

NanoString Technologies Inc  
Form 10-K  
March 09, 2017  
Table of Contents

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

FORM 10-K

ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2016

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was

required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

---

Table of Contents

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

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

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

Large accelerated filer  Accelerated filer

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

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the Registrant, based on the closing sale price of the Registrant's common stock on the last business day of its most recently completed second fiscal quarter, as reported on The NASDAQ Global Market, was approximately \$184.7 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 21,650,894 shares of the Registrant's common stock, \$0.0001 par value per share, outstanding on March 6, 2017.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission in connection with the registrant's 2017 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the registrant's fiscal year ended December 31, 2016.

Table of Contents

NANOSTRING TECHNOLOGIES, INC.  
 ANNUAL REPORT ON FORM 10-K  
 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2016

TABLE OF CONTENTS

	Page
<u>PART I</u>	<u>3</u>
<u>Item 1. Business</u>	<u>3</u>
<u>Item 1A. Risk Factors</u>	<u>21</u>
<u>Item 1B. Unresolved Staff Comments</u>	<u>43</u>
<u>Item 2. Properties</u>	<u>43</u>
<u>Item 3. Legal Proceedings</u>	<u>43</u>
<u>Item 4. Mine Safety Disclosures</u>	<u>43</u>
<u>PART II</u>	<u>44</u>
<u>Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>44</u>
<u>Item 6. Selected Financial Data</u>	<u>46</u>
<u>Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>47</u>
<u>Item 7A. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>62</u>
<u>Item 8. Financial Statements and Supplementary Data</u>	<u>63</u>
<u>Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	<u>89</u>
<u>Item 9A. Controls and Procedures</u>	<u>89</u>
<u>Item 9B. Other Information</u>	<u>89</u>
<u>PART III</u>	<u>90</u>
<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	<u>90</u>
<u>Item 11. Executive Compensation</u>	<u>90</u>
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>90</u>
<u>Item 13. Certain Relationships and Related Transactions and Director Independence</u>	<u>90</u>
<u>Item 14. Principal Accountant Fees and Services</u>	<u>90</u>
<u>PART IV</u>	<u>90</u>
<u>Item 15. Exhibits, Financial Statement Schedules</u>	<u>90</u>
<u>Item 16. Form 10-K Summary</u>	<u>90</u>
<u>SIGNATURES</u>	<u>91</u>

Table of Contents

Special Note Regarding Forward-Looking Information

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

Forward-looking statements are identified by words such as “believe,” “anticipate,” “expect,” “intend,” “plan,” “will,” “may,” and other similar expressions. You should read 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 and capital needs, 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 expand our customer base, develop new products, enter new markets and hire and retain key personnel.

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. In this report, “we,” “our,” “us,” “NanoString,” and “the Company” refer to NanoString Technologies, Inc. and its subsidiaries.

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 disease and to clinical laboratories and medical centers for diagnostic use. As of December 31, 2016, we have an installed base of approximately 480 systems, which our customers have used to publish over 1,450 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 therapeutic treatment.

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. Our technology platform is enabled by a unique, proprietary optical barcoding chemistry only available to us. 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 Analysis System instrument has been FDA 510(k) cleared together with Prosigna and is targeted toward clinical laboratories. All three instruments are capable of running our research consumable products and provide comparable, high-quality data. Our revolutionary new 3D Biology products 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 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. 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.

To date, we have three collaborations with biopharma companies for the development of companion diagnostic assays. In 2014, we initiated our first of these collaborations 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 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

## Table of Contents

expanded a pre-existing research collaboration with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., or Merck, to develop and commercialize a novel diagnostic test to predict response to Merck's anti-PD-1 therapy, 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 \$86.5 million, \$62.7 million and \$47.6 million in 2016, 2015 and 2014, respectively, while incurring net losses of \$47.1 million, \$45.6 million and \$50.0 million in 2016, 2015 and 2014, respectively.

We are organized as, and operate in, one reportable segment. For additional information, see Note 2 of the Notes to Consolidated Financial Statements under Item 8 of this report. For financial information regarding our business, see Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this report and our audited consolidated financial statements and related notes included elsewhere in this report.

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," "Vantage 3D," "3D Biology," "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.

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 polymerase chain reaction, or PCR, and protein expression experiments using flow cytometry, mass spectrometry, immunohistochemistry or enzyme-linked immunosorbent assay, or ELISA, assays. More 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:

-4-

---

## Table of Contents

- 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, providing the potential for seamless transition to clinical diagnostic testing laboratories on a distributed basis, 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 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 therapeutics, 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 therapeutics do not target genetic abnormalities and there are typically 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.

-5-

---

## Table of Contents

### 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.

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, starting in September 2015, we have launched a series of 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 can 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 simultaneously up to 30 proteins. Ultimately, we intend to expand this capability to an increased number of protein targets, limited only by the 800 target capacity of an assay and the number of antibodies that can be sourced and combined without cross-reaction.

**Gene Mutations.** In late 2016, we launched our first assay to detect a particular type of gene mutation, known as single nucleotide variations. Our initial panel, targeting solid tumors, gives researchers the power to measure 104 different gene mutations simultaneously, at the same time as measuring the expression of other genes and proteins.

**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

-6-

---

Table of Contents

these complex structural variants which have been shown to be important in a number of cancers. In 2016, we launched two off-the-shelf panels for analysis of fusion genes relevant to lung cancer and leukemia.

**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 <sup>(1)</sup>	No	Yes	Yes
Diagnostic menu	No	No	Yes
U.S. list price	\$149,000	\$235,000	\$265,000

<sup>(1)</sup>nCounter MAX and FLEX throughput may be 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 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 to their specifications. 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

-7-

---

## Table of Contents

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 30 panels that are pre-manufactured CodeSets, which include curated content relevant to a particular research area, including the following:

**Pan Cancer Gene Expression Panels.** A portfolio of panels designed to comprehensively analyze genes driving the growth of cancer cells, the immune system's response, and the progression of the cancer, including:

**Pathways.** A novel set of 770 essential genes representing the signaling pathways implicated in cancer, including key driver genes, selected using a data-driven approach to identifying the genes most relevant to cancer biology.

**Immune Profiling.** 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.

**Progression.** 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.

**PanCancer RNA: Protein Immune Profiling Panels.** Two panels that combine gene expression analysis of the 770 genes contained in the PanCancer Immune Profiling Gene Expression Panel with the analysis of up to 30 proteins of interest in measuring the immune system's response to cancer or intracellular signaling.

**nCounter Vantage 3D™ Panels.** A portfolio of panels that enable simultaneous analysis of DNA, RNA, and protein, eliminating the need to divide small samples among different experiments, including:

**RNA:Protein Solid Tumor Assay —** Panels for lysates and FFPE that profile key cancer pathway targets at the RNA, total protein, and phospho-protein level, including targets associated with PI3K, MAPK, EGFR, and more.

**DNA SNV Solid Tumor Panel —** A panel targeting 104 single nucleotide variants in 25 genes that are relevant to a variety of solid tumor types, currently available for MAX and FLEX systems.

**RNA Panels —** 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.

**Lung Fusions —** A panel targeting gene fusions that involve the following genes which are important in lung cancer: ALK, ROS, RET, and NTRK1.

**Leukemia Fusions —** A panel targeting 27 gene fusions that are important in leukemia.

**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 laboratory's choice of oligonucleotide probes that it 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, Cartridges and Reagents

For our nCounter MAX or FLEX systems, the 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.

For our nCounter





## Table of Contents

SPRINT Profiler, customers purchase microfluidic cartridges and separate bottles of reagents which together provide the ancillary components for processing samples with CodeSets, Panels or nCounter Elements reagents.

### Molecular Diagnostics

Our nCounter Dx Analysis System 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. nCounter Elements reagents enable assays for gene expression, copy number variation and gene fusions. Many clinical laboratories are currently exploring the use of nCounter Elements reagents to develop assays to replace tests currently performed using fluorescence-based in situ hybridization, or FISH. The first commercial use of an nCounter Elements-based LDT occurred in 2014.

### Prosigna

Prosigna, our first molecular diagnostic test, is based on a collection of 50 genes known as the PAM50 gene signature, which was discovered by several of our research customers. Prosigna can provide a breast cancer patient and her physician with a subtype classification based on the fundamental biology of the patient's tumor, as well as a prognostic score that indicates the probability of cancer recurrence over 10 years. Physicians use Prosigna to help guide therapeutic decisions so that patients receive a therapeutic intervention, such as chemotherapy, 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 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 payer 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.

### 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

-9-

---

Table of Contents

regulatory approval. There have been several amendments to the collaboration agreement to expand the scope of development work and in return we have received additional payments totaling \$2.1 million.

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 payments related to the subsequent amendments, totaling \$13.8 million, have been received from Celgene to date, and we are using these funds in part 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 agreement, we received \$3.9 million in payments 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 received \$12.0 million as an upfront technology access payment and are eligible to receive up to an additional \$12.0 million for potential preclinical milestone payments, of which \$8.5 million has been received to date. Merck is responsible for its own costs under the development collaboration agreement and is funding our development costs, including personnel related and overhead costs for our employees assigned to the project, nCounter systems, clinical study reagents, and other out-of-pocket costs. For the year ended December 31, 2016, our development funding totaled \$9.6 million. In addition, we are eligible to receive other potential downstream milestone payments upon achievement of certain regulatory milestones.

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 have modified our PAM50-based Prosigna Breast Cancer Assay for potential use as a companion diagnostic test for XTANDI (enzalutamide) for triple negative breast cancer. We are responsible for developing and validating the diagnostic test and, if the parties thereafter determine to proceed, we are responsible for seeking regulatory approval for and commercializing the test. We have received a \$6.0 million upfront payment for technology access, \$6.0 million in preclinical milestone payments, and are eligible to receive up to \$10.0 million in development funding, which totaled \$2.9 million in 2016. In addition, we are eligible to receive other potential downstream milestone payments upon

achievement of certain regulatory milestones.

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.

-10-

---

## Table of Contents

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.

### 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, 2016, we owned or exclusively licensed 15 issued U.S. patents and approximately 45 pending U.S. patent applications, including provisional and non-provisional filings. We also owned or licensed approximately 197 pending and granted counterpart applications worldwide, including 73 country-specific validations of seven 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;
- 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.

### 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.

#### 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, which was reduced by 50% in the third quarter of 2016 for the remainder of the license term due to the achievement of a cumulative sales threshold. Through December 31, 2016, we have paid aggregate royalties of \$4.2 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.

-11-

---

## Table of Contents

### Bioclassifier, LLC

In July 2010, we entered into an exclusive license agreement with Bioclassifier, LLC, pursuant to which Bioclassifier granted to us an exclusive, subject to certain government rights, worldwide license, with the right to sublicense, to certain intellectual property rights and technology, including eight non-provisional patent applications, related to the PAM50 gene signature in the field of research products and prognostic and/or diagnostic tests for cancer, including Prosigna. Bioclassifier has licensed these rights from the academic institutions that employed the cancer researchers that discovered or were involved in the initial development of PAM50. Pursuant to the agreement, we are required to pay Bioclassifier the greater of certain minimum royalty amounts and mid-single digit to low double digit percentage royalties on net sales of products and/or methods sold by us that are covered by patent rights or include, use or are technology licensed to us. Our obligation to pay royalties to Bioclassifier expires on a country-by-country basis upon the expiration of the last patent licensed or, if a product or method includes, uses or is technology licensed to us but is not covered by a patent licensed to us, ten years after the first commercial sale of the product or method in such country. We are also required to pay Bioclassifier a low to mid double digit percentage of any income received by us from the grant of a sublicense to the patents or technology licensed to 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, 2016, we have paid Bioclassifier \$0.8 million.

### 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, 2016, including clinical, medical and regulatory affairs, we had 128 employees in research and development, of which 44 hold a Ph.D. degree and 2 hold an M.D. degree. Our research and development expenses for the years ended December 31, 2016, 2015 and 2014 were \$34.7 million, \$24.6 million and \$21.4 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.

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 a new capability for measurement of DNA mutations in 2016. With 3D Biology, research customers are able to measure combinations of DNA, RNA and proteins in a single experiment. We are also continuing to update our panel product line and plan to expand our offerings beyond oncology into areas such as autoimmune, infectious disease and neurobiology applications.

**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. We have initiated development of a new instrument using a novel approach to digital, multiplexed measurement of gene and protein expression with spatial resolution, which we call Digital Spatial Profiling, or DSP, and would be used upstream from an nCounter Analysis System. In November 2016, we initiated a technology access program to provide customers with access to DSP in advance of the commercial launch which is targeted for late 2018. We have also announced our intention to develop a novel DNA and RNA sequencing chemistry called Hyb & Seq, which would require the development of a new instrument in the future. Our near-term goal will be to scale up the chemistry, and to further demonstrate Hyb & Seq's capabilities working with academic groups.

### 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, called the ROBUST trial. We are monitoring 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

-12-

---

## Table of Contents

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. For additional information regarding the development collaboration agreement, see the section of this report captioned “— Collaborations — Celgene Corporation”.

In February 2016, we expanded a research 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, designated Tumor Inflammation Signature, or TIS, to predict response to KEYTRUDA in multiple tumor types. The test is being used in three potential registrational clinical trials across 11 tumor types to evaluate the test's ability to identify patients who are most likely to respond to treatment with KEYTRUDA. If successful, we will own the commercial rights to the test and would make it commercially available in territories in which KEYTRUDA is approved for one or more of the indications and for which we have any necessary regulatory authorizations to approve the test. 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 based on 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. The test is being used to determine whether patients will be enrolled in a Phase 3 clinical trial, called the ENDEAR trial. We are responsible for monitoring the testing process during the Phase 3 study and, if the results are positive, we will be responsible for seeking regulatory approval for and commercializing the test. For additional information regarding the development collaboration agreement, see the section of this report captioned “— Collaborations — Medivation, Inc. and Astellas Pharma, Inc.”.

