses	103,909	93,616	59,900	39,482	28,296
Loss from operations	(41,242)	(46,023)	(28,497)	(16,509)	(10,496)
Other income (expense):					
Interest income	233	272	68	21	10
Interest expense	(4,017)	(4,140)	(1,942)	(804)	(599)
Other income (expense)	(389)	(147)	(66)	(29)	80
Revaluation of preferred stock warrant liability			1,156	(387)	73
Total other income (expense)	(4,173)	(4,015)	(784)	(1,199)	(436)
Net loss before provision for income taxes	(45,415)	(50,038)	(29,281)	(17,708)	(10,932)
Provision for income taxes	(166)				
Net loss	$ (45,581)	$ (50,038)	$ (29,281)	$ (17,708)	$ (10,932)
Accretion of mandatorily redeemable convertible preferred stock			(4,653)	(7,533)	(5,251)
Net loss attributable to common stockholders	$ (45,581)	$ (50,038)	$ (33,934)	$ (25,241)	$ (16,183)
Net loss per share basic and diluted	$ (2.40)	$ (2.80)	$ (4.44)	$ (71.10)	$ (50.10)

Weighted-average shares used in computing basic and diluted net loss per share	19,027	17,839	7,643	355	323

	As of December 31,				
	2015	**2014**	**2013**	**2012**	**2011**
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 49,044	$ 72,225	$ 42,656	$ 21,692	$ 10,868
Working capital	61,882	76,411	42,106[(1)]	19,937[(1)]	12,236[(1)]
Total assets	92,869	102,068	64,372[(1)]	37,406[(1)]	24,584[(1)]
Total long-term debt and lease financing obligations, net of unamortized debt issue costs (includes current portion)	41,226	30,246	18,293[(1)]	12,759[(1)]	1,887[(1)]
Mandatorily redeemable convertible preferred stock				103,622	80,957
Total stockholders equity (deficit)	$ 20,215	$ 44,813	$ 31,469	$ (93,760)	$ (69,451)

(1) Amounts have not been retrospectively modified to reflect the adoption of Accounting Standard Update No. 2015-03. Interest-Imputation of Interest: Simplifying the Presentation of Debt Issuance Costs.

Table of Contents

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis together with the financial statements and the related notes to those statements included elsewhere in this report. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in the section of this report captioned Risk Factors and elsewhere in this report, our actual results may differ materially from those anticipated in these forward-looking statements. Throughout this discussion, unless the context specifies or implies otherwise, the terms NanoString , we , us and our refer to NanoString Technologies, Inc. and its subsidiaries.

Overview

We develop, manufacture and sell robust, intuitive products that unlock scientifically valuable and clinically actionable biologic 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, 2015, we have an installed base of over 350 systems, which our customers have used to publish more than 1,000 peer-reviewed papers. As researchers using our systems discover new biologic insights 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. In addition, we are collaborating with several biopharmaceutical companies to develop companion diagnostics, *in vitro* diagnostic tests to be used to identify which patients are most likely to respond to a particular drug therapy.

We derive a substantial majority of our revenue from the sale of our products to life science researchers, which consist of our nCounter instruments and related proprietary consumables, which we call CodeSets, nCounter Elements reagents and Master Kits. After buying an nCounter Analysis System, research customers purchase consumables from us for use in their experiments. Our instruments are designed to work only with our consumable products. Accordingly, as the installed base of our instruments grows, we expect recurring revenue from consumable sales to become an increasingly important driver of our operating results. We also derive revenue from processing fees related to proof-of-principle studies we conduct for potential customers and extended service contracts for our nCounter Analysis Systems.

In 2013, we began offering instruments and consumables for use in diagnostic testing. In September 2013, we received 510(k) clearance from the FDA to market in the United States a version of Prosigna providing an assessment of a patient s risk of recurrence for breast cancer. In November 2013, we began offering a version of the nCounter Dx Analysis System to high-complexity, CLIA-certified laboratories for research and diagnostics purposes. This FLEX configuration of the nCounter Dx Analysis System provides clinical laboratories a single platform with the flexibility to support both clinical testing, by running Prosigna, and research, by processing translational research experiments using our research consumables. The nCounter Elements reagents provide further flexibility by allowing laboratories to develop their own Laboratory Developed Tests for gene expression, copy number variation and gene fusion signatures, which can be performed by a laboratory and may include genetic tests and other tests for rare conditions.

In December 2013, we commercially launched Prosigna in the United States. National diagnostic laboratories, including Laboratory Corporation of America Holdings and Quest Diagnostics, as well as laboratories at numerous cancer centers and major hospitals have chosen to add Prosigna to their suites of breast cancer diagnostic tests. These laboratories collectively serve the pathology testing needs of a substantial portion of breast cancer patients throughout

the United States. In September 2012, we obtained a CE mark for Prosigna,

Table of Contents

our first diagnostic product, and, in early 2013 we commercially launched Prosigna in Europe and Israel. To support the commercial launch of Prosigna, we added a team of experienced oncology sales, marketing, market access and medical affairs professionals, resulting in increased operating expenses. In February 2015, we combined our two separate sales teams into a single organization selling our entire suite of products, targeted primarily toward major academic medical centers and biopharmaceutical companies. We expect Prosigna sales growth to be dependent on the installation of more systems, inclusion of Prosigna in important breast cancer treatment guidelines and reimbursement by third-party payors becoming more broadly available.

We use third-party contract manufacturers to produce the instruments comprising the nCounter Analysis System. We manufacture consumables at our Seattle, Washington facility. This operating model is designed to be capital efficient and to scale efficiently as our product volumes grow. We focus a substantial portion of our resources on developing new technologies, products and solutions. We invested $24.6 million, $21.4 million and $15.0 million in 2015, 2014 and 2013, respectively, in research and development and intend to continue to make significant investments in research and development.

In March 2014, we entered into a collaboration agreement with Celgene Corporation pursuant to which we are working collaboratively with Celgene to develop, seek regulatory approval for, and commercialize a companion diagnostic assay for use in screening patients with Diffuse Large B-Cell Lymphoma. We received an upfront payment of $5.8 million in June 2014 upon our delivery of certain information to Celgene. We also achieved and were paid for certain development-related milestones totaling $6.0 million during 2014 and recognized the related revenue according to the proportional performance model. We are eligible to receive up to $11.0 million in additional success-based payments related to regulatory milestones. In October 2015, we amended the collaboration agreement to include additional countries to conduct clinical trials and in return we received an upfront payment of $1.6 million in December 2015. We will retain all commercial rights to the diagnostic test developed under this collaboration and, assuming success in the clinical trial process, and subject to regulatory approval, expect to generate revenues from the sale of the resulting *in vitro* diagnostic kits.

In May 2015, we entered into a clinical research collaboration agreement with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. or Merck, to develop an assay intended to optimize immune-related gene expression signatures and evaluate the potential to predict benefit from Merck s anti-PD-1 therapy, KEYTRUDA, in multiple tumor types. We received an upfront payment of $2.0 million in July 2015 and development payments totaling $1.9 million during 2015. In February 2016, we expanded our collaboration with Merck by entering into a new development collaboration agreement to clinically develop and commercialize a novel diagnostic test, based on an optimized gene expression signature, to predict response to KEYTRUDA in multiple tumor types. In May 2015, we entered into a clinical research collaboration agreement with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. or Merck, to develop an assay intended to optimize immune-related gene expression signatures and evaluate the potential to predict benefit from Merck s anti-PD-1 therapy, KEYTRUDA, in multiple tumor types. We received an upfront payment of $2.0 million in July 2015 and development payments totaling $1.9 million during 2015. In February 2016, we expanded our collaboration with Merck by entering into a new development collaboration agreement to clinically develop and commercialize a novel diagnostic test, based on an optimized gene expression signature, to predict response to KEYTRUDA in multiple tumor types. Under the terms of the new development collaboration agreement, we will receive a $12.0 million upfront technology access fee and are eligible to receive up to $12.0 million for potential preclinical regulatory milestone payments. We are also eligible to receive development funding and other potential downstream regulatory milestone payments. For additional information regarding the development collaboration agreement, see the section of this report captioned Business Collaborations Merck & Co., Inc.

Our total revenue increased to $62.7 million in 2015 from $47.6 million in 2014 and $31.4 million in 2013, which was driven primarily by the sale of additional nCounter Analysis Systems and consumables for use on our growing installed base of instruments. Historically, we have generated a substantial majority of our revenue from sales to customers in North America; however, recently, sales revenue has been growing more rapidly outside North America and we believe this trend may continue. We have never been profitable and had net losses of $45.6 million, $50.0 million, and $29.3 million in 2015, 2014 and 2013, respectively. As of December 31, 2015, our accumulated deficit was $222.5 million.

Key Financial Metrics

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

Table of Contents

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

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

Revenue

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

Product Revenue

Our products consist of our nCounter Analysis System and related consumables, including Prosigna *in vitro* diagnostic kits. Our nCounter MAX Analysis System typically consists of one nCounter Digital Analyzer and one nCounter Prep Station, having a U.S. list price of $235,000. The U.S. list price of the similarly configured nCounter Dx FLEX Analysis System is $265,000, or $285,000 if fully enabled to run Prosigna. Our newly developed nCounter *SPRINT* Profiler has a reduced footprint and combines the function of the prep station with the digital analyzer in a single instrument. It has a U.S. list price of $149,000. Outside the United States, depending on the country, the list price is generally higher. Systems are sold to distributors at a discount to list price. Our customer base is primarily composed of academic institutions, government laboratories, biopharmaceutical companies and clinical laboratories that perform analyses or testing using our nCounter Analysis System and purchase related consumables, potentially including Prosigna kits.

