NanoString Technologies Inc
Form 10-K
March 11, 2019

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, 2018
OR
¨ TRANSITION REPORT PURSUANT TO SECTION 13 Or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to_____
Commission file number: 001-35980

NANOSTRING TECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

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

530 Fairview Avenue North
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 ý 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 ý
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 ý No ¨
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes ý 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. ý

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

Large accelerated filer ¨ Accelerated filer ý

Non-accelerated filer ¨ Smaller reporting company ¨

Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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

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 $295.2 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 31,085,236 shares of the Registrant's common stock, $0.0001 par value per share, outstanding on February 28, 2019.

DOCUMENTS INCORPORATED BY REFERENCE

None.

NANOSTRING TECHNOLOGIES, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2018

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 can be identified by words such as "believe," "anticipate," "could," "continue," "depends," "expec "expand," "forecast," "intend," "predict," "plan," "rely," "should," "will," "may," "seek," or the negative of these terms and ot expressions, although not all forward-looking statements contain these words. 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, sufficiency of cash on hand and operating and net loss;
- our ability to successfully launch and commercialize our Digital Spatial Profiling and Hyb & Seq platforms;
- the success, costs and timing of implementation of our business model, strategic plans for our business and future product development plans;
- the regulatory regime and our ability to secure and maintain regulatory clearance or approval or reimbursement for the clinical use of our products, domestically and internationally;
- 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 ability to attract and retain key scientific or management personnel;
- our expectations regarding the competitive position, 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, and you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. 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.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

PART I

Item 1. Business

Overview

We develop, manufacture and sell products that unlock scientifically valuable and clinically actionable information from minute amounts of biological material. Our core technology is a unique, proprietary optical barcoding chemistry that enables the labeling and counting of single molecules. This proprietary chemistry may reduce the number of steps required to conduct certain types of scientific experiments and allow for multiple experiments to be conducted at once. As a result, we are able to develop tools that are easier for researchers to use and that may generate faster and more consistent scientific results.

We use our technology to develop tools for scientific research, primarily in the fields of genomics and proteomics, and also to develop clinical diagnostic tests. We currently have one commercially available product platform, our nCounter Analysis System instruments and related consumables. nCounter can be used to analyze the activity of up to 800 genes in a single experiment. nCounter is also used by clinicians to analyze gene activity relevant for diagnostic applications. Our proprietary nCounter-based Prosigna assay analyzes the activity of 50 genes to assess the risk of recurrence in breast cancer patients previously treated with radiation therapy. As of December 31, 2018, we had an installed base of approximately 730 nCounter systems, which our customers have used to publish more than 2,300 peer-reviewed scientific papers.

We have discovered other novel applications that utilize our proprietary barcoding chemistry, and we have two new product platforms under development. Following completion of product development, each of these new systems is expected to be commercialized as a new instrument along with associated consumables.

The first new platform, our GeoMx Digital Spatial Profiling, or DSP system, is designed to enable the field of spatial genomics. While nCounter and other existing technologies analyze gene activity as a whole throughout the totality of a biological sample, GeoMx DSP is used to analyze specifically selected regions of a biological sample in order to see how gene activity or protein levels might vary across those regions or in certain cell types. In advance of the launch of the commercial version of GeoMx DSP, we have provided early access to the system's capabilities by offering selected customers the opportunity to send biological samples to our Seattle facility to be tested by us on prototype instruments. To date, we have conducted over 70 projects for approximately 50 customers pursuant to this Technology Access Program, or TAP. In addition, in the third quarter of 2018 we announced the GeoMx Priority Site, or GPS, Program. The GPS Program is designed to provide customers the opportunity to be among the first to receive a GeoMx DSP instrument following its commercial launch, as well as advanced service and support. Inclusion in the GPS Program has also provided researchers the opportunity to begin generating data on samples through our TAP service. As of December 31, 2018, we have received over 30 orders for GeoMx DSP pursuant to our GPS Program. The full commercial launch of GeoMx DSP instruments and consumables is expected to commence during the first half of 2019, with installations of commercial instruments expected to commence in the second half of 2019.

The second new platform, our Hyb & Seq molecular profiling system, is designed to use a modified version of our proprietary chemistry to determine and analyze gene sequences within a biological sample, or to potentially profile the activity of an even greater number of genes as compared to our nCounter Analysis System. Hyb & Seq is designed to determine gene sequences using a work flow with fewer steps as compared to currently available gene sequencing technologies. Hyb & Seq is expected to become commercially available during 2021.

New discoveries in genetics have generated a significant amount of scientific information and medical advancement. The decoding of the human genome, and the subsequent generation of large amounts of gene sequence data, has led to the emergence of pathway-based biology whereby researchers seek to understand how networks of genes may work together to produce a biological function or condition. The desire to interpret gene sequence data and map biological pathways has led to demand for technologies that can precisely and efficiently measure the activation state of hundreds of genes simultaneously.

Demand for these new or improved technologies has been driven by researchers in disease areas such as cancer, immunology and neurology. Researchers in these fields are increasingly attempting to determine which sequences of genes or mutations are important in disease-related biological pathways so that new potential treatments might be developed. For example, in the field of cancer, researchers and clinicians have learned that cancer cell behavior is impacted by multiple genes and proteins, and that analysis of these factors together may be important in determining

whether or not a cancer might be responsive to a certain treatment. In addition, more cancers are being detected earlier and tumor samples are becoming smaller and smaller. Tumor samples are often stored in a format known as formalin-fixed paraffin embedded, or FFPE, which complicates subsequent analysis of genetic material. Researchers and clinicians may face similar challenges with analysis of biological samples in other therapeutic areas of interest. Our proprietary chemistry, which has been incorporated into our nCounter product platform and our two product platforms in development, addresses many of the fundamental challenges of genetic and molecular profiling and biological

pathway research. The sensitivity and precision of our chemistry allows the measurement of subtle changes in the activity of multiple genes from minute amounts of a biological sample. Our chemistry is particularly compatible with FFPE, increasing its popularity among cancer researchers. Our chemistry also supports product configurations that are easy to use with simple workflow as compared to many other scientific platforms used for genetic and proteomic research, including absence of library preparation and amplification steps that can be cumbersome or time consuming or that may introduce the possibility of measurement errors. The sensitivity and workflow efficiency of our product platforms also allows for testing of many different samples in a single day, enabling our products to be potentially useful in hospital or similar settings to conduct clinical diagnostic tests.

We market and sell our systems and related consumables to researchers in academic, government and biopharmaceutical laboratories for research use and to clinical laboratories and medical centers for diagnostic use, both through our direct sales force and through selected distributors in certain international markets. We generated revenue of $106.7 million, $114.9 million, and $86.5 million in 2018, 2017, and 2016, respectively, while incurring net losses of $77.4 million, $43.6 million, and $47.1 million in 2018, 2017, and 2016, 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, North, 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,” and “GeoMx.” 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 a full set of biological instructions required to build and maintain life. 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.

By analyzing the variations in genomes, genes, gene activity or expression 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.

Biological pathways are the networks of tens or hundreds of genes that work together to produce a biological function. Understanding the activation state of pathways and disruptions in individual elements provides significant insight into the fundamental basis of health and disease and facilitates data driven treatment decisions. 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 diagnostic tests and drugs to treat disease.

Understanding biological pathways has become particularly important in cancer research and treatment. Cancer is a disease generally caused by genetic mutations in cells. The behavior of cancer cells is extremely complex and depends 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 or less aggressive type of cancer. In some cases, researchers have been able to identify more 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 cancer researchers, in part based on their research of biological pathways and gene expression, 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.

As interest in understanding biological pathways that may be relevant to medicine has increased, academic, government and biopharmaceutical company researchers have aspired to perform analyses of a larger number of genes and samples and are seeking new methods of interrogation that would allow them to:

- increase the number of molecular targets that can be analyzed simultaneously in order to understand the complete biological pathway involving multiple genes;
- provide more reliable, precise and reproducible data about targeted genes and biological pathways;
- maximize the amount of biologic information extracted from precious tissue or other biological 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;
- improve the overall efficiency of their laboratories by simplifying workflow and accelerating the rate of successfully completing their research; and
- create more systematic and reliable ways to help transition their research discoveries into future clinical products.

The interest in new methods of interrogation has led to the development of new research technologies. The newest technologies to experience rapid adoption have been focused primarily on determining the sequence of a person's or organism's DNA, in order to assess how differences among individuals might be predictive of certain aspects of health or disease. In particular, a technology known as next generation sequencing, or NGS, has become widely adopted. In recent years NGS use has accelerated, as the technology has improved and the cost to sequence DNA using NGS has declined. As of December 31, 2018, there were approximately 18,000 NGS systems installed in laboratories globally. While NGS has revolutionized researchers' ability to generate gene sequence data rapidly and cost effectively on large numbers of biological samples, other aspects of examining biological pathways are still done using legacy techniques or new technologies that have proved less capable of providing multiplexed experimentation, ease of use and low cost. Together with determining a gene sequence via NGS, pathway-based research requires further analysis of the activity of multiple genes and sensitivity to small changes in expression, which can be challenging for traditional scientific tools.

Researchers interested in multiplex gene expression or biological pathway analysis have traditionally performed experiments using microarrays or quantitative polymerase chain reaction, or qPCR, and protein expression experiments using flow cytometry, mass spectrometry, immunohistochemistry or enzyme-linked immunosorbent assay, or ELISA, assays. These techniques have been available for decades, and while suitable for analyzing the expression of a smaller number of genes may not be cost effective or scalable enough to study biological pathways. While these types of experiments could be repeated to analyze expression of multiple genes, they are often destructive of biological samples, creating limitations given the amounts of biological sample that may be available. These types of experiments may also involve library preparation and amplification steps that can be cumbersome or time consuming or that may introduce the possibility of measurement errors.

More recently, RNA sequencing, or RNA-Seq, which is done using NGS technology, has enabled researchers to look at the entirety of the gene expression within a single sample, and enhanced researchers' ability to discover patterns of gene expression that have biological meaning. NGS systems have a more complex and time-consuming workflow than traditional methods of analyzing gene or protein expression however, and RNA-Seq generates large amounts of data that may be expensive to store and may not have relevance to the scientific question being explored.

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.

Our Solution

We believe our proprietary chemistry and product platforms provide novel features that address the challenges and technology needs of researchers working to analyze and interpret the increasing amounts of data being generated by NGS and understand biological pathways. Our products support experiments that typically take fewer steps as compared to traditional techniques, perform multiplexed experiments in a single run and have been shown to generate consistent and accurate results from a variety of biological samples, including FFPE imbedded cancer tissue.

Our technology and product platforms offer a number of compelling advantages, including:

- Optimized for Pathway-Based Biology and Development of Multiplexed Biomarkers. Our nCounter Analysis System can profile the activity of up to 800 genes in a single experiment, which allows customers to analyze interactions among hundreds of genes or proteins that mediate biological pathways. Our GeoMx DSP System is designed to enable the multiplex profiling of protein and RNA targets in specifically selected regions of a biological sample.

- Digital Precision. Our molecular barcodes hybridize directly to 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. Our systems are designed to offer minimal sample preparation and automated workflow, which enables the simultaneous analysis of hundreds of genes and proteins in approximately 24 hours between the time a

sample is loaded and results are obtained. Our systems can generate data that customers can evaluate without the use of complex bioinformatics.

- Flexible Sample Requirements. Our systems are designed to unlock biologic information from minute amounts of a variety of challenging tissue samples, including FFPE samples, cell lysates and single cells.
- Efficient Sample Requirements. Our systems also can generate scientific results using very small amounts of biological material, which may be important in settings, such as pharmaceutical product development, where multiple researchers may desire access to samples.
- Versatility. The FLEX configuration of our nCounter Analysis System provides clinical laboratories a single platform with the flexibility to support both clinical testing, by running Prosigna or Laboratory Developed Tests, and research, by processing translational research experiments and multiplexed assays using our research reagents.

Our Products and Technology

We currently have one commercially available product platform based on our technology, our nCounter Analysis System and related consumables. We also have two new product platforms under development enabled by our technology, our GeoMx DSP system and our Hyb & Seq molecular profiling system.

nCounter Analysis System

Our nCounter Analysis System is an automated, multi-application, digital detection and counting system which directly profiles hundreds of molecules simultaneously, using our proprietary optical barcoding chemistry that is powerful enough for use in research, yet simple enough for use in clinical laboratories. 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 they wish to conduct. Our clinical laboratory customers typically purchase instruments from us and also purchase our reagents and related consumables, including Prosigna, for tests that they intend to run.

Our nCounter Analysis System is capable of supporting a number of applications including:

- 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 simultaneously measure 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 by leveraging the nCounter Analysis System’s multiplexing capacity to assay up to 800 DNA regions in a single tube, with as little as 300 ng of DNA.
- Gene Fusions. Researchers can use the nCounter Analysis System to detect gene fusion events that occur when one gene fuses to another gene. A number of design options are available for developing assays for these complex structural variants which have been shown to be important in a number of cancers.
- Molecular Diagnostics. Our nCounter 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. Identifying whether certain genes are active in a biological sample may prove useful in the diagnosis of disease or disease progression, or in determining whether a certain drug therapy may be more or less

effective in a given patient. In addition, nCounter has the precision, reproducibility, and simple workflow required of technologies used in clinical laboratories.

nCounter Instrument Platforms

We currently offer three versions of our nCounter analysis system for commercial sale. 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. Our nCounter SPRINT 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 FLEX, which is targeted toward clinical laboratories, is a version of our MAX system that has been 510(k) cleared by the FDA and CE marked by European regulatory authorities. nCounter FLEX is enabled to run our proprietary Prosigna breast cancer assay, as well as other proprietary or laboratory developed tests, or LDTs, that may be developed.

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

(1) nCounter MAX and FLEX throughput 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 that processes samples after they are hybridized and prepares the samples for data collection on the Digital Analyzer. The 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 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 FLEX system. The nCounter FLEX system was designed and is manufactured under ISO 13485:2003, the current quality standard for in vitro diagnostic platforms and medical devices.

The nCounter SPRINT Profiler is a single instrument targeted to individual researchers that combines the liquid handling steps and the digital analysis through use of a special microfluidic cartridge. 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.

nCounter instrument platforms also include our 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 FLEX system, in addition to running any of our research applications, can also be enabled with software that runs Prosigna to generate individualized patient reports.

nCounter Consumables

All three nCounter instruments are capable of running our research consumable products and provide comparable, high-quality data. The majority of our nCounter consumables sold are standardized off-the-shelf “panel” products that represent important gene signatures for certain disease areas, and also include our proprietary Prosigna breast cancer assay. nCounter consumables can also be customized to a specific set of genes at a customer’s request.