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, the TIS, or other tests discovered by our research customers, either in academia or within biopharmaceutical companies themselves.

### Prosigna Breast Cancer Assay

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 are participating 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 are providing 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 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 24 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. For additional information regarding geographic revenue, see Note 17 of the Notes to Consolidated Financial Statements under Item 8 of this report. For the year ended December 31, 2016, our collaborator, Merck, represented 13% of our total revenue. No customers represented more than 10% of total revenue during the years ended December 31, 2015 and 2014.

-13-

---

## Table of Contents

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

We continue to invest in our commercial channel to increase our reach and productivity. During 2017, we intend to add staff focused on sales of consumables to our existing instrument base. We believe these investments will enable our existing sales representatives to focus on instrument sales and help drive the growth of our installed instrument base.

### 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 gaining inclusion in influential treatment guidelines and 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, 2016, there were approximately 69 laboratories worldwide that had purchased or rented nCounter Analysis Systems with the intent to market and sell Prosigna testing services. 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.

-14-

---

## 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, part of IDEX Health & Science, 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 Agilent Technologies, Becton-Dickinson, Bio-Rad, Bio-Techne, Fluidigm, HTG Molecular Diagnostics, Illumina, Luminex, Merck Millipore, O-Link, Perkin Elmer, Qiagen, 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 Oncotype 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 recently acquired Sividon Diagnostics and its product EndoPredict, a distributed test for breast cancer recurrence. Myriad Genetics has announced its intent to begin selling EndoPredict in the United States after obtaining any necessary regulatory approvals.

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;
- 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.

-15-

---

Table of Contents

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. Preamendment Class III devices for which FDA has not yet required submission of PMAs are also required to submit a 510(k) to FDA. 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, are placed into Class III requiring PMA approval. Devices deemed not substantially equivalent to a previously 510(k)-cleared device or novel devices for which no predicate device exists are placed into Class III, but may be reclassified by FDA into Class I or Class II upon the submission by the manufacturer of a de novo reclassification application. A clinical trial is almost always required to support a PMA application or de novo application, and in many cases is 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 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 a demonstration of reasonable assurance of 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

Table of Contents

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. A device company can ask the FDA at the outset if the de novo route is available for its particular product. When granting a de novo application 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 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, and almost always requires clinical data. 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 the malfunction 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. If FDA were to determine, based on the totality of circumstances, that our products marketed for RUO are intended for diagnostic purposes, they would be considered 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. On October 3, 2014, FDA issued two draft guidances that proposed to actively regulate LDTs using a risk-based approach, and would have required 510(k)s or PMAs for certain “moderate” or “high” risk devices. However, in late November 2016, FDA announced that it would not be finalizing the 2014 draft LDT

Guidances. On January 13, 2017, FDA issued a discussion paper laying out key elements of a possible revised future LDT regulatory framework. We do not expect any guidance document regulating LDTs will go into effect in the near future.

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 breast cancer patient's risk of 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 and analytical 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 have generated dossiers for submission to payors in support of reimbursement for testing services based upon our initial diagnostic product, 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 three studies to date.

### 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 describe the test.

The American Medical Association, or AMA, has issued a 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. MAAA codes 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,

-18-

---

Table of Contents

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. In October 2016, we applied for and received a Category 1 MAAA code for Prosigna. The code will be published in the CPT code book in late August 2017, with an effective date of January 1, 2018.

The 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 at the local level by 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 of clinical utility is collected through a registry or a study to answer outstanding questions on outcomes. Some MACs have developed Coverage with Data Development, or CDD, policies for the same purpose, which are administered at the local level.

Over the past three years, we have pursued Medicare coverage for Prosigna by working with MACs to obtain favorable LCDs. In 2016, Prosigna achieved Medicare coverage in all 50 states through this process.

The Palmetto MolDX program has contracted with McKesson to create unique identifiers for lab tests. A McKesson Z-Code Identifier is a unique identifier associated with a specific advanced diagnostic test. Z-code identifiers 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, CGS, WPS, and Noridian. Laboratories under the MolDX program cannot submit claims for Prosigna until a Z-code identifier 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, such as Prosigna, are paid under the Clinical Laboratory Fee Schedule.

With respect to private insurance coverage, we have made significant progress in obtaining third-party reimbursement for the use of tests that incorporate new technology, such as Prosigna. Over the past three years, we have pursued coverage with all of the large private payers to facilitate reimbursement of Prosigna testing. In 2016, coverage policies were adopted by Cigna and Aetna and, in early 2017, Humana adopted a positive coverage policy. Additionally, the Blue Cross and Blue Shield, or BCBS, Association Evidence Street recently published a positive assessment of Prosigna. Subsequently, we will work with individual BCBS entities that do not currently cover Prosigna to update their coverage policies based on this evaluation.

#### 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, France, Greece, and the United Kingdom. Selected private coverage for testing is available in the United Kingdom, Germany,

Spain, France, the UAE and Hungary. 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 access approach in Europe is similar to that in the United States and involves data driving clinical and economic publications to support guideline inclusion. Initially, we have targeted the private and cash pay market in Europe. In parallel, we are seeking to establish public reimbursement of Prosigna by national and regional governments in Europe.

#### Other Regulations

Our operations in the United States are subject to various federal and state fraud and abuse laws, including, without limitation, the federal anti-kickback statute and state and federal marketing compliance laws. These laws may impact our

Table of Contents

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, 2016, we had 407 employees, of which 104 work in manufacturing, 126 in sales, marketing and business development, 107 in research and development, 21 in clinical, medical and regulatory affairs, and 49 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, 2016, of our 407 employees, 372 were employed in the United States and 35 were employed outside the United States.

Environmental Matters

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

Where You Can Find Additional Information

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



## 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 \$47.1 million and \$45.6 million for the years ended December 31, 2016 and 2015, respectively. As of December 31, 2016, we had an accumulated deficit of \$269.5 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 ongoing 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 revenue 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 the amount and timing of payments pursuant to collaboration agreements 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. For example, in the fourth quarter of 2016, total revenue did not meet expectations which adversely affected our stock price. In addition, these fluctuations may result in unanticipated changes in our available cash, which could negatively affect our business and prospects. Factors that may contribute to fluctuations in our operating results include many of the risks described in this section. In addition, one or more of such factors may cause our revenue or operating expenses in one period to be disproportionately higher or lower relative to the others. Our products involve a significant capital commitment by our customers and accordingly involve a lengthy sales cycle. We may expend significant effort in attempting to make a particular sale, which may be deferred by the customer or never occur. Accordingly, comparing our operating results on a period-to-period basis may not be meaningful, and investors should not rely on our past results as an indication of our future performance. If such fluctuations occur or if our operating results deviate from our expectations or the expectations of securities analysts, our stock price may be adversely affected.

If we do not achieve, sustain or successfully manage our anticipated growth, our business and growth prospects will be harmed.

We have experienced significant revenue growth in a short period of time. We may not achieve similar growth rates in future periods. Investors should not rely on our operating results for any prior periods as an indication of our future operating performance. If we are unable to maintain adequate revenue growth, our financial results could suffer and our stock price could decline. Furthermore, growth will place significant strains on our management and our operational and financial systems and processes. For example, 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, medical, regulatory, manufacturing and quality assurance personnel. In addition, we intend to make further investments in sales and marketing personnel to enable our commercial organization to effectively manage the increased scale and complexity of our business. If we do not successfully generate demand for our products or manage our anticipated expenses accordingly, our operating results will be harmed.

-21-

---

Table of Contents

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. In light of our analysis of fourth quarter 2016 operating results and in an effort to enhance future results, we intend to add sales staff focused on consumable sales to existing customers, thus enabling existing sales representatives to increase focus on instrument sales. 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 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;

- competitor product offerings or pricing;

- 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.

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. These factors also make it difficult to forecast revenue on a quarterly basis. For example, in the fourth quarter of 2016, our actual revenues were lower than our forecasts for many reasons that we did not predict, including reduced funding availability for certain of our potential customers and extended timelines for finalizing purchase decisions by potential customers. 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.

-22-

---

Table of Contents

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.

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. In connection with our collaborations with Merck and Medivation Inc. and Astellas Pharma Inc. to develop companion diagnostic tests, our partners have licensed the technology for such tests to us. 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. 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. 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. We intend to enter into additional similar collaborations over time. The success of the development programs for such assays will be dependent on the success of the

-23-

---

Table of Contents

related drug trials conducted by our collaborators. There is no guarantee that those clinical trials will be successful and, as a result, we may expend considerable time and resources developing in vitro diagnostic assays that cannot gain regulatory approval. Although we expect such collaborations to provide funding to cover our costs of development, failure of these clinical trials would reduce our prospects for introducing new diagnostic products and would adversely impact our growth prospects and future operating results.

Our 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. 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 approval, privacy rights, publication rights, intellectual property ownership and research parameters. In January 2017, the Department of Health and Human Services finalized new rules, which become effective as of January 19, 2018, expanding the language to be included in informed consent forms related to the collection of identifiable private information or identifiable biospecimens. If this new requirement, or other factors arising in the future, impact our ability 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 diagnostic 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

-24-

---



Table of Contents

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 and diagnostic markets are Agilent Technologies, Becton-Dickinson, Bio-Rad, Bio-Techne, Fluidigm, HTG Molecular Diagnostics, Illumina, Luminex, Merck Millipore, O-Link, Perkin Elmer, Qiagen, 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 diagnostic laboratory 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 recently acquired Sividon Diagnostics and its product EndoPredict, a distributed test for breast cancer recurrence. Myriad Genetics has announced its intent to begin selling EndoPredict in the United States after obtaining any necessary regulatory approvals.

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.

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.

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 and patients that Prosigna provides equivalent or better prognostic information than those centralized laboratories. In addition, our diagnostic tests are

-25-

---

Table of Contents

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 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, medical, 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.

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. 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 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, making the management of development projects complex and subject to risks and uncertainties regarding timing, timely delivery of required components or services and satisfactory technical performance of such components or assembled products. For example, in 2016, a portion of the fluidic cartridges used in our nCounter SPRINT systems experienced leakage and we worked with our supplier to determine the root cause of the leakage and institute corrective actions at the supplier's production facility. If we do not achieve the required technical specifications or successfully manage new product development processes, or if 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 revenue 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 limited. If we do not effectively manage the transitions to new product offerings, our revenue, results of operations and business will be adversely affected.

-26-

---

Table of Contents

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. In 2016, we launched additional 3D Biology panels, including our first for the 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.

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 IDEX Corporation of Lake Forest, Illinois to build the fluidics cartridge, a key component of our 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. Additionally, we recently launched our first panel for the measurement of DNA mutations. While all of our CodeSets are produced using the same basic processes, significant variations may be required to meet new 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.

-27-

---

## 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 2016 and 2015, approximately 30% and 34%, 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, such as the anticipated exit of Great Britain from the European Economic Community;
- 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 increasingly 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, 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.

Significant U.K. or European developments stemming from the U.K.'s referendum on membership in the European Union could have a material adverse effect on us.

In June 2016, the United Kingdom held a referendum and voted in favor of leaving the European Union. This has created political and economic uncertainty, particularly in the United Kingdom and the European Union, and this uncertainty may last for years. Our business in the United Kingdom, the European Union, and worldwide could be affected during this period of uncertainty, and perhaps longer, by the impact of the United Kingdom's referendum. There are many ways in which our business could be affected, only some of which we can identify as of the date of this prospectus.

The referendum, and the likely withdrawal of the United Kingdom from the European Union it triggers, has caused and, along with events that could occur in the future as a consequence of the United Kingdom's withdrawal, including the possible breakup of the United Kingdom, may continue to cause significant volatility in global financial markets, including in global currency and debt markets. This volatility could cause a slowdown in economic activity in the United Kingdom, Europe or globally, which could adversely affect our operating results and growth prospects. In addition, our business could be negatively affected by new trade agreements or data transfer agreements between the United Kingdom and other countries, including the United States, and by the possible imposition of trade or other regulatory and immigration barriers in the United Kingdom. In addition, the Europe-wide market authorization framework for our products (and for the drugs sold by our collaboration partners in the pharmaceutical industry) may also change. Furthermore, we currently operate in Europe through a subsidiary based in the United Kingdom, which

provides us with certain operational, tax and other benefits, as well as through other subsidiaries in Europe. The United Kingdom's withdrawal from the European Union could adversely affect our ability to realize those benefits and we may incur costs and suffer disruptions in our European operations as a result. These possible negative impacts, and others resulting from the United Kingdom's actual or threatened withdrawal from the European Union, may adversely affect our operating results and growth prospects.

-28-

---



Table of Contents

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

As of December 31, 2016, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of approximately \$204.9 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 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.

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

-29-

---

Table of Contents

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, harm our reputation and result in reduced revenues. If that occurs, we may also 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 are 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.

If we experience a significant disruption in our information technology systems or breaches of data security, our business could be adversely affected.

We rely on information technology systems to keep financial records, manage our manufacturing operations, fulfill customer orders, capture laboratory data, maintain corporate records, communicate with staff and external parties and operate other critical functions. Our information technology systems are potentially vulnerable to disruption due to breakdown, malicious intrusion and computer viruses or other disruptive events including but not limited to natural disaster. If we were to experience a prolonged system disruption in our information technology systems or those of certain of our vendors, it could negatively impact our ability to serve our customers, which could adversely impact our business. Although we maintain offsite back-ups of our data, if operations at our facilities were disrupted, it may cause a material disruption in our business if we are not capable of restoring function on an acceptable timeframe. In addition, our information technology systems are potentially vulnerable to data security breaches-whether by employees or others-which may expose sensitive data to unauthorized persons. Such data security breaches could lead

to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, customers and others, any of which could have a material adverse effect on our business, financial condition and results of operations. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other negative consequences because of lost or

-30-

---

Table of Contents

misappropriated information. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

**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 diagnostic use, and the products do not include clinical or diagnostic claims, or directions 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. Pursuant to FDA guidance on RUO products, a company may not make clinical or diagnostic claims about an RUO product or provide clinical directions or clinical support services to customers for RUO products. If the FDA were to modify its approach to regulating 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 document 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 document. 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. For example, after the FDA clearance of Prosigna in September 2013, it took over two years to achieve broad Medicare reimbursement of Prosigna testing.