For our research customers, related consumables include (1) custom CodeSets, which we manufacture to the specific requirements of an individual researcher, (2) panels, which are standard pre-manufactured CodeSets, (3) nCounter Elements reagents, and (4) Master Kits, which are ancillary reagents, cartridges, tips and reagent plates required to setup and process samples in our instruments. Product revenue also includes payments for instrument installation. Since 2010, our average consumables revenue per installed system has exceeded $100,000 per year.

For our clinical laboratory customers, related consumables include Prosigna *in vitro* diagnostic kits and nCounter Elements reagents. We sell our nCounter Dx Analysis Systems to clinical laboratory customers or offer to lease them under reagent rental arrangements where an instrument is placed at a customer location at minimal direct cost and the customer commits to purchase a minimum volume of consumable products over a period of time. To date, the majority of our clinical laboratory customers have elected to purchase instruments.

The list price of a Prosigna test in the United States and Europe is $2,080 and 1,550 per patient, respectively. Although the price of Prosigna and our additional future diagnostic products will depend on many factors, including whether and how much third-party payors will reimburse laboratories for conducting such tests, we expect that the gross margin for our diagnostic kits will be higher than for our research consumables. We sell Prosigna kits to our lab customers, who will be responsible for providing the testing service and contracting and billing payors. Prosigna kits are sold to clinical laboratories on a fixed dollars-per-kit basis, which does not expose us to direct third-party payor

reimbursement risk. However, we provide customary volume discounts, and in some cases, introductory pricing during the period in which third-party payor reimbursement is being established. As a result, the average selling price per Prosigna test is lower than list price.

Table of Contents

Service Revenue

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

Collaboration Revenue

Collaboration revenue is primarily derived from our collaborations with Celgene and Merck. As of December 31, 2015, we had received a total of $17.2 million from collaboration these agreements, of which $2.9 million and $5.9 million had been recorded as collaboration revenue in 2014 and 2015, respectively, with the remainder recorded as deferred revenue, which will be recognized as collaboration revenue over our remaining development performance period for each of the agreements. Collaboration revenue also includes revenue recognized under a smaller evaluation study being performed for a different biopharmaceutical company.

Revenue by Geography

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

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

	Year Ended December 31,					
	2015		2014		2013	
	(Dollars in thousands)					
Americas	$ 41,265	66%	$ 32,244	68%	$ 21,855	70%
Europe & Middle East	14,807	24	9,174	19	5,775	18
Asia Pacific	6,595	10	6,175	13	3,773	12
Total	$ 62,667	100%	$ 47,593	100%	$ 31,403	100%

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

Cost of Product and Service Revenue

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

Table of Contents

The average unit costs of our instruments has declined in the current year as compared to prior years as a result of introducing our lower-cost nCounter *SPRINT* Profiler in July 2015. We expect the average unit costs of our instruments to continue to decline as we expand our market opportunity among smaller research laboratories and sell a higher proportion of *SPRINT* systems. We expect the unit costs of consumable products to decline as a result of our ongoing efforts to improve our manufacturing processes and expected increases in production volume and yields. Although the unit costs of our custom CodeSets vary, they are generally higher as a percentage of the related revenue than our panels, *in vitro* diagnostic kits and nCounter Elements reagents.

Operating Expenses

Research and Development

Research and development expenses consist primarily of salaries and benefits, occupancy, laboratory supplies, engineering services, consulting fees, costs associated with licensing molecular diagnostics rights and clinical study expenses (including the cost of tissue samples) to support the regulatory approval or clearance of diagnostic products. We have made substantial investments in research and development since our inception. Our research and development efforts have focused primarily on the tasks required to enhance our technologies and to support development and commercialization of new and existing products and applications. We believe that our continued investment in research and development is essential to our long-term competitive position and expect these expenses to increase in future periods.

Given the relatively small size of our research and development staff and the limited number of active projects at any given time, we have found that, to date, it has been effective for us to manage our research and development activities on a departmental basis. Accordingly, other than for collaborations, we do not require employees to report their time by project nor do we allocate our research and development costs to individual projects. Research and development expense by functional area was as follows:

	Year Ended December 31,		
	2015	2014	2013
	(In thousands)		
Core nCounter platform technology	$ 6,749	$ 6,975	$ 4,330
Manufacturing process development	1,802	2,124	1,588
Life sciences research products and applications	4,982	3,834	2,914
Diagnostic product development	3,727	3,292	1,617
Clinical, regulatory and medical affairs	4,939	3,740	2,988
Facility allocation	2,398	1,439	1,542
Total	$ 24,597	$ 21,404	$ 14,979

Our Prosigna clinical studies have generally 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 patient outcome is known. Such studies are capital efficient as they do not require recruiting new patients and they can be completed much more quickly than typical prospective clinical trials. We intend to use a similar approach whenever possible for additional Prosigna clinical studies, however the clinical studies for companion diagnostic products will be prospective in nature, and while the costs of these studies are being funded by our collaborators, they will generally require several years to complete.

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

Table of Contents

Selling, General and Administrative

Selling, general and administrative expenses consist primarily of costs for our sales and marketing, finance, human resources, information technology, business development, legal and general management functions, as well as professional services, such as legal, consulting and accounting services. We expect selling, general and administrative expenses to increase in future periods as the number of sales, technical support and marketing and administrative personnel grows and we continue to introduce new products, broaden our customer base and grow our business. In particular, during 2014, we established a dedicated oncology focused team to support the commercialization of Prosigna, which has contributed to a 90% increase in selling and marketing expenses over 2013. In February 2015, we combined our two separate sales teams into a single organization selling our entire suite of products, targeted primarily toward major academic medical centers and biopharmaceutical companies. Legal, accounting and compliance costs have also increased as a result of our being a public company, and we expect them to continue to increase as our business grows.

Factors Affecting Our Performance

Instrument Installed Base

Our future financial performance will be driven in large part by the rate of sales of our nCounter Analysis Systems. In July 2015, we introduced our new generation of the nCounter Analysis System, the nCounter *SPRINT* Profiler, which we believe increases our addressable market substantially by making the technology more appealing to individual researchers. The new system is a single instrument with a reduced footprint that combines the prep station and the digital analyzer and is offered at a more affordable price.

We plan to grow our system sales in the coming years through other strategies, including expanding our sales channel in both direct and distributor territories and continuing to enhance the underlying technology and applications for both research and clinical diagnostics use. As part of this strategy, we restructured our sales and marketing organization in early 2015 and plan to add incremental sales territories and augment our field sales team with greater inside sales support in 2016. Similarly, as of December 2015, we have contracted with a total of 22 distributors. As our installed base of instruments grows, we solicit feedback from our customers and focus our research and development efforts on enabling the nCounter Analysis System for additional applications, which in turn helps to drive additional sales of our instruments and consumables.

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

As of December 31, 2015 we had an installed base of more than 350 nCounter Analysis Systems, which we count based on the number of nCounter Digital Analyzers sold given that a system may couple an analyzer with multiple nCounter Prep Stations. Management focuses on instrument unit sales as a primary indicator of current business success and a leading indicator of likely future sales of consumables.

Recurring Consumables Revenue

Our instruments are designed to be used only with our consumables. This closed system model generates recurring revenue from each instrument we sell. Management focuses on recurring consumable revenue per

Table of Contents

system as an indicator of the continuing value generated by each system. We calculate recurring consumable revenue per system quarterly by dividing consumable revenue recognized in a particular quarter (other than consumable revenue related to proof-of-principle studies) by the total number of nCounter Analysis Systems installed as of the last day in the immediately preceding quarter. Historically, a large majority of our systems and related consumables have been sold to research customers. Since 2010, our average consumables revenue per system has exceeded $100,000 per year.

As the installed base of the nCounter Analysis Systems expands, consumables revenue is expected to increase and over time should continue to be an increasingly important contributor to our total revenue. Additionally, we expect Prosigna *in vitro* diagnostic kit revenue to contribute an increasing amount of recurring revenue as we install more diagnostic systems, Prosigna is included in important breast cancer treatment guidelines and reimbursement by third-party payors becomes more broadly available. Furthermore, we intend to launch entirely new applications, such as multi-omics, which will enable researchers to measure gene expression and protein expression in a single experiment. The introduction of new applications has the potential to further increase our consumables revenue stream. Over time, we believe that consumables revenue should be subject to less period-to-period fluctuation than our instrument sales revenue.

Revenue Mix and Gross Margin

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

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

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

	Year Ended December 31,					
	2015		2014		2013	
	(Dollars in thousands)					
Product revenue:						
Instruments	$ 20,974	33%	$ 18,078	38%	$ 12,995	41%
Consumables	30,597	49	23,819	50	16,642	53
In vitro diagnostic kits	2,457	4	668	1	181	1
Total product revenue	54,028	86	42,565	89	29,818	95

Service revenue	2,611	4	1,932	4	1,585	5
Total product and service revenue	56,639	90	44,497	93	31,403	100
Collaboration revenue	6,028	10	3,096	7		
Total revenue	$ 62,667	100%	$ 47,593	100%	$ 31,403	100%

Table of Contents

Diagnostic Product Development

During 2013, we commercially launched the nCounter Dx Analysis System and Prosigna. Over time, we intend to build a menu of additional diagnostic tests that can be run on our nCounter Analysis System. As researchers discover how genomic information can be used to improve clinical decision-making, these discoveries can be translated and validated as diagnostic tests based on our nCounter Elements reagents or, in certain situations, developed as *in vitro* diagnostic assays. Our first example of this is Prosigna, for which we in-licensed the rights to intellectual property from Bioclassifier, LLC, a company founded by several of our research customers. More recently, we in-licensed the rights to the gene signature being developed as an *in vitro* diagnostic assay to subtype DLBCL patients that is the subject of our collaboration with Celgene. We intend to enter into similar arrangements with our research customers and other researchers for future diagnostic gene signatures, which may be developed independently as an *in vitro* diagnostic, or become the subject of future companion diagnostic collaborations.