Panels

We offer more than 30 gene expression and analysis panels for use with a broad range of sample types and species, including human, mouse, non-human primate and other. These pre-manufactured CodeSets include highly-curated content relevant to a particular research area. In certain cases, nCounter panels may be partially customized to address individual research interests with the purchase of an optional Panel Plus CodeSet. Our most significant current nCounter panel offerings include:

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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.
- 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.
- 360 Gene Expression Panels. These panels include our IO 360 and Breast Cancer 360 and represent a series of next generation panels that combine clinically actionable content for evaluating the tumor microenvironment and immune response along with validated signatures such as the Company's Tumor Inflammation Signature and PAM 50 (breast cancer subtyping) along with up to 30 additional signatures encompassing all aspects of the cancer. These panels may be combined with our 360 Data Analysis Service to provide access to propriety signature algorithms.
- CAR-T Characterization Panel. A new panel developed in collaboration with leaders in the CAR-T field for use throughout the CAR-T workflow (development, manufacturing and monitoring post-infusion clinical trials). The panel represents a step toward standardization by providing molecular characterization for 8 essential components of CAR-T biology using 780 genes with a customizable feature to allow for measurement of the transgene insert that creates the CAR-T cell.
- Neuropathology and Neuroinflammation Gene Expression Panels. Two panels built in collaboration with leading drug developers, have been designed to address the growing biomarker needs in the field of neuroscience. These panels, which analyze approximately 770 genes profile mechanisms for neurodegenerative diseases as well as neuropsychiatric disorders.
- Mouse-AD Panel. A new panel developed for use with Alzheimer’s Disease, or AD, research in mouse models. The panel, created in collaboration with The Jackson Laboratories and MODEL-AD Consortium allows for more reliable pre-clinical translational studies by incorporating gene content for 30 clinically derived AD associated gene modules for measuring AD phenotypes and disease progression that were discovered as part of a consortium study of human brain tissue.
- Autoimmune Disease Gene Expression Panels. Two panels created to address the specific challenges of autoimmune disease research and assist with the understanding of the underlying mechanisms of autoimmune disease and for identification of potential responders and non-responders to drug treatments.
- 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.

Custom CodeSets

We work with our customers to design and develop custom gene expression 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 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.

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 SPRINT Profiler, customers purchase microfluidic cartridges and separate bottles of reagents which

together provide the ancillary components for processing samples with CodeSets and Panels.

Molecular Diagnostics

Our nCounter 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 Analysis System 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 Analysis System. Over time, we intend to develop, obtain regulatory authorization for, and sell additional in vitro diagnostic kits.

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. We believe the precision, ease of use and flexibility of the nCounter Analysis System may allow medical technicians to conduct complex molecular diagnostic tests with minimal training. Our clinical laboratory customers use the nCounter FLEX system 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 FLEX system. We have one additional in vitro diagnostic test, our proprietary LymphMark assay, under development pursuant to a collaboration with Celgene Corporation, or Celgene.

- Prosigna. Prosigna, our first in vitro 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 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 FLEX system in clinical laboratories. 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. 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. We sell Prosigna kits to our lab customers on a fixed dollars-per-kit basis. These customers are responsible for providing the testing service and contracting and billing payors. Accordingly, we are not directly exposed to third-party payor reimbursement risk.
- LymphMark. Our proprietary LymphMark assay, an in vitro molecular diagnostic test candidate under development, is intended to identify the cell-of-origin subtype of a tumor for patients with diffuse large B-Cell lymphoma, or DLBCL, a form of blood cancer. LymphMark is designed to aid in the disease characterization of patients newly diagnosed with DLBCL to support disease management in conjunction with other clinical and pathological information. 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. LymphMark is currently being specifically investigated as an aid for identifying DLBCL patients that may be most likely to benefit from treatment with Celgene's drug REVLIMID. Under our collaboration with

Celgene, we have delivered an in vitro companion diagnostic test that was used to subtype and screen patients who enrolled in a pivotal study of REVLIMID for the treatment of DLBCL. The results of Celgene's study are expected to be announced in 2019, after which we may file for regulatory approval with the FDA to market and sell LymphMark.

- Laboratory Developed Tests. Clinical laboratories can use our custom manufacturing services to supply reagents to create LDTs, which are diagnostic tests that are developed, validated and performed by a single laboratory. These reagents enable assays for gene expression, copy number variation and gene fusions. Clinical laboratories can use

these reagents to develop assays to replace tests currently performed using fluorescence-based in situ hybridization, or FISH.

GeoMx DSP

Our second product platform, GeoMx DSP, is currently under development. Our GeoMx DSP system is designed to enable the field of spatial genomics.

nCounter and other existing technologies typically analyze gene activity throughout the totality of a biological sample, using “grind and bind” approaches that analyze average gene expression levels across an entire sample. GeoMx DSP is designed to allow researchers to explore and quantify how the activity of large numbers of proteins or genes vary spatially in different selected regions of interest across the landscape of a heterogeneous tissue biopsy, retaining spatial information and providing high-plex assays that target different regions in the same sample.

The commercial launch of the GeoMx DSP instrument and consumables is expected to commence during the first half of 2019, with installations of commercial instruments expected to commence in the second half of 2019.

Many of the current technologies used to analyze gene activity in selected parts of a biological sample are many decades old. These technologies include primarily immunohistochemistry, or IHC, which is used to estimate amounts of protein, and in-situ hybridization, or ISH, which is used to estimate amounts of RNA. Both IHC and ISH typically use stains that provide the ability to identify typically less than four proteins or RNAs based on assigned colors. The colors aid researchers in identifying where certain proteins or RNA may reside in a sample and provide a visual approximation of amounts. These techniques are limited however in their ability to only look at four proteins or RNAs at a time, with no ability to precisely quantify the amounts present in any given region or cell type. These limitations may lead to misleading or incomplete scientific conclusions as to the most relevant biological pathways in any given sample.

GeoMx DSP is designed to allow researchers to address important questions regarding how protein and gene expression vary spatially across multiple specific regions of interest across the landscape of a heterogeneous tissue biopsy. Our GeoMx DSP instruments are expected to image slide-mounted tissue biopsies, allow selection of regions of interest, and automate the preparation of samples from selected regions for molecular profiling using either an nCounter system or NGS. GeoMx DSP technology is expected to offer a number of advantages compared to traditional technologies, including the ability to profile a larger number of different genes or proteins in each region, more flexibility on the selection of regions, and processing of a larger number of samples per day.

GeoMx DSP Instrument

Our GeoMx DSP instruments use specialized optics and software to image slide-mounted tissue biopsies that have been prepared using IHC or ISH technology that is typically available in research or commercial laboratories. GeoMx then allows a researcher to select regions of interest for analysis on screen, and then prepares samples from selected regions of interest for molecular profiling using either an nCounter system or next generation gene sequencer.

GeoMx DSP Consumables

The initial portfolio of GeoMx DSP consumables at launch is expected to focus on protein and RNA analysis for immuno-oncology applications, and protein analysis for neurobiology applications. GeoMx DSP consumables expected to be available at the commercial launch date will be designed to support the profiling of biological activity, after regions of interest have been identified and samples have been prepared using GeoMx DSP, using our nCounter Analysis System. We have additional GeoMx DSP consumable products under development that are expected to enable profiling of larger numbers of RNA in selected regions of interest using an NGS system. We expect these NGS-enabled consumable products to be commercially available in 2020.

GeoMx DSP consumable products are currently designed as standardized panel products that represent important content for certain disease areas, with an initial “core” panel offered for purchase, and an option for researchers to add content to that core depending on the area of interest or desired number of targets for analysis. Our initial GeoMx DSP consumable product offering is expected to include:

- Immuno-Oncology Panels. An immuno-oncology-focused panel menu that is expected to comprise up to 90 protein targets and 84 RNA targets for analyzing the tumor and tumor microenvironment compartments in human tissue samples. The standard or core panel offering is expected to comprise of 20 targets, and researchers will then have the option of adding over 40 additional targets for analysis, with sets of additional targets focused on specific applications such as immuno-oncology drug target proteins, or human immune activation proteins. We also expect to offer panel

content to allow for the analysis of up to 84 immune pathways RNA. Additionally, 30 protein targets are expected to be released for analyzing mouse samples for pre-clinical applications.

- Neurobiology Panels. A neurobiology-focused menu that is expected to comprise up to 40 protein targets to profile neural cells in human tissue. The standard or core panel offering is expected to comprise of 20 targets, and researchers will then have the option of adding up to 20 additional targets for analysis, with sets of additional targets focused on specific applications such as proteins implicated in AD or Parkinson's disease.

Hyb & Seq Molecular Profiler

Our third product platform, our Hyb & Seq molecular profiling system, is currently under development. Hyb & Seq is designed to use a modified version of our proprietary chemistry to determine and analyze gene sequences within a biological sample, or to potentially profile the activity of an even greater number of genes.

While currently available NGS technology has become widely used for research, challenges relating to complex workflow and the need for a large central laboratory to batch process samples to reduce cost have limited broader NGS adoption for use in clinical diagnostic applications to date.

Hyb & Seq is designed to use a modified version of our proprietary chemistry to determine sequence data similar to NGS. As our chemistry does not require amplification, enzyme application or library preparation, Hyb & Seq may offer a faster, easier to use way of determining gene sequences as compared to existing NGS technologies. Hyb & Seq's simple workflow and compatibility with a variety of sample types may offer the potential for a sample-to-answer solution for clinical sequencing. Hyb & Seq may also offer the ability to rapidly detect and quantify a large number of RNA or DNA targets in parallel. Potential applications of this capability could include gene expression measurement, or infectious disease testing.

Hyb & Seq is expected to become commercially available in 2021.

Collaborations

Lam Research Corporation

In August 2017, we entered into a collaboration agreement with Lam Research Corporation, or Lam, to develop our Hyb & Seq sequencing platform and related assays. Under the terms of the agreement, Lam will contribute up to an aggregate of $50.0 million towards the project. The development funding is non-refundable, unless the parties determine that completion of development of the product will not continue, in which case any funds advanced to us by Lam that have not been committed or spent will be refunded to Lam. We will reimburse Lam for the cost of up to 10 full-time Lam employees each year in accordance with the product development plan. Lam is eligible to receive certain single-digit percentage royalty payments from us on net sales of certain products and technologies developed under the agreement, if any such net sales are recorded. The maximum amount of royalties we may pay to Lam will be capped at an amount up to three times the amount of development funding actually provided by Lam. We retain exclusive rights to obtain regulatory approval, manufacture and commercialize any Hyb & Seq products.

All intellectual property made or conceived solely by us pursuant to the collaboration will be owned by us and licensed to Lam solely for the purposes of the collaboration. All intellectual property made or conceived solely by Lam pursuant to the collaboration will be owned by Lam and, subject to certain restrictions on use with Lam competitors, licensed to us for the purposes of the collaboration and further development and commercialization of our Hyb & Seq platform, as well as certain other products and technologies resulting from the collaboration in the field of molecular profiling. Jointly created intellectual property will be jointly owned, provided that neither we nor Lam use such jointly owned intellectual property in the other party's competitive field.

The collaboration agreement establishes a joint steering committee to oversee, review and coordinate our and Lam's activities under the collaboration agreement and monitor progress and expenditures against the associated development plan. The joint steering committee is comprised of three employees from each of us and Lam, and will be chaired by one of our employees. We will have final decision-making authority on the joint steering committee, subject to certain exceptions for decisions regarding development failure, material changes to the development plan, budget, and the Hyb & Seq product being developed under the agreement, and intellectual property ownership, which require consensus of the parties. The collaboration agreement also contains customary representations, warranties, covenants, indemnities and other obligations of the parties.

The term of the collaboration agreement is 15 years. Either we or Lam may terminate the collaboration agreement in the case of a material breach by the other party after providing notice and an opportunity to cure or in the case of bankruptcy or insolvency of the other party. The joint steering committee may also terminate the collaboration agreement if development is discontinued in the case of a development failure. Lam may also terminate the

collaboration agreement on or after the first anniversary in the event we undergo a change of control.

In connection with the execution of the collaboration agreement, we issued Lam a warrant to purchase up to 1.0 million shares of our common stock with the number of underlying shares exercisable at any time proportionate to the amount of the $50.0 million commitment that has been provided by Lam. The exercise price of the warrant is $16.75 per share, and it

will expire on the seventh anniversary of the issuance date. The warrant was determined to have a fair value of $6.7 million upon issuance, which will be recorded as additional paid in capital proportionately from the quarterly collaboration payments made by Lam.

In connection with the entry into the collaboration agreement and issuance of the warrant, we and Lam have agreed, subject to certain exceptions applicable to Lam, to be bound by certain “standstill” provisions. Pursuant to the “standstill” provisions, until the third anniversary of the entry into the collaboration agreement, we, Lam and our respective officers, directors, employees or contractors acting on their behalf will not (1) acquire, offer to acquire, agree to acquire or publicly propose or offer to acquire, securities, indebtedness, businesses, properties or assets of the other party or any subsidiary or division thereof; (2) initiate, induce or attempt to induce any other person or group to initiate any transaction referred to in clause (1), any stockholder proposal regarding the other party or call hold or convene a stockholders’ meeting of the other party; (3) make or participate in any solicitation of proxies to vote or seek to advise or influence any person with respect to the voting of any voting securities of the other party; (4) make any public announcement with respect to, or submit a proposal or offer for any extraordinary transaction involving the other party or any of its securities or assets; (5) form, join or in any way participate in a group as defined in Section 13(d)(3) of the Securities Exchange Act of 1934, as amended, in connection with any of the foregoing prohibited activities; (6) act or seek to control or influence the management, board of directors or policies of the other party; (7) take any action that could reasonably be expected to require the other party to make a public announcement regarding the possibility of any of the prohibited activities described in clauses (1) through (6) or (8) advise, assist or encourage any other person in connection with any of the foregoing prohibited activities.

In addition, Lam has agreed, subject to certain exceptions, not to offer, sell or transfer any of our common stock or securities convertible into or exchangeable or exercisable for our common stock, for three years after the entry into the collaboration agreement without first obtaining our consent, which we may withhold in our sole discretion, unless the collaboration agreement has been terminated, in which case our consent may not be unreasonably withheld.