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 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 June 2016, CMS released the final 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, though PAMA limits these reductions to no more than 10% less than the prior year during calendar

Table of Contents

years 2018-2020 and no more than 15% less during years 2021-2023. 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 France, 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 and coverage decisions from government insurance plans, managed care organizations and private insurance plans. From time to time, if positive coverage decisions are obtained, we may 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.

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 tests 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 regulations. In October 2014, the FDA issued draft guidance documents proposing the use of a risk-based approach to regulating LDTs. Any restrictions on LDTs by the FDA could decrease demand for our nCounter Elements reagents.

Additionally, compliance with additional regulatory burdens could be time consuming and costly for our customers. While FDA announced in November 2016 that it did not intend to seek finalization of the draft LDT guidances, 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 nCounter Elements reagents.

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, New Zealand, Hong Kong, Australia, Thailand, and Argentina, 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 and, potentially, 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. Some of the compensation we expect to receive pursuant to these collaborations is based on the receipt of such approvals.

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 expand 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.

-32-

---



Table of Contents

Approval and/or clearance by the FDA and foreign regulatory authorities for our diagnostic tests will take significant time and require significant research, development and clinical study expenditures and ultimately may not succeed. Before we begin to label and market our products for use as clinical diagnostics in the United States, thereby subjecting them to FDA regulation as medical devices, unless an exemption applies, we are required to obtain either prior 510(k) clearance or prior pre-market application approval, or PMA approval, 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 may pursue additional intended uses for Prosigna that 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. In July 2016, the FDA issued a draft co-development companion diagnostic and therapeutic guidance document which similarly reflected this information. The draft guidance appears to also relate, at least in part, to what may be considered complementary diagnostics, i.e., diagnostics that do not meet the definition of an IVD companion diagnostic but are nonetheless beneficial for therapeutic product development or clinical decision making. If we developed a diagnostic device that was cleared or approved apart from a therapeutic product, rather than as a companion diagnostic, this may result in potentially reduced revenue for the test as the test would not be necessary for prescribing of the drug.

Any 510(k) clearance or PMA approval we obtain for any future product would 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 obligation to comply with 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 from submission, and generally requires detailed and comprehensive scientific and clinical data, as well as compliance with FDA regulations. In addition, we have limited experience in obtaining PMA approval from the FDA and are therefore supplementing our operational capabilities to manage the more complex processes needed to obtain and maintain PMAs. 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 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 to fulfill product registration requirements in foreign countries, 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 ensure compliance with various procedures required under good clinical practices. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our diagnostic products.

## Table of Contents

In many countries, we are not permitted to directly apply for product registrations, and therefore must rely on third-party contractors or product distributors resident in those countries to fulfill the product registration requirements. Our reliance on these third parties reduces our control over the registration activities, and those parties may not appropriately register the products. Our reliance on third parties does not relieve us of the obligation to comply with applicable requirements, and therefore any failure on the part of the third parties could subject us to enforcement action in the country in which the registration was not properly fulfilled.

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 mid-2017 the European Union will adopt the IVD Directive Regulation, currently being finalized, which would increase the regulatory requirements applicable to some in vitro diagnostics in the EU and would require that we re-classify and obtain pre-approval for our existing CE-marked IVD products within 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. For example, following discussions with the FDA regarding the appropriate classification for our nCounter Elements TagSets as General Purpose Reagents, we submitted a de novo application to the FDA requesting classification of nCounter Elements TagSets as a Class I medical device. 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. 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.

-34-

---

## Table of Contents

Healthcare policy changes, including legislation reforming the United States healthcare system, may have a material adverse effect on our financial condition and results of operations.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education 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 Budget Control Act of 2011, contained automatic spending cuts to the federal budget known as sequestration. As a result of sequestration, Medicare payments are reduced by 2% per year. For Prosigna this occurs through adjustment to the Clinical Laboratory Fee Schedule. These or any future proposed or mandated reductions in payments may apply to some or all of the clinical laboratory tests that our customers use our technology to deliver to Medicare beneficiaries, and may indirectly reduce demand for our products.

Other significant measures contained in the ACA include coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The ACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. In addition, the ACA establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce health care expenditures, which may have a negative impact on payment rates for services, including our tests. The IPAB proposals may impact payments for clinical laboratory services that our customers use our technology to deliver beginning in 2016 and for hospital services beginning in 2020, and may indirectly reduce demand for our products.

In addition to the ACA, the effect of which cannot presently be quantified, various healthcare reform proposals have also emerged from federal and state governments. Changes in healthcare policy, such as the creation of broad test utilization limits for diagnostic products in general or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially impact the sales of our tests, increase costs and divert management's attention from our business. Such co-payments by Medicare beneficiaries for laboratory services were discussed as possible cost savings for the Medicare program as part of the debt ceiling budget discussions in mid-2011 and may be enacted in the future. In addition, sales of our tests outside of the United States will subject us to foreign regulatory requirements, which may also change over time.

We cannot predict whether future healthcare initiatives, including potential repeal of the ACA in whole or in part by Congress following the election of President Trump, 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. Changes in 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, 2016, we owned or licensed 15 issued U.S. patents and approximately 45 pending U.S. patent applications, including provisional and non-provisional filings. We also owned or licensed approximately 197 pending and granted counterpart applications worldwide, including 73 country-specific validations of seven 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. Additionally, we cannot assure investors that our currently pending or future patent applications have or will be filed in all of our potential markets. 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

Table of Contents

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. Furthermore, in view of these decisions, in December 2014 the USPTO published revised guidelines for patent examiners to apply when examining process claims for patent eligibility. This guidance was updated by the USPTO in July 2015 and additional illustrative examples provided in May 2016. The guidance indicates that claims directed to a law of nature, a natural phenomenon, or an abstract idea that do not meet the eligibility requirements should be rejected as non-statutory, patent ineligible subject matter. We cannot assure you that our patent portfolio will not be negatively impacted by the current uncertain state of the law, new court rulings or changes in guidance or procedures issued by the USPTO. From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability and validity of patents within the genomic diagnostic space, and any such changes could have a negative impact on our business.

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

-36-

---



Table of Contents

protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If our intellectual property is not adequately protected so as to protect our market against competitors' products and methods, our competitive position could be adversely affected, as could our business.

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

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

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

We rely on licenses in order to be able to use various proprietary technologies that are material to our business, including our core digital molecular barcoding technology licensed from the Institute for Systems Biology, technology relating to Prosigna licensed from Bioclassifier, LLC and the intellectual property relating to a gene signature for lymphoma subtyping from the National Institutes of Health for use in our collaboration with Celgene Corporation. We do not own the patents that underlie these licenses. Our rights to use these technologies and employ the inventions claimed in the licensed patents are subject to the continuation of and compliance with the terms of those licenses.

We may need to license other technologies to commercialize future products. We may also need to negotiate licenses to patents and patent applications after launching any of our commercial products. Our business may suffer if the patents or patent applications are unavailable for license or if we are unable to enter into necessary licenses on acceptable terms.

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. Therefore, our business may suffer if these licenses terminate, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties or if the licensed patents or other rights are found to be invalid. 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

-37-

---

Table of Contents

secrets, infringement by us of third-party patents and trademarks or other rights, or the validity of our patents, trademarks or other rights, will not be asserted or prosecuted against us.

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

As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. In addition, competitors may develop their own versions of our tests in countries where we did not apply for patents, where our patents have not issued or where our intellectual property rights are not recognized and compete with us in those countries and markets. 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, we may be unaware of pending third-party patent applications that relate to our technology and our competitors and others may have patents or may in the future obtain patents and claim that use of our products infringes these patents. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and obtain one or more licenses from third parties, or be prohibited from selling certain products. We may not be able to obtain these licenses at a reasonable cost, if at all. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. In addition, we could encounter delays in product introductions while we attempt to develop alternative methods or products to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing products, and the prohibition of sale of any of our products could materially affect our ability to grow and gain market acceptance for our products.

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

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

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

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

## Table of Contents

to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. A loss of key research personnel work product could hamper or prevent our ability to commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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

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

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

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

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

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

### Risks Related to 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;

-39-

---

Table of Contents

issuance of new or changed securities analysts' reports or recommendations for our stock;  
developments or disputes concerning our intellectual property or other proprietary rights;  
commencement of, or our involvement in, litigation;  
market conditions in the research and diagnostics markets;  
manufacturing disruptions;  
any future sales of our common stock or other securities;  
any change to the composition of the board of directors or key personnel;  
announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;  
general economic conditions and slow or negative growth of our markets; and  
the other factors described in this "Risk Factors" section.

The stock market in general, and market prices for the securities of life sciences and diagnostic companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. In several recent situations where the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

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

Although our common stock is listed on The NASDAQ Global Market, the market for our shares has demonstrated varying levels of trading activity 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 3.4 million shares (including shares underlying outstanding warrants), or approximately 16%, of our outstanding shares as of December 31, 2016, 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 could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

Our officers and directors, and their respective affiliates, own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

Our executive officers and directors together with their respective affiliates, own approximately 19% of our outstanding common stock as of December 31, 2016. Accordingly, our executive officers and directors together with their

-40-

---



Table of Contents

respective affiliates, will be able to exert significant influence over matters submitted to our stockholders for approval, as well as our management and affairs. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material adverse effect on our stock price and may prevent attempts by our stockholders to replace or remove the board of directors or management.

Anti-takeover provisions in our charter documents and under Delaware or Washington law could make an acquisition of us difficult, limit attempts by our stockholders to replace or remove our current management and limit our stock price.

Provisions of our certificate of incorporation and bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our stock. Among other things, the certificate of incorporation and bylaws:

- permit the board of directors to issue up to 15,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;

- provide that the authorized number of directors may be changed only by resolution of the board of directors;

- provide that all vacancies, including newly-created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

- divide the board of directors into three classes;

- provide that a director may only be removed from the board of directors by the stockholders for cause;

- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be taken by written consent;

- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and meet specific requirements as to the form and content of a stockholder's notice;

- prevent cumulative voting rights (therefore allowing the holders of a plurality of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);

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

- provide that stockholders are permitted to amend the bylaws only upon receiving at least two-thirds of the total votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. Likewise, because our principal executive offices are located in Washington, the anti-takeover provisions of the Washington Business Corporation Act may apply to us under certain circumstances now or in the future. These provisions prohibit a "target corporation" from engaging in any of a broad range of business combinations with any stockholder constituting an "acquiring person" for a period of five years following the date on which the stockholder became an "acquiring person."

We are an "emerging growth company," and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012, and, for as long as we continue to be an "emerging growth company," we have chosen to take advantage of exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including, but not limited to, not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the

requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an “emerging growth company” until December 31, 2018, although, if we have more than \$1.0 billion in annual revenue, if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of June 30 of any year, or we issue more than \$1.0 billion of non-convertible debt over a three-year period before the end of that five-year period, we would cease to be an “emerging growth company” as of the following December 31. If some investors find our common stock

-41-

---

Table of Contents

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 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 year ended December 31, 2015 and included a Conflict Minerals Report as an exhibit to such 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

-42-

---

Table of Contents

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 104,538 square feet of space used for general office, laboratory, manufacturing, operations, and research and development purposes in Seattle, Washington. The long-term operating leases 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. In addition, we have two office leases outside of Seattle, Washington, totaling 2,202 square footage, with terms of two years or less.

Our landlords hold security deposits of approximately \$314,000. 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.

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, 2016	High	Low
First quarter	\$17.51	\$11.89
Second quarter	\$16.46	\$12.28
Third quarter	\$19.98	\$12.78
Fourth quarter	\$23.27	\$18.39
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 6, 2017, there were approximately 26 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.

## Securities Authorized for Issuance under Equity Compensation Plans

The following table summarizes information about our equity compensation plans as of December 31, 2016. All outstanding awards relate to our common stock.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) <sup>(1)</sup>
Equity compensation plans approved by security holders:			
2004 Stock Option Plan	1,123,660	\$ 3.28	—
2013 Equity Incentive Plan	3,761,883	14.08	353,766
2013 Employee Stock Purchase Plan	—	N.A.	193,507

Edgar Filing: NanoString Technologies Inc - Form 10-K

Equity compensation plans not approved by security holders:	—	N.A.	—
Total	4,885,543	N.A.	547,273

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

-44-

---

Table of Contents

on the first day of each fiscal year, equal to the least of: (a) 1% of the outstanding shares of common stock on the first day of such fiscal year; (b) 281,250 shares; and (c) such other amount as the board of directors, or a committee appointed by the board of directors, may determine.

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 May 2016, we issued an aggregate of 41,994 shares of our common stock to certain warrant holders upon the exercise of outstanding warrants at a price of \$8.45 per share to purchase an aggregate of 89,296 shares of our common stock pursuant to a net exercise mechanism under the warrants. In October 2016, we issued 60,915 shares of our common stock to certain warrant holders upon the exercise of outstanding warrants at a price of \$8.45 per share to purchase an aggregate of 103,404 shares of our common stock pursuant to a net exercise mechanism under the warrants. In December 2016, we issued 29,848 shares of our common stock to certain warrant holders upon the exercise of outstanding warrants at a price of \$8.45 per share to purchase an aggregate of 47,348 shares of our common stock pursuant to a net exercise mechanism under the warrants. These issuances were exempt from registration under the Securities Act of 1933, as amended, under Section 3(a)(9) thereof as an exchange with existing security holders where no commission or other remuneration is paid or given for soliciting such exchange.



