NanoString Technologies Inc
Form 10-K
March 07, 2018
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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, 2017
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 ¨ No ý

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 ¨

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Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes 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	¨ (Do not check if a smaller reporting company)	Smaller reporting company	¨
Emerging growth company	ý		

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 $347.3 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 25,440,469 shares of the Registrant's common stock, $0.0001 par value per share, outstanding on February 28, 2018.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission in connection with the registrant's 2018 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the registrant's fiscal year ended December 31, 2017.

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NANOSTRING TECHNOLOGIES, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2017

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Special Note Regarding Forward-Looking Information

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

Forward-looking statements 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 or and 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;
- 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 regulatory clearance or approval or reimbursement for the clinical use of our products, domestically and internationally;
- our ability to successfully commercialize Prosigna, our first in vitro diagnostic product;
- our ability to realize the potential payments set forth in our collaboration agreements;
- our strategic relationships, including with patent holders of our technologies, manufacturers and distributors of our products, collaboration partners and third parties who conduct our clinical studies;
- our intellectual property position;
- our ability to attract and retain key scientific or management personnel;
- our expectations regarding the market size and growth potential for our business; and
- our ability to sustain and manage growth, including our ability to expand our customer base, develop new products, enter new markets and hire and retain key personnel.

All forward-looking statements are based on information available to us on the date of this Annual Report on Form 10-K and we will not update any of the forward-looking statements after the date of this Annual Report on Form 10-K, except as required by law. Our actual results could differ materially from those discussed in this Annual Report on Form 10-K. The forward-looking statements contained in this Annual Report on Form 10-K, and other written and oral forward-looking statements made by us from time to time, are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements, 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.

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PART I

Item 1. Business

Overview

We develop, manufacture and sell robust, intuitive products that unlock scientifically valuable and clinically actionable biologic information from minute amounts of tissue. Our nCounter Analysis System directly profiles hundreds of molecules simultaneously using a novel barcoding technology that is powerful enough for use in research, yet simple enough for use in clinical laboratories worldwide. We market our systems and related consumables to researchers in academic, government, and biopharmaceutical laboratories for use in understanding fundamental biology and the molecular basis of disease and to clinical laboratories and medical centers for diagnostic use. As of December 31, 2017, we had an installed base of approximately 605 nCounter systems, which our customers have used to publish more than 1,800 peer-reviewed papers. As researchers using our systems discover new biologic insights to improve clinical decision-making, these discoveries may be translated and validated as diagnostic tests. For example, our first molecular diagnostic product is the Prosigna Breast Cancer Assay, which provides an assessment of a patient's risk of recurrence for breast cancer. In addition, we collaborate with biopharmaceutical companies to develop companion diagnostics, that may be used to identify which patients are most likely to respond to a particular therapeutic treatment.

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

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

In addition to the nCounter Analysis System, we are currently developing two new systems enabled by our proprietary optical barcoding chemistry. 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 in development, Digital Spatial Profiling, or DSP, is designed to allow researchers to address important questions regarding how protein and gene expression vary spatially for regions of interest across the landscape of a heterogeneous tissue biopsy. Our 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 next generation sequencer. 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. Early access sales of DSP instruments are expected to start in late 2018 and the commercial launch of DSP instruments is expected during the first half of 2019.

The second new platform in development, Hyb & Seq, is a next generation sequencing platform. Hyb & Seq is designed to have a workflow that is simpler and faster than current sequencing methods, due to the absence of library preparation, enzymes and amplification. Hyb & Seq's simple workflow and compatibility with a variety of sample types offers

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the potential for a sample-to-answer solution for clinical sequencing. The commercial launch of a research version of Hyb & Seq is expected during 2020.

We generated revenue of $114.9 million, $86.5 million and $62.7 million in 2017, 2016 and 2015, respectively, while incurring net losses of $43.6 million, $47.1 million and $45.6 million in 2017, 2016 and 2015, 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.” Each other trademark, trade name or service mark appearing in this Annual Report on Form 10-K belongs to its holder.