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

Results of Operations

Comparison of Years Ended December 31, 2015 and 2014

Revenue

	Year Ended December 31,		Change 2015 v. 2014	
	2015	2014	Dollars	Percentage
	(Dollars in thousands)			
Product revenue:				
Instruments	$ 20,974	$ 18,078	$ 2,896	16%
Consumables	30,597	23,819	6,778	28
In vitro diagnostic kits	2,457	668	1,789	268
Total product revenue	54,028	42,565	11,463	27
Service revenue	2,611	1,932	679	35
Total product and service revenue	56,639	44,497	12,142	27
Collaboration revenue	6,028	3,096	2,932	95
Total revenue	$ 62,667	$ 47,593	$ 15,074	32%

Instruments, consumables and service revenue increased significantly for the year ended December 31, 2015 due to the increased volume of instruments sold. The total growth in the installed base of our instruments in 2015 was 34%.

The increase in consumables revenue was primarily driven by growth in our installed base of instrument systems as the average amount of consumable revenue sold was over $100,000 per installed system in 2015 and 2014. In vitro diagnostic kit revenue represents sales of Prosigna assays, which increased as more providers came online, and testing volumes increased. The increase in service revenue was primarily related to an increase in the number of instruments covered by service contracts. Collaboration revenue increased largely due to the collaboration with Merck, which was initiated in May 2015.

Table of Contents

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

	Year Ended December 31,		Change	
	2015	2014	Dollars	Percentage
	(Dollars in thousands)			
Cost of product and service revenue	$ 26,126	$ 21,149	$ 4,977	24%
Product and service gross profit	$ 30,513	$ 23,348	$ 7,165	31
Product and service gross margin	54%	52%		

The increase in cost of product and service revenue for 2015 was related to the increased volume of instruments, consumables, *in vitro* diagnostic kits and services sold. The increase in gross margin on product and service revenues is primarily due to a product mix shift towards consumables and other factors, including improved margins on consumable revenues and service revenue as a result of increasing scale.

Research and Development Expense

	Year Ended December 31,		Change	
	2015	2014	Dollars	Percentage
	(Dollars in thousands)			
Research and development expense	$ 24,597	$ 21,404	$ 3,193	15%

The increases in research and development expense in 2015 reflected a $3.6 million increase in personnel-related expenses and a $0.9 million increase in supply costs to support primarily the advancement of our diagnostic and product development activities, including activities to support our collaboration agreements. In addition, facility costs increased $0.9 million due to expansion of our leased space for research and development activities. These increases were partially offset by decreases of $2.1 million in engineering and consulting costs primarily for the development of our nCounter technologies in 2015.

Selling, General and Administrative Expense

	Year Ended December 31,		Change	
	2015	2014	Dollars	Percentage
	(Dollars in thousands)			
Selling, general and administrative expense	$ 53,186	$ 51,063	$ 2,123	4%

The increases in selling, general and administration expense in 2015 were primarily attributable to a $3.7 million increase in staffing and personnel-related costs to support sales and marketing and administration; and increased facilities costs of $1.3 million as a result of our expanded leased space for operational and administrative activities. Partially offsetting the increase was a reduction of $2.8 million in marketing program costs in 2015.

Other Income (Expense)

	Year Ended December 31,	Change

	2015	2014	Dollars	Percentage
	(Dollars in thousands)			
Interest income	$ 233	$ 272	$ (39)	(14)%
Interest expense	(4,017)	(4,140)	123	(3)
Other expense	(389)	(147)	(242)	165
Total other income (expense)	$ (4,173)	$ (4,015)	$ (158)	4

The $0.1 million decrease in interest expense in 2015 was related to the costs incurred to pay off our former credit facility in April 2014, offset by an overall increase in borrowing in 2015. In 2014, we incurred and recorded $1.4 million of interest expense related to the repayment of our former credit facility, including a loss on extinguishment of debt of $0.6 million. The impact of these expenses not recurring in 2015 was partially offset by a $1.3 million increase in interest expense attributable to our increase in borrowings outstanding for the respective periods. Long-term debt and lease financing obligations outstanding increased to $41.2 million as of December 31, 2015 as compared to $30.2 million as of December 31, 2014. The average balance of long-term debt and lease financing obligations outstanding was $31.4 million in 2015 compared to $22.5 million in 2014.

Table of Contents

Comparison of Years Ended December 31, 2014 and 2013

Revenue

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

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

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

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

The increase in cost of product and service revenue for 2014 was related to the increased volume of instruments, consumables, *in vitro* diagnostic kits and services sold. Product and service gross margin was approximately the same for both periods. Although gross margin for instrument revenues in 2014 improved slightly by 1.7 percentage points over 2013, this was largely offset by a 1.0 percentage point reduction in gross margin for consumables, *in vitro* diagnostic kits and service.

Research and Development Expense

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

The increases in research and development expense in 2014 reflected a $4.1 million increase in personnel-related expenses primarily to support the advancement of our nCounter technology. In addition, there was a $1.5 million increase in engineering costs for development of the next generation of our nCounter system and an

Table of Contents

increase in costs to support the Celgene collaboration agreement. Partially offsetting the increase was a reduction of $0.4 million in clinical study costs. The remaining $1.2 million change was due to various other operating expense fluctuations that were individually immaterial.

Selling, General and Administrative Expense

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

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

Other Income (Expense)

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

The increase in interest expense in 2014 was related to the costs incurred to pay off our former credit facility in April 2014 and an overall increase in borrowing. In 2014, we incurred and recorded $1.4 million of interest expense related to the repayment of our former credit facility, including a loss on extinguishment of debt of $0.6 million. Long-term debt outstanding increased to $30.2 million as of December 31, 2014 as compared to $18.3 million as of December 31, 2013. The average net debt balance was $22.5 million in 2014 compared to $16.7 million in 2013.

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

Liquidity and Capital Resources

As of December 31, 2015, we had cash, cash equivalents and short-term investments of $49.0 million, compared to $72.2 million as of December 31, 2014. We believe our existing cash, cash equivalents and short-term investments,

together with the additional borrowing capacity under our term loan agreement, will be sufficient to meet our working capital and capital expenditure needs for at least the next 12 months. However, we may need to raise additional capital to expand the commercialization of our products, fund our operations and further our research and development activities. Our future funding requirements will depend on many factors, including: market acceptance of our products; the cost and timing of establishing additional sales, marketing and distribution capabilities; the cost of our research and development activities; the cost and timing of regulatory clearances or approvals; the effect of competing technological and market developments; the nature and timing of any additional companion diagnostic development collaborations we may establish; and the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Table of Contents

If we require additional funds in the future, we may not be able to obtain such funds on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or additional equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets, or delay, reduce the scope of or eliminate some or all of our development programs. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations.

Sources of Funds

Our cash used in operations for the year ended December 31, 2015 was $43.4 million and we expect to continue to require cash to fund our operations for at least the next several years.

In May 2015, we entered into a sales agreement with a sales agent to sell shares of our common stock through an at the market equity offering program for up to $40 million in total sales proceeds. Under the sales agreement, we sold 960,400 shares during 2015 for net proceeds of $12.5 million. The sale agreement allows for us to set the parameter for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limits the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. As of December 31, 2015, approximately $27.0 million of common stock is available to be sold under the at the market equity offering program. We cannot guarantee that we will be able to sell the remaining available shares under the sales agreement under favorable market conditions.

In April 2014, we entered into a term loan agreement under which we may borrow up to $45.0 million, including an option to defer payment of a portion of the interest that would accrue on the borrowing under the term loan agreement. Upon initial closing, we borrowed $20.0 million, the proceeds of which were primarily used to repay the outstanding balance under our former credit facility plus a related $1.0 million end of term payment, a $0.3 million make-whole premium, and deferred interest. We incurred and recorded a total charge to interest expense of $1.4 million related to the repayment of our former credit facility, including a loss on extinguishment of debt of $0.6 million. In October 2014, we borrowed an additional $10.0 million under the term loan agreement.

In October 2015, we amended our term loan agreement to, among other provisions, increase the maximum borrowing capacity to $60 million (excluding accrued interest), reduce the applicable interest rate from 12.5% to 12.0%, extend the interest-only period through March 2021, and extend the final maturity to March 2022. Under the amended agreement, borrowings accrue interest at 12.0% annually, payable quarterly, of which 3.0% can be deferred during the first six years of the term at our option and paid together with the principal at maturity. We have elected to exercise the option to defer a portion of the interest and we have recorded $1.5 million of deferred interest through December 31, 2015. In December 2015, we borrowed an additional $10 million under the terms of the amended agreement and we are required to borrow an additional $5 million no later than June 30, 2016. At our option, we may borrow up to an additional $15 million through December 31, 2016. Total borrowings under the amended term loan agreement were $41.5 million as of December 31, 2015.