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, 2016, 2015 and 2014 and Consolidated Balance Sheet data as of December 31, 2016 and 2015 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, 2013 and 2012 and Consolidated Balance Sheet data as of December 31, 2014, 2013 and 2012 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,				
	2016	2015	2014	2013	2012
	(In thousands, except per share amounts)				
<b>Consolidated Statements of Operations:</b>					
Revenue	\$86,489	\$62,667	\$47,593	\$31,403	\$22,973
Costs and expenses:					
Cost of revenue	30,245	26,126	21,149	15,009	12,361
Research and development	34,720	24,597	21,404	14,979	11,635
Selling, general and administrative	62,700	53,186	51,063	29,912	15,486
Total costs and expenses	127,665	103,909	93,616	59,900	39,482
Loss from operations	(41,176 )	(41,242 )	(46,023 )	(28,497 )	(16,509 )
Other income (expense):					
Interest income	390	233	272	68	21
Interest expense	(5,672 )	(4,017 )	(4,140 )	(1,942 )	(804 )
Other income (expense)	(515 )	(389 )	(147 )	(66 )	(29 )
Revaluation of preferred stock warrant liability	—	—	—	1,156	(387 )
Total other income (expense)	(5,797 )	(4,173 )	(4,015 )	(784 )	(1,199 )
Net loss before provision for income taxes	(46,973 )	(45,415 )	(50,038 )	(29,281 )	(17,708 )
Provision for income taxes	(116 )	(166 )	—	—	—
Net loss	\$(47,089)	\$(45,581)	\$(50,038)	\$(29,281)	\$(17,708)
Accretion of mandatorily redeemable convertible preferred stock	—	—	—	(4,653 )	(7,533 )
Net loss attributable to common stockholders	\$(47,089)	\$(45,581)	\$(50,038)	\$(33,934)	\$(25,241)
Net loss per share—basic and diluted	\$(2.34 )	\$(2.40 )	\$(2.80 )	\$(4.44 )	\$(71.10 )
Weighted-average shares used in computing basic and diluted net loss per share	20,116	19,027	17,839	7,643	355
	As of December 31,				
	2016	2015	2014	2013	2012
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments	\$74,036	\$49,044	\$72,225	\$42,656	\$21,692
Working capital	77,402	61,882	76,411	42,106 <sup>(1)</sup>	19,937 <sup>(1)</sup>
Total assets	126,373	92,869	102,068	64,372 <sup>(1)</sup>	37,406 <sup>(1)</sup>
Total long-term debt and lease financing obligations, net of unamortized debt issue costs (includes current portion)	47,424	41,226	30,246	18,293 <sup>(1)</sup>	12,759 <sup>(1)</sup>
Mandatorily redeemable convertible preferred stock	—	—	—	—	103,622
Total stockholders’ equity (deficit)	\$12,305	\$20,215	\$44,813	\$31,469	\$(93,760)

<sup>(1)</sup>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.

-46-

---

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 disease and to clinical laboratories and medical centers for diagnostic use. As of December 31, 2016, we have an installed base of approximately 480 systems, which our customers have used to publish over 1,450 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, 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 \$34.7 million, \$24.6 million and \$21.4 million in 2016, 2015 and 2014, respectively, in research and development and intend to continue to make significant investments in research and development.

-47-

---

Table of Contents

In March 2014, we entered into a collaboration agreement with Celgene Corporation, or Celgene, 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. For additional information regarding the development collaboration agreement, see the section of this report captioned “Business—Collaborations—Celgene Corporation”.

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. 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 “Business—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 (enzalutamide) for triple negative breast cancer. For additional information regarding the development collaboration agreement, see the section of this report captioned “Business—Collaborations—Medivation, Inc. and Astellas Pharma, Inc.”. Our total revenue increased to \$86.5 million in 2016 from \$62.7 million in 2015 and \$47.6 million in 2014, which was driven primarily by the sale of additional nCounter Analysis Systems and consumables for use on our growing installed base of instruments, as well as revenue under our collaborations. Historically, we have generated a substantial majority of our revenue from sales to customers in North America; however, 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. We have never been profitable and had net losses of \$47.1 million, \$45.6 million, and \$50.0 million in 2016, 2015 and 2014, respectively. As of December 31, 2016, our accumulated deficit was \$269.5 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. 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.

**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 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, cartridges and reagents, which are ancillary reagents, cartridges, tips and reagent plates required to setup and process samples in our instruments. 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

-48-

---

Table of Contents

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. Since 2010, our average consumables revenue per installed system has exceeded \$100,000 per year.

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.

**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, Merck, and Medivation and Astellas. As of December 31, 2016, we have received a total of \$61.0 million from these collaboration agreements, of which \$16.7 million, \$5.9 million, and \$2.9 million have been recorded as collaboration revenue in 2016, 2015, and 2014, 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 several smaller collaborations.

**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, and Australia.

	Year Ended December 31,					
	2016		2015		2014	
	(Dollars in thousands)					
Americas	\$60,330	70 %	\$41,265	66 %	\$32,244	68 %
Europe & Middle East	18,497	21 %	14,807	24 %	9,174	19 %
Asia Pacific	7,662	9 %	6,595	10 %	6,175	13 %
Total revenue	\$86,489	100%	\$62,667	100%	\$47,593	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.

-49-

---



Table of Contents

The average unit costs of our instruments has declined in the current year as compared to prior years primarily 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, all of which can be manufactured at much larger scale than most custom CodeSets.

## 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 nCounter systems used in collaborations) 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 and certain major technology development projects, 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,		
	2016	2015	2014
	(In thousands)		
Core nCounter platform technology	\$10,312	\$6,749	\$6,975
Manufacturing process development	2,582	1,802	2,124
Life sciences research products and applications	6,298	4,982	3,834
Diagnostic product development	6,648	3,727	3,292
Clinical, regulatory and medical affairs	5,111	4,939	3,740
Facility allocation	3,769	2,398	1,439
Total research and development expense	\$34,720	\$24,597	\$21,404

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 are 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.

## 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 2017, we intend to add staff focused on sales of consumables to our existing instrument base. We believe this investment will enable our existing sales representatives to focus on instrument sales and help drive the growth of our installed instrument base. Legal, accounting and compliance costs

-50-

---

## Table of Contents

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 has increased 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 added incremental sales territories and augmented our field sales team with greater inside sales support in 2016. Similarly, as of December 31, 2016, we have contracted with a total of 24 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. For example, in the fourth quarter of 2016, total revenue did not meet our expectations due in part to reduced funding availability for certain of our potential customers and extended timelines for finalizing purchase decisions by potential customers.

As of December 31, 2016 we had an installed base of approximately 480 nCounter Analysis Systems, which we count based on the number of nCounter SPRINT Profilers and nCounter Digital Analyzers sold, given that a system may couple one analyzer with multiple nCounter Prep Stations. Management focuses on instrument unit sales as a primary indicator of current business success and a leading indicator of likely future sales of consumables.

#### Recurring Consumables Revenue

Our instruments are designed to be used only with our consumables. This closed system model generates recurring revenue from each instrument we sell. Management focuses on recurring consumable revenue per system as an indicator of the continuing value generated by each system. We calculate recurring consumables revenue per system (also known as pull-through) quarterly by dividing consumables and in vitro diagnostic kits revenue recognized in a particular quarter (other than consumables 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 our Vantage 3D assays, which enable researchers to measure gene expression, protein expression and DNA mutations 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 nCounter Analysis System instruments 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. For 2015 and 2016, we experienced an increase in gross margin on product and service revenues, primarily due to a favorable mix of consumable products and other factors, including improved margins on consumable revenues and service revenue as a result of increasing scale. Although

-51-

---

Table of Contents

future results may vary period to period, over time, as our installed base of systems grows, consumables should continue to constitute a larger percentage of total product revenue, which would tend to increase our gross margins. In addition, both the average selling price and manufacturing cost of our instruments is decreasing with the introduction of the nCounter SPRINT Profiler and this trend may continue with future generations of our nCounter Analysis System. For example, although we sold approximately 40% more systems in 2016 compared to 2015, our instrument revenue only increased 16%. This was largely due to substantially increased sales of the lower priced SPRINT systems in 2016. 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, Merck, and Medivation and Astellas, 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,					
	2016		2015		2014	
	(Dollars in thousands)					
Product revenue:						
Instruments	\$24,229	28 %	\$20,974	33 %	\$18,078	38 %
Consumables	37,545	43 %	30,597	49 %	23,819	50 %
In vitro diagnostic kits	4,168	5 %	2,457	4 %	668	1 %
Total product revenue	65,942	76 %	54,028	86 %	42,565	89 %
Service revenue	3,192	4 %	2,611	4 %	1,932	4 %
Total product and service revenue	69,134	80 %	56,639	90 %	44,497	93 %
Collaboration revenue	17,355	20 %	6,028	10 %	3,096	7 %
Total revenue	\$86,489	100%	\$62,667	100%	\$47,593	100%

**Diagnostic Product Development**

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

We believe that there is significant potential to enter into more companion diagnostic collaborations of a similar nature to our collaborations with Celgene, Merck, and Medivation and Astellas. 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.

Table of Contents

## Results of Operations

## Comparison of Years Ended December 31, 2016 and 2015

## Revenue

	Year Ended December		Change	
	2016	2015	Dollars	Percentage
	(Dollars in thousands)			
Product revenue:				
Instruments	\$24,229	\$20,974	\$3,255	16%
Consumables	37,545	30,597	6,948	23%
In vitro diagnostic kits	4,168	2,457	1,711	70%
Total product revenue	65,942	54,028	11,914	22%
Service revenue	3,192	2,611	581	22%
Total product and service revenue	69,134	56,639	12,495	22%
Collaboration revenue	17,355	6,028	11,327	188%
Total revenue	\$86,489	\$62,667	\$23,822	38%

Instruments revenue increased for the year ended December 31, 2016 due to the increased volume of instruments sold. We sold approximately 140 instrument systems in 2016, of which approximately 60 were nCounter SPRINT Profilers. Although we sold approximately 40% more systems in 2016 compared to 2015, our instrument revenue only increased 16%. This was largely due to substantially increased sales of the lower priced SPRINT systems in 2016. The increase in consumables revenue was primarily driven by growth in our installed base of instrument systems as the average amount of consumables revenue was over \$100,000 per installed system in 2016 and 2015. In vitro diagnostic kit revenue represents sales of Prosigna assays, which increased as more testing 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 \$9.8 million in 2016 due to our new collaboration agreements with Merck and Medivation and Astellas.

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

	Year Ended December		Change	
	2016	2015	Dollars	Percentage
	(Dollars in thousands)			
Cost of product and service revenue	\$30,245	\$26,126	\$4,119	16%
Product and service gross profit	\$38,889	\$30,513	\$8,376	27%
Product and service gross margin	56	% 54	%	

The increase in cost of product and service revenue for the year ended December 31, 2016 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 was primarily due to improved gross margin on consumable revenue resulting from efficiencies of scale and a favorable mix of consumable products sold during the year. In addition, gross margin benefited from a reduced technology royalty rate across all products for a portion of the year due to the achievement of a cumulative revenue milestone under the license of our foundational nCounter patents. Costs related to collaboration revenue are included in research and development expense.

## Research and Development Expense

	Year Ended December		Change	
	2016	2015	Dollars	Percentage
	(Dollars in thousands)			
Research and development expense	\$34,720	\$24,597	\$10,123	41%

The increase in research and development expense in 2016 reflected a \$5.5 million increase in personnel-related expenses and a \$3.3 million increase in supply costs to primarily support the advancement of our diagnostic and product development activities, including activities to support our collaboration agreements. In addition, facility costs increased \$1.4 million due to expansion of our leased space for research and development activities. These increases were partially offset by decreases of \$0.6 million in costs related to clinical trials.



Table of Contents

## Selling, General and Administrative Expense

	Year Ended December		Change	
	2016	2015	Dollars	Percentage

(Dollars in thousands)

Selling, general and administrative expense \$62,700 \$53,186 \$9,514 18%

The increase in selling, general and administration expense in 2016 were primarily attributable to a \$5.4 million increase in staffing and personnel-related costs to support sales and marketing and administration; increased legal and other professional fees of \$1.8 million; increased sales and marketing costs of \$1.3 million related to promotional events and other external activities; and increased state and local gross receipts-based taxes of \$0.7 million, primarily related to amounts received under our collaboration agreements.

## Other Income (Expense)

	Year Ended December		Change	
	2016	2015	Dollars	Percentage

(Dollars in thousands)

Interest income \$390 \$233 \$157 67%

Interest expense (5,672 ) (4,017 ) (1,655 ) 41%

Other expense (515 ) (389 ) (126 ) 32%

Total other income (expense) \$(5,797) \$(4,173) \$(1,624) 39%

The increased interest expense for the year ended December 31, 2016 was due to an increase in borrowing in 2016. Long-term debt and lease financing obligations outstanding increased to \$47.4 million as of December 31, 2016 as compared to \$41.2 million as of December 31, 2015. The average balance of long-term debt and lease financing obligations outstanding was \$44.9 million in 2016 compared to \$31.4 million in 2015.