Our Market Opportunity

Every living organism has a genome that contains the full set of biological instructions required to build and maintain life. By analyzing the variations in genomes, genes, gene activity, and proteins in and between organisms, researchers can determine their functions and roles in health and disease. An improved understanding of the genome and its functions allows researchers to drive advancements in scientific discovery. As they make scientific discoveries, researchers have been able to translate some of these findings into clinical applications that improve patient care.

A gene is a specific set of instructions embedded in the DNA of a cell. For a gene to be “turned on,” or “expressed,” the cell must first transcribe a copy of its DNA sequence into molecules of messenger RNA. Then, the cell translates the expressed information contained in the RNA into proteins that control most biological processes. In addition to the translated RNAs, there are many types of non-coding RNAs that are involved in many cellular processes and the control of gene expression, including microRNA, or miRNA.

Biological pathways are the networks of tens or hundreds of genes that work in concert to produce a biological function. Understanding the activation state of pathways and disruptions in individual elements of these pathways provides significant insight into the fundamental basis of disease and facilitates data driven treatment decisions. Therapeutic interventions, such as drugs, can be used to treat disease by activating or inactivating biological pathways that are relevant to disease. As a result, pathway-based biology has become a widely adopted paradigm that researchers use to understand biological processes and has assisted them in the development of diagnostics and drugs to treat disease. This is particularly important in cancer research and treatment.

Over the last decade, methods of measuring genomic information have advanced substantially. However, pathway-based research and the development of diagnostic tests require analysis of multiple genes and sensitivity to small changes in expression, which can be challenging for traditional genomic tools. In both life sciences research and clinical medicine, there is a growing need for improved technologies that can precisely and rapidly measure the activation state of hundreds of genes simultaneously across a large number of precious samples. Furthermore, there is an untapped opportunity for technologies capable of simultaneously profiling the activity of genes and related proteins, which ultimately dictate biological activity.

Life Sciences Research

Academic, government, and biopharmaceutical researchers engaged in gene expression or protein analysis typically focus on making biological discoveries that may lead to the development of relevant medical products and better informed treatment decisions for physicians and patients. They have traditionally performed gene expression experiments using microarrays or quantitative polymerase chain reaction, or PCR, and protein expression experiments using flow cytometry, mass spectrometry, immunohistochemistry or enzyme-linked immunosorbent assay, or ELISA, assays. More recently, RNA sequencing, or RNA-Seq, has dramatically enhanced researchers’ ability to discover patterns of gene expression that have biological meaning. However, related workflows and data analysis can be cumbersome and time consuming, and simultaneous analysis of proteins is not possible. Researchers are increasingly

performing analyses on a larger number of genes and samples and are seeking new methods of interrogation that would allow them to:

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

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- improve the overall efficiency of their laboratories by simplifying workflow and accelerating the rate of successfully completing their research;
- provide more reliable, precise and reproducible data about targeted genes and biological pathways;
- maximize the amount of biologic information extracted from precious tissue samples;
- minimize the computational intensity of complex genomic and proteomic analysis;
- process difficult-to-work-with specimens, such as tumor biopsies stored in FFPE format; and
- create more systematic and reliable ways to help transition their research discoveries into future clinical products.

We believe that the above items create an opportunity for technologies like ours that are optimized for pathway-based biology, providing the potential for seamless transition to clinical diagnostic testing laboratories on a distributed basis, with the capability to analyze both genomic and proteomic information.

Molecular Diagnostics

Growth in the molecular diagnostics market is being driven by technological innovations that have enabled unprecedented biological insights that may be used to inform treatment decisions. New and improved technologies have also led to increased test sensitivity, decreased turnaround times, simplified workflow, and lowered costs when compared to previous techniques. In addition, the medical community has seen a trend in favor of decentralized diagnostic testing as a result of the convenience of local testing, hospitals and medical centers increasingly viewing their laboratories as profit centers and a need to increase access to tests for patients outside of the United States. We believe that there is an opportunity to improve the quality of diagnosis and treatment of diseases by developing and commercializing comprehensive, simple and widely available diagnostic products based initially on gene expression analysis, and ultimately based on our 3D Biology capability.