Celgene Corporation

In March 2014, we entered into a collaboration agreement with 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. Pursuant to our agreement, as amended in February 2018, we are eligible to receive payments from Celgene totaling up to $24.8 million, of which $5.8 million was received as an upfront payment and $19.0 million is for development funding and potential success-based developmental and regulatory milestones. In February 2018, Celgene agreed to provide us with additional funding for work intended to enable a subtype and prognostic indication for the test being developed under the agreement. In connection with this amendment, we agreed to remove the right to receive payments from Celgene in the event commercial sales of the companion diagnostic test do not exceed certain pre-specified minimum annual revenues during the first three years following regulatory approval. In addition, the amendment allows Celgene, at its election, to use trial samples with additional technologies for companion diagnostics.

Under the collaboration agreement with Celgene, we have delivered an in vitro companion diagnostic test that was used to subtype and screen patients who 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 $14.5 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 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, seek regulatory approval for, and commercialize a companion diagnostic test 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. In October 2017, we were notified by Merck of the decision not to pursue regulatory approval of the companion diagnostic test for KEYTRUDA. As a result, in August 2018, we and Merck agreed to mutually terminate our development collaboration agreement, effective as of September 30, 2018, following the completion of certain close-out activities.

Medivation, Inc. and Astellas Pharma, Inc.

In January 2016, we entered into a collaboration with Medivation, Inc., or Medivation, and Astellas Pharma Inc., or 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. In September 2016, Medivation was acquired by Pfizer, Inc., or Pfizer, and became a wholly owned subsidiary of Pfizer. In May 2017, we received notification from Pfizer and Astellas terminating the collaboration agreement as a result of a decision to discontinue the related clinical trial.

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, 2018, we owned or exclusively licensed 27 issued U.S. patents and approximately 36 pending U.S. patent applications, including provisional and non-provisional filings. We also owned or licensed approximately 266 pending and granted counterpart applications worldwide, including 118 country-specific validations of 13 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 typically have negotiated license or assignment provisions to obtain 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 generally relate to the following main areas:

- our nCounter Analysis System biology, chemistry, methods and hardware;
- specific applications for our nCounter Analysis System technology;
- our gene expression markers, methods and gene signatures for recurrence and drug response in certain forms of cancer;
- biological and chemical compositions, methods and hardware for enzyme and amplification free sequencing; and
- biological and chemical compositions, methods and hardware for multiplexed detection and quantification of protein and/or nucleic acid expression in a defined region of a tissue or cell.

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, 2018, we have paid aggregate royalties of $5.7 million under the license agreement. Unless terminated earlier in accordance with the terms of the amended license agreement, the agreement will terminate upon the expiration of the last to expire patent licensed to us. The Institute for Systems Biology has the right to terminate the agreement under certain situations, including our failure to meet certain diligence requirements or our uncured material breach of the agreement.

Bioclassifier, LLC

In July 2010, we entered into an exclusive license agreement with Bioclassifier, LLC, pursuant to which Bioclassifier granted to us an exclusive, subject to certain government rights, worldwide license, with the right to sublicense, to certain intellectual property rights and technology, including eight non-provisional patent applications, related to the PAM50 gene signature in the field of research products and prognostic and/or diagnostic tests for cancer, including Prosigna. Bioclassifier has licensed these rights from the academic institutions that employed the cancer researchers that discovered or were involved in the initial development of PAM50. Pursuant to the agreement, we are required to pay Bioclassifier the greater of certain minimum royalty amounts and mid-single digit to low double digit percentage royalties on net sales of products and/or methods sold by us that are covered by patent rights or include, use or are technology licensed to us. Our obligation to pay royalties to Bioclassifier expires on a country-by-country basis upon the expiration of the last patent licensed or, if a product or method includes, uses or is technology licensed to us but is not covered by a patent licensed to us, ten years after the first commercial sale of the product or method in such country. We are also required to pay Bioclassifier a percentage of any income received by us from the grant of a sublicense to the patents or technology licensed to us under the agreement. In July 2018, we agreed to amend our license agreement with Bioclassifier to increase the current royalty rate paid to Bioclassifier on sales of licensed products in the United States to an upper-single digit percentage, which became effective January 1, 2018. 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, 2018, we have paid Bioclassifier $2.2 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 are continuously seeking to improve our product platforms, including the technology, software, accessibility and overall capability. We also seek to develop additional research consumable content, and new potential molecular diagnostic tests. 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, 2018, we had 173 employees in research and development, of which 58 hold a Ph.D. degree and one holds an M.D. degree.

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 28 distributors, each of which is specific to a certain territory. In the event a 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 distribution of revenue, see Note 16 of the Notes to Consolidated Financial Statements under Item 8 of this report. For the year ended December 31, 2018, our collaborator, Lam, represented 17% of our total revenue. For the year ended December 31, 2017, two customers/collaborators, Merck, and Medivation, Inc. and Astellas Pharma Inc., represented 25% and 10%, respectively, of our total revenue. For the year ended December 31, 2016, Merck represented 13% of our total revenue.

Instrumentation and Research Consumables

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 have continued to invest in our commercial channel to increase our reach and productivity. During 2017 and 2018, we added staff focused on sales of our consumable products to support our existing instrument-focused sales staff. We believe these investments helped to drive the growth of our installed instrument base, and the continued utilization of our consumables by our installed base of instrument users.

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. 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 certain raw materials for our consumables. We build our consumables, including our Panels, Custom CodeSets and reagent packages at our Seattle, Washington facility.

Instruments

We outsource manufacturing of our 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 and our GeoMx DSP instrument 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.

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 10x Genomics, 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 a central laboratory in Redwood City, California. We also face competition from companies such as Agendia and bioTheranostics, 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, and its product EndoPredict, a distributed test for breast cancer recurrence.

We believe that we have multiple competitive advantages in the research market, including the automated nature of our systems with 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.

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 screening or diagnosis and/or detection of diseases, conditions or infections, including, without limitation, the presence of certain chemicals, genetic or other

biomarkers.

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. Class III devices that were on the market before May 28, 1976 and 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 submission 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 six to 12 months, but it can take significantly longer, particularly for a novel type of product. The FDA will also not begin a substantive review of the filing until it verifies the application contains all necessary information required to commence a substantive review. If the application does not contain all required information, the FDA will not file the application and return it to the submitter, highlighting the deficiencies in the application.

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. If the modified device has been commercialized, 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 stringent 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 an approval for specific indications, which can be more limited than those originally

sought by the manufacturer. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device including, among other things, post-approval studies and restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval or placement of restrictions on the sale of the device until the conditions are satisfied.

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

De Novo Pathway. If no predicate can be identified, the product is automatically classified as Class III, requiring a PMA. However, the FDA can reclassify, or use "de novo classification" for, a device for which there was no predicate device if the device is low or moderate risk. A device company can submit a de novo application at the outset, rather than submitting a 510(k) application 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 satisfy, 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 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 quality manufacturing requirements set forth in 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 unannounced 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 regulatory letter or a 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."

Products Labeled for Research Use Only. In essence, RUO products are not regulated as medical devices and are therefore not subject to the regulatory requirements enforced by the FDA. 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 products labeled RUO, 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 circumstances to determine if the product is intended for diagnostic purposes. If FDA were to determine, based on the totality of circumstances, that our products labeled and marketed for RUO are intended for diagnostic purposes, they would be considered medical devices that will require clearance or approval prior to commercialization.

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 laboratory. 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.

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.

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 European Union, or 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 FLEX 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, 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 October 2016, we applied for and received a Category 1 MAAA code for Prosigna. The code was 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.

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. For additional information, see the section of this report captioned “Risk Factors — Risks Related to Government Regulation and Diagnostic Product Reimbursement.”

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. Most individual BCBS entities have updated their coverage policies to include Prosigna 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, Switzerland, Denmark 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 and abroad are subject to various fraud and abuse laws, including, without limitation, the federal anti-kickback statute and state and federal marketing compliance laws in the United States. These laws may impact our operations directly, or indirectly through our customers, and may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include the following federal laws and their counterparts at the state level:

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

Employees

As of December 31, 2018, we had 476 employees, of which 115 work in manufacturing, 141 in sales, marketing and business development, 173 in research and development, and 47 in general and administrative. None of our U.S. employees are represented by a labor union or are the subject of a collective bargaining agreement. As of December 31, 2018, of our 476 employees, 432 were employed in the United States and 44 were employed outside the United States.

Environmental Matters

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

Where You Can Find Additional Information

We make available free of charge through our investor relations website, www.nanostring.com, our annual reports, quarterly reports, current reports, proxy statements and all amendments to those reports as soon as reasonably practicable after such material is electronically filed or furnished with the SEC. These reports may also be obtained without charge by contacting Investor Relations, NanoString Technologies, Inc., 530 Fairview Avenue, North, Seattle, Washington 98109, e-mail: investorrelations@nanostring.com. Our Internet website and the information contained therein or incorporated therein are not intended to be incorporated into this Annual Report on Form 10-K. In addition, the SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding reports that we file or furnish electronically with them at www.sec.gov.

Table of Contents

Item 1A. Risk Factors

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

Risks Related to Our Business and Strategy

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

We have incurred losses since we were formed and expect to incur losses in the future. We incurred net losses of $77.4 million, $43.6 million, and $47.1 million for the years ended December 31, 2018, 2017, and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of $391.3 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. 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. Also, 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. For example, in May 2017, our collaboration with Medivation, Inc. and Astellas Pharma Inc., or Astellas Pharma, was terminated, resulting in the recognition of $11.3 million of collaboration revenue during the second quarter of 2017. In October 2017, Merck notified us of the decision to not continue to pursue regulatory approval of the companion diagnostic for their product, KEYTRUDA, under our collaboration, resulting in the recognition of $11.6 million of collaboration revenue during the fourth quarter of 2017. In August 2018, we and Merck agreed to mutually terminate our development collaboration agreement, effective as of September 30, 2018, following the completion of certain close-out activities. Furthermore, our instruments 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 recent periods and we may not achieve similar growth rates in the future. 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, the commercial launch of our GeoMx DSP, which we anticipate will occur in 2019, is a key element of our growth strategy and will require us to hire and retain additional sales and marketing personnel and resources. If we do not successfully generate demand for our GeoMx DSP instrument, other new product offerings, or manage our anticipated

expenses accordingly, our operating results will be harmed.

Our future success is dependent upon our ability to expand our customer base and introduce new applications and products.

Our current customer base is primarily composed of academic and government research laboratories, biopharmaceutical companies and clinical laboratories (including physician-owned 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. During 2017, in an effort to enhance future results, we added sales staff focused on consumable sales to existing customers, 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. In the U.S., Medicare and most private insurers provide coverage and payment for patients to be tested with Prosigna; however, other countries, such as Germany, provide more limited coverage and payment for Prosigna.

We also plan to develop and introduce new products which would be sold primarily to new customer types, such as our GeoMx DSP instrument for use in pathology labs and a sequencer based on our Hyb & Seq chemistry targeted for use by hospitals and oncology clinics. We anticipate that our GeoMx DSP instrument will become commercially available in 2019 and scaling and training our sales force to attract new customers will require substantial time and expense. Any failure to expand our existing customer base through the launch of our GeoMx DSP instrument, or other new applications and products would adversely affect 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. With the

introduction of our nCounter SPRINT system in July 2015, which is targeted at individual researchers that often have less certain funding than other potential customers, our visibility regarding timing of sales has decreased. 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. Furthermore, from time-to-time, we may lease instruments or place instruments under reagent rental agreements, wherein a customer does not purchase an instrument upfront but instead pays a rental fee associated with each purchase of reagents. An increase in instruments placed under these lease or reagent rental agreements may reduce the number of instruments we would otherwise sell in any period. In addition, any failure to meet customer expectations could result in customers choosing to continue to use their existing systems or to purchase systems other than ours.

Our reliance on distributors for sales of our products outside of the United States, and on clinical laboratories for delivery of Prosigna testing services, could limit or prevent us from selling our products and impact our revenue.

We have established distribution agreements for our nCounter Analysis Systems and related consumable products in many countries where we do not sell directly. 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, including physician-owned laboratories, 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 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 and revolving credit facility, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. However, we may need to raise substantial additional capital to:

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

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

- market acceptance of our products;
- the cost and timing of establishing additional sales, marketing and distribution capabilities;
- 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, or convertible debt, our stockholders may experience dilution. For example, in January 2018, we entered into a sales agreement with Cowen and Company, LLC, or Cowen, to sell up to $40.0 million worth of shares of our common stock, from time to time, through an “at the market” equity offering program under which Cowen will act as sales agent. In July 2018 and August 2018, we sold an aggregate of 4,600,000 shares of common stock in an underwritten public offering for net proceeds of $53.8 million. In October 2018, we entered into a new $100.0 million term loan facility with CR Group L.P. 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. We have in the past pursued these types of transactions, and may in the future

pursue similar transactions or other strategic transactions, on our own or with other advisors, that may impact our business and prospects and the value of our common stock. 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 became 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.

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 2017, we continued to work with our supplier of cartridges used in our nCounter SPRINT systems to improve the design which resolved the previous leakage issues in the microfluidic device produced for us. 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. 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.

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 and 2017, we launched additional 3D Biology panels, including our first for the measurement of DNA mutations and in 2017 we launched our 360 panels for use in breast cancer, immuno-oncology and hematology. In 2018, we expanded beyond oncology and launched panels in neuroscience and CAR-T characterization. We recently launched our GeoMx DSP product on an early access basis, which will target the pathology market, a market we have not previously targeted.

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. 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 and GeoMx DSP, 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, quality issues with components and materials sourced from third-party suppliers or failure to strictly follow procedures or meet specifications, could result in delays or shortfalls in production or require us to voluntarily recall our consumable products. Identifying and resolving the cause of any such manufacturing or supplier 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 as well as new suppliers. For example, our GeoMx DSP systems may require that we establish supply relationships with antibody providers. 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 and negotiating supply agreements 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.

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

For 2018, 2017, and 2016 approximately 40%, 40%, and 38% respectively, of our product and service 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 product and service 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 decision to withdraw from 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, and in March 2017, the government of the United Kingdom formally initiated the withdrawal process. Negotiations for the United Kingdom's exit from the EU, or Brexit, 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 report.

The decision of the United Kingdom to withdraw from the European Union has caused and, along with events that could occur in the future as a consequence of the United Kingdom’s withdrawal 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) and access to European Union research funding by research scientists based in the United Kingdom 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.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the legislation commonly known as the Tax Cut & Jobs Act, which was signed into law on December 22, 2017, significantly revised the Internal Revenue Code of 1986, as amended, or the Code. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including a reduction of the federal statutory rates from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income, elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. It is also unknown if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is likewise uncertain and could be adverse.