## Comparison of Years Ended December 31, 2015 and 2014

## Revenue

	Year Ended December		Change	
	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 annual installed base 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		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 the year ended December 31, 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 was 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		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		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		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

### Liquidity and Capital Resources

As of December 31, 2016, we had cash, cash equivalents and short-term investments of \$74.0 million, compared to \$49.0 million as of December 31, 2015. We believe our existing cash, cash equivalents and short-term investments will be sufficient to meet our working capital and capital expenditure needs for at least the next 12 months. However, we may need to raise additional capital to expand the commercialization of our products, fund our operations and further our research and development activities. Our future funding requirements will depend on many factors, including: the nature and timing of any additional companion diagnostic development collaborations we may establish; market acceptance of our products; the cost and timing of establishing additional sales, marketing and distribution capabilities; the cost of our research and development activities; the cost and timing of regulatory clearances or approvals; the effect of competing technological and market developments; the nature and timing of any additional companion diagnostic development collaborations we may establish; and the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

If we require additional funds in the future, we may not be able to obtain such funds on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or additional equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third 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

Since inception, we have financed our operations primarily through the sale of equity securities and, to a lesser extent, from borrowings. Our cash used in operations for the year ended December 31, 2016 was \$6.1 million, including \$43.8 million in cash receipts from our collaboration agreements. However, the timing and amount of such receipts in the future are uncertain and therefore we may require larger amounts of cash to fund our operations over 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 \$40.0 million in total sales proceeds. Pursuant to the sales agreement, we sold 1,331,539 and 960,400 shares during 2016 and 2015, respectively, for net proceeds of \$26.1 million and \$12.5 million, respectively. The sales agreement automatically terminated when we sold the maximum number of shares allowed under the agreement.

In April 2014, we entered into a term loan agreement under which up to \$45.0 million could be borrowed, 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 and 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 \$2.8 million of deferred interest through December 31, 2016. In December 2015, we borrowed an additional \$10.0 million under the terms of the amended agreement and in June 2016 we borrowed an additional \$5.0 million. Total borrowings under the amended term loan agreement were \$47.8 million as of December 31, 2016.

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 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, 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

Table of Contents

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 \$70.0 million for 2016 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, 2016.

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.

Use of Funds

Our principal uses of cash are funding our operations, capital expenditures, 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, supporting our companion diagnostic collaborations with Celgene, Merck, and Medivation and Astellas, and investing in technologies that we believe have the potential to drive the long-term growth of our business.

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 under our three biopharma collaborations, 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, nor can we be certain that we will be successful in continuing to generate cash from new collaborations to help fund our operations.

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

Historical Cash Flow Trends

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

	Year Ended December 31,		
	2016	2015	2014
	(In thousands)		
Cash used in operating activities	\$(6,079)	\$(43,362)	\$(38,061)
Cash provided by (used in) investing activities	(30,261)	23,769	(24,275)
Cash provided by financing activities	35,093	24,268	69,566

Operating Cash Flows

We derive operating cash flows from cash collected from the sale of our products and services and 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 2016 consisted of our net loss of \$47.1 million partially offset by \$27.5 million of changes in our operating assets and liabilities, including \$29.9 million related to our collaboration agreements, and by \$13.5 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 accretion of discount on

short-term investments.

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,

-57-

---

Table of Contents

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.

**Investing Cash Flows**

Our most significant investing activities for the years ended December 31, 2016, 2015 and 2014 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, 2016, 2015 and 2014, we purchased \$4.0 million, \$3.8 million, and \$1.9 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 2016 consisted of net proceeds of \$26.2 million from the sale of shares through an “at the market” equity offering program, proceeds of \$5.0 million from our amended term loan agreement, Employee Stock Purchase Plan proceeds of \$1.5 million, and \$2.6 million of proceeds from the exercise of stock options. These proceeds were partially offset by payment of lease financing obligations of \$0.2 million.

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 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.

**Contractual Obligations**

The following table reflects a summary of our contractual obligations as of December 31, 2016.

Contractual Obligations <sup>(1)</sup>	Payments due by period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
	(In thousands)				
Lease obligations <sup>(2)</sup>	\$ 51,301	\$ 4,822	\$ 10,495	\$ 10,949	\$ 25,035
Long-term debt obligations <sup>(3)</sup>	47,844	—	—	35,883	11,961
Inventory purchase obligations <sup>(4)</sup>	9,300	9,300	—	—	—
<b>Total</b>	<b>\$ 108,445</b>	<b>\$ 14,122</b>	<b>\$ 10,495</b>	<b>\$ 46,832</b>	<b>\$ 36,996</b>

<sup>(1)</sup>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.

<sup>(2)</sup>Lease costs are primarily for office, laboratory and manufacturing space.

<sup>(3)</sup>Includes principal and deferred interest on long-term debt obligations.

<sup>(4)</sup>Purchase obligations consist of contractual and legally binding commitments under outstanding purchase orders to purchase long lead time inventory items.





## Table of Contents

### Critical Accounting Policies and Significant Estimates

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

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

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

### Revenue Recognition

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

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

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

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

For multiple-element arrangements, we allocate arrangement consideration at the inception of the arrangement to the deliverables based on the relative selling price method. The selling price used for each deliverable is based on vendor-specific objective evidence, or VSOE, if available, third-party evidence, or TPE, if VSOE is not available, or best estimated selling price, or BEBP, if neither VSOE nor TPE is available. BEBP is determined in a manner consistent with that used to establish the price to sell the deliverable on a stand-alone basis. To date, selling prices have been established by reference to VSOE based on stand-alone sales transactions for each deliverable. VSOE is

considered to have been established when a substantial majority of individual sales transactions within the previous 12-month period fall within a reasonably narrow range, which we have defined to be plus or minus 15% of the median sales price of actual stand-alone sales transactions. Allocated revenue is only recognized for each deliverable when the revenue recognition criteria have been met.

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

-59-

---

## Table of Contents

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

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

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

### Stock-based Compensation

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

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

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

### Inventory Valuation

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

### 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.

-60-

---

## Table of Contents

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

### 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, 2016, we had federal net operating loss carryforwards, or NOLs, of approximately \$204.9 million and federal research and experimentation credit carryforwards of approximately \$4.6 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 2037.

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

For information regarding recent accounting pronouncements, see Note 2 of the Notes to the Consolidated Financial Statements under Item 8 of this report.

### 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.

-61-

---

Table of Contents

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, 2017 and sustained throughout the period ending December 31, 2017, would not be material.

As of December 31, 2016, the principal and deferred interest outstanding under our term borrowings was \$47.8 million. The interest rates on our term borrowings under our credit facility are fixed. If overall interest rates had increased by 10% during the periods presented, our interest expense would not have been affected.

Foreign Currency Exchange Risk

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

Table of Contents

Item 8. Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS  
NANOSTRING TECHNOLOGIES, INC.

	Page(s)
Financial Statements:	
<u>Report of Independent Registered Public Accounting Firm</u>	<u>64</u>
<u>Consolidated Balance Sheets</u>	<u>65</u>
<u>Consolidated Statements of Operations</u>	<u>66</u>
<u>Consolidated Statements of Comprehensive Loss</u>	<u>67</u>
<u>Consolidated Statements of Changes in Stockholders' Equity</u>	<u>68</u>
<u>Consolidated Statements of Cash Flows</u>	<u>69</u>
<u>Notes to Consolidated Financial Statements</u>	<u>71</u>



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 stockholders' equity and of cash flows present fairly, in all material respects, the financial position of NanoString Technologies, Inc. and its subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2016 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 financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit 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 9, 2017

Table of ContentsNanoString Technologies, Inc.  
Consolidated Balance Sheets

	December 31,	
	2016	2015
	(In thousands, except par value amounts)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 20,583	\$ 21,856
Short-term investments	53,453	27,188
Accounts receivable, net	22,193	19,725
Inventory	13,812	10,138
Prepaid expenses and other current assets	3,744	3,886
Total current assets	113,785	82,793
Restricted cash	143	143
Deferred offering costs	—	181
Property and equipment, net	12,158	9,414
Other assets	287	338
Total assets	\$ 126,373	\$ 92,869
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,935	\$ 3,243
Accrued liabilities	12,344	12,181
Deferred revenue, current portion	19,033	5,261
Deferred rent, current portion	13	—
Lease financing obligations, current portion	58	226
Total current liabilities	36,383	20,911
Deferred revenue, net of current portion	22,664	6,486
Deferred rent and other liabilities, net of current portion	7,655	4,257
Long-term debt and lease financing obligations, net of current portion and debt issuance costs	47,366	41,000
Total liabilities	114,068	72,654
Commitments and contingencies (Note 15)		
Stockholders' equity		
Preferred stock, \$0.0001 par value, 15,000 shares authorized; none issued	—	—
Common stock, \$0.0001 par value, 150,000 shares authorized; 21,528 and 19,570 shares issued and outstanding at December 31, 2016 and 2015, respectively	2	2
Additional paid-in-capital	281,900	242,693
Other comprehensive loss	(57	) (29
Accumulated deficit	(269,540	) (222,451
Total stockholders' equity	12,305	20,215
Total liabilities and stockholders' equity	\$ 126,373	\$ 92,869

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

Table of ContentsNanoString Technologies, Inc.  
Consolidated Statements of Operations

	Years Ended December 31,		
	2016	2015	2014
	(In thousands, except per share amounts)		
Revenue:			
Product and service	\$ 69,134	\$ 56,639	\$ 44,497
Collaboration	17,355	6,028	3,096
Total revenue	86,489	62,667	47,593
Costs and expenses:			
Cost of product and service revenue	30,245	26,126	21,149
Research and development	34,720	24,597	21,404
Selling, general and administrative	62,700	53,186	51,063
Total costs and expenses	127,665	103,909	93,616
Loss from operations	(41,176 )	(41,242 )	(46,023 )
Other income (expense):			
Interest income	390	233	272
Interest expense	(5,672 )	(4,017 )	(4,140 )
Other expense	(515 )	(389 )	(147 )
Total other income (expense)	(5,797 )	(4,173 )	(4,015 )
Net loss before provision for income taxes	(46,973 )	(45,415 )	(50,038 )
Provision for income taxes	(116 )	(166 )	—
Net loss	\$ (47,089 )	\$ (45,581 )	\$ (50,038 )
Net loss per share—basic and diluted	\$ (2.34 )	\$ (2.40 )	\$ (2.80 )
Weighted average shares used in computing basic and diluted net loss per share	20,116	19,027	17,839

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,		
	2016	2015	2014
	(In thousands)		
Net loss	\$(47,089)	\$(45,581)	\$(50,038)
Other comprehensive income (loss):			
Change in unrealized gain (loss) on short-term investments	(28 )	14	(65 )
Comprehensive loss	\$(47,117)	\$(45,567)	\$(50,103)

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

Table of ContentsNanoString Technologies, Inc.  
Consolidated Statements of Changes in Stockholders' Equity

	Common Stock Shares	Amount	Additional Paid-in Capital	Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	(In thousands, except share amounts)					
Balances at December 31, 2013	14,619,818	\$ 1	\$ 158,278	\$ 22	\$(126,832)	\$ 31,469
Issuance of common stock net of issuance costs of \$4,413	3,318,917	1	56,986	—	—	56,987
Issuance of common stock for employee stock purchase plan	141,386	—	987	—	—	987
Exercise of stock options	164,394	—	411	—	—	411
Exercise of common stock warrants, net	27,269	—	136	—	—	136
Stock-based compensation	—	—	4,926	—	—	4,926
Net loss	—	—	—	—	(50,038)	(50,038)
Other comprehensive loss	—	—	—	(65)	—	(65)
Balances at December 31, 2014	18,271,784	2	221,724	(43)	(176,870)	44,813
Issuance of common stock net of issuance costs of \$447	960,400	—	12,518	—	—	12,518
Issuance of common stock for employee stock purchase plan	136,078	—	1,295	—	—	1,295
Exercise of stock options	201,622	—	876	—	—	876
Exercise of common stock warrants, net	250	—	2	—	—	2
Stock-based compensation	—	—	6,278	—	—	6,278
Net loss	—	—	—	—	(45,581)	(45,581)
Other comprehensive income	—	—	—	14	—	14
Balances at December 31, 2015	19,570,134	2	242,693	(29)	(222,451)	20,215
Issuance of common stock net of issuance costs of \$961	1,331,539	—	26,073	—	—	26,073
Issuance of common stock for employee stock purchase plan	139,195	—	1,489	—	—	1,489
Exercise of stock options	348,983	—	2,607	—	—	2,607
Exercise of common stock warrants, net	132,757	—	—	—	—	—
Vesting of restricted stock units	5,000	—	—	—	—	—
Stock-based compensation	—	—	9,038	—	—	9,038
Net loss	—	—	—	—	(47,089)	(47,089)
Other comprehensive income	—	—	—	(28)	—	(28)
Balances at December 31, 2016	21,527,608	\$ 2	\$ 281,900	\$ (57)	\$(269,540)	\$ 12,305

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

Table of ContentsNanoString Technologies, Inc.  
Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2016	2015	2014
	(In thousands)		
Operating activities			
Net loss	\$(47,089)	\$(45,581)	\$(50,038)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	2,977	2,377	1,590
Stock-based compensation expense	9,038	6,278	4,926
Loss on extinguishment of debt	—	—	581
(Accretion) amortization of discount or premium on short-term investments	(20)	) 270	86
Interest accrued on long-term debt	158	18	(348)
Conversion of accrued interest to long-term debt	1,357	1,067	420
(Gain) loss on disposal of property and equipment	(2)	) 3	—
Bad debt expense	—	34	—
Gain on sale of investments	—	—	(5)
Changes in operating assets and liabilities			
Accounts receivable	(2,476)	) (7,328)	) (4,109)
Inventory	(5,035)	) (5,354)	) (1,252)
Prepaid expenses and other	72	1,199	(2,132)
Other assets	37	(7)	) (70)
Accounts payable	869	(166)	) 21
Accrued liabilities	851	1,162	3,379
Deferred revenue	29,948	(127)	) 9,497
Deferred rent and other liabilities	3,236	2,793	(607)
Net cash used in operating activities	(6,079)	) (43,362)	) (38,061)
Investing activities			
Purchases of property and equipment	(3,991)	) (3,796)	) (1,900)
Proceeds from sale of property and equipment	4	6	—
Proceeds from sale of short-term investments	4,700	3,000	4,500
Proceeds from maturity of short-term investments	34,800	57,309	35,977
Purchases of short-term investments	(65,774)	) (32,750)	) (62,911)
Decrease in restricted cash	—	—	59
Net cash provided by (used in) investing activities	(30,261)	) 23,769	) (24,275)
Financing activities			
Proceeds from long-term debt	5,000	10,000	30,000
Deferred costs related to long-term debt	—	—	(770)
Repayment of long-term debt and lease financing obligations	(226)	) (271)	) (18,214)
Proceeds from sale of common stock, net	26,223	12,518	57,015
Proceeds from exercise of common stock warrants	—	2	230
Proceeds from issuance of common stock for employee stock purchase plan	1,489	1,295	988
Repurchase of shares related to common stock warrant exercise	—	—	(94)
Deferred offering costs	—	(152)	) —
Proceeds from exercise of stock options	2,607	876	411
Net cash provided by financing activities	35,093	24,268	69,566
Net increase (decrease) in cash and cash equivalents	(1,247)	) 4,675	7,230
Effect of exchange rate changes on cash and cash equivalents	(26)	) (42)	) 52

Edgar Filing: NanoString Technologies Inc - Form 10-K

Cash and cash equivalents			
Beginning of year	21,856	17,223	9,941
End of year	\$20,583	\$21,856	\$17,223

-69-

---

Table of Contents

NanoString Technologies, Inc.