Cancer is a disease generally caused by genetic mutations in cells. The behavior of cancer cells is extremely complex, depending on the activity of many different genes and proteins. It is often impossible for researchers to identify a single gene or protein that adequately predicts a more aggressive or less aggressive type of cancer. In some cases, researchers have been able to identify more aggressive or less aggressive types of cancer through gene expression analysis of biological pathways, enabling oncologists to determine which specific treatments are most likely to be effective for an individual patient, monitor a patient's response to those treatments, and determine the likelihood of recurrence.

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

In addition, the medical community has favored a trend toward decentralized diagnostic testing. Tests for HIV, Hepatitis C, Influenza and MRSA, which were once centralized, are now often conducted in hospital laboratories or at the point of care. We believe that this trend of decentralized testing will continue as a result of many factors, including:

- Convenience. We believe that physicians would prefer that molecular diagnostic tests be performed at a local level and in the same laboratory that performs other tests that the physicians may order. Local molecular diagnostic testing could provide physicians the same rapid turnaround of test results that they have learned to expect for other types of tests.
- Economic Advantages. We believe that hospitals and medical centers desire to make their clinical laboratories profit centers by performing tests and billing third-party payors. As diagnostic technologies become less complicated to administer, hospitals and medical centers tend to favor in-sourcing tests.
- International Availability. There is a critical need to increase access to molecular diagnostic tests for patients that live outside the United States. Currently, patients living outside the United States may be challenged to gain access to tests that are provided only by specialized laboratories located within the United States. We believe advanced molecular diagnostic testing will become more available to patients throughout the world when it can be provided by their local

clinical laboratories.

We believe that these factors create an opportunity for technologies like ours that can facilitate the development and use of complex molecular diagnostics, potentially targeting gene mutations, gene expression and protein expression, with a high level of precision on a decentralized basis.

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Our Solution

Our nCounter Analysis System is an automated, multi-application, digital detection and counting system which directly profiles hundreds of molecules simultaneously using a novel barcoding technology that is powerful enough for use in research, yet simple enough for use in clinical laboratories worldwide. Our nCounter Analysis System is based on automated instruments that prepare and analyze tissue samples using proprietary reagents, which can only be obtained from us. Our research customers purchase instruments from us and then purchase our reagents and related consumables for the specific experiment or assay they wish to conduct. Our clinical laboratory customers either purchase or lease instruments from us and also purchase our reagents and related consumables for tests that they intend to run.

Our nCounter Analysis System offers a number of compelling advantages, including:

- Optimized for Pathway-Based Biology. The nCounter Analysis System can profile up to 800 molecules in a single test tube, which allows customers to analyze interactions among hundreds of genes or proteins that mediate biological pathways.
- Digital Precision. Our molecular barcodes hybridize directly to the target molecules in a sample allowing them to be counted. This generates digital data (1 molecule = 1 count) of excellent quality over a wide dynamic range of measurements and provides excellent reproducibility.
- Simple Workflow. The nCounter Analysis System's minimal sample preparation and automated workflow enable the simultaneous analysis of hundreds of genes and proteins in approximately 24 hours between the time a sample is loaded into the system and results are obtained. Our nCounter Analysis System generates data that customers can evaluate without the use of complex bioinformatics.
- Flexible Sample Requirements. The nCounter Analysis System is able to unlock biologic information from minute amounts of a variety of challenging tissue samples, including FFPE samples, cell lysates and single cells.
- Versatility. The FLEX configuration of the nCounter Analysis System provides clinical laboratories a single platform with the flexibility to support both clinical testing, by running Prosigna or Laboratory Developed Tests using nCounter-based reagents, and research, by processing translational research experiments and multiplexed assays using our research reagents.