Under the amended term loan agreement, we may pay interest-only for the first seven years of the term and principal payments are due in four equal installments during the eighth year of the term. We have the option to

Table of Contents

prepay the term loan, in whole or part, at any time subject to payment of a redemption fee of up to 4%, which declines 1% annually thereafter, with no redemption fee payable if prepayment occurs after the fourth year of the loan. In addition, a facility fee equal to 2.0% of the amount borrowed plus any deferred interest is payable at the end of the term or when the loan is repaid in full. A long-term liability of $1.1 million is being accreted using the effective interest method for the facility fee over the term of the loan agreement. Obligations under the term loan agreement are collateralized by substantially all of our assets.

The term loan agreement contains customary conditions to borrowings, events of default and negative covenants, including covenants that could limit our ability to, among other things, incur additional indebtedness, liens or other encumbrances, make dividends or other distributions; buy, sell or transfer assets; engage in any new line of business; and enter into certain transactions with affiliates. The term loan agreement also includes a $2.0 million minimum liquidity covenant and revenue-based financial covenants, which was $55.0 million for 2015 with annual increases of $15.0 million for each subsequent fiscal year thereafter. If our actual revenues are below the minimum annual revenue requirement for any given year, we may avoid a related default by generating proceeds from an equity or subordinated debt issuance equal to the shortfall between our actual revenues and the minimum revenue requirement. We were in compliance with our covenants as of December 31, 2015.

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

In July 2013, we raised $54.0 million, before offering expenses, in our initial public offering. Net of offering expenses, our initial public offering generated approximately $46.8 million. In April 2013, we incurred $5.0 million of the remaining term loan borrowings under our previous credit facility.

Use of Funds

Our principal uses of cash are funding our operations, satisfaction of our obligations under our debt instruments, and other working capital requirements. Over the past several years, our revenue has increased significantly from year to year and, as a result, our cash flows from customer collections have increased. However, our operating expenses have also increased as we have invested in growing our existing research business, developing and commercializing Prosigna, and supporting our companion diagnostic collaborations with Celgene and Merck. As a result, our cash used in operating activities has increased. Our operating cash requirements may increase in the future as we (1) increase sales and marketing activities to expand the installed base of our nCounter Analysis Systems among research customers and clinical laboratories and continue to promote consumable usage, including Prosigna, (2) commercialize, and conduct studies to expand the clinical utility of Prosigna and develop new diagnostic tests, such as LST for DLBCL, and (3) develop new applications, chemistry and instruments for our nCounter platform, as we cannot be certain our revenues will grow sufficiently to offset our operating expense increases.

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

Table of Contents

Historical Cash Flow Trends

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

	Year Ended December 31,		
	2015	2014	2013
	(In thousands)		
Cash used in operating activities	$ (43,362)	$ (38,061)	$ (31,346)
Cash provided by (used in) investing activities	23,769	(24,275)	(32,955)
Cash provided by financing activities	24,268	69,566	52,550

Operating Cash Flows

We derive operating cash flows from cash collected from the sale of our products and services and, beginning in 2014, from collaborations. These cash flows received are outweighed by our use of cash for operating expenses to support the growth of our business. As a result, we have historically experienced negative cash flows from operating activities and this will likely continue for the foreseeable future.

Net cash used in operating activities for 2015 consisted of our net loss of $45.6 million and $7.8 million of changes in our operating assets and liabilities. These uses were partially offset by $10.0 million of net non-cash income and expense items, such as stock-based compensation, depreciation and amortization, deferred interest converted to principal for the term loan, and amortization of premium on short-term investments.

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

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

Investing Cash Flows

Our most significant investing activities for the years ended December 31, 2015, 2014 and 2013 were related to the purchase and sale of short-term investments. Because we manage our cash usage with respect to our total cash, cash equivalents and short-term investments, we do not consider these cash flows to be important to an understanding of our liquidity and capital resources.

In the years ended December 31, 2015, 2014 and 2013, we purchased $3.8 million, $1.9 million, and $0.8 million respectively, of property and equipment required to support the growth and expansion of our operations.

Financing Cash Flows

Historically, we have funded our operations through the issuance of equity securities and debt borrowings.

Net cash provided by financing activities for 2015 consisted of net proceeds of $12.5 million from the sale of shares through an at the market equity offering program, proceeds of $10.0 million from our amended term loan agreement, Employee Stock Purchase Plan proceeds of $1.3 million, and $0.9 million of proceeds from the exercise of stock options. These proceeds were partially offset by payment of lease financing obligations of $0.3 million and payment of deferred offering costs related to the equity offering program of $0.2 million.

Net cash provided by financing activities for 2014 consisted of net proceeds of $57.0 million from our public offering of common stock, proceeds of $30.0 million from our term loan agreement, Employee Stock

Table of Contents

Purchase Plan proceeds of $1.0 million, $0.4 million of proceeds from the exercise of stock options, and net proceeds of $0.2 million from the exercise of common stock warrants. These proceeds were partially offset by the repayment of the outstanding balance under our former credit facility in the amount of $18.2 million, payment of deferred costs related to our term loan agreement in the amount of $0.8 million, and the repurchase of shares related to common stock warrant exercises of $0.1 million.

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

Contractual Obligations

The following table reflects a summary of our contractual obligations as of December 31, 2015.

	Payments due by period				
Contractual Obligations[1]	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
			(In thousands)		
Lease obligations[2]	$ 41,494	$ 3,282	$ 7,660	$ 8,099	$ 22,453
Long-term debt obligations[3]	41,771	226	58		41,487
Inventory purchase obligations[4]	9,230	9,230			
Total	$ 92,495	$ 12,738	$ 7,718	$ 8,099	$ 63,940

(1) Excludes royalty obligations based on net sales of products, including royalties payable to the Institute for Systems Biology, as any such amounts are not currently determinable.
(2) Lease costs are primarily for office, laboratory and manufacturing space and exclude the additional costs related to the February 2016 lease amendment.
(3) Includes principal and deferred interest on long-term debt obligations.
(4) Purchase obligations consist of contractual and legally binding commitments under outstanding purchase orders to purchase long lead time inventory items.

Critical Accounting Policies and Significant Estimates

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

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

accounting policies and estimates include those related to:

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

Table of Contents

Revenue Recognition

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

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

Instruments, consumables and *in vitro* diagnostic kits are considered to be separate units of accounting as they are sold separately and revenue is recognized upon transfer of ownership, which is generally upon shipment. Instrument revenue related to installation and calibration services is recognized when services are rendered. For instruments sold for use primarily to run Prosigna assays, training must be provided prior to instrument revenue recognition. Instrument revenue from leased instruments is recognized ratably over the lease term.

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

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

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

Accruals for estimated warranty expenses are made at the time that the associated revenue is recognized. We use judgment to estimate these accruals and, if we were to experience an increase in warranty claims or if costs of

servicing our products under warranty were greater than our estimates, our cost of revenue could be adversely affected in future periods.

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

Table of Contents

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

Stock-based Compensation

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

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

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

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

Inventory Valuation

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

could be required.

Table of Contents

Fair Value Measurements

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

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

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

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

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

Income Taxes

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

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

At December 31, 2015, we had federal net operating loss carryforwards, or NOLs, of approximately $165.4 million and federal research and experimentation credit carryforwards of approximately $4.2 million, which may be used to reduce future taxable income or offset income taxes due. These NOLs and credit carryforwards expire beginning in

2025 through 2036.

Table of Contents

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

We do not anticipate that the amount of our existing unrecognized tax benefits will significantly increase or decrease within the next 12 months. Due to the presence of NOLs in most jurisdictions, our tax years remain open for examination by taxing authorities back to 2004.

Recent Accounting Pronouncements

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

In May 2014, the Financial Accounting Standards Board, or FASB issued an accounting standards update entitled ASU 2014-09, Revenue from Contracts with Customers. The standard requires entities to recognize revenue through the application of a five step model, which includes identification of the contract, identification of the performance obligations, determination of the transaction price, allocation of the transaction price to the performance obligations, and recognition of revenue as the entity satisfies the performance obligations. The standard will become effective for us beginning January 1, 2018. We are currently assessing the impact adoption of this standard will have on our consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

In June 2014, FASB issued an accounting standards update entitled ASU 2014-12, Compensation Stock Compensation. The standard requires entities that grant their employees share-based payments in which the terms of the award provide that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. The standard will become effective for us beginning January 1, 2016. We do not anticipate the adoption will have a material impact on our consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

In August 2014, FASB issued an accounting standards update entitled ASU 2014-15, Presentation of Financial Statements Going Concern. The standard requires entities to evaluate for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity s ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). The standard will become effective for us beginning January 1, 2017. We do not anticipate the adoption will have a material impact on our consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

Table of Contents

In July 2015, FASB issued an accounting standards update entitled ASU 2015-11, Inventory Simplifying the Measurement of Inventory. The standard requires entities to measure inventory at the lower of cost and net realizable value. The standard will become effective for us beginning January 1, 2017. We do not anticipate the adoption will have a material impact on our consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

In November 2015, FASB issued an accounting standards update entitled ASU 2015-17 Balance Sheet Classification of Deferred Taxes. The standard required deferred income tax liabilities and assets be classified as noncurrent in our consolidated balance sheet. The standard is effective for us beginning January 1, 2018. We do not anticipate the adoption will have a material impact on our consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

In February 2016, FASB issued an accounting standards update entitled ASU 2016-02, Leases Recognition and Measurement of Financial Assets and Financial Liabilities. The standard requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition. The standard requires lessors to classify leases as either sales-type, finance or operating. A sales-type lease occurs if the lessor transfers all of the risks and rewards, as well as control of the underlying asset, to the lessee. If risks and rewards are conveyed without the transfer of control, the lease is treated as a financing lease. If the lessor does not convey risks and rewards or control, an operating lease results. The standard will become effective for us beginning January 1, 2019. We are currently assessing the impact adoption of this standard will have on our consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

Off-Balance Sheet Arrangements

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

Inflation

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Interest Rate Risk

Generally, our exposure to market risk has been primarily limited to interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term debt securities. The primary objective of our investment activities is to preserve principal while at the same

time maximizing the income we receive without significantly increasing risk. To minimize risk, we maintain our portfolio of cash, cash equivalents and short-term investments in a variety of interest-bearing instruments, which have included U.S. government and agency securities, high-grade U.S. corporate bonds, asset-backed securities, and money market funds. Declines in interest rates, however, would reduce future investment income. A 10% decline in interest rates, occurring on January 1, 2016 and sustained throughout the period ending December 31, 2016, would not be material.

