#### **OUTPERFORM**

Reason for report: INITIATION

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#### NANOSTRING TECHNOLOGIES

**Novel Technology Bridges Gap between Research and Diagnostics** 

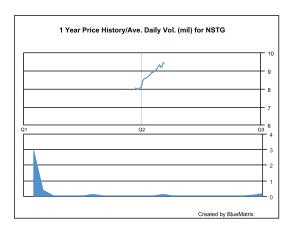
- **Bottom Line**: We believe NanoString's business is poised for accelerated revenue growth with several catalysts on tap in both research and diagnostics. We are initiating coverage on NanoString's stock with an Outperform rating and \$15 price target.
- Proprietary technology offers important advantages. NanoString's proprietary CodeSet technology enables highly multiplexed, direct profiling of individual molecules in a single reaction without amplification. This technology offers advantages in measuring the expression levels of tens to hundreds of genes (up to 800), a range that falls between the optimal economic and logistical space for traditional quantitative polymerase chain reaction (qPCR) (a few genes) and microarrays (hundreds of thousands to millions of genes).
- New product launches should accelerate research revenue growth. We believe growth of NanoString's installed base of >140 instruments will accelerate following the launch of new, more flexible chemistry in late 2013 and the launch of a smaller, less expensive version of its nCounter in 2014. We've forecasted NanoString's installed base will grow from 127 instruments in 2012 to 367 instruments in 2015. Accordingly, we have forecasted NanoString's life science revenue growth rate will accelerate from ~25% in 2013e to nearly 30% in 2014e.
- Diagnostics business poised to take off on heels of new product cycle. NanoString's technology is uniquely able to automate complex diagnostic tests, and thus enable many labs worldwide to run such tests. The company's first test is Prosigna, a test for breast cancer prognosis (i.e., risk of distant recurrence). This test has been favorably validated in two large studies with >2,400 patients. NanoString launched this test in Europe and Israel in Feb. 2013 and we expect an early 2014 entry into the U.S. market, following late 2013 FDA clearance. We believe a broader range of pathology labs are eager to participate in the \$240M+ market WW for breast cancer recurrence tests, a market currently served almost exclusively by two labs, and thus forecast strong growth for the test. We expect sales of this test will generate ~\$30M in revenue for NanoString in 2015.
- Favorable recurring revenue mix to improve further with diagnostics launch. NanoString enjoys a favorable mix of recurring, high margin consumables revenue. Consumables revenue comprised 58% of NanoString's total product revenue and generated, on average, more than 40% of the list price per instrument in 2012. We believe that NanoString's consumable revenue will comprise nearly 75% of total revenue within the next two years following uptake of its Prosigna test.

## Key Stats: (NASDAQ:NSTG)

HEALTHCARE EQUITY RESEARCH

S&P 600 Health 0	Care Index:	1,070.49
Price:		\$9.44
Price Target:		\$15.00
Methodology:	~3.5x revs for TTM	ended Jun 2015e
52 Week High:		\$10.00
52 Week Low:		\$7.81
Shares Outstanding	ng (mil):	14.6
Market Capitalizat	ion (mil):	\$137.8
Book Value/Share	:	\$2.90
Cash Per Share:		\$3.46
Net Debt to Total (	Capital:	(27)%
Dividend (ann):		\$0.00
Dividend Yield:		0.0%
Deels Value (Cha		

Book Value/Share: estimated Net Debt to Total Capital: estimated



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	PEG
2012A	\$4.5	\$5.9	\$6.0	\$6.5	\$23.0	(\$0.46)	(\$0.49)	(\$0.53)	(\$0.72)	(\$2.21)	NM
2013E	\$5.7A	\$6.7	\$7.9	\$9.8	\$30.1	(\$0.79)	(\$0.85)	(\$0.65)	(\$0.90)	(\$3.18)	NM
2014E					\$51.7					(\$2.18)	NM
2015E					\$82.2					(\$1.18)	NM

Source: Company Information and Leerink Swann LLC Research

Revenues in \$millions

EPS ex-extraordinary 1x items, FAS 123 option expense included

Please refer to Pages 19 - 21 for Analyst Certification and important disclosures. Price charts and disclosures specific to covered companies and statements of valuation and risk are available at https://leerink2.bluematrix.com/bluematrix/Disclosure2 or by contacting Leerink Swann LLC Publishing Department, One Federal Street, 37th Floor, Boston, MA 02110.



#### **INVESTMENT THESIS**

We are initiating coverage of Seattle, Washington-based NanoString Technologies (NanoString) with an Outperform rating and a \$15 price target. The company's proprietary technology fills an important role in the research market by enabling mid-density gene analysis in formalin-fixed, paraffin embedded (FFPE) samples. This capability translates readily to oncology diagnostics, in which NanoString's nCounter Analysis System promises to enable complex molecular testing in a decentralized setting. Our Outperform rating reflects a view that NanoString's revenue growth opportunities, in both life science research and clinical diagnostics, are underappreciated at current levels.

#### **INVESTMENT POSITIVES**

Proprietary technology, favorable mix, multiple catalysts to accelerate revenue growth

Proprietary technology offers important advantages. NanoString's proprietary CodeSet technology enables highly multiplexed, direct profiling of individual molecules in a single reaction without amplification. This technology offers advantages in measuring the expression levels of tens to hundreds of genes (up to 800), a range that falls between the optimal economic and logistical space for traditional quantitative polymerase chain reaction (qPCR) (a few genes) and microarrays (hundreds of thousands to millions of genes). Additionally, NanoString's ability to generate test results without amplification makes it especially suited for complex samples, such as FFPE samples, important in cancer research. These benefits translate readily from life science research into diagnostics, where NanoString's technology promises to automate and decentralize complex cancer testing.

New product launches should accelerate research revenue growth. We believe growth of NanoString's installed base of >140 instruments will accelerate following the launch of new, more flexible chemistry in late 2013 and the launch of a smaller, less expensive version of its nCounter in 2014. We've forecasted NanoString's installed base will grow from 127 instruments in 2012 to 367 instruments in 2015. Accordingly, we have forecasted NanoString's life science revenue growth rate will accelerate from ~25% in 2013e to nearly 30% in 2014e.