Life Sciences Research

Our nCounter Analysis System is capable of supporting a number of research applications based upon the measurement of the concentration or amount of a target molecule. Additionally, starting in September 2015, we have launched a series of 3D Biology applications, which enable the simultaneous analysis of DNA, RNA and proteins in a single sample. Key applications currently supported include:

- Gene Expression. Researchers can use the nCounter Analysis System to measure the degree to which individual genes in pathways are turned "on" or "off" by simultaneously quantifying the amount of messenger RNA, or mRNA, associated with each of up to 800 genes.
- Protein Expression. Today, researchers can use the nCounter Analysis System to measure simultaneously up to 30 proteins. Ultimately, we intend to expand this capability to an increased number of protein targets, limited only by the 800 target capacity of an assay and the number of antibodies that can be sourced and combined without cross-reaction.
- Gene Mutations. In late 2016, we launched our first assay to detect a particular type of gene mutation, known as single nucleotide variations. Our initial panel, targeting solid tumors, gives researchers the power to measure 104 different gene mutations simultaneously, at the same time as measuring the expression of other genes and proteins.
- miRNA Expression. Researchers can use the nCounter Analysis System to measure the simultaneous expression levels of up to 800 different miRNAs. The nCounter Analysis System is capable of highly multiplexed, direct digital detection and counting of miRNAs in a single reaction without amplification, thereby delivering high levels of sensitivity, specificity, precision, and linearity.
- Copy Number Variation. Researchers can use the nCounter Analysis System to probe for structural variations that result in cells having an abnormal number of copies of one or more sections of the DNA. Researchers are able to conduct large-scale, statistically-powered studies of these copy number variations, or CNVs, by leveraging the nCounter Analysis System's multiplexing capacity to assay up to 800 DNA regions in a single tube, with as little as

300 ng of DNA.

- Gene Fusions. Researchers can use the nCounter Analysis System to detect gene fusion events that occur when one gene fuses to another gene. A number of design options are available for developing assays for

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

Molecular Diagnostics

We believe that the attributes that make the nCounter Analysis System attractive to researchers also make the system attractive to hospitals and clinical laboratories that desire to conduct molecular diagnostic tests. The precision, ease of use and flexibility of the nCounter Analysis System will allow medical technicians in pathology labs to conduct complex molecular diagnostic tests with minimal training. We expect these tests to encompass both Laboratory Developed Tests based on our nCounter-based reagents and in vitro diagnostic kits.

Our Products and Technology

Instruments and Software

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

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

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

The nCounter MAX and FLEX systems comprise a Prep Station and a Digital Analyzer. The Prep Station is the automated liquid handling component of the nCounter Analysis System that processes samples after they are hybridized and prepares the samples for data collection on the nCounter Digital Analyzer. The nCounter Digital Analyzer collects data from samples by taking images of the immobilized fluorescent reporters in the sample cartridge and processing the data into output files, which include the target identifier and related count numbers along with a broad set of internal controls that validate the precision of each assay. The nCounter SPRINT Profiler is a single instrument targeted to individual researchers that provides both the liquid handling steps and the digital analysis through use of a microfluidic cartridge. 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. We also provide our research customers with the nSolver Analysis Software, a data analysis program that offers researchers the ability to quickly and easily quality check, normalize, and analyze their data without having to use any additional software for data analysis. The diagnostic version of our instrument, the nCounter Analysis Dx FLEX System, was FDA 510(k) cleared and CE-marked together with Prosigna. The FLEX System can be enabled with the software that runs Prosigna to generate individualized patient reports, in addition to running any of our research applications.

The nCounter MAX and FLEX Systems employ a simple three-step workflow that takes approximately 24 hours and requires approximately 15 minutes of hands-on time by the user. When run in research mode, a user can process up to 48 samples per day by installing one Prep Station with a single Digital Analyzer. One can increase the number of samples analyzed to 96 samples per day on a single Digital Analyzer if it is coupled with two Prep Stations. This throughput can be quadrupled using sample multiplexing for experiments targeting 200 genes or fewer. For Prosigna, a clinical laboratory can process up to 30 samples per day on an nCounter Dx Analysis System. The nCounter