As of December 31, 2015, the principal and deferred interest outstanding under our term borrowings was $41.5 million. The interest rates on our term borrowings under our credit facility are fixed. If overall interest rates had increased by 10% during the periods presented, our interest expense would not have been affected.

Foreign Currency Exchange Risk

As we continue to expand internationally our results of operations and cash flows will become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Historically, a majority of our revenue has been denominated in U.S. dollars, although we sell our products and services directly in certain markets

Table of Contents

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

Table of Contents

Item 8. Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

NANOSTRING TECHNOLOGIES, INC.

Table of Contents

Report of Independent Registered Public Accounting Firm

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of comprehensive loss, of changes in mandatorily redeemable convertible preferred stock and stockholders equity (deficit) and of cash flows present fairly, in all material respects, the financial position of NanoString Technologies, Inc. and its subsidiaries (the Company) at December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Seattle, Washington

March 11, 2016

Table of Contents

NanoString Technologies, Inc.

Consolidated Balance Sheets

	December 31,	
	2015	2014
	(In thousands, except par value amounts)	
Assets		
Current assets:		
Cash and cash equivalents	$ 21,856	$ 17,223
Short-term investments	27,188	55,002
Accounts receivable, net	19,725	12,436
Inventory	10,138	5,444
Prepaid expenses and other current assets	3,886	5,114
Total current assets	82,793	95,219
Restricted cash	143	143
Deferred offering costs	181	
Property and equipment, net	9,414	6,366
Other assets	338	340
Total assets	$ 92,869	$ 102,068
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 3,243	$ 3,380
Accrued liabilities	12,181	10,403
Deferred revenue, current portion	5,261	4,627
Deferred rent, current portion		147
Lease financing obligations, current portion	226	251
Total current liabilities	20,911	18,808
Deferred revenue, net of current portion	6,486	7,135
Deferred rent, net of current portion	4,257	1,317
Long-term debt and lease financing obligations, net of current portion and debt issuance costs	41,000	29,995
Total liabilities	72,654	57,255
Commitments and contingencies (Note 15)		
Stockholders equity		
Preferred stock, $0.0001 par value, 15,000 shares authorized; none issued		
	2	2

Common stock, $0.0001 par value, 150,000 shares authorized; 19,570 and 18,272 shares issued and outstanding at December 31, 2015 and 2014, respectively		
Additional paid-in-capital	242,693	221,724
Other comprehensive loss	(29)	(43)
Accumulated deficit	(222,451)	(176,870)
Total stockholders equity	20,215	44,813
Total liabilities and stockholders equity	$ 92,869	$ 102,068

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

Table of Contents

NanoString Technologies, Inc.

Consolidated Statements of Operations

	Years Ended December 31,		
	2015	2014	2013
	(In thousands, except per share amounts)		
Revenue:			
Product and service	$ 56,639	$ 44,497	$ 31,403
Collaboration	6,028	3,096	
Total revenue	62,667	47,593	31,403
Costs and expenses:			
Cost of product and service revenue	26,126	21,149	15,009
Research and development	24,597	21,404	14,979
Selling, general and administrative	53,186	51,063	29,912
Total costs and expenses	103,909	93,616	59,900
Loss from operations	(41,242)	(46,023)	(28,497)
Other income (expense):			
Interest income	233	272	68
Interest expense	(4,017)	(4,140)	(1,942)
Other expense	(389)	(147)	(66)
Revaluation of preferred stock warrant liability			1,156
Total other income (expense)	(4,173)	(4,015)	(784)
Net loss before provision for income taxes	(45,415)	(50,038)	(29,281)
Provision for income taxes	(166)		
Net loss	(45,581)	(50,038)	(29,281)
Accretion of mandatorily redeemable convertible preferred stock			(4,653)
Net loss attributable to common stockholders	$ (45,581)	$ (50,038)	$ (33,934)
Net loss per share basic and diluted	$ (2.40)	$ (2.80)	$ (4.44)
Weighted average shares used in computing basic and diluted net loss per share	19,027	17,839	7,643

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

Table of Contents

NanoString Technologies, Inc.

Consolidated Statements of Comprehensive Loss

	Years Ended December 31,		
	2015	2014	2013
	(In thousands)		
Net loss	$ (45,581)	$ (50,038)	$ (29,281)
Other comprehensive income (loss):			
Unrealized gain (loss) on short-term investments	14	(65)	22
Comprehensive loss	$ (45,567)	$ (50,103)	$ (29,259)

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

Table of Contents

NanoString Technologies, Inc.

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

Period From December 31, 2012 Through December 31, 2015

nt	Series B Preferred Stock Shares	Series B Preferred Stock Amount	Series C Preferred Stock Shares	Series C Preferred Stock Amount	Series D Preferred Stock Shares	Series D Preferred Stock Amount	Series E Preferred Stock Shares	Series E Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additio Paid-C Capita
				(In thousands, except share amounts)							
05	515,836	$ 13,865	3,551,060	$ 38,592	2,430,054	$ 20,323	1,063,951	$ 15,237	411,226	$	$
33		577		1,604		1,140		649			(8
									5,400,000		46,8
38)	(515,836)	(14,442)	(3,551,060)	(40,196)	(2,430,054)	(21,463)	(1,063,951)	(15,886)	8,631,427	1	108,2
											2,5
									177,165		3
											1,1
									14,619,818	1	158,2

				3,318,917	1	56,9
				141,386		9
				164,394		4
				27,269		1
						4,9
				18,271,784	$ 2	$ 221,7
				960,400		12,5
				136,078		1,2
				201,622		8
				250		
						6,2
$	$	$	$	19,570,134	$ 2	$ 242,6

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

Table of Contents

NanoString Technologies, Inc.

Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2015	2014	2013
	(In thousands)		
Operating activities:			
Net loss	$ (45,581)	$ (50,038)	$ (29,281)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	2,377	1,590	1,990
Stock-based compensation	6,278	4,926	1,145
Revaluation of preferred stock warrant liability			(1,156)
Loss on extinguishment of debt		581	
Amortization of premium on short-term investments	270	86	(518)
Interest accrued on long-term debt	18	(348)	259
Conversion of accrued interest to long-term debt	1,067	420	
Bad debt expense	34		
Loss on disposal of property and equipment	3		1
Gain on sale of investments		(5)	
Changes in operating assets and liabilities			
Accounts receivable, net	(7,328)	(4,109)	(5,009)
Inventory	(5,354)	(1,252)	(1,370)
Prepaid expenses and other	1,199	(2,132)	(1,679)
Other assets	(7)	(70)	(268)
Accounts payable	(166)	21	1,601
Accrued liabilities	1,162	3,379	2,678
Deferred revenue	(127)	9,497	1,025
Deferred rent	2,793	(607)	(764)
Net cash used in operating activities	(43,362)	(38,061)	(31,346)
Investing activities:			
Purchases of property and equipment	(3,796)	(1,900)	(759)
Proceeds from sale of short-term investments	3,000	4,500	
Proceeds from maturity of short-term investments	57,309	35,977	
Purchases of short-term investments	(32,750)	(62,911)	(32,175)
Proceeds from sale of property and equipment	6		
Decrease (increase) in restricted cash		59	(21)
Net cash provided by (used in) investing activities	23,769	(24,275)	(32,955)
Financing activities:			
Proceeds from long-term debt	10,000	30,000	5,000
Deferred costs related to long-term debt		(770)	

Repayment of long-term debt and lease financing obligations	(271)	(18,214)	(211)
Net proceeds from public offerings of common stock	12,518	57,015	47,374
Proceeds from exercise of common stock warrants	2	230	
Proceeds from issuance of common stock for employee stock purchase plan	1,295	988	
Repurchase of shares related to common stock warrant exercise		(94)	
Deferred offering costs	(152)		
Proceeds from exercise of stock options	876	411	387
Net cash provided by financing activities	24,268	69,566	52,550
Net increase (decrease) in cash and cash equivalents	4,675	7,230	(11,751)
Effect of exchange rate changes on cash and cash equivalents	(42)	52	
Cash and cash equivalents:			
Beginning of year	17,223	9,941	21,692
End of year	$ 21,856	$ 17,223	$ 9,941
Supplemental disclosures:			
Cash paid for interest	$ 2,844	$ 3,479	$ 1,474
Cash paid for taxes	69		
Accrual of construction costs for leasehold improvements	640		
Rental instruments reclassified from inventory	772	2,541	
Non-cash inventory exchange for services	112		
Non-cash capital lease	48	262	410
Accrual of offering costs	29		29
Accretion of preferred stock			4,653
Issuance of preferred stock warrants with debt			138
Conversion of convertible preferred stock to common stock			108,275
Conversion of convertible preferred stock warrants to common stock warrants			2,514

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

Table of Contents

NanoString Technologies, Inc.