Diagnostics business poised to take off on heels of new product cycle. NanoString's technology is uniquely able to automate complex diagnostic tests, and thus enable many labs worldwide to run such tests. The company's first test is Prosigna, a test for breast cancer prognosis (i.e., risk of distant recurrence). This test has been favorably validated in two large studies with >2,400 patients. NanoString launched this test in Europe and Israel in Feb. 2013 and we expect an early 2014 entry into the U.S. market, following late 2013 FDA clearance. We believe a broader range of pathology labs are eager to participate in the \$240M+ market WW for breast cancer recurrence tests, a market currently served almost exclusively by two labs, and thus forecast strong growth for the test. We expect sales of this test will generate ~\$30M in revenue for NanoString in 2015.

Favorable recurring revenue mix to improve further with diagnostics launch. NanoString enjoys a favorable mix of recurring, high margin consumables revenue. Consumables revenue



comprised 58% of NanoString's total product revenue and generated, on average, more than 40% of the list price per instrument in 2012. We believe that NanoString's consumable revenue will comprise nearly 75% of total revenue within the next two years following uptake of its Prosigna test.

#### **INVESTMENT RISKS**

Prosigna commercialization risks at the forefront

**FDA uncertainties loom large.** NanoString submitted a 510(k) application for its Prosigna test to the FDA in December 2012. While we expect FDA clearance in December 2013, we recognize that this is a complicated submission and timing cannot be assured. The nature of the claims allowed by the FDA also remains to be seen. We believe NanoString will be able to report its risk-of-recurrence quantitative score as well as the risk category for the FDA-cleared version of the test. However, we cannot discount the chance that the FDA only allows NanoString to report the risk category, similar to Agendia's Mammaprint test, which is the predicate device in NanoString's submission. A more limited label could adversely impact the rate of Prosigna adoption, in our view.

Timing and level of reimbursement to be determined. NanoString and its lab customers plan to pursue reimbursement for Prosigna in both the U.S. and abroad. All eyes will be on timing and level of U.S. reimbursement, as the U.S. market represents the larger market opportunity today (>\$210M). Competitor Genomic Health didn't receive Medicare reimbursement for its analogous Oncotype DX test until the product was on the market for two years. However, we see a number of pronounced differences between the Genomic Health experience and Prosigna: 1) NanoString should have multiple peer reviewed published studies validating the clinical utility of Prosigna prior to seeking reimbursement (first already published in the Journal of Clinical Oncology earlier this month), 2) NanoString is not creating a new expense category for payors, but rather just seeking to replace an existing test at comparable pricing, and 3) Prosigna's proposed status as an FDA-cleared product could boost its reimbursement case. We expect NanoString's customers could receive Medicare reimbursement for Prosigna in 1H 2014, with commercial payors following shortly thereafter. NanoString's competitors receive >\$3,000 / test from Medicare and we believe NanoString's reimbursement will fall in the same ballpark.

Significant entrenched competitor in breast cancer recurrence testing. NanoString's Prosigna test will face off in the U.S. market against an entrenched competitor (Genomic Health [OP]) and a newer entrant which has been gaining steam (Agendia). Since Genomic Health launched its Oncotype DX test in 2004, the test has been extensively validated, used to guide treatment in more than 350,000 breast cancer patients worldwide, achieved almost universal reimbursement coverage in the U.S., and has been incorporated in all major breast cancer guidelines (e.g., American Society of Clinical Oncology [ASCO], National Comprehensive Cancer Network [NCCN]). Additionally, Oncotype DX is predictive of chemotherapy response, a claim that Prosigna will not be armed with out of the gate. To NanoString's credit, Prosigna's peer-reviewed head-to-head comparison vs. Oncotype DX concluded that Prosigna provides more prognostic information in estrogen receptor positive (ER+), node-negative (N-) patients than Oncotype DX, with better differentiation of intermediate- and higher-risk groups. Also, Agendia's growth (\$15M in



2012 revenue, its first year with an FFPE offering for Mammaprint, up from \$6.2M in 2010) shows that Genomic Health's market position is not bullet proof, in our view. Finally, NanoString's distributed model will leverage the sales forces of reference labs around the world, and thus it could better reach the eligible women who currently don't receive breast cancer recurrence testing (2 in 5 in the U.S.). In Europe, NanoString will not require doctors to ship samples across borders, and also will provide subtype classification for a patient's breast tumor, information that the St. Gallen Expert Consensus has highlighted as important for therapy.

**Business model still needs to be market tested.** NanoString's distributed business model carries many advantages. However, application of this model to esoteric, high-ticket breast cancer prognostic tests still needs to be market tested. The success of NanoString's Prosigna test depends on its lab customers, so the company cedes partial control of its destiny to these customers. We believe the reference lab community in the U.S. is sufficiently incented to find growth that the success of NanoString's Prosigna assay will receive appropriate attention.

Considerable academic and government exposure. The majority of NanoString's current customers are academic and governmental research institutions, and we expect academic/government research budgets will be tight worldwide until 2015. Specifically, NanoString has the largest exposure in our research tools coverage to U.S. academic/government funding, which comprises nearly half of its revenue. U.S. research funding is under pressure. Sequestration has reduced the FY13 NIH research budget by ~5%, and the gap between the President's and the House FY2014 budget is \$10.4B, which suggests an increase for FY2014 may not be easy to achieve.

#### **COMPANY PROFILE**

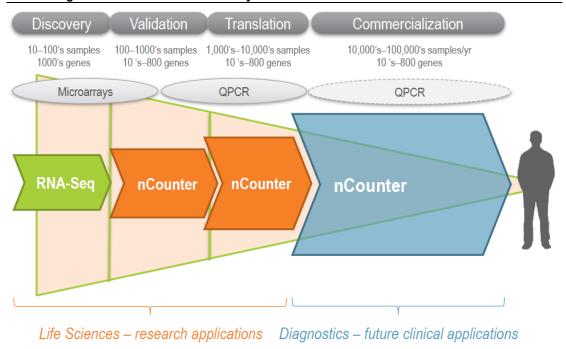
Novel digital barcoding technology with broad application, early in its life cycle

NanoString Technologies was founded in 2003 and in early 2004 acquired an exclusive license to its core digital barcoding technology, conceived in the labs of Dr. Leroy Hood at the Institute for Systems Biology (ISB). In 2008 the company launched its first commercial instrument system, the nCounter Analysis System, a system currently used by life science researchers who are performing cancer research, biomarker validation and screening, and validation of nextgen sequencing data. NanoString has an installed base of more than 140 systems, which its customers have used to publish more than 220 peer-reviewed papers. We anticipate NanoString's nCounter system will increasingly gain traction as a tool for cancer diagnostics.