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

As of December 31, 2018, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of approximately $288.7 million. The federal NOL carryforwards generated during and after fiscal 2018 totaling $55.0 million are carried forward indefinitely, while all others, if not utilized, will expire in various years beginning in 2025. A lack of future taxable income would adversely affect our ability to utilize these NOLs. In addition, under Section 382 of the 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 Code. Our NOLs may also be impaired under similar provisions of state law or limited pursuant to provisions of the recent Tax Cut and Jobs Act amendments to the Code. 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 new term loan agreement with CR Group L.P., and revolving credit facility with Silicon Valley Bank require 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 or revolving credit facility, 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;
- 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 strategic transaction may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

If we are unable to recruit, train and retain key personnel, we may not achieve our goals.

Our future success depends on our ability to recruit, train, retain and motivate key personnel, including our senior management, research and development, manufacturing and sales and marketing personnel. Competition for qualified personnel is intense, particularly in the Seattle, Washington area. Our growth depends, in particular, on attracting, retaining and motivating highly-trained sales personnel with the necessary scientific background and ability to understand our systems at a technical level to effectively identify and sell to potential new customers. We do not maintain fixed term employment contracts or key man life insurance with any of our employees. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to attract, train, retain and motivate qualified personnel could materially harm our operating results and growth prospects.

Undetected errors or defects in our products could harm our reputation, decrease market acceptance of our products or expose us to product liability claims.

Our products may contain undetected errors or defects when first introduced or as new versions are released. Disruptions or other performance problems with our products may damage our customers' businesses, 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, an acquired business or our suppliers 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, reputation, financial condition and results of operations. In addition, any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, including state data protection regulations and the E.U. General Data Protection Regulation, or GDPR, and other regulations, the breach of which could result in significant penalties. 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.

We intend to seek strategic collaborations and partnerships and other transactions, which may result in the use of a significant amount of our management resources or significant costs, and we may not be able to fully realize the potential benefit of such transactions.

We intend to seek strategic collaborations and partnerships to support the continued growth of the company. Accordingly, we may be engaged in evaluating potential transactions including, without limitation, strategic partnerships, divestitures of existing businesses or assets, a merger or consolidation with a third party that results in a change in control, a sale or transfer of all or a significant portion of our assets or a purchase by a third party of our securities that may result in a minority or control investment by such third party. From time to time, we may engage in discussions that may result in one or more transactions. Although there would be uncertainty that any of these discussions would result in definitive agreements or the completion of any transaction, we may devote a significant amount of our management resources to such a transaction, which could negatively impact our operations. In addition, we may incur significant costs in connection with seeking strategic transactions regardless of whether the transaction is completed. In the event that we consummate a strategic collaboration or partnership or other transaction in the future, we cannot assure you that we would fully realize the potential benefit of such a transaction which could adversely affect our future financial results or that such transaction would positively impact the value of stockholders' investment in us.

Our strategy to seek to enter into strategic collaborations and licensing arrangements with third parties to develop diagnostic tests and other products 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 and research products. 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 collaboration with Merck to develop a companion diagnostic test and the subsequent termination of the collaboration agreement, Merck granted to us a non-exclusive license to certain intellectual property that relates to Merck's tumor inflammation signature. We intend to enter into more such arrangements with our research customers and other researchers,

including biopharmaceutical companies and research institutions, for development of future diagnostic products. However, there is no assurance that we will be successful in doing so. 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. Certain parties may seek to partner with companies in addition to us in connection with a project. This, in turn, may limit the commercial potential of any products that are the subject of such collaborations. Potential collaborators or licensors may elect not to work with us based upon their assessment of our financial, regulatory, commercial or intellectual property position. 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.

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 or products we develop individually or with our collaborators.

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 addition, the success of the development programs for any product candidates or assays developed in collaboration with others will be dependent on the continued pursuit and success of the related drug trials by our collaborators. For example, in October 2017, Merck notified us of their decision not to continue to pursue regulatory approval of the companion diagnostic we were developing for their product, KEYTRUDA, and in August 2018, we and Merck agreed to mutually terminate our development collaboration agreement. There is no guarantee that our collaborators will continue to pursue clinical trials for product candidates or assays that are the subject of our collaborations or that such clinical trials will be successful and, as a result, we may expend considerable time and resources developing in vitro diagnostic assays that will not gain regulatory approval. For example, pursuant to our collaboration with Celgene Corporation, we are developing a companion diagnostic, LymphMark, that is expected to be a potential companion diagnostic to aid in identifying patients with diffuse large B-cell lymphoma for treatment. Depending on the outcome of the clinical trial being run by Celgene, we anticipate we may file for regulatory approval of LymphMark with the U.S. Food and Drug Administration. Furthermore, significant consolidation in the life sciences industry has occurred during the last several years and in connection with such consolidation, the combined company often reassesses its development priorities which may impact our existing collaborations or future opportunities. For example, in May 2017, Astellas Pharma announced a joint decision with Pfizer Inc., or Pfizer, to discontinue the planned ENDEAR trial which was the subject of our collaboration. We were informed that the decision resulted from an oncology portfolio review by Astellas Pharma and Pfizer. In January 2019, Bristol Myers Squibb announced that it was acquiring Celgene; this transaction is expected to close in the third quarter of 2019. Even if we establish new relationships, we or our collaborators may terminate those relationships or they may never result in the successful development or commercialization of future tests or other products. From time to time we have agreed to modify the terms of our agreements with collaborators, including financial terms, and in the future it is possible that we will agree to modify the terms of existing and future agreements with collaborators.

In August 2017, we entered into a collaboration agreement with Lam Research Corporation, or Lam, with respect to the development and commercialization of our Hyb & Seq sequencing platform and related assays. Pursuant to the terms of the collaboration agreement, Lam will contribute up to $50.0 million, payable quarterly, for allowable development costs. In exchange, Lam is eligible to receive certain single-digit percentage royalty payments on net sales by us of certain products and technologies developed under the collaboration agreement, if any. In addition, we issued Lam a warrant to purchase up to 1.0 million shares of our common stock. Any product development activities pursuant to this collaboration are uncertain and development costs may exceed $50.0 million, in which case we would need to obtain additional funding to complete development of our Hyb & Seq sequencing platform and related assays. Ultimately the development may not be successful, which could negatively impact our prospects for future revenue

growth.

Although we expect such collaborations to provide funding to cover our costs of development, the failure, discontinuation or modification of these clinical trials could negatively impact our ability to attract new collaboration partners, and would reduce our prospects for introducing new diagnostic products, revenue growth, and future operating results.

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 and additional applications. These companies use well-established laboratory techniques such as microarrays or quantitative

PCR as well as newer technologies such as next generation sequencing such as RNA-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 10x Genomics. In addition, there are a number of new market entrants in the process of developing novel technologies for the life sciences market, including those that may compete with GeoMx DSP.

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 Myriad Genetics.

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. For example, we recently concluded that certain of our customers have shifted certain types of experiments that previously had been performed on our nCounter system to RNA-sequencing technology. Although we are pursuing several strategies to mitigate this trend, there can be no assurance we will be successful in doing so. 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 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 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 healthcare 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 on a widespread basis, 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.

Risks Related to Government Regulation and Diagnostic Product Reimbursement

Our "Research Use Only" products for the research, life sciences market could become subject to more stringent regulatory surveillance 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 provide directions to use as diagnostic products, they are not subject to the same level of control by the Food and Drug Administration, or FDA, as medical devices. In particular, while the FDA regulations require that RUO products be appropriately labeled, "For Research Use Only," 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 requirements for dual use instruments could change causing additional costs and delays for development of these products. 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, or the instruments are being promoted for off-label use. 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. In July 2017, FDA adopted a new regulation exempting certain clinical multiplex test systems, like the ones used with our Prosigna assay, from premarket notification requirements. However, these new regulations will not impact the FDA clearance requirements for our nCounter Dx Analysis System which will still require 510(k) clearance for use with specific assays, such as Prosigna.

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, or revise or rescind reimbursement rates, 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 diagnostic products would be compromised and our revenue would be significantly limited. Even if we do obtain reimbursement for our tests, Medicare, Medicaid 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 our 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. The Protecting Access to Medicare Act, or PAMA, of 2014 revised the Medicare Clinical Laboratory Fee Schedule, or CLFS, to base prices on private payor rates that are reported to the Centers for Medicare and Medicaid Services, or CMS. In June 2016, CMS released the final Clinical Diagnostic Tests Laboratory Payment System regulations, in response to PAMA. Under the definitions in the regulations, Prosigna is defined as a Clinical Diagnostic Laboratory Test, or CDLT, and therefore will be repriced every three years based on a weighted median of private payor payments submitted by reporting labs. As a result, if private payor 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 years 2018-2020 and no more than 15% less during years 2021-2023. In 2017, as part of the market-based pricing determinations for 2018 required by PAMA, only one private payor payment from a single commercial laboratory was reported, and it was an anomalous payment amount, well below the current Medicare reimbursement price. CMS used that single payment amount as the weighted median, which triggered an automatic 10% reduction in Prosigna's Medicare reimbursement rate of $3,443 to $3,099, effective January 1, 2018, followed by a subsequent 10% reduction to $2,789, effective January 1, 2019. There will be an additional 10% automatic reduction in the Medicare reimbursement rate for Prosigna for calendar year 2020. Reductions in the prices at which testing services based on our technology are reimbursed could reduce our customers' interest in offering Prosigna and have a negative impact on our revenue.

Under PAMA, CMS is required to reprice CLDTs, including Prosigna, every three years. The next repricing will be announced by CMS in late 2020, based on private payor reimbursement data collected by reporting laboratories during the period January 1, 2019 to June 30, 2019. These new prices will take effect on January 1, 2021. Depending on the pricing data reported by these laboratories to CMS, Prosigna's Medicare reimbursement price may change.

In many countries outside of the United States, various coverage, pricing and reimbursement approvals are required. For example, we have received positive reimbursement decisions for Prosigna have occurred in France, certain regions of Spain, Canada, Israel, Switzerland and Denmark, but 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 reagents may be used by clinical laboratories to create Laboratory-Developed Tests, (LDT), 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.

A clinical laboratory can use our custom-manufactured 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 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 guidance in the near term, FDA could alter its position or Congress could enact legislation that could result in FDA regulation of some LDTs. To date, draft legislative proposals have been discussed, but no legislation has been introduced. If FDA changed its policy or legislation were enacted, it could adversely affect demand for these specialized reagents or our instruments.

Our nCounter reagents allow users to design and validate their own customized assays using standard sets of barcodes provided by us with the laboratories' choice of oligonucleotide probes. These reagents, which are offered to customers in the United States through a custom manufacturing service, may be used by laboratories in conjunction with analyte-specific reagents and general purpose reagents to create diagnostic tests or test systems validated within the accredited testing laboratory.

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, unless an exemption applies we are required to obtain prior 510(k) clearance, or pre-market approval (PMA) from the FDA. In September 2013, we received FDA 510(k) clearance for Prosigna as a prognostic indicator for distant recurrence-free survival at 10 years in post-menopausal women with Stage I/II lymph node-negative or Stage II lymph node-positive (1-3 positive nodes) hormone receptor-positive breast cancer who have undergone surgery in conjunction with locoregional treatment and consistent with the standard of care. In addition, we are currently collaborating with Celgene on a companion diagnostic test for their drug REVLIMID. 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), FDA 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 are beneficial for therapeutic product development or clinical decision making but that do not meet the definition of an IVD companion diagnostic. If we developed a diagnostic device to be used in conjunction with a pharmaceutical product that was then cleared or approved but not as a companion diagnostic for the therapeutic product, this may result in potentially reduced revenue for the test as the labeling of the drug may not reference the need for the diagnostic test.

Any 510(k) clearance, de novo authorization 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, de novo authorizations, or 510(k) clearance. Even if we were to obtain regulatory approval, authorization 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.

If we are unable to obtain additional regulatory clearances, registrations, 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, we have obtained a CE mark for

Prosigna which permits us to market that assay for diagnostic purposes in the European Union, and we have received regulatory clearances in selected other jurisdictions. Other than with respect to Prosigna in such jurisdictions in which we have received regulatory clearance, 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 any 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. For example, we are currently working on the development of LymphMark, a companion diagnostic test for REVLIMID that we have developed in a collaboration with Celgene. Some of the

compensation we expect to receive pursuant to these collaborations is based on the receipt of such approvals. Any failure to obtain regulatory approvals for our diagnostic tests in a particular jurisdiction may also reduce sales of our nCounter systems for clinical use in that jurisdiction, as the lack of a robust menu of available diagnostic tests would make those systems less attractive to testing laboratories.

We cannot assure investors that we will be successful in obtaining these regulatory clearances, registrations, 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.

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. Accordingly, we expect to rely on third parties, such as medical institutions, clinical investigators, consultants, and our pharmaceutical collaborators to conduct such studies. For example, we contract with clinical laboratories to perform the companion diagnostic tests we have developed that are used in the clinical trials run by pharmaceutical companies pursuant to our companion diagnostic collaborations. 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 the 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 and regulatory requirements. 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, the studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our diagnostic products. In addition, under our contracts with our pharmaceutical collaborators, we potentially could be held liable for the failure of our third party subcontractors to perform their contractual obligations.

Our pharmaceutical collaborators may decide to end their clinical program, modify or terminate a clinical trial, or not pursue regulatory filings for a companion diagnostic test. For example, in October 2017, Merck notified us of the decision to not continue to pursue regulatory approval of the companion diagnostic for their product, KEYTRUDA, under our collaboration and, in August 2018, we and Merck agreed to mutually terminate our development collaboration agreement. It is also possible that a clinical trial run by one of our collaborators may not meet its endpoint and consequently may not support a regulatory filing for the companion diagnostic we are developing.

In many countries, we are not able 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 in vitro diagnostic medical devices, including Prosigna and the nCounter FLEX Analysis System. Accordingly, we and certain of our contract manufacturers are subject to ongoing International Organization for Standardization, or ISO, as well as regulation by the FDA and other national health authorities. These may include routine inspections by Notified Bodies, FDA, and other health authorities, 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 adverse event and malfunction

reporting; reporting certain corrections and removals; 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. On May 25, 2017 the European Union adopted the IVD Directive Regulation, which increases the regulatory requirements applicable to some in vitro diagnostics in

the EU and would require that we re-classify and obtain approval, registration, or clearance for our existing CE-marked IVD products within a five-year grace period (by May 25, 2022).