Notes to Consolidated Financial Statements

1. Description of the Business

NanoString Technologies, Inc. (the Company) was incorporated in the state of Delaware on June 20, 2003. The Company s headquarters is located in Seattle, Washington. The Company s technology enables direct detection, identification and quantification of individual target molecules in a biological sample by attaching a unique color coded fluorescent reporter to each target molecule of interest. The Company markets its proprietary nCounter Analysis System, consisting of instruments and consumables, including its Prosigna Breast Cancer Assay, to academic, government and biopharmaceutical and clinical laboratory customers. In addition, the Company is collaborating with multiple biopharma companies to develop companion diagnostic tests for various cancer therapies.

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

Reverse Stock Split

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

Public Offerings

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

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

In May 2015, the Company entered into a sales agreement with a sales agent to sell shares of the Company s common stock through an at the market equity offering program for up to $40.0 million in total sales proceeds. Under the sales agreement, the Company sold 960,400 shares during 2015 for net proceeds of $12.5 million. The sales agreement allows the Company to set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limits on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Under the terms of the Sales Agreement, commission expenses to the sales agent will not exceed 3% of the gross sales price per share sold through the sales agent. The Sales Agreement shall automatically terminate upon the issuance and sale of placement shares equaling

sales proceeds of $40.0 million and may be terminated earlier by either the Company or the sales agent upon five days notice. As of December 31, 2015, the Company has sold an aggregate of 960,400 shares of the Company s common stock for total gross

Table of Contents

proceeds of $13.0 million. The net proceeds from the sale of the shares, after deducting the sales agent commission and other expenses of the offering, were approximately $12.5 million. As of December 31, 2015, approximately $27.0 million of common stock is available to be sold under the at the market equity offering program.

2. Significant Accounting Policies

Accounting Principles and Principles of Consolidation

The consolidated financial statements and accompanying notes were prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP). The accompanying consolidated financial statements reflect the accounts of the Company and its wholly-owned subsidiaries. Each of the subsidiaries operates as a sales and support office. The functional currency of each subsidiary is the U.S. dollar. All significant intercompany balances and transactions have been eliminated.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and that affect the reported amounts of revenue and expenditures during the reporting period. Actual results could differ from those estimates. Significant estimates inherent in the preparation of the accompanying consolidated financial statements include the estimation of the valuation of inventory, the fair value of the Company s equity securities, the calculation of stock-based compensation and the estimated future cost of ongoing collaboration agreements, for which revenues are recognized on a proportional performance basis.

Cash and Cash Equivalents

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

Investments

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

If the estimated fair value of a security is below its carrying value, the Company evaluates whether it is more likely than not that it will sell the security before its anticipated recovery in market value and whether evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. The Company also evaluates whether or not it intends to sell the investment. If the impairment is considered to be

other-than-temporary, the security is written down to its estimated fair value. In addition, the Company considers whether credit losses exist for any securities. A

Table of Contents

credit loss exists if the present value of cash flows expected to be collected is less than the amortized cost basis of the security. Other-than-temporary declines in estimated fair value and credit losses are charged against other income (expense).

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are stated at the amount management expects to collect from customers based on their outstanding invoices. Management reviews accounts receivable regularly to determine if any receivable will potentially be uncollectible and to estimate the amount of allowance for doubtful accounts necessary to reduce accounts receivable to its estimated net realizable value by analyzing the status of significant past due receivables. The allowance for doubtful accounts was $96,600 and $63,000 as of December 31, 2015 and 2014, respectively. Additions to the allowance were $33,600, $63,000 and $0 for the years ended December 31, 2015, 2014 and 2013, respectively. There were no write-offs of uncollectible accounts during the years ended December 31, 2015, 2014 and 2013.

Concentration of Credit Risks

Financial instruments that potentially expose the Company to concentrations of credit risk consist principally of cash and cash equivalents, short-term investments and accounts receivable. Cash is invested in accordance with the Company s investment policy, which includes guidelines intended to minimize and diversify credit risk. Most of the Company s investments are not federally insured. The Company has credit risk related to the collectability of its accounts receivable. The Company performs initial and ongoing evaluations of its customers credit history or financial position and generally extends credit on account without collateral. The Company has not experienced any significant credit losses to date.

The Company had no customers that individually represented more than 10% of total revenue during the years ended December 31, 2015, 2014 and 2013. The Company had no customers that represented more than 10% of total accounts receivable at December 31, 2015 and one customer represented 21% of accounts receivable at December 31, 2014.

The Company is also subject to supply chain risks related to the outsourcing of the manufacturing of its instruments to sole suppliers. Although there are a limited number of manufacturers for instruments of this type, the Company believes that other suppliers could provide similar products on comparable terms. A change in suppliers, however, could cause a delay in manufacturing and a possible loss of sales, which would adversely affect operating results.

Fair value of financial instruments

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

Inventory

Inventory consists of finished goods, work in process, raw materials and certain component parts to be used in manufacturing the Company s products. Inventory is stated at the lower of cost or market. Cost is determined using a standard cost system, whereby the standard costs are updated periodically to reflect current costs and market

represents the lower of replacement cost or estimated net realizable value. The Company s policy is to establish inventory reserves when conditions exist that suggest that inventory may be in excess of anticipated demand, obsolete, slow moving or impaired. In the event that the Company identifies these conditions exist in its inventory, its carrying value is reduced to its net realizable value. Inventory reserves were $2.2 million, $2.2 million, $2.1 million and $3.5 million as of December 31, 2015, 2014, 2013 and 2012, respectively. Additions to the reserves were $0.2 million, $0.2 million and $0.4 million for the years ended December 31, 2015, 2014 and 2013, respectively. Write-offs of inventory reserves for the years ended December 31, 2015, 2014 and 2013 were $0.3 million, $0.1 million and $1.8 million, respectively.

Table of Contents

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

Property and Equipment

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

Leases and Leasehold Improvements

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

Impairment of Long-Lived Assets

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

Deferred Offering Costs

Deferred offering costs represent legal, accounting and other direct costs related to the Company s efforts to raise capital through public offerings of the Company s common stock. Costs are deferred until the completion of the applicable offering, at which time they are reclassified to additional paid-in capital as a reduction of the proceeds. The Company recorded deferred offering costs of $181,000 as a non-current asset as of December 31, 2015. The Company had no deferred offering costs recorded as of December 31, 2014.

Table of Contents

Segments

Operating segments are defined as components of an entity for which separate financial information is available and evaluated regularly by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company s chief operating decision maker is the chief executive officer, who manages the operations and evaluates the financial performance on a total Company basis. The Company s principal operations and decision-making functions are located at its corporate headquarters in the United States.

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

Revenue Recognition

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

Instruments, consumables and *in vitro* diagnostic kits are considered to be separate units of accounting as they are sold separately and revenue is recognized upon transfer of ownership, which is generally upon shipment. Instrument revenue related to installation and calibration services is recognized when services are rendered by the Company. Such services can also be provided by the Company s distribution partners. For instruments sold for use primarily to run Prosigna assays, training must be provided prior to instrument revenue recognition. Instrument revenue from leased instruments is recognized ratably over the lease term.

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

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

-88-

Table of Contents

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

Cost of Revenue

Cost of revenue consists primarily of costs incurred in the production process, including costs of purchasing instruments from third-party contract manufacturers, consumable component materials and assembly labor and overhead, installation, warranty, service and packaging and delivery costs. In addition, cost of revenue includes royalty costs for licensed technologies included in the Company s products, provisions for slow-moving and obsolete inventory and stock-based compensation expense. Cost of revenue for instruments and consumables is recognized in the period the related revenue is recognized. Shipping and handling costs incurred for product shipments are included in cost of revenue in the consolidated statements of operations.

Reserve for Product Warranties

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

Research and Development

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

Selling, General and Administrative

Selling expenses consist primarily of personnel related costs for sales and marketing, contracted services and service fees and are expensed as the related costs are incurred. Advertising costs are charged to operations as incurred and are included in sales and marketing expenses. Advertising costs totaled approximately $2.6 million, $5.1 million and $3.3 million during the years ended December 31, 2015, 2014 and 2013, respectively.

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

Table of Contents

Income Taxes

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

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

Stock-Based Compensation

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

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

Guarantees and Indemnifications

In the normal course of business, the Company guarantees and/or indemnifies other parties, including vendors, lessors and parties to transactions with the Company, with respect to certain matters. The Company has agreed to hold the other parties harmless against losses arising from breach of representations or covenants, or out of intellectual property infringement or other claims made against certain parties. It is not possible to determine the maximum potential amount the Company could be required to pay under these indemnification agreements, since the Company has not had any prior indemnification claims, and each claim would be based upon the unique facts and circumstances of the claim and the particular provisions of each agreement. In the opinion of management, any such claims would not be expected to have a material adverse effect on the Company s consolidated results of operations, financial condition or cash flows. The Company did not have any related liabilities recorded at December 31, 2015 and 2014.