The company's nCounter instrument occupies a space in which scientists wish to measure the expression levels of tens to hundreds of genes (up to 800), a range that falls between the optimal economic and logistical space for traditional quantitative polymerase chain reaction (qPCR) (a few genes) and microarrays (hundreds of thousands to millions of genes). These capabilities are particularly useful when scientists validate discoveries generated on sequencing or microarray platforms, and attempt to translate validated discoveries into something clinically useful. The following table illustrates the current and future uses of and opportunities for NanoString's technology in translational genomics.



#### NanoString's Position in the Genetic Analysis Market



Source: NanoString

For a nascent commercial operation, NanoString already has a favorable mix of instrument-to-consumable revenue (42%-to-58% in 2012). 65% of the company's sales in 2012 emanated from the U.S., 18% from Europe, 13% from the Asia Pacific region, and 4% from Canada. We estimate academic/government-sponsored research comprised ~75% of 2012 sales, and pharma/biotech comprised 25%.

#### **TECHNOLOGY OVERVIEW**

Barcodes enable multiplexing and direct detection

NanoString has commercialized a novel digital molecular barcoding technology through the nCounter Analysis System, an automated digital detection system which directly profiles hundreds of mRNAs, microRNAs, or DNA targets simultaneously (multiplexing). nCounter has some unique features as compared to traditional intensity based arrays. Specifically, it uses direct digital detection requiring minimal sample intervention. The "direct" refers to the process of counting individual tagged nucleic acids without any need for amplification and the "digital" nature refers to the capacity to use absolute and specific quantitation, independent of relative measures like intensity or amplification cycles. As such, the platform is useful for an array of study designs (multiplexed samples, joint miRNA - mRNA code sets) and sample types (FFPE, plasma, whole lysate, single cells).



We consider nCounter's use of non-enzymatic detection one of its main selling points. Also, no reverse transcription is necessary. These attributes offer the technology specific advantages in analyzing RNA samples of poor quality, such as FFPE samples.

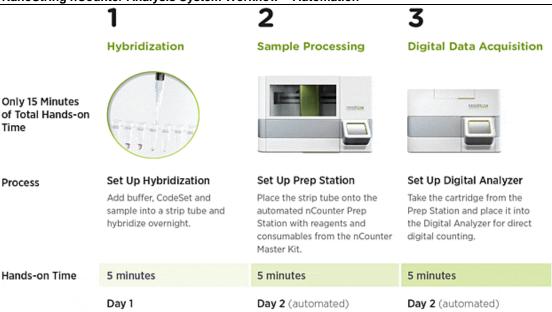
nCounter Workflow: The nCounter Analysis System is based on gene-specific probe pairs that are hybridized to the sample in solution. The protocol eliminates any enzymatic reactions that might introduce bias in the results (step 1). The reporter probe carries the fluorescent signal; the capture probe allows the complex to be immobilized for data collection. Hundreds of pairs of probes specific for a particular set of genes are combined with a series of internal controls to form a CodeSet. After hybridization of the CodeSet with a target such as mRNA, samples are transferred to the nCounter Prep Station (step 2) where excess probes are removed and probe / target complexes are aligned and immobilized in the nCounter Cartridge. Cartridges are then placed in the nCounter Digital Analyzer for data collection (step 3). Each target molecule of interest is identified by the color code generated by six ordered fluorescent spots present on the reporter probe. The reporter probes on the surface of the cartridge are then counted and tabulated for each target molecule.

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Source: NanoString



#### NanoString nCounter Analysis System Workflow - Automation



Source: NanoString

The nCounter Prep Stations can readily process 36 samples per day, and the nCounter Digital Analyzer can process 72 samples per run unattended, or 108 samples per day in two runs. The throughput of the system can be increased four-fold when indexing samples targeting 200 genes or fewer.

NanoString's nCounter Analysis System is a closed system, meaning that the company is the exclusive producer of the assays and reagents that run on the nCounter Analysis System. This resembles the classic razor/razor blade model and generates a recurring stream of high margin consumable revenue. From 2010-2012, the average consumable revenue pull-through was approximately \$100k per installed system.

#### SEGMENT OVERVIEW

Room for further penetration in both life sciences and diagnostics

NanoString's segments its businesses across two key end-markets: 1) Life Sciences Research and 2) Diagnostics. In the following section we discuss the dynamics within each end-market, the products that NanoString sells into each market and also the competitive landscape.

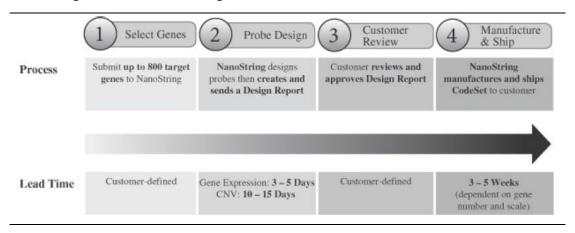
#### Life Sciences Research (71% of FY2014e revenue)

NanoString's primary end-market today is life sciences research. The company develops custom CodeSets for its customers to enable them to evaluate specific genes that are the subject of their studies. The design process uses full length sequences for the DNA or RNA molecules that the



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:

#### NanoString Custom CodeSet Design Process



Source: NanoString

We estimate custom CodeSets comprise ~2/3 of NanoString's life science consumables revenue.

The company also sells 20 pre-manufactured CodeSet panels for copy number variation (CNV) and gene expression targeted experiments, including: gene expression panels; miRNA expression assay kits; cancer CNV panels; nCounter leukemia fusion gene assay kits; and, human karyotype panels.