We may also be subject to additional FDA or global regulatory authority post-marketing obligations or requirements by the FDA or global regulatory authority to change our current product classifications which would impose additional regulatory obligations on us. The promotional claims we can make for Prosigna are limited to the intended use as required by regulatory authority. 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 healthcare fraud and abuse laws and other 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 fraud and abuse laws, including, without limitation, the federal and state anti-kickback statutes and state, federal and foreign 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 privacy regulations by both the federal government and the states in which we conduct our business as well as by foreign governments and entities. The laws that may affect our ability to operate include:

- the federal Anti-kickback Law and state equivalents;
- 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 and state equivalents;
- state physician gift bans and state, federal and foreign marketing expenditure disclosure laws;
- the Foreign Corrupt Practices Act, which applies to our international activities; and
- the European Union's General Data Protection Regulation.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education 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. In January 2018, Congress suspended the tax again for a two-year period. The tax applies to our listed medical device products, which include the nCounter Dx Analysis System and Prosigna. 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, pricing changes can occur through the annual adjustment to the CLFS; this resulted in a 10% reduction in the Medicare reimbursement price for Prosigna starting on January 1, 2018 and future 10% reductions in 2019 and 2020. 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 included 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 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. 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, 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, 2018, we owned or licensed 27 issued U.S. patents and approximately 36 pending U.S. patent applications, including provisional and non-provisional filings. We also owned or licensed approximately 266 pending and granted counterpart applications worldwide, including 118 country-specific validations of 13 European patents. We continue to file new patent applications to protect the full range of our technologies. 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.

Our success depends in part on obtaining patent protection for our products and processes, preserving trade secrets, patents, copyrights and trademarks, operating without infringing the proprietary rights of third parties, and acquiring licenses for technology or products. 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. As the patent and prior art landscape for translational research and molecular diagnostic life science products grows more crowded and becomes more complex we may find it more difficult to obtain patent protection for our products including those related to digital spatial profiling and sequencing, for example. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products and may therefore fail to provide us with any competitive advantage. 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 unenforceability or invalidity of such patents and could deprive us of the ability to prevent others from using the technologies claimed in such issued 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 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 U.S. Patent and Trademark Office, or 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 USPTO provided additional guidance on examination procedures pertaining to subject matter eligibility in April 2018 and June 2018. 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; however, method of

treatment claims that practically apply natural relationships should be considered patent eligible. 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 protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. 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. 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, intellectual property relating to a gene signature for lymphoma subtyping from the National Institutes of Health for use in our collaboration with Celgene Corporation, and intellectual property relating to the tumor inflammation signature from Merck. 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.

Involvement 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, 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 have led and may lead to litigation. We cannot assure investors that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets, infringement by us of third-party patents and trademarks or other rights, or the validity of our patents, trademarks or other rights, will not be asserted or prosecuted against us. Litigation may also be necessary for us to protect or enforce our patent and proprietary rights, defend against third-party claims 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 and reduce our ability to compete in the marketplace. The outcome of any litigation or other proceeding is inherently uncertain and might not

be favorable to us. 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.

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. Our success depends in part on our non-infringement of the patents or proprietary rights of third parties. We develop complex products that integrate a wide range of technologies which

may impact our ability to do so clear of third party rights and therefore may need to license other technologies or challenge the scope, coverage and validity of the proprietary rights of others to commercialize future products. As we develop new technologies such as those related to genomic diagnostic tests, digital spatial profiling and sequencing, for example, and move into new markets and applications for our products, we expect incumbent participants in such markets may assert their patents and other proprietary rights against us as part of a business strategy to slow our entry into such markets, impede our successful competition and/or extract substantial license and royalty payments from us. 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. 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. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have an adverse impact on our stock price, which may be disproportionate to the actual impact of the ruling itself. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and obtain one or more licenses from third parties, or be prohibited from selling certain products. We may not be able to obtain these licenses at a reasonable cost, if at all. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. In addition, we could encounter delays in product introductions while we attempt to develop alternative methods or products to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing products, and the prohibition of sale of any of our products could materially affect our ability to grow and gain market acceptance for our products.

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

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

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

Many of our employees were previously employed at universities or other life sciences companies, including our competitors or potential competitors. Although no claims against us are currently pending, we or our employees may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. A loss of key research personnel work product could hamper or prevent our ability to commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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;
- 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.

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, including by our officers, directors and their respective affiliates. 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.

We 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. For example, in July and August 2018, we sold an aggregate of 4,600,000 shares of common stock in an underwritten public offering for net proceeds of $53.8 million. Any such future issuance, including any issuances pursuant to our “at the market” equity offering program under our sales agreement with Cowen, could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

We have broad discretion over the use of the proceeds to us from our July 2018 and August 2018 underwritten public offering and our October 2018 term loan agreement and will have broad discretion over the use of the proceeds to us from our “at the market” equity offering program and may apply the proceeds to uses that do not improve our operating results or the value of your securities.

We have broad discretion over the use of proceeds to us from our July 2018 and August 2018 underwritten public offering and our October 2018 term loan agreement and we will have broad discretion to use the net proceeds to us from our “at the market” equity offering program put into place in January 2018, and investors will be relying solely on the judgment of our board of directors and management regarding the application of these proceeds. Although we expect to use the net proceeds from our “at the market” equity offering program for general corporate purposes, investors will not have the opportunity, as part of their investment decision, to assess whether the proceeds are being used appropriately. Our use of the proceeds may not improve our operating results or increase the value of the securities offered pursuant to the foregoing fundraising transactions.

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."

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, we incur and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. We ceased to be an "emerging growth company" on December 31, 2018 and are no longer eligible for reduced disclosure requirements and exemptions applicable to "emerging growth companies." As such, we will be required to hold a say-on-pay vote and a say-on-frequency vote at our 2019 annual meeting of stockholders. We expect that our loss of "emerging growth company" status will require additional attention from management and will result in increased costs to us, which could include higher legal fees, accounting fees and fees associated with investor relations activities, among others. 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 the SEC to implement new requirements on registrants, and these new requirements that were implemented require, among other things, that we assess the effectiveness of our internal control over financial reporting annually and SEC requirements also require us to assess 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 to attest to, the effectiveness of our internal control over financial reporting. As an "emerging growth company," we availed 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 since we ceased to be an "emerging growth company" on December 31, 2018. As a result, our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting and 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.

As disclosed in Part II, Item 9A, during the fourth quarter of fiscal 2018, management identified material weaknesses in internal control related to ineffective aspects of its overall control environment related to information technology general

controls. This material weakness contributed to additional material weaknesses, specifically in the areas of: (i) user access and program change management over certain information technology systems and (ii) controls over monitoring of certain access rights related to processing journal entries, both of which support our financial reporting processes. As a result, management concluded that our internal control over financial reporting was not effective as of December 31, 2018. We have taken initial steps to implement remediation efforts; however, there can be no assurance that our efforts to remediate the material weaknesses will be successful or will be completed by the end of our 2019 fiscal year. Pursuing these remediation efforts will result in additional technology and other expenses.

If we are unable to remediate these material weaknesses, or are otherwise unable to maintain effective internal control over financial reporting or disclosure controls and procedures, our ability to record, process and report financial information accurately, and to prepare financial statements within required time periods, could be adversely affected, which could subject us to litigation or investigations requiring management resources and payment of legal and other expenses and negatively impact the price of our common stock. In addition, 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 as a result of the material weaknesses in our internal controls, 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 remediate the material weaknesses effectively or efficiently or avoid future material weaknesses, it could harm our operations, financial reporting, or financial results and could result in an adverse opinion on our internal control over financial reporting from our independent registered public accounting firm.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We 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 four office leases outside of Seattle, Washington, totaling approximately 3,363 square footage, with terms of three years or less.

Our landlords hold security deposits of approximately $328,000. 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.

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.

Holders

As of February 28, 2019, there were approximately 24 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.

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 December 31, 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

On November 1, 2018 we issued an aggregate of 5,292 shares of our common stock to a warrant holder upon the exercise of outstanding warrants to purchase an aggregate of 11,837 shares of our common stock pursuant to a net exercise mechanism under the warrants. Each warrant had an exercise price of $8.448 per share. The issuances of these shares were exempt from registration under the Securities Act of 1933, as amended, pursuant to Section 3(a)(9) thereof as an exchange with an existing security holder where no commission or other remuneration is paid or given for soliciting such exchange.

Securities Authorized for Issuance under Equity Compensation Plans

The following table summarizes information about our equity compensation plans as of December 31, 2018. 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)) [1]
Equity compensation plans approved by security holders:			
2004 Stock Option Plan	695,640	$ 2.95	—
2013 Equity Incentive Plan	5,357,841	11.20	737,732
2013 Employee Stock Purchase Plan	—	N.A.	266,884
Equity compensation plans not approved by security holders[2]:	130,000	5.96	120,000
Total	6,183,481	N.A.	1,124,616

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

[2] On January 15, 2018, our board of directors adopted the NanoString Technologies, Inc. 2018 Inducement Equity Incentive Plan, or the Inducement Plan, and, subject to the adjustment provisions of the Inducement Plan, reserved 250,000 shares of our common stock for issuance pursuant to equity awards granted under the Inducement Plan. The Inducement Plan was adopted without stockholder approval pursuant to Rule 5635(c)(4) and Rule 5635(c)(3) of the Nasdaq Listing Rules. The Inducement Plan provides for the grant of equity-based awards, including nonstatutory stock options, restricted stock units, restricted stock, stock appreciation rights, performance shares and performance units, and its terms are substantially similar to our 2013 Equity Incentive Plan, including with respect to treatment of equity awards in the event of a “merger” or “change in control” as defined under the Inducement Plan, but with such other terms and conditions intended to comply with the Nasdaq inducement award exception or to comply with the Nasdaq acquisition and merger exception. However, our 2013 Equity Incentive Plan permits certain exchange programs (including repricings) without stockholder approval, while the Inducement Plan requires stockholder approval for such exchange programs.

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, 2018, 2017, and 2016 and Consolidated Balance Sheet data as of December 31, 2018 and 2017 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, 2015 and 2014 and Consolidated Balance Sheet data as of December 31, 2016, 2015, and 2014 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,				
	2018	2017	2016	2015	2014
	(In thousands, except per share amounts)				
Consolidated Statements of Operations:					
Revenue[1]	$106,732	$114,905	$86,489	$62,667	$47,593
Costs and expenses:					
Cost of product and service revenue	36,331	31,880	30,245	26,126	21,149
Research and development	61,599	46,888	34,720	24,597	21,404
Selling, general and administrative	78,195	74,334	62,700	53,186	51,063
Total costs and expenses	176,125	153,102	127,665	103,909	93,616
Loss from operations	(69,393)	(38,197)	(41,176)	(41,242)	(46,023)
Other income (expense):					
Interest income	1,331	809	390	233	272
Interest expense	(7,431)	(6,153)	(5,672)	(4,017)	(4,140)
Other income (expense)	(1,658)	183	(515)	(389)	(147)
Total other income (expense)	(7,758)	(5,161)	(5,797)	(4,173)	(4,015)
Net loss before provision for income taxes	(77,151)	(43,358)	(46,973)	(45,415)	(50,038)
Provision for income taxes	(249)	(204)	(116)	(166)	—
Net loss	$(77,400)	$(43,562)	$(47,089)	$(45,581)	$(50,038)
Net loss per share—basic and diluted	$(2.78)	$(1.84)	$(2.34)	$(2.40)	$(2.80)
Weighted-average shares used in computing basic and diluted net loss per share	27,883	23,731	20,116	19,027	17,839

	As of December 31,				
	2018	2017	2016	2015	2014
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$93,997	$77,555	$74,036	$49,044	$72,225
Working capital	88,592	86,002	77,402	61,882	76,411
Total assets	147,558	136,762	126,373	92,869	102,068
Long-term debt and lease financing obligations, net of discounts	58,396	48,931	47,424	41,226	30,246
Total stockholders' equity	$36,869	$40,109	$12,305	$20,215	$44,813

[1]Amounts have not been retrospectively modified to reflect the adoption of Accounting Standard Update No. 2014-09, Revenue from Contracts with Customers, for the years ended December 31, 2014, 2015, 2016 and 2017.

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 products that unlock scientifically valuable and clinically actionable information from minute amounts of biological material. Our core technology is a unique, proprietary optical barcoding chemistry that enables the labeling and counting of single molecules. This proprietary chemistry may reduce the number of steps required to conduct certain types of scientific experiments and allow for multiple experiments to be conducted at once. As a result, we are able to develop tools that are easier for researchers to use and that may generate faster and more consistent scientific results.

We use our technology to develop tools for scientific research, primarily in the fields of genomics and proteomics, and also to develop clinical diagnostic tests. We currently have one commercially available product platform, our nCounter Analysis System instruments and related consumables. We market and sell our instruments and related consumables to researchers in academic, government, and biopharmaceutical laboratories for research use and to clinical laboratories and medical centers for diagnostic use, both through our direct sales force and through selected distributors in certain international markets. As of December 31, 2018, we had an installed base of approximately 730 nCounter systems, which our customers have used to publish more than 2,300 peer-reviewed papers.

We derive a substantial majority of our revenue from the sale of our products, which consist of our nCounter instruments and related proprietary consumables. 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. Additionally, we generate revenue through product development collaborations.

We use third-party contract manufacturers to produce the instruments comprising our 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 $61.6 million, $46.9 million and $34.7 million in 2018, 2017, and 2016, respectively, in research and development and intend to continue to make significant investments in research and development.

We have discovered other novel applications that utilize our proprietary barcoding chemistry, and we have two new product platforms under development. Following completion of product development, each of these new systems is expected to be commercialized as a new instrument along with associated consumables.

The first new platform, our GeoMx Digital Spatial Profiling, or GeoMx DSP system, is designed to enable the field of spatial genomics. While nCounter and other existing technologies analyze gene activity as a whole throughout the totality of a biological sample, GeoMx DSP is used to analyze specifically selected regions of a biological sample in order to see how gene activity or protein levels might vary across those regions or in certain cell types. In advance of the launch of the commercial version of GeoMx DSP, we have provided early access to the system's capabilities by offering selected customers the opportunity to send biological samples to our Seattle facility to be tested by us on prototype instruments. To date, we have conducted over 70 projects for approximately 50 customers pursuant to this Technology Access Program, or TAP. In addition, in the third quarter of 2018 we announced the GeoMx Priority Site, or GPS, Program. The GPS Program is designed to provide customers the opportunity to be among the first to receive a GeoMx DSP instrument following its commercial launch, as well as advanced service and support. Inclusion in the GPS Program has also provided researchers the opportunity to begin generating data on samples through our TAP service. As of December 31, 2018, we have received over 30 orders for GeoMx DSP pursuant to our GPS Program. The full commercial launch of GeoMx DSP instruments and consumables is expected to commence during the first half of 2019, with installations of commercial instruments expected to commence in the second half of 2019.