Consolidated Statements of Cash Flows (continued)

	Years Ended		
	December 31,		
	2016	2015	2014
	(In thousands)		
Supplemental disclosures			
Cash paid for interest	\$4,071	\$2,844	\$3,479
Cash paid for taxes	217	69	—
Purchases of property and equipment, accrued but not paid	275	640	—
Rental instruments reclassified from inventory	801	772	2,541
Non-cash inventory exchange for services	28	112	—
Non-cash capital lease	—	48	262
Accrual of offering costs	—	29	—

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.

#### Public Offerings

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. Pursuant to the sales agreement, the Company sold 1,331,539 and 960,400 shares during 2016 and 2015, respectively, for net proceeds of \$26.1 million and \$12.5 million, respectively. The Sales Agreement automatically terminated when the Company sold the maximum number of shares allowed under the agreement.

### 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

-71-

---

## Table of Contents

investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Amortization of premiums and accretion of discounts are included in other income (expense). Interest and dividends earned on all securities are included in other income (expense). Investments in securities with maturities of less than one year, or where management's intent is to use the investments to fund current operations, or to make them available for current operations, are classified as short-term investments.

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

### Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are stated at the amount management expects to collect from customers based on their outstanding invoices. Management reviews accounts receivable regularly to determine if any receivable will potentially be uncollectible and to estimate the amount of allowance for doubtful accounts necessary to reduce accounts receivable to its estimated net realizable value by analyzing the status of significant past due receivables. The allowance for doubtful accounts was \$91,300 and \$96,600 as of December 31, 2016 and 2015, respectively. Additions to the allowance were \$0, \$33,600 and \$63,000 for the years ended December 31, 2016, 2015 and 2014, respectively. There was a write-off of uncollectible accounts of approximately \$5,000 during the year ended December 31, 2016, and there were no write-offs during the years ended December 31, 2015 and 2014.

### 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 one customer/collaborator, Merck, that individually represented 13% of total revenue for the year ended December 31, 2016 and no customers or collaborators that represented more than 10% of total revenue for the years ended December 31, 2015 and 2014. The Company had no customers or collaborators that represented more than 10% of total accounts receivable as of December 31, 2016 and 2015.

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 or servicing 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 cost or market (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 as of December 31, 2016 and 2015. Additions to the reserves were \$0.8

-72-

---

## Table of Contents

million, \$0.2 million and \$0.2 million for the years ended December 31, 2016, 2015 and 2014, respectively. Write-offs of inventory reserves for the years ended December 31, 2016, 2015 and 2014 were \$0.7 million, \$0.3 million and \$0.1 million, respectively.

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 and the Company had no deferred offering costs recorded as of December 31, 2016.

### 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 and the Company operates as a single reportable segment.

### 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

-73-

---

## Table of Contents

be provided prior to instrument revenue recognition. Instrument revenue from leased instruments is recognized ratably over the lease term.

Service revenue is recognized when earned, which is generally upon the rendering of the related services. Service agreements and service fees for assay processing are each considered separate units of accounting as they are sold separately. The Company offers service agreements on its nCounter Analysis System for periods ranging from 12 to 36 months after the end of the standard 12-month warranty period. Service agreements are generally separately priced. Revenue from service agreements is deferred and recognized in income on a straight-line basis over the service period. For arrangements with multiple deliverables, the Company allocates the agreement consideration at the inception of the agreement to the deliverables based upon their relative selling prices. To date, selling prices have been established by reference to vendor specific objective evidence based on stand-alone sales transactions for each deliverable. Vendor specific objective evidence is considered to have been established when a substantial majority of individual sales transactions within the previous 12-month period fall within a reasonably narrow range, which the Company has defined to be plus or minus 15% of the median sales price of actual stand-alone sales transactions. The Company uses its best estimate of selling price for individual deliverables when vendor specific objective evidence or third-party evidence is unavailable. Allocated revenue is only recognized for each deliverable when the revenue recognition criteria have been met.

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

### Cost of Revenue

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

### Reserve for Product Warranties

The Company generally provides a one-year warranty on its nCounter Analysis Systems and establishes 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 \$5.3 million, \$2.6 million and \$5.1 million during the years ended December 31, 2016, 2015 and 2014, respectively.

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

### Income Taxes

The Company accounts for income taxes under the liability method. Under the liability method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and income tax bases of assets and

-74-

---



## Table of Contents

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, 2016 and 2015.

### 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 August 2014, the Financial Accounting Standards Board ("FASB") issued "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 Company applied ASU 2014-15 as of December 31, 2016 and adoption did not impact the Company's consolidated results of operations, financial condition, and statements of cash flows.

In November 2015, FASB issued "ASU 2015-17, Balance Sheet Classification of Deferred Taxes." The standard requires deferred income tax liabilities and assets be classified as noncurrent in the consolidated balance sheet. The Company applied ASU 2015-17 in the fourth quarter of fiscal 2016 and has presented deferred income tax liabilities and assets as noncurrent in the financial statement disclosures. Adoption did not otherwise impact the Company's consolidated results of operations, financial condition, and statements of cash flows.

### 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. As a result, its financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies.

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

amount of revenue to which it expects to be entitled for the transfer of promised goods or services to a customer. This guidance will replace most existing revenue recognition guidance and will become effective for the Company in fiscal year 2018, including interim periods within that reporting period, based on the FASB decision in July 2015 (ASU 2015-14, Revenue from Contracts with Customers – Deferral of the Effective Date) to delay the effective date of the new revenue recognition standard by one

-75-

---

Table of Contents

year, but providing entities a choice to adopt the standard as of the original effective date. In March 2016, the FASB issued “ASU 2016-08, Principal vs Agent Considerations (Reporting Revenue Gross versus Net)” which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued “ASU 2016-10, Identifying Performance Obligations and Licensing” which clarifies the implementation guidance on identifying performance obligations and the licensing implementation guidance. In May 2016, the FASB issued “ASU 2016-12, Narrow-Scope Improvements and Practical Expedients” which provides practical expedients for contract modifications and clarification on assessing the collectability criterion, presentation of sales taxes, measurement date for noncash consideration and completed contracts at transition. The new guidance can be applied retrospectively to each prior reporting period presented, or retrospectively with the cumulative effect of the change recognized at the date of the initial application. The Company is assessing all of the potential impacts of the revenue recognition guidance on our accounting policies and internal control processes and has not yet selected an adoption method. The Company will adopt the new guidance effective January 1, 2018.

Although the Company has not yet completed its assessment of the new revenue recognition guidance, the Company's analysis of contracts related to the sale of its instruments and consumables under the new revenue recognition guidance supports the recognition of revenue at a point-in-time, which is consistent with its current revenue recognition model. Instruments and consumables, including in vitro diagnostic kits, represents approximately 76% of the Company's sales for the year ended December 31, 2016. The Company is currently assessing the potential impact of the guidance on contracts related to collaboration agreements.

In July 2015, FASB issued “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 January 2016, FASB issued “ASU 2016-01, Financial Instruments: Overall.” The standard addresses certain aspects of recognition, measurement, presentation and disclosure of financial instruments. The standard will become effective for the Company beginning January 1, 2018. 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 February 2016, FASB issued “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.

In March 2016, FASB issued “ASU 2016-09, Improvements to Employee Share-Based Payment Accounting” which amends Accounting Standard Codification Topic 718, “Compensation – Stock Compensation”. The standard includes provisions intended to simplify various aspects related to the accounting and presentation for stock-based payments in the financial statements, including the income tax effects of stock-based payments, minimum withholding requirements upon award settlement, and the method of calculating forfeitures in the recognition of stock compensation expense. The standard will become effective for the Company beginning January 1, 2018. 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 2016, FASB issued “ASU 2016-13, Financial Instruments: Credit Losses”. The standard provides information about expected credit losses on financial instruments at each reporting date, and to change how other than temporary impairments on investments securities are recorded. The standard will become effective for the Company beginning on January 1, 2020 with early adoption permitted. 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 August 2016, FASB issued “ASU No. 2016-15, Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments”. The standard provides guidance on how certain cash receipts and cash payments are presented and classified in the statement of cash flows and is intended to reduce diversity in practice with respect to these items. The standard is applied using a retrospective transition method and is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, with early adoption permitted. The Company does not anticipate adoption of this standard will have a material impact on its consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

In November 2016, FASB issued “ASU 2016-18, Statement of Cash Flows: Restricted Cash”. The standard requires companies to include amounts generally described as restricted cash and restricted cash equivalents, along with cash and cash

Table of Contents

equivalents, when reconciling the beginning-of-period and end-of-period amounts shown on the statement of cash flows. The standard is effective for annual reporting periods beginning after December 15, 2017 and interim periods within those annual periods, with early adoption permitted. The Company does not anticipate adoption of this standard will have a material impact 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 securities as of December 31, 2016	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Corporate debt securities	\$ 36,198	\$ 4	\$ (42 )	\$ 36,160
U.S. government-related debt securities	17,312	1	(20 )	\$ 17,293
Total available-for-sale securities	\$ 53,510	\$ 5	\$ (62 )	\$ 53,453

  

Type of securities 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

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

	2016	2015
Maturing in one year or less	\$46,310	\$27,188
Maturing in one to three years	7,143	—
Total available-for-sale securities	\$53,453	\$27,188

The Company has both the intent and ability to sell its available-for-sale investments maturing greater than one year within 12 months from the balance sheet date and, accordingly, has classified these securities as current in the consolidated balance sheet. The Company has no investments that have been in a continuous unrealized loss position as of December 31, 2016.

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, 2016, 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.

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.

Table of Contents

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

As of December 31, 2016	Fair value measurement using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market fund	\$16,715	\$—	\$	—\$16,715
Short-term investments:				
Corporate debt securities	—	36,160	—	36,160
U.S. government-related debt securities	—	17,293	—	17,293
Total	\$16,715	\$53,453	\$	—\$70,168
As of December 31, 2015	Fair value measurement using:			
	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

## 5. Inventory

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

	2016	2015
Raw materials	\$4,277	\$3,575
Work in process	4,046	2,895
Finished goods	5,489	3,668
Total inventory	\$13,812	\$10,138

In 2016 and 2015, \$0.8 million and \$0.8 million, respectively, of inventory leased, loaned, or assigned for internal use in the Company's facilities were transferred into property and equipment.

## 6. Prepaid Expenses and Other Current Assets

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

	2016	2015
Deposits for inventory	\$1,262	\$1,664
Subsidiary bank trust deposits	500	539
Marketing events	735	518
Software licensing fees	412	278
Insurance	328	314
Interest receivable from marketable securities	186	166
Dues and subscriptions	107	96
Service agreements	93	163
Other	121	148
Total prepaid expenses and other current assets	\$3,744	\$3,886

Table of Contents

## 7. Property and Equipment

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

	Useful Life (Years)	2016	2015
Manufacturing equipment	5	\$6,445	\$4,543
Lease and loaner instruments	1 - 5	3,581	3,318
Prototype instruments	2	2,975	2,956
Computer equipment	3	1,592	1,847
Furniture and fixtures	5	1,642	1,390
Leasehold improvements	Various	8,878	5,874
Construction in progress		1,861	1,921
Total property and equipment, gross		26,974	21,849
Less: Accumulated depreciation and amortization		(14,816 )	(12,435)
Total property and equipment, net		\$12,158	\$9,414

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

Accumulated depreciation on lease and loaner instruments was \$1.5 million and \$0.9 million at December 31, 2016 and 2015, respectively.

Depreciation and amortization expense related to property and equipment for the years ended December 31, 2016, 2015 and 2014 totaled approximately \$2.9 million, \$2.3 million and \$1.5 million, respectively.

## 8. Accrued Liabilities

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

	2016	2015
Employee compensation	\$8,240	\$8,039
Royalties payable	896	828
Accounting and legal	567	427
Sales, use and other taxes	420	551
Clinical study costs	370	563
Warranty reserves	304	299
Other accrued liabilities	1,547	1,474
Total accrued liabilities	\$12,344	\$12,181

## 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 a portion of the interest and has recorded \$2.8 million of deferred interest through December 31, 2016. In December 2015, the Company borrowed an additional \$10.0 million under the terms of the amended agreement. In





Table of Contents

June 2016, the Company borrowed an additional \$5.0 million. Total borrowings under the amended term loan agreement were \$47.8 million and \$41.5 million as of December 31, 2016 and 2015, 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, 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 the loan agreement. 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 \$70.0 million for 2016 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, 2016.