To determine NanoString's market opportunity in the life science research market, we think it instructive to use Affymetrix's (MP) installed base of microarray scanners as a proxy, since Affymetrix was the leader in high throughput gene expression for years. Affymetrix last reported an instrument installed base of nearly 2,000 instruments in Q1 2010. An opportunity that comprises even half of this implies substantial upside from NanoString's current installed base of >140 instruments. We believe two forthcoming product launches will enable the company to better access this opportunity. We expect NanoString will launch more flexible CodeSets by year-end 2013, which will enable it to better serve scientists who wish to tinker with the genes in their experiments (i.e., much of the academic research community). Additionally, we expect the company will launch a new generation of its nCounter system in 2014. The new system will be a single instrument with a reduced footprint that combines the prep station and the digital analyzer. We expect the new instrument will sell for ~\$100,000, less than half the price of the current nCounter, but carry a higher gross margin due to the adoption of newer, less expensive technologies.

NanoString's nCounter broadly belongs to what we categorize as the mid-density class of genetic analysis research tools, tools designed to analyze tens to hundreds of genes/data points per sample. In this category we consider it most competitive with Fluidigm's (MP) BioMark, Life Technologies' (OP) QuantStudio, Raindance's ThunderStom, Luminex's (OP) FlexMAP 3D, and HTG's Edge. Other competitors in the broad genetic analysis market include Affymetrix, Agilent



(OP), Bio-Rad (MP), Exiqon, Illumina (OP), Perkin Elmer (OP), Qiagen (OP), Roche, Sequenom, and Wafergen.

#### Diagnostics (29% of FY2014e revenue)

The nCounter's ability to simultaneously quantify gene expression on tens or hundreds of genes from minimal amounts of FFPE tissue make it well suited for profiling pathway activation in tumor samples. Thus, we believe NanoString's nCounter platform is a compelling option to automate complex molecular testing in a decentralized setting. The company launched its first diagnostic test, Prosigna, in Feb. 2013, and has both a pipeline of additional indications for this test as well as a license to a gene signature for a liver cancer prognostic test.

**Prosigna Assay:** Prosigna is NanoString's brand name for the PAM50 gene signature, which measures the expression of 50 genes (and 8 housekeeping genes) to provide prognostic information for breast cancer patients. Specifically, Prosigna provides two important pieces of diagnostic information for patients with breast cancer: 1) it classifies the patient's tumor into one of four intrinsic subtypes (Luminal A, Luminal B, HER2-enriched, or Basel-like); and, 2) it provides a prognostic score that estimates the probability of distant cancer recurrence for a patient, i.e., the risk-of-recurrence (ROR) score.

In 2011 and 2012, NanoString performed two large clinical validation studies (TransATAC and ABCSG8; total patient population of 2,485) to test the ability of Prosigna to estimate the prognosis of postmenopausal women with hormone receptor positive (HR+) early-stage breast cancer who have been treated with endocrine therapy alone. TransATAC is a translational group study with patients from the ATAC (Arimidex, Tamoxifen, Alone or in Combination) trial and the ABCSG8 study evaluated patients from the Austrian Breast & Colorectal Cancer Study Group 8; NanoString's collaborators presented the results from both studies in December 2011 and 2012, respectively, at the San Antonio Breast Cancer Symposium. Both studies met their primary and secondary objectives.

- Primary objective of both studies: the ROR score was significantly related to outcome, and added significant prognostic information about 10-year distant recurrence risk to standard, clinical pathological variables in the study populations as a whole.
- Secondary objective of both studies: similar results were achieved in all three
  prospectively defined clinically important subsets of patients: node-negative, nodepositive and HER2-negative.
- Primary objective of the ABCSG8 study: the low, intermediate, and high risk patient
  groups as defined by Prosigna had different distant recurrence free survival rates at 10
  years in the study population as a whole, showing that Prosigna can accurately
  categorize patients based on prognosis; and
- Secondary objective of both studies: patients with different intrinsic subtypes as reported
  by Prosigna had significantly different outcomes when treated with endocrine therapy
  alone, reinforcing the power of intrinsic subtyping as a descriptor of breast cancer tumor
  biology.



The following table summarizes the risk of distant cancer recurrence as indicated by the Prosigna ROR score in the TransATAC and ABCSG8 studies.

Risk of Distant Recurrence as Indicated by Prosigna ROR Score

		<u> </u>		
	TransAT	_	ABCSG	-
	Est	imated DR at	Est	imated DR at
Risk Group	# of patients	10 years	# of patients	10 years
Low	437	4%	502	3%
Intermediate	254	14%	478	9%
<u>High</u>	<u>316</u>	37%	<u>498</u>	20%
Total	1,007		1,478	

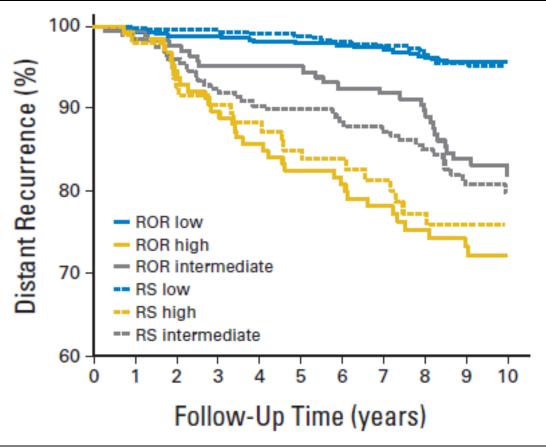
Source: TransATAC, ABCSG8, NanoString, Leerink Swann

DR = distant recurrence

The spread between the low and the high risk groups suggests the Prosigna test can be used to determine prognosis for HR+ breast cancer patients. Additionally, since the TransATAC population had been previously used to clinically validate Genomic Health's Oncotype DX test for breast cancer prognosis, the investigators in the TransATAC study performed a comparison between Prosigna and Oncotype DX. They concluded that the Prosigna ROR score provides more prognostic information in endocrine-treated patients with ER+, N- disease than the Oncotype RS (recurrence score), with better differentiation of intermediate- and higher-risk groups. The ROR score and the RS score categorized a similar number of patients as low risk, but the ROR score categorized more patients as high risk and fewer as intermediate risk than the RS score. Specifically, Prosigna assigned 26% fewer patients to the intermediate risk group than did Oncotype DX (179 patients vs. 243 patients). However, the low and high risk groups defined by each test have similar outcomes as illustrated by the overlapping Kaplan-Meier curves in the following table.