The second new platform, our Hyb & Seq molecular profiling system, is designed to use a modified version of our proprietary chemistry to determine and analyze gene sequences within a biological sample, or to potentially profile the activity of an even greater number of genes as compared to our nCounter Analysis System. Hyb & Seq is designed to determine gene sequences using a work flow with fewer steps as compared to currently available gene sequencing technologies. Hyb & Seq is expected to become commercially available during 2021.

In August 2017, we entered into a collaboration agreement with Lam Research Corporation, or Lam, to support the development of our Hyb & Seq product candidate and related assays. For additional information regarding this development collaboration agreement, see the section of this report captioned “Business—Collaborations—Lam Research Corporation”.

In March 2014, we entered into a collaboration agreement with Celgene Corporation, or 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 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 October 2017, we were notified by Merck of the decision not to pursue regulatory approval of the companion diagnostic test for KEYTRUDA. As a result, in August 2018, we and Merck agreed to mutually terminate our development collaboration agreement, effective as of September 30, 2018, following the completion of certain close-out activities.

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. In September 2016, Medivation was acquired by Pfizer, Inc., or Pfizer, and became a wholly owned subsidiary of Pfizer. In May 2017, we received notification from Pfizer and Astellas terminating the collaboration agreement as a result of a decision to discontinue the related clinical trial.

Our product and service revenue increased 16.0% to $83.5 million in 2018, compared to $72.0 million in 2017. The increase was driven primarily by increased revenue from consumables and Prosigna, and increased revenue from service contracts associated with our growing installed base of nCounter Analysis Systems and for our GeoMx DSP technology access service.

Our total revenue in 2018 was $106.7 million compared to $114.9 million in 2017 and $86.5 million in 2016. Our total revenue has varied more significantly as compared to our product and service revenue, and may do so in future periods, as a result of the timing of revenue recognition associated with our collaboration agreements. Revenue recognition relating to these agreements, which is recorded as collaboration revenue, primarily consists of recognizing deferred revenue relating to cash payments received previously from our collaborators. Collaboration revenue recognized may vary significantly depending on the timing and cost of certain research and development activities relating to a collaboration, the expected time frame for completing certain collaboration activities, the outcome of research and development activities being conducted pursuant to a collaboration, the contractual terms of a particular collaboration agreement and other factors.

Historically, we have generated a substantial majority of our revenue from sales to customers in North America; however, we expect sales in other regions may increase over time. We have never been profitable and had net losses of $77.4 million, $43.6 million, and $47.1 million in 2018, 2017, and 2016, respectively. As of December 31, 2018, our accumulated deficit was $391.3 million.

Key Financial Metrics

We are organized as, and operate in, one reportable segment: 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 product revenue consists of sales of our nCounter Analysis Systems 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, list prices are generally higher. In certain cases,

customers may pay less than the list price for our various nCounter instruments. For example, some of our systems are sold to customers through independent distributors, and these distributors may purchase systems from us 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 gene and protein expression analysis panels, which are standardized and pre-manufactured, custom CodeSets, which we manufacture to the specific requirements of an individual researcher, and 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 our Prosigna in vitro diagnostic kits. Our average consumables revenue per installed system was approximately $80,000 for the year ended December 31, 2018.

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 may 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 service contracts and conducting proof-of-principle studies. We include a one-year warranty with the sale of our instruments and offer 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, and in some cases allow customers early access to technologies under development, such as our GeoMx DSP system, for which we generate data and perform analysis services on their behalf.

Collaboration Revenue

Collaboration revenue has been derived primarily from our collaborations with Lam, Celgene and Merck and historically, our terminated collaboration with Medivation and Astellas. As of December 31, 2018, we have received a total of $106.8 million from these collaboration agreements, of which $22.8 million, $42.3 million, and $16.7 million has been recorded as collaboration revenue in 2018, 2017, and 2016, respectively, with the remainder recorded as deferred revenue and customer deposits, 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 continue 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. For sales to distributors, their geographic location may be different from the geographic locations of the ultimate end customer. Americas consists of the United States, Canada, Mexico and South America; and Asia Pacific includes Japan, China, South Korea, Singapore, Malaysia, India and Australia.

	Year Ended December 31,		
	2018	2017	2016
	(Dollars in thousands)		

Americas	$74,137	70	%	$86,099	75	%	$60,330	70	%
Europe & Middle East	25,715	24	%	21,791	19	%	18,497	21	%
Asia Pacific	6,880	6	%	7,015	6	%	7,662	9	%
Total revenue	$106,732	100	%	$114,905	100	%	$86,489	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. The average unit cost of our instruments has declined in the current year as compared to prior years primarily as a result of increased placements of our lower-cost nCounter SPRINT Profiler. We expect the average unit costs of our nCounter 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 standard panel products and in vitro Prosigna diagnostic kits.

Operating Expenses

Research and Development

Research and development expenses consist primarily of salaries and benefits, occupancy costs, laboratory supplies, engineering services, consulting fees, costs associated with licensing molecular diagnostics rights and clinical study expenses 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 to continue to make investments in research and development activities at levels consistent with our current levels. In particular, following our entry into the Lam collaboration in August 2017, which provides up to $50.0 million of funding for our Hyb & Seq program, we have experienced a substantial increase in related research and development expenses in 2018 and we may continue to invest at similar levels in future periods as we continue our development activities related to the Hyb & Seq platform. To date, we have found that it has been effective for us to manage our research and development activities on a departmental basis. Accordingly, other than pursuant to terms of certain of our collaborations, we have neither required employees to report their time by project nor allocated our research and development costs to individual projects. Research and development expense by functional area was as follows:

	Year Ended December 31,		
	2018	2017	2016
	(In thousands)		
Platform technology	$28,634	$16,645	$10,312
Manufacturing process development	4,689	3,025	2,582
Life sciences research products and applications	10,107	7,933	6,298
Diagnostic product development	7,004	7,161	6,648
Clinical, regulatory and medical affairs	5,439	7,036	5,111
Facility allocation	5,726	5,088	3,769
Total research and development expense	$61,599	$46,888	$34,720

Selling, General and Administrative

Selling, general and administrative expense consists primarily of costs for our sales and marketing, finance, human resources, information technology, business development, legal and general management functions, as well as professional fees for 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 to support the expected introduction of new products and product platforms, including our GeoMx DSP and Hyb and Seq product candidates, as well as the general broadening of our customer base and growth of our existing nCounter business. Legal, accounting and compliance costs have 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, as well as our ability to drive consumable sales through our installed base of these systems. As of December 31, 2018, we had an installed base of approximately 730 nCounter Analysis Systems, which we count based on the number of nCounter SPRINT, MAX or FLEX Profilers sold, given that a system may couple one system with multiple nCounter Prep Stations. In the year ended December 31, 2018 our annualized rate of consumable sales per installed system, including sales of nCounter consumables and Prosigna, was approximately $80,000.

In addition to growth related to our nCounter platform of instruments and consumables, we plan to grow our system and consumable sales in the coming years through the introduction of new product platforms such as our GeoMx DSP and Hyb & Seq product candidates.

In addition to seeking to increase sales of our existing nCounter platform and consumables and from our expected new product platform introductions, we will continue to employ other growth strategies, including expanding our sales channel in both direct and distributor territories, developing new consumable content for our nCounter platform and enhancing certain features of our nCounter platform. As part of this strategy, in both 2017 and 2018, we added incremental sales territories and augmented our field sales team, and have continued to grow our base of distributors. As our installed base of instruments grows, we solicit feedback from our customers and focus our research and development efforts on improving our nCounter Analysis System or enabling 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 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 may be up to 12 months or longer. Given the length and uncertainty of our sales cycle, we will likely experience fluctuations in our future instrument sales on a period-to-period basis.

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. Our average annualized consumables revenue per installed system was approximately $80,000 for the year ended December 31, 2018.

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. Our consumables revenue per system installed may fluctuate in the future, reflecting the mix of our installed instruments, and potential shifts in the mix, or type, of consumables sold to our installed customer base. 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. In 2017 we launched our “360” panels for use in breast cancer, immuno-oncology and hematology. In 2018, we expanded the number of panels in oncology, specifically focused on breast cancer and immuno-oncology, and also added panels in two new research areas, neuroscience and autoimmunity. In 2019, we intend to continue to expand our nCounter panels, primarily focused on neuroscience and immune-related diseases. The introduction of new applications has the potential to further increase our

consumables revenue stream. Over time, we believe that consumables revenue may 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 may be fluctuations in sales mix between instruments and consumables from period to period. For example, during 2018 our total product and service revenue increased by 16%, which included 18% growth in revenues related to our consumables, including in vitro diagnostic kits, compared to 2017 and 3% growth in our instrument sales compared to 2017. However, during 2017 our total product and service revenues increased by 4%, which included an 11% decline in instrument sales compared to 2016. This decline in instrument sales was offset by revenue growth from our consumables, including Prosigna in vitro diagnostic kits, and increased revenue from service contracts resulting from our growing installed base of nCounter Analysis Systems. Although future results may vary period to period, over time, as our installed base of systems grows, consumables may continue to constitute a larger percentage of total product revenue, which would tend to increase our gross margins. Such gross margin increases may be offset by the mix of consumable products sold, or in the event we introduce new instrument product platforms that become increasing components of our product sales, such as GeoMx DSP or Hyb and Seq. In addition, both the average selling price and manufacturing cost of our instruments has decreased 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 12% more systems in 2018 compared to 2017, our instrument revenue only increased 3%. This was largely due to substantially increased sales of lower priced SPRINT systems in 2018. Future instrument selling prices and gross margins may fluctuate as we grow our volume of distribution partners in geographies outside of the United States, 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 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 primarily derived from our diagnostic and other collaborations with Celgene, Merck, Lam, and historically, our collaboration with Medivation and Astellas.

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

	Year Ended December 31,					
	2018		2017		2016	
	(Dollars in thousands)					
Product revenue:						
Instruments	$21,441	20 %	$20,839	18 %	$24,229	28 %
Consumables	43,847	41 %	38,311	33 %	37,545	43 %
In vitro diagnostic kits	9,445	9 %	6,745	6 %	4,168	5 %
Total product revenue	74,733	70 %	65,895	57 %	65,942	76 %
Service revenue	8,790	8 %	6,115	5 %	3,192	4 %
Total product and service revenue	83,523	78 %	72,010	62 %	69,134	80 %
Collaboration revenue	23,209	22 %	42,895	38 %	17,355	20 %
Total revenue	$106,732	100%	$114,905	100%	$86,489	100%

Results of Operations

Comparison of Years Ended December 31, 2018 and 2017

Revenue

	Year Ended December 31,		Change	
	2018	2017	Dollars	Percentage
	(Dollars in thousands)			
Product revenue:				
Instruments	$21,441	$20,839	$602	3%
Consumables	43,847	38,311	5,536	14%
In vitro diagnostic kits	9,445	6,745	2,700	40%
Total product revenue	74,733	65,895	8,838	13%
Service revenue	8,790	6,115	2,675	44%
Total product and service revenue	83,523	72,010	11,513	16%
Collaboration revenue	23,209	42,895	(19,686)	(46)%
Total revenue	$106,732	$114,905	$(8,173)	(7)%

Instrument revenue for the year ended December 31, 2018 increased as compared to the prior year, due primarily to an increase in the number of instruments sold. The magnitude of the instrument revenue increase was partially offset by a shift in sales mix towards our SPRINT instruments, which generally have lower average selling prices than our MAX and FLEX instruments. Consumables revenue increased for the year ended December 31, 2018, primarily as a result of our growing installed base of nCounter Analysis Systems, as well as growth in sales of our standardized panel consumable products. In vitro diagnostic kit revenue represents sales of Prosigna assays, which increased for the year ended December 31, 2018 as more testing providers commenced providing services and testing volumes increased, most significantly in territories outside of the United States. The increase in service revenue was primarily related to an increase in the number of installed instruments covered by service contracts, and also increases in revenue generated from technology access fees, particularly fees related to services offered pursuant to our GeoMx DSP Technology Access Program. Our product and service revenue may continue to increase in future periods as a result of our increased investments in sales and marketing activities, the growth in sales of our nCounter consumable products as driven by our increasing installed base of nCounter instruments, the introduction of new nCounter consumable products, the continued sale of additional nCounter instruments and the potential commercial launch of new product platforms such as our GeoMx DSP and Hyb & Seq product candidates. As an offset to our anticipated expenses relating to the development of our Hyb & Seq platform, Lam has committed to provide up to $50.0 million in funding, of which $35.1 million has been funded as of December 31, 2018.

Collaboration revenue decreased for the year ended December 31, 2018 as compared to the prior year, due primarily to the termination of our collaboration with Medivation and Astellas in 2017. The termination resulted in the recognition of deferred collaboration revenue of $11.5 million for the year ended December 31, 2017, which represented all of the remaining deferred revenue relating to the terminated collaboration. In addition, the scope of our collaboration with Merck changed during the fourth quarter of 2017, resulting in a further reduction of collaboration revenue in 2018 as compared to the same period in 2017. These decreases were partially offset by collaboration revenue generated from our agreements with Lam and Celgene. Our collaboration agreement with Lam was entered into during the third quarter of 2017 and represented $18.6 million of collaboration revenue for the year ended December 31, 2018. Collaboration revenue related to our agreement with Lam was $3.7 million for the year ended December 31, 2017.

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

	Year Ended December 31,		Change	
	2018	2017	Dollars	Percentage
	(Dollars in thousands)			
Cost of product and service revenue	$36,331	$31,880	$4,451	14%
Product and service gross profit	$47,192	$40,130	$7,062	18%
Product and service gross margin	57 %	56 %		

For the year ended December 31, 2018, cost of product and service revenue increased as compared to the same periods in 2017, due to higher volumes of instruments and consumables sold, including our Prosigna in vitro diagnostic kits, as well as increased volume of service contracts associated with our growing installed base of nCounter instruments. Our gross margin on product and service revenue for the year ended December 31, 2018 increased compared to the prior year primarily as a result of increased consumable revenue as a percentage of our overall sales mix, including sales of our Prosigna in vitro diagnostic kits,

which generally have higher gross margins than our instrument placements, as well as increasing sales of our nCounter panel products as a percentage of our consumables revenue. The favorable mix shift towards consumables comprising a higher percentage of our total product and service revenues was partially offset by an increase in the number of lower margin SPRINT instrument sales, and modestly lower average selling prices realized across all instrument sales, as compared to the prior year. In addition, our gross margin during the year ended December 31, 2018 was also impacted by increases in outside consulting and other costs relating to quality assurance and system requirements for diagnostic products related manufacturing.