The Company incurred \$5.7 million, \$4.0 million and \$4.1 million of interest expense under the term loan agreement for the years ended December 31, 2016, 2015 and 2014, 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.

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 \$0.7 million for leased property is included in property and equipment at December 31, 2016 and 2015, with accumulated depreciation of \$0.5 million and \$0.3 million at December 31, 2016 and 2015, respectively.

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

	2016	2015
Term loans payable	\$47,844	\$41,487
Lease financing obligations	58	284
Total long-term debt and lease financing obligations	47,902	41,771
Unamortized debt issuance costs	(478 )	(545 )
Current portion of lease financing obligations	(58 )	(226 )
Long-term debt and lease financing obligations, net of debt issuance costs and current portion	\$47,366	\$41,000

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

December 31:

2017	\$58
2018	—
2019	—
2020	—
2021	35,883
Thereafter	11,961
	\$47,902



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 using the nCounter Analysis System to identify a subset of 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 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 revenue during the first three years following regulatory approval. There have been several amendments to the collaboration agreement to expand the scope of development work and in return the Company has received additional payments totaling \$2.1 million.

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.

The Company recognized collaboration revenue related to the Celgene agreement of \$3.2 million, \$2.2 million and \$2.9 million for the years ended December 31, 2016, 2015, and 2014, respectively. At December 31, 2016, the Company had recorded \$5.5 million of deferred revenue related to the Celgene collaboration, of which \$1.2 million is estimated to be recognizable as revenue within one year.

## Merck &amp; 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. Under the terms of the collaboration agreement, the Company received \$3.9 million in payments during 2015. In February 2016, the Company expanded its 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, the Company and Merck terminated the May 2015 clinical research collaboration and moved all remaining activities under the related work plan to the new development collaboration agreement. Under the terms of the new collaboration agreement, the Company is responsible for developing and validating the diagnostic test and, if the parties thereafter determine to proceed, will also be responsible for seeking regulatory approval for and commercializing the related test products. During 2016, the Company received \$12.0 million upfront as a technology access fee and is eligible to receive up to an additional \$12.0 million of near-term preclinical milestone payments, of which \$8.5 million has been received during the year ended December 31, 2016, and other potential downstream regulatory milestone payments. In addition, the Company is eligible to receive

funding for certain development costs and for the year ended December 31, 2016, development funding totaled \$9.6 million.

The Company recognized collaboration revenue related to the Merck agreement of \$8.6 million and \$3.7 million for the years ended December 31, 2016 and 2015, respectively, and none for the year ended December 31, 2014. As of December 31, 2016, the Company had recorded \$21.4 million of deferred revenue related to the Merck collaboration, \$10.1 million of which is estimated to be recognized as revenue within one year.

-81-

---

## Table of Contents

Medivation, Inc. and Astellas Pharma, Inc.

In January 2016, the Company entered into a collaboration agreement with Medivation, Inc. ("Medivation") and Astellas Pharma Inc. ("Astellas") 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, the Company will modify its PAM50-based Prosigna Breast Cancer Assay for potential use as a companion diagnostic test for XTANDI (enzalutamide) for triple negative breast cancer. XTANDI is currently approved by the U.S. Food and Drug Administration 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. Under the terms of the collaboration agreement, the Company will be responsible for developing and validating the diagnostic test and, if the parties thereafter determine to proceed, will also be responsible for seeking regulatory approval for and commercializing the test. During 2016, the Company received \$6.0 million upfront for technology access, \$6.0 million in pre-clinical milestones, and is eligible to receive up to \$10.0 million in development funding over the term of the agreement, in addition to other potential downstream milestone payments. For the year ended December 31, 2016, development funding totaled \$2.9 million.

The Company recognized collaboration revenue of \$4.8 million related to the Medivation/Astellas agreement for the year ended December 31, 2016, and none for the years ended December 31, 2015 and 2014. As of December 31, 2016, the Company had recorded \$10.0 million of deferred revenue related to the Medivation/Astellas collaboration, \$4.0 million of which is estimated to be recognized as revenue within one year.

### 11. Common Stock and Preferred 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, 2016, 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.

#### 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. As of December 31, 2016 there were 332,198 common stock warrants outstanding with a weighted average exercise price of \$9.01 per share and expiration dates ranging from 2018 to 2023.

### 12. Stock-based Compensation

#### 2004 Stock Option Plan and 2013 Equity Incentive Plan

The Company's 2004 Stock Option Plan and 2013 Equity Incentive Plan (the "Plans") authorize the grant of options, restricted stock units ("RSUs") and other equity awards to employees, directors and consultants. As of December 31, 2016, there were 6,425,421 shares authorized 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

-82-

---

Table of Contents

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.

## Stock Option Activity

A summary of the Company's stock option activity under the Plans is as follows:

	Shares	Weighted- average exercise price per share	Weighted- average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2015	4,151,962	\$ 10.98	7.81	\$ 18,943
Granted	1,219,675	14.51		
Canceled and forfeited	(300,713 )	12.85		
Exercised	(348,983 )	7.94		
Outstanding at December 31, 2016	4,721,941	\$ 12.00	7.41	\$ 48,670

## December 31, 2016:

Options vested and expected to vest	4,423,662	\$ 11.83	7.33	\$ 46,353
Options exercisable	2,666,260	\$ 10.03	6.50	\$ 32,714

The weighted-average grant-date fair value per share of options granted with exercise prices equal to the market price on the date of the grant were \$6.79, \$7.07, and \$9.45 for the years ended December 31, 2016, 2015, and 2014, respectively. The aggregate intrinsic value in the table above is calculated as the difference between the exercise price of the underlying options and the quoted price of the Company's common stock for all options that were in-the-money at December 31, 2016. The aggregate intrinsic value of options exercised was \$5.0 million during 2016, \$2.1 million during 2015, and \$2.2 million during 2014, determined as of the option exercise date. The fair value of options vested was \$6.8 million, \$6.5 million, and \$3.5 million for the years ended December 31, 2016, 2015, and 2014, respectively. The following table summarizes information about the Company's stock options outstanding at December 31, 2016:

Exercise Price	Outstanding		Exercisable	
	Number of Shares	Weighted- Average Remaining Contractual Life in Years	Number of Shares	Weighted- Average Remaining Contractual Life in Years
\$0.00 – \$1.92	520,391	5.21	520,391	5.21
\$2.24 – \$6.72	589,559	4.64	584,346	4.63
\$8.96 – \$12.60	510,578	7.58	316,203	7.23
\$12.77	754,288	8.12	320,425	8.12
\$12.94	654,721	9.10	126,423	9.10
\$13.58 – \$14.95	365,131	8.59	108,188	7.95
\$15.12 – \$17.50	64,479	8.64	114,588	8.01
\$18.18 – \$18.90	36,894	7.09	533,742	7.09
\$19.45 – \$22.70	25,900	9.17	41,954	7.33
	4,721,941		2,666,260	

Table of Contents

## Restricted Stock Unit (RSU) Activity

A summary of RSU activity under the Plans is as follows:

Non-vested RSUs	Share Equivalent	Weighted-Average Grant Date Fair Value
Non-vested at December 31, 2015	15,000	\$ 12.77
Changes during the year:		
Granted	153,602	15.89
Vested	(5,000 )	12.77
Forfeited	—	—
Non-vested at December 31, 2016	163,602	\$ 15.70

The fair value of the RSUs is determined based on the closing price of the Company's common stock on the date of grant. The fair value of vested RSUs was \$64,000 for the year ended December 31, 2016. There were no vested RSUs for the years ended December 31, 2015 and 2014.

## Stock-based compensation

The following table sets forth stock-based compensation expense related to stock-based arrangements under the Plans for the years ended December 31 as follows (in thousands):

	2016	2015	2014
Cost of revenue	\$548	\$471	\$281
Research and development	2,046	1,453	1,018
Selling, general and administrative	5,602	3,919	3,234
Total stock-based compensation expense	\$8,196	\$5,843	\$4,533

As of December 31, 2016, total unrecognized stock-based compensation cost related to non-vested options was \$15.6 million. This cost will be recognized on a straight-line basis over the weighted-average remaining service period of 2.40 years. The Company utilizes newly issued shares to satisfy option exercises. No tax benefit was recognized related to stock-based compensation cost since the Company has not reported taxable income to date and has established a full valuation allowance to offset all of the potential tax benefits associated with its deferred tax assets.

## Valuation assumptions

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

	2016	2015	2014
Risk-free interest rates	1.18% – 2.12%	1.37% – 1.97%	1.74% – 2.15%
Expected term (years)	6.22	6.25	6.25
Expected dividend yield	—	—	—
Expected volatility	47.0%	57.0%	57.0%

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

## Employee Stock Purchase Plan

The Company's 2013 Employee Stock Purchase Plan ("ESPP") provides eligible employees with an opportunity to purchase common stock from the Company and to pay for their purchases through payroll deductions. The ESPP has overlapping offering periods of approximately 12 months in length. The offering periods generally start with the first trading day on or after March 1 and September 1 of each year and end on the first trading day on or after March 1 and September 1 of





Table of Contents

the following year, approximately 12 months later. Within each offering period, shares are purchased each six months on an exercise date.

An employee electing to participate in the ESPP (a “participant”) will be granted an option at the start of the offering period to purchase shares with contributions in any whole percentage ranging from 0% to 10% (or greater or lesser percentages or dollar amounts that the administrator determines) of the participant’s eligible compensation. The participant’s contributions will be accumulated and then used to purchase the Company’s shares on each exercise date. The purchase price on the exercise date will be 85% of the fair market value of the lesser of the Company’s share price on either the first trading day of the offering period or on the exercise date.

During 2016, 2015, and 2014, 139,195, 136,078, and 141,386 shares were issued under the ESPP, respectively. The Company recorded share-based compensation expense for shares issued from the ESPP of \$0.8 million, \$0.4 million, and \$0.4 million for the years ended December 31, 2016, 2015, and 2014 respectively. A total of 610,166 shares of common stock have been reserved for issuance under the ESPP, of which 193,509 shares were available for issuance as of December 31, 2016.

#### Note 13. Defined Contribution Retirement Plan

The Company maintains a 401(k) defined contribution retirement plan covering substantially all of its employees. The plan provides for matching and discretionary contributions by the Company. Contributions were \$0.9 million, \$0.5 million, and \$0.4 million for the years ended December 31, 2016, 2015, and 2014 respectively.

#### 14. Income Taxes

Loss before income taxes for the years ended December 31 consisted of the following (in thousands):

	2016	2015	2014
Domestic	\$(47,562)	\$(46,065)	\$(50,455)
Foreign	589	650	417
Loss before income taxes	\$(46,973)	\$(45,415)	\$(50,038)

Significant components of our provision for income taxes for the years ended December 31 are as follows (in thousands):

	2016	2015	2014
Current:			
Domestic	\$—	\$—	\$—
Foreign	116	166	—
Total provision for income taxes	\$116	\$166	\$—

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

	2016	2015	2014
Income tax provision at statutory rate	\$(16,010)	\$(15,662)	\$(17,013)
Nondeductible items	135	401	456
Change in tax credits	(1,449 )	(792 )	(678 )
Change in valuation allowance	17,824	16,706	17,911
Foreign tax and other	(384 )	(487 )	(676 )
Total provision for income taxes	\$116	\$166	\$—

Net operating loss (“NOL”) carryforwards created by excess tax benefits from the exercise of non-qualified stock options are not recorded as deferred income tax assets. To the extent such NOL carryforwards are utilized, the benefit realized will increase stockholders’ equity. At December 31, 2016, for income tax return purposes the Company has gross federal and state NOL carryforwards totaling \$204.9 million and tax credit carryforwards of \$4.6 million. These carryforwards may be subject to limitations under the Internal Revenue Code and applicable state tax law. If not utilized, a portion of the carryforwards will begin to expire in 2025 through 2037.

The Company does not expect to utilize any of its net operating loss and tax credit carryforwards in the near term. The Company may have already experienced one or more ownership changes. Depending on the timing of any future utilization of



Table of Contents

its carryforwards, the Company may be limited as to the amount that can be utilized each year as a result of such previous ownership changes. However, the Company does not believe such limitations will cause its carryforwards to expire unutilized.

Future changes in the Company's stock ownership as well as other changes that may be outside the Company's control could potentially result in further limitations on the Company's ability to utilize its net operating loss and tax credit carryforwards.

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

	2016	2015
Net operating loss carryforwards	\$70,694	\$57,158
Research and development tax credit carryforwards	4,572	3,124
Stock-based compensation	5,360	3,212
Other	7,827	7,135
Total deferred tax assets	88,453	70,629
Less: Valuation allowance	(88,453 )	(70,629 )
Net deferred tax assets	\$—	\$—

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

The table below summarizes changes in the deferred tax asset valuation allowance for the years ended December 31 (in thousands):

	2016	2015	2014
Balance at beginning of year	\$70,629	\$53,923	\$36,012
Charged to costs and expenses	17,824	16,706	17,911
Write-offs	—	—	—
Balance at end of year	\$88,453	\$70,629	\$53,923

The total balance of unrecognized gross tax benefits for the years ended December 31, resulting from research and development tax credits claimed on the Company's annual tax return was as follows (in thousands):

	2016	2015	2014
Unrecognized tax benefits at beginning of year	\$1,041	\$777	\$551
Additions (reductions) based on current year tax positions	483	264	226
Unrecognized tax benefits at end of year	\$1,524	\$1,041	\$777

The Company classifies applicable interest and penalties on amounts due to tax authorities as a component of the provision for income taxes. The amount of accrued interest and penalties recorded in 2016, 2015 or 2014 was not significant. The Company does not anticipate that the amount of its existing unrecognized tax benefits will significantly increase or decrease within the next 12 months. Due to the presence of net operating loss carryforwards in most jurisdictions, the Company's tax years remain open for examination by U.S. taxing authorities back to 2004.