#### Distant Recurrence Over 10 Year for Node Negative Populations, As Predicted by ROR and RS



Source: Dowsett et al., Comparison of PAM50 Risk of Recurrence Score With Oncotype DX and IHC4 for Predicting Risk of Distant Recurrence After Endocrine Therapy, Journal of Clinical Oncology, published online 7/1/2013

NanoString has also presented results at medical meetings from further analysis of the TransATAC and ABCSG8 studies which suggest that: the ROR score provided by Prosigna adds significant prognostic information to clinical-pathology variables for recurrence between five and 10 years after diagnosis (late recurrence); Prosigna provides valuable information that could assist with treatment decisions by helping to identify patients at highest risk of this late recurrence; and, Prosigna can identify a clinically significant number of low risk patients with one or two positive lymph nodes. NanoString has several additional analyses of the ABCSG8 and ATAC studies planned or ongoing.

NanoString obtained CE mark designation for the Prosigna test in Sept 2012 and commercially launched the test in France, Germany, Italy, Spain, the United Kingdom, and Israel in February 2013, at a list price of €1,550 per patient. The company submitted a 510(k) application to the FDA in December 2012, and plans to commercially launch in the U.S. in Q1 2014, pending FDA clearance.



The decentralized business model: NanoString's business model differs from the other two primary purveyors of breast cancer recurrence tests (Genomic Health and Agendia) in that, rather than conduct all of its testing in one central lab, NanoString sells (or rents) instruments and kits to customers to enable decentralized testing. The company presented results of its multi-site analytical validation study for Prosigna in March 2013, which showed that the assay provides consistent and reliable results between different labs, instruments, and operators. We believe labs eagerly await the opportunity to perform complex gene expression testing in house, and thus participate in one of the faster growing segments of the clinical lab industry. Additionally, we believe the price of the test (average sales price of competitor Oncotype DX is >\$3,000, price of Prosigna to be determined) leaves enough money around the table for all parties (payors, labs, NanoString) to successfully participate in the economics. The decentralized model could also prove interesting in Europe, where samples do not easily cross borders. NanoString does forego some control of its destiny with the decentralized model, but enjoys lower capital and infrastructure costs.

Reimbursement: We expect NanoString will help its customers achieve reimbursement for the Prosigna test. In Europe, where reimbursement for market leader Oncotype DX is less prevalent than in the U.S., we believe reimbursement will be in part contingent on successful completion of decision impact studies, studies which will evaluate Prosigna's impact on adjuvant treatment decisions in early stage breast cancer. NanoString has already entered into agreements with two European cooperative groups to initiate decision impact studies during 2013. In the U.S., we believe testing services enabled by Prosigna will be classified as a Multianalyte Assay with Algorithmic Analysis (MAAA), and ultimately be reimbursed using MAAA codes. The company intends to apply for a Category 1 MAAA code for use in reimbursement of testing services based on Prosigna. In the meantime, prior to receipt of this code, we expect NanoString's customers will seek reimbursement for Prosigna using the Current Procedural Terminology (CPT) code designated for "Unlisted Multianalyte Assay with Algorithmic Analysis (81599)". We ultimately expect NanoString's customers will be able to achieve similar reimbursement to that provided for Oncotype DX, or >\$3,000.

The pipeline: NanoString's pipeline today consists of several additional indications for Prosigna as well as an effort to develop a test around a hepatocellular carcinoma (HCC) signature. The company's efforts to expand the clinical utility of Prosigna are focused on chemotherapy selection, radiation therapy in early stage breast cancer, and ductal carcinoma in situ (DCIS). NanoString has already secured access to tissue samples and outcomes from two randomized, controlled clinical studies that may be used to validate Prosigna to aid in the selection of chemotherapy regimen in breast cancer patients. The company has secured access to tissue samples and outcomes from one randomized, controlled clinical study that may be used to validate Prosigna's ability to identify postmenopausal women with early stage breast cancer who are likely to receive little or no benefit from treatment with adjuvant radiation therapy. NanoString has applied for access to a cohort of DCIS samples which could be used to validate the ability of Prosigna to identify DCIS patients who may be spared aggressive treatment. Finally, in Feb. 2013, the company secured an option to acquire an exclusive worldwide license for a 186 gene signature that could be used to determine the prognosis of patients diagnosed with HCC, or with hepatits C-



related early-stage cirrhosis. NanoString plans to assess the feasibility of developing a diagnostic based on the HCC gene signature for use on the nCounter.

#### **VALUATION**

High growth profile and favorable revenue mix trading at a discount multiple

NanoString's current enterprise value is ~3.5x forward twelve month revenue, a multiple which is consistent with the median multiple for our broader life science tools and diagnostics coverage, but a discount to the most appropriate comparable peer group (see following table). While we think this discount inappropriate, our current \$15 price target merely assumes NanoString sustains this multiple and creates value through revenue growth.

NanoString's Peer Group Valuations (dollars in millions, except share price)

					Revenue			EV/Rev	venue
Company	Ticker	Stock price	Mkt Cap	EV	2013e	2014e	Growth	2013e	2014e
Affymetrix	AFFX	\$4.70	\$307.9	\$470.2	\$318.7	\$325.5	2.2%	1.5x	1.4x
Atossa Genetics	ATOS	4.92	71.5	71.5	3.6	14.6	300.0%	19.6x	4.9x
Cepheid	CPHD	34.64	2,291.0	2,304.1	382.7	449.9	17.6%	6.0x	5.1x
Exact Sciences	EXAS	13.74	880.7	880.7	4.1	35.7	771.8%	215.3x	24.7x
Fluidigm	FLDM	17.00	428.3	369.5	64.6	80.0	23.9%	5.7x	4.6x
Genomic Health	GHDX	35.72	1,064.3	979.1	261.9	296.5	13.2%	3.7x	3.3x
Genmark	GNMK	10.22	328.0	328.0	29.8	41.4	39.2%	11.0x	7.9x
Illumina	ILMN	75.28	9,316.0	9,101.2	1,353.1	1,505.9	11.3%	6.7x	6.0x
Luminex	LMNX	23.21	962.3	890.9	225.4	249.2	10.6%	4.0x	3.6x
Myriad Genetics	MYGN	31.80	2,457.3	2,285.2	598.4	664.6	11.1%	3.8x	3.4x
Nanosphere	NSPH	3.31	182.0	182.0	13.0	29.5	126.8%	14.0x	6.2x
PacBio	PACB	2.76	161.8	161.8	27.2	34.8	28.0%	5.9x	4.6x
Qiagen	QGEN	20.51	4,858.4	5,589.9	1,310.3	1,387.8	5.9%	4.3x	4.0x
Sequenom	SQNM	4.64	537.8	535.5	199.3	278.7	39.9%	2.7x	1.9x
TrovaGene	TROV	\$6.87	\$109.2	\$109.2	\$0.9	\$4.5	399.9%	120.9x	24.2x
MEDIAN							23.9%	5.9x	4.6x