We expect our cost of product and service revenue to increase in future periods, primarily due to our expected growth in product and service revenue. We expect our gross margin on product and service revenue may fluctuate in future periods, depending upon our mix of instrument sales, from which we typically record lower gross margins, as compared to our sales of consumable products or services, the impact of the launch, and any sales achieved, of our new product platforms such as our GeoMx or Hyb & Seq product platforms, which during any initial launch may impact our mix of instruments sold as compared to consumables, and potential expenses we may incur for regulatory compliance, quality assurance or related to the expansion of our manufacturing capacity. Any costs related to collaboration revenue are included in research and development expense.

Research and Development Expense

	Year Ended December 31,		Change	
	2018	2017	Dollars	Percentage
	(Dollars in thousands)			
Research and development expense	$61,599	$46,888	$14,711	31%

The increase in research and development expense for the year ended December 31, 2018 was primarily attributable to an increase in staffing and personnel-related costs of $6.2 million, as well as increased supply costs of $4.1 million and professional fees of $3.6 million. These increased costs were incurred primarily to support the development of our GeoMx DSP and Hyb & Seq platforms.

We expect that research and development costs may continue to increase in future periods to support remaining product development activities relating to our GeoMx DSP and Hyb & Seq platforms.

Selling, General and Administrative Expense

	Year Ended December 31,		Change	
	2018	2017	Dollars	Percentage
	(Dollars in thousands)			
Selling, general and administrative expense	$78,195	$74,334	$3,861	5%

The increase in selling, general and administrative expense for the year ended December 31, 2018 was primarily attributable to an increase in staffing and personnel-related costs of $2.6 million to support our sales, marketing and administrative functions, as well as an increase in professional fees of $1.1 million related to legal, consulting and other costs associated with activities and implementation of certain processes relating to our compliance with the Sarbanes Oxley Act. These increases were partially offset by lower sales and marketing costs of $1.0 million related to fewer promotional events and other external activities.

We expect selling, general and administrative expense to increase in future periods as the number of sales, technical support and marketing and administrative personnel grows to support the expected growth in our existing lines of business, as well as to support the introduction of new products and product platforms, including our new GeoMx DSP and Hyb & Seq product platforms.

Other Income (Expense)

	Year Ended December 31,		Change	
	2018	2017	Dollars	Percentage
	(Dollars in thousands)			
Interest income	$1,331	$809	$522	65%
Interest expense	(7,431)	(6,153)	(1,278)	21%
Other income (expense), net	(1,658)	183	(1,841)	(1,006)%
Total other income (expense), net	$(7,758)	$(5,161)	$(2,597)	50%

Interest expense increased for the year ended December 31, 2018 due primarily to having a higher average balance of long-term debt outstanding during 2018 which was $52.5 million as compared to $48.6 million for 2017. In addition, as a result of the replacement of our long-term debt facility with CRG, we incurred a loss on extinguishment of the original long-term debt

which totaled $0.8 million. Interest income increased for the year ending December 31, 2018, due to higher interest rates as well as an increased average investment balance during the year. Other income (expense), net is primarily related to estimated costs for certain state and local taxes and to realized and unrealized gains or losses associated with foreign currency transactions primarily denominated in the Euro and British Pounds, both of which generally weakened relative to the U.S. Dollar for the year ending December 31, 2018, compared to the prior year.

Comparison of Years Ended December 31, 2017 and 2016

Revenue

	Year Ended December 31,		Change	
	2017	2016	Dollars	Percentage
	(Dollars in thousands)			
Product revenue:				
Instruments	$20,839	$24,229	$(3,390)	(14)%
Consumables	38,311	37,545	766	2%
In vitro diagnostic kits	6,745	4,168	2,577	62%
Total product revenue	65,895	65,942	(47)	—%
Service revenue	6,115	3,192	2,923	92%
Total product and service revenue	72,010	69,134	2,876	4%
Collaboration revenue	42,895	17,355	25,540	147%
Total revenue	$114,905	$86,489	$28,416	33%

Instruments revenue decreased for the year ended December 31, 2017, due primarily to fewer instruments sold during the year, and to a lesser extent, the realization of a lower average price per instrument sold. We sold approximately 125 instruments in 2017, down from approximately 140 instruments in 2016. While our mix of instruments sold remained relatively consistent year over year, the average price per instrument sold in 2017 was impacted by a greater proportion of instruments being sold through distributors during 2017, for which we typically record lower selling prices, as well as lower prices recorded related to sales of our nCounter SPRINT Profilers as compared to 2016.

Consumables revenue increased during 2017, primarily as a result of our growing installed base of nCounter Analysis Systems, as well as growth in various European markets. 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, and also increases in revenue generated from technology access fees, data analysis, and other services related to new potential customers and technologies which are under development. Our product and service revenue may continue to increase in future periods, as a result of our increased investments in sales and marketing activities, the introduction of new nCounter consumable products, and the potential commercial launch of our GeoMx DSP and Hyb & Seq product candidates.

Collaboration revenue increased by $25.5 million in 2017, due largely to changes in estimates related to future costs associated with our collaborations with Merck and Medivation and Astellas. Our collaboration with Medivation and Astellas was terminated during the second quarter of 2017, and during the fourth quarter of 2017, we were notified by Merck of a change in scope associated with planned future regulatory activities. Both of these events resulted in a decrease of the total expected costs associated with the collaborations, and as a result, the completion percentage used in the proportional performance model used for revenue recognition increased substantially. These changes in estimates resulted in an acceleration of revenue recognized during 2017, relative to the original planned project time lines and estimated costs. The addition of our new collaboration agreement with Lam, which was entered into during the third quarter of 2017, also contributed to our increased collaboration revenue in 2017 as compared to the prior year.

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

	Year Ended December 31,		Change	
	2017	2016	Dollars	Percentage
	(Dollars in thousands)			
Cost of product and service revenue	$31,880	$30,245	$1,635	5%
Product and service gross profit	$40,130	$38,889	$1,241	3%

Product and service gross margin	56	%	56	%

For the year ended December 31, 2017, cost of product and service revenue increased due to higher volumes of consumables sold, including our Prosigna in vitro diagnostic kits, as well as increased revenue from service contracts and data analysis services as compared to 2016. These increases were partially offset by the lower volume of instruments sold during the

year. Our gross margin on product and service revenue in 2017 benefited from a shift in revenue mix from instruments to consumables, driven in large part by continued growth in Prosigna in vitro diagnostic kit revenue, the addition of new higher margin service revenue from our GeoMx DSP technology access program, and a lower royalty rate on our license of the foundational nCounter patents due to the achievement of a cumulative revenue milestone that took effect in the third quarter of 2016. These increases were offset by lower average selling prices realized on certain sales of our nCounter Analysis Systems, as a result of selected promotion and sales related activities during the period, the reduction in certain higher gross margin custom consumable orders, and increased reserves for slow-moving inventory. We expect our cost of product and service revenue to increase in future periods, primarily due to our expected continued growth in product and service revenue. We expect our gross margin on product and service revenue to remain stable or potentially increase in future periods, as we increase our sales of consumables through a larger instrument installed base, as we introduce new nCounter consumable products that may have lower gross margins during their initial launch period, and as a greater proportion of nCounter SPRINT Profilers are sold in future periods as a percentage of our total instrument sales. Costs related to collaboration revenue are included in research and development expense.

Research and Development Expense

	Year Ended December 31,		Change	
	2017	2016	Dollars	Percentage
	(Dollars in thousands)			
Research and development expense	$46,888	$34,720	$12,168	35%

The increase in research and development expense in 2017 was primarily attributable to an increase in staffing and personnel-related costs of $6.2 million, as well as increased supply costs of $2.2 million and professional fees of $1.8 million. These increased costs were incurred primarily to support the advancement of our collaborations and technology and product development activities, including GeoMx DSP and Hyb & Seq, product candidates. In addition, facility costs increased by $1.4 million in 2017, due to expansion of our leased space for research and development activities. We expect that research and development costs will continue to increase in future periods in support of remaining development activities relating to our GeoMx DSP product candidate, and as a result of our new collaboration agreement with Lam and the resulting expansion of our development of the Hyb & Seq product candidate. As an offset to this expected increase in expense relating to Hyb & Seq, Lam has committed to provide up to $50.0 million in funding. We expect the majority of the Hyb and Seq program development efforts and related costs to be incurred during 2018 and the first half of 2019.

Selling, General and Administrative Expense

	Year Ended December 31,		Change	
	2017	2016	Dollars	Percentage
	(Dollars in thousands)			
Selling, general and administrative expense	$74,334	$62,700	$11,634	19%

The increase in selling, general and administrative expense in 2017 was primarily attributable to an increase in staffing and personnel-related costs of $8.8 million to support our sales, marketing and administrative functions, increased sales and marketing costs of $1.6 million related to promotional events and other external activities, and increased professional fees of $0.6 million. These increases were partially offset by $0.6 million of lower state and local gross receipt-based taxes primarily as a result of lower amounts received under our collaboration agreements. We expect selling, general and administrative expenses may increase in future periods, in the event we make additional investments to support the sales of our existing products, or launch activities relating to new product candidates, such as our GeoMx DSP product candidate, for which material commercial launch activities are expected to commence in 2019.

Other Income (Expense)

	Year Ended December 31,		Change	
	2017	2016	Dollars	Percentage
	(Dollars in thousands)			
Interest income	$809	$390	$419	107%
Interest expense	(6,153)	(5,672)	(481)	8%

Other income (expense), net	183	(515)	698	(136)%
Total other income (expense), net	$(5,161)	$(5,797)	$636	(11)%

Interest expense increased in 2017, due primarily to increases in our long-term debt borrowings during these periods. The average balance of long-term debt outstanding during 2017 and 2016 was $48.6 million and $44.9 million, respectively. Interest income increased in 2017, due to higher interest rates as well as an increased average investment balance in 2017.

Other income (expense), net is primarily related to realized and unrealized gains or losses associated with foreign currency transactions during 2017, in which we benefited from the weakening of the U.S. dollar versus foreign currencies, primarily the Euro and the British pound.

Liquidity and Capital Resources

As of December 31, 2018, we had cash, cash equivalents and short-term investments of $94.0 million, compared to $77.6 million as of December 31, 2017. 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 and the level of sales of our existing products and new product candidates; the nature and timing of any additional research, product development or other partnerships or collaborations we may establish; the cost and timing of establishing additional sales, marketing and distribution capabilities; the cost of our research and development activities; the cost and timing of regulatory clearances or approvals; the effect of competing technological and market developments; and the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions. We will require additional funds in the future and 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 partnership, collaboration or 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, delay or reduce the scope of or eliminate some or all of our research and development programs, delay development, launch activities or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize, or 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, 2018 was $54.1 million, including $23.6 million in cash receipts from our collaboration agreements. The timing and amount of such receipts in the future are uncertain, and therefore we may be required to secure larger amounts of cash to fund our planned operations.

Equity Financings

In July 2018, we completed an underwritten public offering of 4,600,000 shares of common stock, including the exercise in full by the underwriters of their option to purchase 600,000 additional shares of common stock in August 2018, for total gross proceeds of $57.5 million. After underwriter’s commissions and other expenses of the offering, our aggregate net proceeds were approximately $53.8 million.

In January 2018, 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 gross cash proceeds. The sales agreement allows us to set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limits on the number of shares that may be sold in any one trading day and a minimum price below which sales may not be made. Under the terms of the Sales Agreement, commission expenses to the sales agent will be 3% of the gross sales price per share sold through the sales agent. The Sales Agreement shall automatically terminate upon the issuance and sale of placement shares equaling sales proceeds of $40.0 million and may be terminated earlier by either us, or the sales agent upon five days’ notice. As of the date of this report, there had been no shares of common stock sold under this agreement.

In June 2017, we completed an underwritten public offering of 3,450,000 shares of common stock, including the exercise by the underwriter of an over-allotment option for 450,000 shares of common stock, for total gross proceeds of $57.8 million. After underwriters’ fees and commissions and other expenses of the offering, our aggregate net proceeds were approximately $56.5 million.

Debt Instruments

Term Loan Agreements

In April 2014, we entered into a term loan agreement, or the 2014 Term Loan, under which we could borrow up to $45.0 million. In October 2015, we amended the 2014 Term Loan primarily to 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 2014 Term Loan, borrowings accrued interest at 12.0% annually, payable quarterly, of which 3.0% could be deferred during the first six years of the amended term at our option and paid together with the principal at maturity. We borrowed a total of $45.0 million under the 2014 Term Loan through June 2016, excluding deferred interest. On December 31, 2016, our option to borrow the remaining $15.0 million under the 2014 Term Loan expired. Total borrowings and deferred interest under the 2014 Term Loan were $49.3 million as of December 31, 2017.

In October 2018, we entered into an amended and restated term loan agreement, or the 2018 Term Loan, under which we may borrow up to $100.0 million, which is due and payable in September 2024. At closing, we received net proceeds of approximately $7.8 million, pursuant to borrowings of $60.0 million under the new facility, net of repayment of our 2014 Term Loan of $50.4 million, including deferred interest and transaction-related fees and expenses. Of the $40.0 million in additional borrowing capacity under the 2018 Term Loan, we have the option to borrow up to $20.0 million until June 2019 subject to no further terms and conditions, and up to an additional $20.0 million until March 2020, subject to the achievement of annual revenue thresholds as at or prior to December 31, 2019.

The 2018 Term Loan accrues interest at a rate of 10.5%, payable quarterly, of which 3.0% may be deferred during the six year term at our option and repaid at maturity together with the principal. We paid an upfront fee of 0.5% of the aggregate principal amount of the initial borrowing under the 2018 Term Loan, and will pay a facility fee equal to 2.0% of the total amount borrowed including any deferred interest at the time the principal is repaid. A long-term liability of $1.4 million is being accreted using the effective interest method for the facility fee over the term of the 2018 Term Loan. Additional borrowings under the 2018 Term Loan will bear the same upfront and facility fees.

In connection with 2018 Term Loan, warrants to purchase an aggregate of 341,578 shares of common stock with an exercise price per share of $21.12 were issued to the lenders, and, in the event additional amounts are drawn under the 2018 Term Loan, additional warrants will be issued on each subsequent draw date for 0.3% of the fully-diluted shares then outstanding. The exercise price for additional warrants will be set at a 25.0% premium to the average closing trading price for the 30-day trading period as of the date immediately before the applicable draw date. The warrants issued in conjunction with the initial borrowing under the 2018 Term Loan were determined to be closely linked to our common stock, and as such, were recorded as an equity security in additional paid in capital at their relative fair value of $1.6 million with a corresponding debt discount recorded against 2018 Term Loan balance outstanding.