## 15. Commitments and Contingencies

### Operating Leases

The Company is obligated to make future minimum payments under five operating leases for 106,740 square feet of space used for general office, laboratory, manufacturing, operations, and research and development purposes primarily in Seattle. The leases expire beginning in 2018 to 2026 and include options to renew at the then current fair market rental for each of the facilities. The lease agreements contain rent abatement periods, scheduled rent increases and provide for tenant improvement allowances. Accordingly, the Company has recorded a deferred rent liability of \$7.5 million and \$4.3 million as of December 31, 2016 and 2015, respectively. This deferred rent liability is amortized over the term of the related lease.

Rent expense totaled approximately \$3.8 million, \$3.2 million and \$1.4 million for the years ended December 31, 2016, 2015 and 2014, respectively.



Table of Contents

Future minimum lease payments under noncancelable operating leases as of December 31, 2016 were as follows (in thousands):

2017	\$4,822
2018	5,241
2019	5,254
2020	5,398
2021	5,551
Thereafter	25,035
	\$51,301

**Purchase Commitments**

The Company has non-cancellable purchase obligations totaling \$9.3 million at December 31, 2016 related to binding commitments to purchase inventory.

**Contingencies**

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

**16. Net Loss Per Share**

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

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

	2016	2015	2014
Options to purchase common stock	4,711	4,069	3,295
Restricted stock units	115	—	—
Common stock warrants	491	572	572

**17. Information about Geographic Areas**

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

	2016	2015	2014
Americas	\$60,330	\$41,265	\$32,244
Europe & Middle East	18,497	14,807	9,174
Asia Pacific	7,662	6,595	6,175
Total revenue	\$86,489	\$62,667	\$47,593

Total revenue in the United States was \$58.0 million, \$37.9 million and \$29.0 million for the years ended December 31, 2016, 2015 and 2014, respectively. The Company's assets are primarily located in the United States and not allocated to any specific geographic region. Substantially all of the Company's long-lived assets are located in the United States.

Table of Contents

## 18. Condensed Quarterly Financial Data (unaudited)

The following table contains selected unaudited financial data for each quarter of 2016 and 2015. The unaudited information should be read in conjunction with the Company's financial statements and related notes included elsewhere in this report. The Company believes that the following unaudited information reflects all normal recurring adjustments necessary for a fair statement of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

	Three months ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share data)			
2016				
Total revenue	\$14,697	\$22,627	\$ 23,933	\$ 25,232
Net loss	\$(14,603)	\$(10,805)	\$ (10,088 )	\$ (11,593 )
Net loss per share – basic and diluted	\$(0.74 )	\$(0.55 )	\$ (0.51 )	\$ (0.55 )
2015				
Total revenue	\$11,593	\$13,066	\$ 15,693	\$ 22,315
Net loss	\$(14,894)	\$(12,404)	\$ (9,467 )	\$ (8,816 )
Net loss per share – basic and diluted	\$(0.81 )	\$(0.66 )	\$ (0.49 )	\$ (0.44 )

-88-

Table of Contents

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2016. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the U.S.

Securities and Exchange Commission’s, or SEC’s, rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2016, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management’s Annual Report on Internal Control Over Financial Reporting

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

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

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute, assurances. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate. Our management assessed the effectiveness of NanoString’s internal control over financial reporting as of December 31, 2016. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) Internal Control—Integrated Framework (2013). Based on our assessment using those criteria, our management has concluded that, as of December 31, 2016, NanoString’s internal control over financial reporting was effective.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended December 31, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



Item 9B. Other Information

None.

-89-

---

Table of Contents

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by Item 10 of Form 10-K is incorporated by reference to our Proxy Statement for the 2017 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2016.

Item 11. Executive Compensation

The information required by Item 11 of Form 10-K is incorporated by reference to our Proxy Statement for the 2017 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2016.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by Item 12 of Form 10-K is incorporated by reference to our Proxy Statement for the 2017 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2016.

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

The information required by Item 13 of Form 10-K is incorporated by reference to our Proxy Statement for the 2017 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2016.

Item 14. Principal Accountant Fees and Services

The information required by Item 14 of Form 10-K is incorporated by reference to our Proxy Statement for the 2017 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2016.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) The following documents are filed as part of this report:

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

(2) Financial Statement Schedules — The financial statement schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or the notes thereto.

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

(b) Exhibits

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

Item 16. Form 10-K Summary

Not applicable.

Table of Contents

## SIGNATURES

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

Dated: March 9, 2017

NANOSTRING TECHNOLOGIES, INC.

By: /s/ R. Bradley Gray

R. Bradley Gray

President and Chief Executive Officer

## POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ R. Bradley Gray R. Bradley Gray	President, Chief Executive Officer and Director (Principal Executive Officer)	March 9, 2017
/s/ James A. Johnson James A. Johnson	Chief Financial Officer (Principal Accounting and Financial Officer)	March 9, 2017
/s/ William D. Young William D. Young	Chairman of the Board of Directors	March 9, 2017
/s/ Nicholas Galakatos Nicholas Galakatos	Director	March 9, 2017
/s/ Robert M. Hershberg Robert M. Hershberg	Director	March 9, 2017
/s/ Kirk D. Malloy Kirk D. Malloy	Director	March 9, 2017
/s/ Gregory Norden Gregory Norden	Director	March 9, 2017

/s/ Charles P. Waite  
Charles P. Waite

Director

March 9,  
2017

-91-

---

Table of Contents

## EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference			Filing Date
		Form	File No.	Exhibit	
3.1	Amended and Restated Certificate of Incorporation of the Registrant	10-Q	001-35980	3.1	August 8, 2013
3.2	Amended and Restated Bylaws of the Registrant	10-Q	001-35980	3.2	August 8, 2013
4.1	Specimen Common Stock Certificate of the Registrant.	S-1/A	333-188704	4.1	June 13, 2013
4.2	Amended and Restated Investors' Rights Agreement, dated November 29, 2012, by and among the Registrant and the investors named therein.	S-1	333-188704	4.2	May 20, 2013
4.3	Amendment to Amended and Restated Investors' Rights Agreement, dated December 20, 2012, by and among the Registrant and the investors named therein.	S-1	333-188704	4.3	May 20, 2013
4.4	Form of amended and restated warrant to purchase shares of Series D Preferred Stock, issued to investors on June 23, 2011 and September 26, 2011 in connection with the Registrant's 2011 bridge financing.	S-1	333-188704	4.6	May 20, 2013
4.5	Form of warrant to purchase shares of Series D Preferred Stock, issued to the investors on November 1, 2011 and December 28, 2011 in connection with the Registrant's preferred stock and warrant financing.	S-1	333-188704	4.7	May 20, 2013
4.6	Form of warrant to purchase Series D Preferred Stock, issued to lenders on March 30, 2012 and December 10, 2012 under Registrant's March 2012 credit facility.	S-1	333-188704	4.8	May 20, 2013
4.7	Form of warrant to purchase Series E Preferred Stock, issued to lenders on December 31, 2012 and April 30, 2013 in connection with the amendments of the Registrant's March 2012 credit facility.	S-1	333-188704	4.9	May 20, 2013
10.1	Form of Director and Executive Officer Indemnification Agreement.	S-1/A	333-188704	10.1	June 13, 2013
10.2	2004 Stock Option Plan, as amended.	S-1	333-188704	10.2	May 20, 2013
10.3	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2004 Stock Option Plan, as amended.	S-1	333-188704	10.3	May 20, 2013
10.4	Form of Notice of Stock Option Grant and Stock Option Agreement permitting early exercise under the 2004 Stock Option Plan, as amended.	S-1	333-188704	10.4	May 20, 2013
10.5	2013 Equity Incentive Plan.	S-1/A	333-188704	10.5	June 13, 2013
10.6	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2013 Equity Incentive Plan.	S-1/A	333-188704	10.6	June 13, 2013
10.7	Form of Notice of Restricted Stock Grant and Restricted Stock Agreement under the 2013 Equity Incentive Plan.	S-1/A	333-188704	10.7	June 13, 2013
10.8	Form of Notice of Restricted Stock Unit Grant and Restricted Stock Unit Agreement under the 2013 Equity Incentive Plan.	S-1/A	333-188704	10.8	June 13, 2013
10.9	2013 Employee Stock Purchase Plan.	S-1/A	333-188704	10.9	June 13, 2013
10.10+	Employment Agreement, dated May 24, 2010, between the Registrant and R. Bradley Gray.	S-1	333-188704	—	May 20, 2013
10.11+	Employment Agreement, dated September 7, 2012, between the Registrant and Jim Johnson.	S-1	333-193322	—	January 13, 2014
10.12+		10-K	001-35980	—	March 11, 2016

Employment Agreement, dated November 20, 2013, between  
the Registrant and David W. Ghesquiere.

-92-

---

Table of Contents

Exhibit Number	Description	Incorporated by Reference			Filing Date
		Form	File No.	Exhibit	
10.13	Lease between the Registrant and BMR-530 Fairview Avenue LLC, dated October 19, 2007, as amended through December 22, 2014 (including Amendment No. 1 through Amendment No. 7).	10-K	001-35980	10.14	March 13, 2015
10.14	Amendment No. 8 to Lease between the Registrant and BMR-530 Fairview Avenue LLC, dated February 27, 2015.	10-K	001-35980	10.13	March 11, 2016
10.15	Lease between the Registrant and BMR-500 Fairview Avenue LLC, dated December 22, 2014.	10-K	001-35980	10.15	March 13, 2015
10.16	Amendment No. 1 to Lease between the Registrant and BMR-500 Fairview Avenue LLC, dated June 27, 2016.	10-Q	001-35980	10.1	August 4, 2016
10.17	Office Lease Agreement between the Registrant and Blume Roy Building LLC, dated December 26, 2013, as amended through November 18, 2014.	10-K	001-35980	10.16	March 13, 2015
10.18	Amendment No. 2 to Office Lease Agreement between the Registrant and Blume Roy Building LLC, dated February 1, 2016.	10-Q	001-35980	10.1	May 6, 2016
10.19	Sales Agreement, dated as of May 11, 2015, between NanoString Technologies, Inc. and Cowen and Company, LLC.	8-K	001-35980	1.1	May 12, 2015
10.20	Term Loan Agreement dated April 1, 2014 among the Registrant and certain of the Registrant's subsidiaries and Capital Royalty Partners II L.P., Capital Royalty Partners II – Parallel Fund "A" L.P. and Parallel Investment Opportunities Partners II L.P. and forms of promissory note and PIK loan note to be issued thereunder.	10-Q	001-35980	10.1	August 8, 2014
10.21	Amendment No 1 to Term Loan Agreement dated April 16, 2015, between the Registrant and Capital Royalty Partners II L.P., Capital Royalty Partners II (Cayman) L.P, Capital Royalty Partners II – Parallel Fund "B" (Cayman) L.P., and Parallel Investment Opportunities Partners II L.P.	10-Q	001-35980	10.2	August 5, 2015
10.22	Amendment No 2 to Term Loan Agreement dated October 30, 2015, between the Registrant and Capital Royalty Partners II L.P., Capital Royalty Partners II (Cayman) L.P., Capital Royalty Partners II – Parallel Fund "B" (Cayman) L.P. and Parallel Investment Opportunities Partners II L.P.	10-K	001-35980	10.19	March 11, 2016
10.23	Security Agreement dated April 17, 2014 among the Registrant and certain of the Registrant's subsidiaries and Capital Royalty Partners II L.P., Capital Royalty Partners II – Parallel Fund "A" L.P. and Parallel Investment Opportunities Partners II L.P. and form of joinder agreement to be issued thereunder.	10-Q	001-35980	10.2	August 8, 2014
10.24†	Exclusive License Agreement, dated February 4, 2004, between the Registrant and The Institute for Systems Biology.	S-1	333-188704	10.19	May 20, 2013
10.25†	Amendment No. 1 to Exclusive License Agreement, dated February 5, 2007, between the Registrant and The Institute for Systems Biology.	S-1	333-188704	10.20	May 20, 2013
10.26	Amendment No. 2 to Exclusive License Agreement, dated May 17, 2007, between the Registrant and The Institute for Systems Biology.	S-1	333-188704	10.21	May 20, 2013

Table of Contents

Exhibit Number	Description	Incorporated by Reference		
		Form	File No.	Exhibit Filing Date
10.27†	Amended and Restated Exclusive License Agreement, effective July 7, 2010, between the Registrant and Bioclassifier, LLC.	S-1	333-188704	10.2 May 20, 2013
10.28	First Amendment to Amended and Restated Exclusive License Agreement between the Company and Bioclassifier, LLC, dated March 31, 2015.	10-Q	001-35980	10.1 May 11, 2015
10.29	Amendment No. 2 to Amended and Restated Exclusive License Agreement between the Company and Bioclassifier, LLC, dated June 24, 2016.	10-Q	001-35980	10.2 August 4, 2016
21.1	List of subsidiaries of the Registrant.	10-K	001-35980	21.1 March 27, 2014
<u>23.1*</u>	<u>Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.</u>			
24.1*	Powers of Attorney (contained on signature page).			
<u>31.1*</u>	<u>Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.</u>			
<u>31.2*</u>	<u>Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.</u>			
<u>32.1*</u>	<u>Certification of Principal Executive Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.</u>			
<u>32.2*</u>	<u>Certification of Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.</u>			
101.INS*	XBRL Instance Document.			
101.SCH*	XBRL Taxonomy Extension Schema Document.			
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.			
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.			
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.			
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.			

\* Filed herewith.

† Indicates a management contract or compensatory plan.

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