Source: Leerink Swann, FactSet (all estimates are FactSet consensus); prices are 7/18 close

NanoString's stock looks similarly mispriced when one considers comparable transaction values. For example, Roche purchased Nimblegen, a microarray supplier, in 2007 for \$270M following a year in which Nimblegen generated \$13.5M in sales. Bio-Rad purchased QuantaLife, a company which developed an instrument for digital PCR, for \$162M in advance of a year in which it perhaps recorded ~\$15M in revenue as part of Bio-Rad.

#### **RISKS TO VALUATION**

Risks to our valuation for NanoString include the uncertainty of the successful commercialization of Prosigna as well as the type of label that the FDA deems appropriate for the test. The reimbursement level for Prosigna has not yet been determined and NanoString must compete with an entrenched test in the breast cancer space. The company's revenues may be pressured by federal budgetary constraints as the majority of its customers are academic and governmental research institutions. While we model the company raising equity in 2014 to help fund operations, its ability to tap the equity markets or obtain additional funding may be a potential uncertainty.



#### **MANAGEMENT**

Relevant experience all around the table

**Brad Gray, CEO.** Brad Gray has served as NanoString's President and Chief Executive Officer since June 2010. Prior to joining NanoString, Gray held various positions at Genzyme. He served as Vice President of Product & Business Development for Genzyme Genetics, the diagnostic services division of Genzyme, from June 2008 to May 2010, leading the development of molecular diagnostics and partnering activities. From September 2006 to June 2008, he served as Vice President of Business & Strategic Development for Genzyme Genetics, leading growth efforts through partnerships and licensing. Mr. Gray joined Genzyme in October 2004 as Director of Corporate Development, supporting business development and leading Genzyme Ventures, the corporate venture capital fund of Genzyme. Prior to joining Genzyme, Mr. Gray was a management consultant in the healthcare practice of McKinsey & Company, from September 2000 to October 2004. Gray received a B.A. in Economics and Management from Oxford University, where he studied as a British Marshall Scholar, and an S.B. in Chemical Engineering from the Massachusetts Institute of Technology.

James A. Johnson, CFO. James Johnson has served as Chief Financial Officer since October 2012. Prior to joining NanoString, Johnson was Chief Financial Officer of Relypsa, Inc., a privately-held clinical-stage biopharmaceutical company, from May 2011 to September 2012. From September 2009 to October 2010, Johnson served as Executive Vice President, Chief Financial Officer, Treasurer and Secretary of ZymoGenetics, Inc., a biopharmaceutical company acquired by Bristol-Myers Squibb in October 2010. Johnson served as ZymoGenetics' Executive Vice President, Chief Financial Officer and Treasurer from July 2007 to September 2009 and as ZymoGenetics' Senior Vice President, Chief Financial Officer, Treasurer from February 2001 to July 2007. Johnson served as Chief Financial Officer, Treasurer and Secretary of Targeted Genetics Corporation from 1994 to February 2001. From 1990 to 1994, Mr. Johnson served as Vice President, Finance, and, from 1988 to 1990, as Director of Finance, at Immunex Corporation. Johnson received a B.A. in Business Administration from the University of Washington.

J. Wayne Cowens, M.D., CMO. Wayne Cowens, M.D. has served as Chief Medical Officer since February 2011. Prior to joining NanoString, Dr. Cowens served in a series of senior medical positions at Genomic Health beginning in 2004. From April 2004 to March 2010, he served as Genomic Health's Vice President, Clinical Oncology. In this position, he was responsible for the development of the Oncotype DX product pipeline for gene expression profiling tests, initiated the programs in colon, prostate, and renal cell cancer and designed both development and validation clinical studies. In addition, he developed Genomic Health's program in health economics and focused on studies designed to support reimbursement of the Oncotype DX Breast Cancer Assay both in the United States and the European Union. Prior to joining Genomic Health, Dr. Cowens held senior product development positions at several pharmaceutical and biotechnology companies, including Chiron and Ribozyme Pharmaceuticals. Dr. Cowens is a licensed medical oncologist and author of 70 scientific abstracts and papers. He received a H.A.B. in Classical Languages and Mathematics from Xavier University, a M.S. in Mathematics from Northwestern University and an M.D. from Johns Hopkins University.



Wayne Burns, Senior Vice President, Operations & Administration. Wayne Burns has served as Senior Vice President, Operations and Administration since October 2012 and served as Chief Financial Officer from April 2007 to September 2012. During the period from March 2009 through June 2010, Burns served as Acting Chief Executive Officer as well as Chief Financial Officer. Prior to joining NanoString, Burns served as Chief Operating Officer and Chief Financial Officer at Action Engine, a developer of a mobile application platform, from 2001 to 2006. Burns spent five years with PricewaterhouseCoopers in the United States and Italy and received a B.A. in Business Administration with a concentration in Accounting from the University of Washington.