Comprehensive Loss

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

Recently Adopted Accounting Pronouncement

In April 2015, the Financial Accounting Standards Board (FASB) issued an accounting standards update entitled ASU 2015-03, Interest-Imputation of Interest: Simplifying the Presentation of Debt Issuance Costs. The standard simplifies the presentation of debt issuance costs by requiring that debt issuance costs related to a recognized debt liability be presented in the consolidated balance sheet as a direct reduction from the carrying amount of the debt liability, which is consistent with the treatment of debt discounts. The Company has applied ASU 2015-03 in the fourth quarter of

fiscal 2015 and has reclassified debt issuance costs from current and other long-term assets to long-term debt for all years presented. Adoption did not otherwise impact the Company s consolidated results of operations and statements of cash flows.

Table of Contents

Recent Accounting Pronouncements

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

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

In June 2014, FASB issued an accounting standards update entitled ASU 2014-12, Compensation Stock Compensation. The standard requires entities that grant their employees share-based payments in which the terms of the award provide that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. The standard will become effective for the Company beginning January 1, 2016. The Company does not anticipate adoption of the standard will have a material impact on its consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

In August 2014, FASB issued an accounting standards update entitled ASU 2014-15, Presentation of Financial Statements Going Concern. The standard requires entities to evaluate for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity s ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). The standard will become effective for the Company beginning January 1, 2017. The Company does not anticipate adoption of the standard will have a material impact on its consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

In July 2015, FASB issued an accounting standards update entitled ASU 2015-11, Inventory Simplifying the Measurement of Inventory. The standard requires entities to measure inventory at the lower of cost and net realizable value. The standard will become effective for the Company beginning January 1, 2017. The Company does not anticipate adoption of the standard will have a material impact on its consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

In November 2015, FASB issued an accounting standards update entitled ASU 2015-17, Balance Sheet Classification of Deferred Taxes. The standard requires deferred income tax liabilities and assets be classified as noncurrent in our consolidated balance sheet. The standard will become effective for the Company beginning January 1, 2018. The Company does not anticipate adoption of the standard will have a material impact on its consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

In February 2016, FASB issued an accounting standards update entitled ASU 2016-02, Leases Recognition and Measurement of Financial Assets and Financial Liabilities. The standard requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition. The standard requires lessors to classify leases as either sales-type, finance or operating. A sales-type lease occurs if the lessor transfers all of the risks and rewards, as well as control of the underlying asset, to the lessee. If risks and rewards are conveyed without the transfer

of control, the lease is treated as a financing lease. If the lessor does not convey risks and rewards or control, an operating lease results. The standard will become effective for the Company beginning January 1, 2019. The Company is currently assessing the impact adoption of this standard will have on its consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

3. Short-term Investments

Short-term investments consisted of available-for-sale securities as follows (in thousands):

Type of security as of December 31, 2015	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Corporate debt securities	$ 26,116	$	$ (28)	$ 26,088
U.S. government-related debt securities	1,101		(1)	1,100
Total available-for-sale securities	$ 27,217	$	$ (29)	$ 27,188

Table of Contents

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

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

	2015	2014
Maturing in one year or less	$ 27,188	$ 51,235
Maturing in one to three years		3,767
Total available-for-sale securities	$ 27,188	$ 55,002

The following table summarizes investments that have been in a continuous unrealized loss position as of December 31, 2015 (in thousands):

	Less Than 12 Months		More Than 12 Months		Total	
	Fair value	Gross unrealized losses	Fair value	Gross unrealized losses	Fair value	Gross unrealized losses
Corporate debt securities	$ 23,357	$ (24)	$ 2,730	$ (4)	$ 26,087	$ (28)
U.S. government-related debt securities	1,100	(1)			1,101	(1)
Total	$ 24,457	$ (25)	$ 2,730	$ (4)	$ 27,188	$ (29)

The Company reviews the individual securities in its portfolio to determine whether a decline in a security s fair value below the amortized cost basis is other-than-temporary. The Company determined that as of December 31, 2015, there were no investments in its portfolio that were other-than-temporarily impaired.

4. Fair Value Measurements

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

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

Table of Contents

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

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

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

	Fair value measurement using:			
As of December 31, 2015	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents:				
Money market fund	$ 5,371	$	$	$ 5,371
Short-term investments:				
Corporate debt securities		26,088		26,088
U.S. government-related debt securities		1,100		1,100
Total	$ 5,371	$ 27,188	$	$ 32,559

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

5. Inventory

Inventory consisted of the following at December 31 (in thousands):

	2015	**2014**
Raw materials	$ 3,575	$ 1,299
Work in process	2,895	2,157
Finished goods	3,668	1,988
	$ 10,138	$ 5,444

In 2015 and 2014, $0.8 million and $2.5 million, respectively, of inventory leased, loaned, or assigned for internal use in the Company s facilities were transferred into property, plant, and equipment.

6. Prepaid Expenses and Other Current Assets

Prepaid expenses and other consisted of the following at December 31 (in thousands):

	2015	2014
Deposits for inventory	$ 1,664	$ 2,207
Subsidiary bank trust deposits	539	626
Marketing events	518	525
Insurance	314	309
Software licensing fees	278	220
R&D equipment service agreements	163	220
Dues and subscriptions	96	151
Other	314	856
	$ 3,886	$ 5,114

Table of Contents

7. Property and Equipment

Property and equipment consisted of the following at December 31 (in thousands):

	Useful Life (Years)	2015	2014
Manufacturing equipment	5	$ 4,543	$ 3,654
Lease and loaner instruments	1 -5	3,318	2,629
Prototype instruments	2	2,956	2,157
Computer equipment	3	1,847	1,430
Furniture and fixtures	5	1,390	831
Leasehold improvements	Various	5,874	4,888
Construction in progress		1,921	1,058
		21,849	16,647
Less: Accumulated depreciation and amortization		(12,435)	(10,281)
		$ 9,414	$ 6,366

Prototype instruments consist of nCounter instruments used in internal testing and other development activities.

Accumulated depreciation on lease and loaner instruments was $867,000 and $128,000 at December 31, 2015 and 2014, respectively.

Depreciation and amortization expense for the years ended December 31, 2015, 2014 and 2013 totaled approximately $2.3 million, $1.5 million and $1.8 million, respectively.

8. Accrued Liabilities

Accrued liabilities consisted of the following at December 31 (in thousands):

	2015	2014
Employee compensation	$ 8,039	$ 6,838
Royalties payable	828	632
Construction related costs for leasehold improvements	640	50
Clinical study costs	563	572
Sales, use and other taxes	551	543
Warranty reserves	299	503
Accounting and legal	427	297
Other accrued liabilities	834	968
	$ 12,181	$ 10,403

Table of Contents

9. Long-Term Debt

2014 Term Loan Agreement

In April 2014, the Company entered into a term loan agreement under which it may borrow up to $45.0 million, including an option to defer payment of a portion of the interest that would accrue on the borrowing under the term loan agreement. Upon initial closing, the Company borrowed $20.0 million, the proceeds of which were primarily used to repay the outstanding balance under the Company s former credit facility plus a related $1.0 million end of term payment, a $0.3 million make-whole premium, and deferred interest. The Company incurred and recorded a total charge to interest expense of $1.4 million related to the repayment of the former credit facility, including a loss on extinguishment of debt of $0.6 million. In October 2014, the Company borrowed an additional $10.0 million under the term loan agreement.

In October 2015, the Company amended the term loan agreement to, among other provisions, increase the maximum borrowing capacity to $60.0 million (excluding deferred interest), reduce the applicable interest rate from 12.5% to 12.0%, extend the interest-only period through March 2021, and extend the final maturity to March 2022. Under the amended agreement, borrowings accrue interest at 12.0% annually, payable quarterly, of which 3.0% can be deferred during the first six years of the term at the Company s option and paid together with the principal at maturity. The Company has elected to exercise the option to defer payment of interest and has recorded $1.5 million of deferred interest through December 31, 2015. In December 2015, the Company borrowed an additional $10.0 million under the terms of the amended agreement and is required to borrow an additional $5.0 million no later than June 30, 2016. At its option, the Company may borrow up to an additional $15.0 million through December 31, 2016. Total borrowings and deferred interest under the amended term loan agreement were $41.5 million and $30.4 million as of December 31, 2015 and 2014, respectively.

Under the amended term loan agreement, the Company may pay interest-only for the first seven years of the term and principal payments are due in four equal installments during the eighth year of the term. The Company has the option to prepay the term loan, in whole or part, at any time subject to payment of a redemption fee of up to 4%, which declines 1% annually thereafter, with no redemption fee payable if prepayment occurs after the fourth year of the loan. In addition, a facility fee equal to 2.0% of the amount borrowed plus any accrued interest is payable at the end of the term or when the loan is repaid in full. A long-term liability of $1.1 million is being accreted using the effective interest method for the facility fee over the term of loan agreement, with a corresponding reduction to the debt. Obligations under the term loan agreement are collateralized by substantially all of the Company s assets.

The term loan agreement contains customary conditions to borrowings, events of default and negative covenants, including covenants that could limit the Company s ability to, among other things, incur additional indebtedness, liens or other encumbrances, make dividends or other distributions; buy, sell or transfer assets; engage in any new line of business; and enter into certain transactions with affiliates. The term loan agreement also includes a $2.0 million minimum liquidity covenant and revenue-based financial covenants, which was $55.0 million for 2015 with annual increases of $15.0 million for each subsequent fiscal year thereafter. If the Company s actual revenues are below the minimum annual revenue requirement for any given year, it may avoid a related default by generating proceeds from an equity or subordinated debt issuance equal to the shortfall between its actual revenues and the minimum revenue requirement. The Company was in compliance with its financial covenants as of December 31, 2015.