Total borrowings and deferred interest under the 2018 Term Loan were $60.4 million as of December 31, 2018. The balance of the 2018 Term Loan as of December 31, 2018 is net of discounts related to the warrants, debt issuance costs and other upfront fees of $2.0 million.

We have the option to prepay the 2018 Term Loan, in whole or part, at any time subject to payment of a redemption fee of up to 4.0%, which declines 1.0% after the first year of the term, with no redemption fee payable if prepayment occurs after the second year of the loan.

Obligations under the 2018 Term Loan are collateralized by substantially all of our assets. The 2018 Term Loan contains customary conditions to borrowings, events of default and negative covenants, including covenants that could limit our ability to, among other things, incur additional indebtedness, liens or other encumbrances, make dividends or other distributions; buy, sell or transfer assets; engage in any new line of business; and enter into certain transactions with affiliates. The 2018 Term Loan also includes a $2.0 million minimum liquidity covenant and annual minimum revenue-based financial covenants. 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.

2018 Revolving Loan Facility

In January 2018, we entered into a $15.0 million secured revolving loan facility, with availability subject to a borrowing base consisting of eligible accounts receivable. In November 2018, we entered into an amended and

restated loan and security agreement to increase the borrowing capacity under the facility to $20.0 million, amend the borrowing base to include finished goods inventory, and extend the final maturity under the facility to November 2021. As of December 31, 2018, no amounts had been drawn on the facility.

Interest on borrowings is payable monthly and accrues at a yearly rate equal to the greater of the prime rate as reported in the Wall Street Journal plus 0.50%, or 4.75%. During an event of default, amounts drawn accrue interest at a yearly rate equal to 8.75%. Obligations under the agreement are secured by our cash and cash equivalents, accounts receivable and proceeds thereof, and inventory and proceeds from the sale thereof. The lender's interest in the collateral under the loan facility is senior to the lender's interest in such collateral under the term loan agreement. The loan facility contains various customary representations and warranties, conditions to borrowing, events of default, including cross default provisions with respect to the loan facility, and covenants, including financial covenants requiring the maintenance of minimum annual revenue and liquidity.

We were in compliance with our financial covenants under the 2018 Term Loan agreement and the secured revolving loan facility as of December 31, 2018.

Use of Funds

Our principal uses of cash are funding our operations, capital expenditures, working capital requirements and satisfaction of any outstanding obligations under our revolving or term loan facilities, respectively. 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 our sales and marketing activities and growing our existing product sales, in research and development of new product platforms and technologies that we believe have the potential to drive the long-term growth of our business, and in support of our various collaborations.

Our operating cash requirements may increase in the future as we invest in the research and development of new product platforms including GeoMx DSP and Hyb & Seq, increase sales and marketing activities to expand the installed base of our nCounter Analysis Systems and continue to promote consumable usage, including Prosigna, and develop new applications, chemistry and instruments for our nCounter platform. 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 partnerships or collaborations to help fund our operations. As a result, 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.

Historical Cash Flow Trends

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

	Year Ended December 31,		
	2018	2017	2016
	(In thousands)		
Cash used in operating activities	$(54,065)	$(51,657)	$(6,079)
Cash used in investing activities	(22,925)	(2,490)	(30,261)
Cash provided by financing activities	75,081	59,668	35,093

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 currently 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 2018 consisted of our net loss of $77.4 million partially offset by $8.9 million of changes in our operating assets and liabilities and $14.4 million of net non-cash income and expense items, such as stock-based compensation, depreciation and amortization, deferred interest converted to principal pursuant to our term loan agreement, and provisions for bad debt and inventory obsolescence.

Net cash used in operating activities for 2017 consisted of our net loss of $43.6 million, plus the negative impact of decreases in our deferred revenue related to collaboration agreements of $29.2 million. The decrease in deferred revenue related to collaborations was due primarily to the termination of our Medivation and Astellas collaboration agreement and the change in scope of the Merck collaboration agreement, both of which resulted in the completion percentage used in the proportional performance model used for revenue recognition to increase substantially. As a result, we accelerated the recognition of revenue recognized during 2017, relative to the original planned project time

lines and estimated costs. These unfavorable “uses” of funds were partially offset by $3.3 million of changes in our operating assets and liabilities and $17.8 million of net non-cash income and expense items, such as stock-based compensation, depreciation and amortization, deferred interest converted to principal pursuant to our term loan agreement, and provisions for bad debt and inventory obsolescence.

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.

Investing Cash Flows

Our most significant investing activities for the years ended December 31, 2018, 2017, and 2016 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, 2018, 2017, and 2016, we purchased $4.5 million, $4.3 million, and $4.0 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 2018 consisted of net proceeds of $53.8 million from an underwritten public offering, $13.5 million of net proceeds from our 2018 Term Loan, $3.5 million of proceeds from the exercise of stock options, and $1.5 million from proceeds associated with our Employee Stock Purchase Plan.

Net cash provided by financing activities for 2017 consisted of net proceeds of $56.5 million from an underwritten public offering, $1.8 million from proceeds associated with our Employee Stock Purchase Plan, and $1.1 million of proceeds from the exercise of stock options.

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, $1.5 million from proceeds associated with our Employee Stock Purchase Plan, and $2.6 million of proceeds from the exercise of stock options.

Contractual Obligations

The following table reflects a summary of our contractual obligations as of December 31, 2018.

	Payments due by period				
Contractual Obligations[1]	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
	(In thousands)				
Lease obligations[2]	$41,714	$ 5,526	$ 11,153	$ 11,577	$ 13,458
Long-term debt obligations[3]	60,400	—	—	—	60,400
Purchase obligations[4]	17,698	17,698	—	—	—
Total	$119,812	$ 23,224	$ 11,153	$ 11,577	$ 73,858

[1]Excludes royalty obligations based on net sales of products, including royalties payable to the Institute for Systems Biology, as any such amounts are not currently determinable.

[2]Lease costs are primarily for office, laboratory and manufacturing space.

[3]Includes principal and deferred interest on long-term debt obligations.

[4]Purchase obligations consist of contractual and legally binding commitments under outstanding purchase orders to purchase long lead time inventory and other research and development items.

Critical Accounting Policies and Significant Estimates

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

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

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

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 instrument service contracts and service fees for assay processing.

Revenue is recognized when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration expected to be received in exchange for those products and services. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. Performance obligations are considered satisfied once control of a product or service has transferred to the customer, meaning the customer has the ability to use and obtain the benefit of the product or service. Revenue is recognized for satisfied performance obligations only when there are no uncertainties regarding payment terms or transfer of control.

Revenue from instruments, consumables and in vitro diagnostic kits is recognized generally upon shipment to the end customer, which is when title of the product has been transferred to the customer. Instrument revenue related to installation and calibration services is recognized when the customer has possession of the instrument and the services have been performed. Such services can also be provided by our distribution partners and other third parties. For instruments sold solely to run Prosigna assays, an initial training course must be provided by us prior to instrument revenue recognition.

Instrument service contracts are sold with contract terms ranging from 12-36 months and cover periods after the end of the initial 12-month warranty. These contracts include services to maintain performance within our designed specifications and a minimum of one preventative maintenance service procedure during the contract term. Revenue from services to maintain designed specifications is considered a stand-ready obligation and recognized evenly over the contract term and service revenue related to preventative maintenance of instruments is recognized when the procedure is completed. Revenue from service fees for assay processing is recognized upon the rendering of the related performance obligation.

For arrangements with multiple performance obligations, we allocate the contract price in proportion to its stand-alone selling price. We use our best estimate of stand-alone selling price for its products and services based on average selling prices over a 12-month period and reviews its stand-alone prices annually.

Product and service revenues from sales to customers through distributors are recognized consistent with the policies and practices for direct sales to customers, as described above.

We enter into collaboration agreements that may generate upfront fees, and in some cases subsequent milestone payments that may be earned upon completion of certain product development milestones or other designated activities. We are able to estimate the total expected cost of product development and other services under these arrangements and recognize collaboration revenue using a contingency-adjusted 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, amounts contractually due, or the amounts of any product development or other contractual milestone payments when achievement of a milestone is deemed to be probable. Changes in estimates of total expected collaboration product development or other costs are accounted for prospectively as a change in

estimate. From period to period, collaboration revenue can fluctuate substantially based on the achievement or probable achievement of product development or other milestones, or as estimates of total expected collaboration product development or other costs are changed or updated. We may recognize revenue from collaboration agreements that do not include upfront or milestone-based payments. Amounts due to collaboration partners are recognized when the related activities have occurred and are classified in the statement of operations, generally as research and development expense, based on the nature of the related activities.

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. Volatility through 2016 was based on the estimated volatility of similar companies whose share prices are publicly available. In 2017, we calculated volatility based on our share price activity throughout the year.

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.

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.

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, 2019 and sustained throughout the period ending December 31, 2019, would not be material.

As of December 31, 2018, the principal and deferred interest outstanding under our term borrowings was $60.4 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.

Inflation Risk

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

Item 8. Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
NANOSTRING TECHNOLOGIES, INC.

Report of Independent Registered Public Accounting Firm

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

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of NanoString Technologies, Inc. and its subsidiaries (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, of comprehensive loss, of changes in stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2018, including the related notes ("collectively referred to as the consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control – Integrated Framework (2013) issued by the COSO because material weaknesses in internal control over financial reporting existed as of that date related to: (i) an ineffective control environment as the Company had an insufficient complement of resources with an appropriate level of information technology ("IT") controls knowledge, expertise and training commensurate with the Company's financial reporting requirements which contributed to additional material weaknesses in that the Company (ii) did not design and maintain effective controls over certain IT general controls for the significant applications used in the preparation of the financial statements, and (iii) did not design and maintain controls to timely detect and independently review instances where individuals with access to post a journal entry may also have edited or created the journal entry.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses referred to above are described in Management's Annual Report on Internal Control Over Financial Reporting appearing under Item 9A. We considered these material weaknesses in determining the nature, timing, and extent of audit tests applied in our audit of the 2018 consolidated financial statements, and our opinion regarding the effectiveness of the Company's internal control over financial reporting does not affect our opinion on those consolidated financial statements.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in management's report referred to above. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included

performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's 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 the assets of the company; (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 receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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.

/s/ PricewaterhouseCoopers LLP
Seattle, Washington
March 11, 2019

We have served as the Company's auditor since 2008.

NanoString Technologies, Inc.
Consolidated Balance Sheets

	December 31,	
	2018	2017
	(In thousands, except par value amounts)	
Assets		
Current assets:		
Cash and cash equivalents	$ 24,356	$ 26,136
Short-term investments	69,641	51,419
Accounts receivable, net	17,279	19,564
Inventory, net	13,173	20,057
Prepaid expenses and other current assets	7,258	4,745
Total current assets	131,707	121,921
Restricted cash	—	143
Property and equipment, net	15,171	14,057
Other assets	680	641
Total assets	$ 147,558	$ 136,762
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,636	$ 4,092
Accrued liabilities	3,705	4,507
Accrued compensation and other employee benefits	12,060	8,634
Customer deposits	8,167	8,945
Deferred revenue, current portion	9,890	9,229
Deferred rent, current portion	657	512
Total current liabilities	43,115	35,919
Deferred revenue, net of current portion	1,620	3,304
Deferred rent and other liabilities, net of current portion	7,558	8,499
Long-term debt, net of discounts	58,396	48,931
Total liabilities	110,689	96,653
Commitments and contingencies (Note 14)		
Stockholders' equity		
Preferred stock, $0.0001 par value, 15,000 shares authorized; none issued	—	—
Common stock, $0.0001 par value, 150,000 shares authorized; 30,913 and 25,421 shares issued and outstanding at December 31, 2018 and 2017, respectively	3	2
Additional paid-in-capital	428,162	353,308
Other comprehensive loss	(40)	(99)
Accumulated deficit	(391,256)	(313,102)
Total stockholders' equity	36,869	40,109
Total liabilities and stockholders' equity	$ 147,558	$ 136,762

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

NanoString Technologies, Inc.
Consolidated Statements of Operations

	Years Ended December 31,		
	2018	2017	2016
	(In thousands, except per share amounts)		
Revenue:			
Product and service	$ 83,523	$ 72,010	$ 69,134
Collaboration	23,209	42,895	17,355
Total revenue	106,732	114,905	86,489
Costs and expenses:			
Cost of product and service revenue	36,331	31,880	30,245
Research and development	61,599	46,888	34,720
Selling, general and administrative	78,195	74,334	62,700
Total costs and expenses	176,125	153,102	127,665
Loss from operations	(69,393)	(38,197)	(41,176)
Other income (expense):			
Interest income	1,331	809	390
Interest expense	(7,431)	(6,153)	(5,672)
Other income (expense)	(1,658)	183	(515)
Total other income (expense)	(7,758)	(5,161)	(5,797)
Net loss before provision for income taxes	(77,151)	(43,358)	(46,973)
Provision for income taxes	(249)	(204)	(116)
Net loss	$ (77,400)	$ (43,562)	$ (47,089)
Net loss per share—basic and diluted	$ (2.78)	$ (1.84)	$ (2.34)
Weighted average shares used in computing basic and diluted net loss per share	27,883	23,731	20,116

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

NanoString Technologies, Inc.
Consolidated Statements of Comprehensive Loss

	Years Ended December 31,		
	2018	2017	2016
	(In thousands)		
Net loss	$(77,400)	$(43,562)	$(47,089)
Other comprehensive income (loss):			
Change in unrealized gain (loss) on short-term investments	59	(42)	(28)
Comprehensive loss	$(77,341)	$(43,604)	$(47,117)

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

NanoString 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)					
Balances at January 1, 2016	19,570	$ 2	$ 242,693	$ (29)	$ (222,451)	$ 20,215
Issuance of common stock net of issuance costs of $1.0 million	1,333	—	26,073	—	—	26,073
Issuance of common stock for employee stock purchase plan	139	—	1,489	—	—	1,489
Exercise of stock options	349	—	2,607	—	—	2,607
Exercise of common stock warrants, net	133	—	—	—	—	—
Vesting of restricted stock units	5	—	—	—	—	—
Stock-based compensation	—	—	9,038	—	—	9,038
Net loss	—	—	—	—	(47,089)	(47,089)
Other comprehensive (income) loss	—	—	—	(28)	—	(28)
Balances at December 31, 2016	21,529					