Barney Saunders, Ph.D., Senior Vice President & General Manager - Life Sciences. Barney Saunders, Ph.D. has served as Senior Vice President & General Manager, Life Sciences, since September 2012 and served as NanoString's Chief Commercial Officer since September 2010. Prior to joining NanoString, Dr. Saunders served as Chief Commercial Officer of Microchip Biotechnologies (now IntegenX), a manufacturer of automation systems enabling micro-sample preparation and analysis for the life sciences, from September 2005 to June 2010. Prior to joining Microchip Biotechnologies, Dr. Saunders served as General Manager at Agilent Technologies from 2000 to 2004, where he led the team that launched the first commercially-available, complete genome arrays for human, rat and mouse and also entered the array CGH (comparative genomic hybridization) market. Dr. Saunders began his career with Amersham International, where he held a variety of commercial positions, of increasing responsibility, in the United States and Europe from 1988 to 2000. Dr. Saunders received a B.Sc. Hons in Biological Sciences and Ph.D. in Rice Resistance Gene Expression from Birmingham University, England.

Bruce J. Seeley, Senior Vice President & General Manager - Diagnostics. Bruce J. Seeley has served as Senior Vice President & General Manager, Diagnostics, since May 2012. Prior to joining NanoString, Seeley was Executive Vice President, Commercial, at Seattle Genetics (OP), from October 2009 to March 2012. While at Seattle Genetics, Seeley built and led the commercial organization and successfully launched Seattle Genetics' first product: ADCETRIS, a targeted therapy for lymphoma. Prior to Seattle Genetics, Seeley served in various commercial roles at Genentech, Inc. from August 2004 to October 2009. From 2006 to 2009, he served as Genentech's Senior Director, Marketing, HER2 Brands, where he led the launch of HERCEPTIN in adjuvant breast cancer. From 2004 to 2006, he served as Genentech's Senior Director of Pipeline Brand Management and BioOncology Business Unit Operations, leading strategy and cross franchise commercial activities. From 2000 to 2004, Seeley worked for Aventis Pharmaceuticals in increasing roles of responsibility, including Senior Director of New Product Commercialization and Licensing, Oncology Global Marketing. Prior to Aventis, he held various marketing and sales positions at Rhone-Poulenc Rorer and Bristol-Myers Squibb. Mr. Seeley received a Bachelor of Arts in Sociology from the University of California at Los Angeles.

Joseph M. Beechem, Ph.D., Senior Vice President of Research & Development. Joseph Beechem, Ph.D. has served as Senior Vice President of Research and Development, since April 2012. Prior to joining NanoString, Dr. Beechem held various positions at Life Technologies, most recently as Vice President, Head of Advanced Sequencing and Head of Global Sequencing Chemistry, Biochemistry and Biophysics from January 2010 to April 2012. From December 2007 to December 2012, he served as Chief Technology Officer of Life Technologies. During his career



at Life Technologies, he led the design and development of multiple genetic analysis technologies, the latest advanced SOLiD sequencing technology and the single molecule nano-DNA sequencing technology. Prior to joining Life Technologies, Dr. Beechem was Chief Scientific Officer at Invitrogen, a publicly-traded biotechnology company that acquired Applied Biosystems in November 2008 to form Life Technologies, from August 2003 to December 2007 and Director of Biosciences at Molecular Probes, a biotechnology company acquired by Invitrogen in 2003, from August 2000 to August 2003. Prior to his industry experience, Dr. Beechem led an NIH-funded research laboratory for 11 years as a tenured associate professor at Vanderbilt University. He has authored or co-authored more than 100 peer-reviewed papers in diverse fields such as biomathematics, physics, chemistry, physiology, spectroscopy, diagnostics and biology. Dr. Beechem is also named on nearly 30 U.S. patents or patent applications and has served on a number of editorial and scientific advisory boards. He received a B.S. in Chemistry and Biology from Northern Kentucky University and a Ph.D. in Biophysics from The Johns Hopkins University.

# NanoString (NSTG) Income Statement

Dan Leonard, 212-277-6116 dan.leonard@leerink.com

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thousands, except EPS)	2010	2011	Mar-12	Jun-12	Sep-12	Dec-12	2012	Mar-13	Jun-13e	Sep-13e	Dec-13e	2013e	2014e	2015e
Revenue														
Product	\$11,506	\$17,109	\$3,833	\$5,335	\$5,456	\$6,235	\$20,859	\$5,338	\$6,295	\$7,493	\$9,417	\$28,543	\$50,086	\$80,447
Service	<u>224</u>	<u>691</u>	<u>669</u>	608	<u>579</u>	<u>258</u>	<u>2,114</u>	<u>338</u>	<u>365</u>	405	<u>400</u>	<u>1,508</u>	<u>1,583</u>	<u>1,742</u>
Total revenue	11,730	17,800	4,502	5,943	6,035	6,493	22,973	5,676	6,660	7,898	9,817	30,051	51,670	82,188
COGS	<u>9,128</u>	<u>9,777</u>	2,655	3,334	3,086	3,286	12,361	<u>2,882</u>	3,530	4,054	<u>4,873</u>	<u>15,339</u>	21,247	29,830
Gross profit	2,602	8,023	1,847	2,609	2,949	3,207	10,612	2,794	3,130	3,844	4,944	14,712	30,423	52,358
SG&A	8,027	9,529	3,165	3,249	4,382	4,690	15,486	6,126	6,927	8,372	12,370	33,794	43,919	50,135
R&D	<u>7,547</u>	<u>8,990</u>	<u>1,998</u>	3,126	2,650	3,860	11,635	3,059	3,863	4,502	<u>5,301</u>	<u>16,725</u>	21,701	22,886
Operating income (loss)	(12,972)	(10,496)	(3,317)	(3,766)	(4,083)	(5,343)	(16,509)	(6,391)	(7,659)	(9,030)	(12,727)	(35,807)	(35,198)	(20,662)
Interest expense (income)	65	589	307	202	107	167	783	382	479	469	473	1,803	1,870	1,836
Other expense, net	(269)	<u>(153)</u>	<u>61</u>	<u>(9)</u>	<u>75</u>	<u>289</u>	<u>416</u>	<u>486</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>486</u>	<u>0</u>	<u>0</u>
Pretax income	(12,768)	(10,932)	(3,685)	(3,959)	(4,265)	(5,799)	(17,708)	(7,259)	(8,138)	(9,499)	(13,200)	(38,096)	(37,068)	(22,499)
Taxes	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	0	0	0	0	<u>0</u>	<u>0</u>	<u>0</u>
Net income	(\$12,768)	(\$10,932)	(\$3,685)	(\$3,959)	(\$4,265)	(\$5,799)	(\$17,708)	(\$7,259)	(\$8,138)	(\$9,499)	(\$13,200)	(\$38,096)	(\$37,068)	(\$22,499)
Basic shares outstanding			8,018	8,018	8,018	8,018	8,018	9,195	9,610	14,645	14,695	12,036	16,820	19,020
Diluted shares outstanding			8,018	8,018	8,018	8,018	8,018	9,195	9,610	14,645	14,695	12,036	16,820	19,020
EPS diluted			(\$0.46)	(\$0.49)	(\$0.53)	(\$0.72)	(\$2.21)	(\$0.79)	(\$0.85)	(\$0.65)	(\$0.90)	(\$3.18)	(\$2.18)	(\$1.18)
EPS growth														
Sales growth		51.7%					29.1%	26.1%	12.1%	30.9%	51.2%	30.8%	71.9%	59.1%
Gross margin	22.2%	45.1%	41.0%	43.9%	48.9%	49.4%	46.2%	49.2%	47.0%	48.7%	50.4%	49.0%	58.9%	63.7%
SG&A % of revenue	68.4%	53.5%	70.3%	54.7%	72.6%	72.2%	67.4%	107.9%	104.0%	106.0%	126.0%	112.5%	85.0%	61.0%
R&D % of revenue	64.3%	50.5%	44.4%	52.6%	43.9%	59.5%	50.6%	53.9%	58.0%	57.0%	54.0%	55.7%	42.0%	27.8%
Operating margin	(110.6%)	(59.0%)	(73.7%)	(63.4%)	(67.7%)	(82.3%)	(71.9%)	(112.6%)	(115.0%)	(114.3%)	(129.6%)	(119.2%)	(68.1%)	(25.1%)
Tax rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
D&A	\$972	\$1,454	\$815	\$573	\$579	(\$20)	\$1,947	\$464	\$450	\$535 (\$2.405)	\$673	\$2,122	\$1,644	\$2,413
EBITDA	(\$12,000)	(\$9,042)	(\$2,502)	(\$3,193)	(\$3,504)	(\$5,363)	(\$14,562)	(\$5,927)	(\$7,209)	(\$8,495)	(\$12,054)	(\$33,685)	(\$33,553)	(\$18,249)
Free cash flow						г					_	Т		
Operarating cash flow	(\$10,965)	(\$10,692)	(\$2,630)	(\$4,113)	(\$3,859)	(\$4,206)	(\$14,808)	(\$9,009)				(\$38,030)	(\$36,668)	(\$21,498)