The Company incurred $4.0 million, $4.1 million and $1.9 million of interest expense under the term loan agreement for the years ended December 31, 2015, 2014 and 2013, respectively. In 2014, the Company incurred $1.4 million of interest expense related to the repayment of the former credit facility, including a loss on extinguishment of debt of $0.6 million.

Table of Contents

2012 Credit Facility

In 2012, the Company entered into a credit facility and incurred $13.0 million and $5.0 million in term loan borrowings during the years ended December 31, 2012 and 2013, respectively. In connection with the term loan borrowings during 2012, the Company issued warrants to purchase an aggregate of 76,940 shares of Series D and 20,837 shares of Series E preferred stock at exercise prices of $8.45 and $14.40 per share, respectively. In connection with the term loan borrowings during 2013, the Company issued warrants to purchase an aggregate of 10,418 shares of Series E preferred stock. The issued warrants were valued at the date of issuance using the Black-Scholes option pricing model with the following assumptions: fair value of preferred stock equal to exercise price of warrant, volatility of 57.0 to 61.0% and a risk free interest rate of 1.63 to 2.20%. The warrants were treated as a debt discount and were amortized over the term of the debt. In connection with the Company s initial public offering, these warrants became exercisable for shares of the Company s common stock.

Lease Financing Obligations

The Company has entered into agreements to lease certain hardware, software and capitalized installation costs, the longest of which expires in June 2017. Ownership of the leased property transfers to the Company at the end of the lease terms. The fair value at lease inception is recorded in property, plant and equipment and is depreciated over the shorter of the useful life of the assets or the lease term. A total cost of $716,500 and $668,500 and accumulated depreciation of $286,600 and $102,600 for leased property is included in property, plant and equipment at December 31, 2015 and 2014, respectively.

Long-term debt and lease financing obligations consisted of the following at December 31 (in thousands):

	2015	2014
Term loans payable	$ 41,487	$ 30,420
Lease financing obligations	284	506
Total long-term debt and lease financing obligations	41,771	30,926
Unamortized debt issuance costs	(545)	(680)
Current portion of lease financing obligations	(226)	(251)
Long-term debt and lease financing obligations, net of debt issuance costs and current portion	$ 41,000	$ 29,995

Scheduled future payments of principal for outstanding debt and lease financing obligations were as follows at December 31:

2016	$ 226
2017	58
2018	
2019	
2020	
Thereafter	41,487

	$ 41,771

Table of Contents

10. Collaboration Agreements

The Company uses a proportional performance model to recognize collaboration revenue over the Company s performance period for the related collaboration agreement. Costs incurred to date compared to total expected costs are used to determine proportional performance, as this is considered to be representative of the delivery of outputs under the arrangement. Revenue recognized at any point in time is limited to cash received and amounts contractually due. Changes in estimates of total expected costs are accounted for prospectively as a change in estimate. All amounts received or due are classified as collaboration revenue as they are earned.

Celgene Corporation

In March 2014, the Company entered into a collaboration agreement with Celgene Corporation (Celgene) to develop, seek regulatory approval for, and commercialize a companion diagnostic assay for use in screening patients with Diffuse Large B-Cell Lymphoma. The Company is eligible to receive payments totaling up to $45.0 million, of which $5.8 million was received as an upfront payment upon its delivery of certain information to Celgene, $17.0 million is for potential success-based development 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. In October 2015, the parties amended the collaboration agreement to include additional countries to conduct clinical trials and in return the Company received an upfront payment of $1.6 million in December 2015.

The Company will retain all commercial rights to the diagnostic test developed under this collaboration, subject to certain backup rights granted to Celgene to commercialize the diagnostic test in a particular country if the Company elects to cease distribution or elects not to distribute the diagnostic in such country. Assuming success in the clinical trial process, and subject to regulatory approval, the Company will market and sell the diagnostic assay and Celgene has agreed to make certain potential commercial payments to the Company in the event sales of the assay do not exceed certain pre-specified minimum annual revenues during the first three years following regulatory approval.

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

For the years ended December 31, 2015 and 2014, the Company recognized collaboration revenue related to the Celgene agreement of $2.2 million and $2.9 million, respectively. No such amounts were recognized in 2013. At December 31, 2015, the Company had recorded $8.2 million of deferred revenue related to the collaboration, of which $2.8 million is estimated to be recognized as revenue within one year.

Merck & Co., Inc.

In May 2015, the Company entered into a clinical research collaboration agreement with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. (Merck), to develop an assay intended to optimize immune-related gene expression signatures and evaluate the potential to predict benefit from Merck s anti-PD-1 therapy, KEYTRUDA, in multiple tumor types. The Company received an upfront payment of $2.0 million in July 2015 and development payments totaling $1.9 million during 2015.

Table of Contents

For the year ended December 31, 2015, the Company recognized collaboration revenue related to the Merck agreement of $3.7 million. No such amounts were recognized in 2014 and 2013. At December 31, 2015, the Company had recorded $147,000 of deferred revenue related to the collaboration which is estimated to be recognized as revenue within one year.

11. Common Stock and Preferred Stock

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

Common Stock

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

Preferred Stock

Pursuant to the amended and restated certificate of incorporation filed by the Company immediately prior to the completion of its initial public offering, the Company s board of directors is authorized to issue up to 15,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, redemption rights, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing change in the Company s control or other corporate action. As of December 31, 2015, no shares of preferred stock were issued or outstanding, and the board of directors has not authorized or designated any rights, preferences, privileges and restrictions for any class of preferred stock.

Mandatorily Redeemable Convertible Preferred Stock

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

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

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

related issuance costs or discounts.

Table of Contents

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

Warrants

Prior to the Company s initial public offering, warrants to purchase preferred stock were issued related to certain financing transactions. Such warrants were recorded as liabilities and measured at fair value at each reporting date. All preferred stock warrants were converted into warrants to purchase common stock upon the effectiveness of the initial public offering. The preferred stock warrant liability was reclassified to stockholders equity and recorded as common stock warrants upon the closing of the Company s initial public offering. These warrants are no longer re-measured to fair value at each reporting date. As of December 31, 2015 there were 572,246 common stock warrants outstanding with a weighted average exercise price of $8.77 per common stock warrant and expiration dates ranging from 2018 to 2023.

12. Stock-based Compensation

Stock Option Plans

The Company s 2004 Stock Option Plan and 2013 Equity Incentive Plan (the Plans) authorize the grant of options, restricted stock units and other equity awards to employees, directors and consultants. As of December 31, 2015, there were 5,446,915 shares available under the Plans. All options granted have a ten-year term and generally vest and become exercisable over four years of continued employment or service as defined in each option agreement. The Board of Directors determines the option exercise price and may designate stock options granted as either incentive or nonstatutory stock options. The Company generally grants stock options to employees with exercise prices equal to the estimated fair value of the Company s common stock on the date of grant.

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

	Shares	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2014	3,294,822	$ 9.98	8.08	$ 17,985
Granted	1,455,150	12.94		
Canceled	(45,939)	14.97		
Forfeited	(335,449)	14.00		
Exercised	(201,622)	3.58		
Outstanding at December 31, 2015	4,166,962	$ 10.94	7.81	$ 19,163

December 31, 2015:					
Options vested and expected to vest	4,117,768	$	10.93	7.80	$ 19,074
Options exercisable	2,108,076	$	8.37	6.94	$ 15,006

Table of Contents

The following table summarizes information about the Company s options outstanding at December 31, 2015:

	Options Outstanding		Options Exercisable	
Exercise Price	Number of Shares	Weighted-Average Remaining Contractual Life in Years	Number of Shares	Weighted-Average Remaining Contractual Life in Years
$0.00 1.92	645,113	6.26	589,799	6.19
2.24 3.84	317,814	4.28	317,796	4.28
5.12 6.72	371,802	6.98	277,781	6.97
8.96 10.94	273,276	8.32	113,223	7.82
11.14 12.56	283,315	8.49	87,449	8.09
12.77 13.93	972,726	9.11	216,977	9.09
14.04 16.22	414,690	9.24	64,635	8.45
$17.24 20.65	888,226	8.10	440,416	8.10
	4,166,962		2,108,076	

The following table summarizes information about the Company s stock option plan for the years ended December 31:

	2015	2014	2013
Fair value of vested stock options (in thousands)	$ 6,468	$ 3,543	$ 920
Aggregate intrinsic value for options exercised (in thousands)	$ 2,067	$ 2,220	$ 681
Weighted-average grant date fair value per share	$ 7.20	$ 9.45	$ 5.30

Options granted during the three years ended December 31, 2015 were granted at exercise prices that the Company s board of directors believed to be equal to the fair value of the common stock underlying such options on the date of grant. Prior to completion of its initial public offering, the Company assessed its estimate of fair value of its common stock for financial reporting purposes. Following this assessment, it was determined that for financial reporting purposes the fair value of the Company s common stock was higher than the board of directors fair market value estimate for certain options previously granted. In 2013, the Company granted options of 101,487 shares that were subsequently determined to be granted at exercise prices that were less than the estimated per share value of the underlying common stock on the date of grant. The valuations of these stock options were adjusted to reflect the increase in estimated fair value of the underlying stock options.

Stock-based compensation

The following table sets forth stock-based compensation expense related to stock-based arrangements under the 2004 Stock Option Plan and the 2013 Equity Incentive Plan for the years ended December 31 as follows (in thousands):

	2015	2014