(117)

(\$4,323)

(428)

(\$15,236)

(136)

(\$9,145)

#### Guidance

CapX

Total revenue

Free cash flow

Notes:

Source: Company reports and Leerink Swann estimates

(1,932)

(\$12,897)

(2,688)

(\$13,380)

(133)

(\$2,763)

(91)

(\$4,204)

(87)

(\$3,946)

(3,829)

(\$41,859)

(3,360)

(\$40,028)

(7,108)

(\$28,605)

NanoString (NSTG)

Balance Sheet (\$ thousands)	Mar-12	Jun-12	Sep-12	Dec-12	Mar-13	Jun-13e	Sep-13e	Dec-13e
Assets			•					
Cash, equivalents, and short-term investments	\$13,783	\$9,412	\$5,361	\$21,692	\$11,794	\$50,532	\$40,842	\$26,121
Accounts receivable	2,613	3,702	4,111	3,322	4,356	4,139	4,927	6,192
Inventory	3,742	4,098	3,905	5,380	5,337	4,642	5,331	6,408
Other	<u>2,201</u>	<u>1,531</u>	2,984	<u>1,320</u>	<u>2,162</u>	3,022	<u>3,597</u>	4,520
Total current assets	22,339	18,743	16,361	31,714	23,649	62,335	54,696	43,242
Property and equipment, net	4,843	4,445	4,040	3,674	3,346	3,597	4,282	5,381
Goodwill	0	0	0	0	0	0	0	0
Other intangibles	0	0	0	0	0	0	0	0
Other	<u>331</u>	<u>383</u>	<u>378</u>	<u>2,018</u>	2,580	2,580	2,580	2,580
Total assets	\$27,513	\$23,571	\$20,779	\$37,406	\$29,575	\$68,513	\$61,558	\$51,204
Liabilities and shareholders' equity								
Notes payable and current maturities of long-term d€	\$0	\$0	\$0	\$2,789	\$4,021	\$1,911	\$1,894	\$1,879
Accounts payable	2,174	1,571	2,259	2,865	1,839	1,709	2,859	3,586
Accruals and other	3,709	4,066	<u>5,306</u>	<u>6,123</u>	<u>5,539</u>	<u>5,540</u>	6,594	8,287
Total current liabilities	5,883	5,637	7,565	11,777	11,399	9,159	11,347	13,753
Long-term debt	7,478	7,447	7,413	9,970	8,814	10,828	10,735	10,648
Other	3,230	3,052	<u>2,866</u>	<u>2,265</u>	6,206	<u>6,206</u>	<u>6,206</u>	6,206
Total liabilities	\$16,591	\$16,136	\$17,844	\$24,012	\$26,419	\$26,193	\$28,288	\$30,606
Shareholders' equity	\$10,922	\$7,435	\$2,935	\$13,394	\$3,156	\$42,320	\$33,270	\$20,597
Total liabilities, shareholders' equity, and minority inter-	\$27,513	\$23,571	\$20,779	\$37,406	\$29,575	\$68,513	\$61,558	\$51,204



# **Disclosures Appendix Analyst Certification**

I, Dan Leonard, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.



	Distribution of Ratings/Investment Bank	ing Services (IE	,	erv./Past 12 Mos.
Rating	Count	Percent	Count	Percent
BUY [OP] HOLD [MP]	103 61	62.80 37.20	30 2	29.00 3.00
SELL [UP]	0	0.00	0	0.00

## **Explanation of Ratings**

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

<u>Market Perform (Hold/Neutral):</u> We expect this stock to perform in line with its benchmark over the next 12 months.

<u>Underperform (Sell):</u> We expect this stock to underperform its benchmark over the next 12 months. The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.

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