NanoString Technologies Receives FDA 510(k) Clearance for Prosigna™ Breast Cancer Prognostic Gene Signature Assay

Prosigna Assay on the nCounter® Dx Analysis System Provides Compelling Clinical Data, Clear Patient Report, and Decentralized Testing in Qualified Labs

SEATTLE — September 9, 2013 — NanoString Technologies, Inc., (NASDAQ: NSTG) a provider of life science tools for translational research and molecular diagnostic products, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its Prosigna™ Breast Cancer Prognostic Gene Signature Assay. Based on the PAM50 gene signature, Prosigna is the company's first FDA-cleared *in vitro* diagnostic assay and uses the gene expression profile of cells found in breast cancer tissue to assess a patient's risk of distant recurrence of disease. The Prosigna Assay is performed using the nCounter® Dx Analysis System, which can be placed in qualified laboratories throughout the United States, empowering oncologists and pathologists to quickly and easily meet the testing needs of their breast cancer patients.

"Receipt of FDA 510(k) clearance for Prosigna marks a key milestone for NanoString and is an important step forward in the treatment of breast cancer. This achievement is a testament to the ongoing dedication and professionalism of our team, and the commitment of our collaborators," said Brad Gray, President and Chief Executive Officer of NanoString Technologies. "Prosigna illustrates our approach of using nCounter technology to translate genomic discoveries into powerful *in vitro* diagnostic products, and it represents a significant growth opportunity beyond our robust life sciences research business."

The Prosigna Assay is intended for use as a prognostic indicator for distant recurrence-free survival at 10 years, and 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 Assay reports the Prosigna Score (referred to as Risk of Recurrence Score, or ROR Score, in the scientific literature, including the TransATAC study recently published in the *Journal of Clinical Oncology*[1]) 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.

Other key features of the Prosigna Breast Cancer Prognostic Gene Signature Assay include:

- All-in-one assay consumables, including RNA extraction kits, allowing laboratories to test as little as a single section of formalin-fixed paraffin embedded (FFPE) tumor tissue
- High-throughput workflow allowing each nCounter Dx Analysis System to process up to 30 patient samples per eight hour work day

[1] Dowsett M. et al. on behalf of the ATAC and LATTE Trialists Group. 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*. ePub ahead of print July 1, 2013 as 10.1200/JCO.2012.46.1558

- Automated generation of personalized full-color patient reports that can be quickly and easily shared electronically with ordering oncologists

Bruce Seeley, Senior Vice President & General Manager of Diagnostics of NanoString Technologies commented: “We believe that the compelling clinical data, clear patient reporting, and unique delivery model position Prosigna for success in the U.S. market. By integrating the Prosigna Assay into existing laboratory workflows, we are offering physicians and patients seamless and timely access to clinical insights and a powerful tool that can aid in making more informed treatment decisions.”

Prosigna-enabled nCounter Dx Analysis Systems are expected to be available for placement in high-complexity Clinical Laboratory Improvement Amendments (CLIA) certified laboratories late in the fourth quarter of 2013. Prosigna testing services are expected to be available through qualified U.S. clinical laboratories beginning in the first quarter of 2014.

Conference Call
NanoString management will host an investment community conference call on Tuesday September 10 beginning at 5:30am PT / 8:30am ET to discuss these developments. Individuals interested in listening to the conference call may do so by dialing (888) 793-9492 for domestic callers, or (734) 385-2643 for international callers, or from the webcast on the investor relations section of the company's website at: www.nanostring.com. The webcast will be available on the company's website for 14 days following the completion of the call.

About the Prosigna™ Breast Cancer Prognostic Gene Signature Assay
Prosigna provides a risk category and numerical score for assessment of the risk of distant recurrence of disease at 10 years in postmenopausal women with node-negative (Stage I or II) or node-positive (Stage II), hormone receptor-positive (HR+) breast cancer. Based on the PAM50 gene signature initially discovered by Charles Perou, Ph.D. and colleagues, the Prosigna Assay is an *in vitro* diagnostic tool that utilizes gene expression data weighted together with clinical variables to generate a risk category and numerical score, to assess a patient’s risk of distant recurrence. The Prosigna Assay measures gene expression levels of RNA extracted from formalin-fixed paraffin-embedded (FFPE) breast tumor tissue.

The Prosigna Assay requires minimal hands-on time and runs on NanoString's proprietary nCounter Dx Analysis System, which offers a reproducible and cost-effective way to profile many genes simultaneously with high sensitivity and precision.

The Prosigna Assay will be available for diagnostic use when ordered by a physician in the U.S. The Prosigna Assay has been CE-marked and is available for use by healthcare professionals in the European Union and other countries that recognize the CE Mark and in which Prosigna is registered.

Prosigna is not intended for diagnosis, to predict or detect response to therapy, or to help select the optimal therapy for patients in the U.S.

For more information, please visit www.prosigna.com.

About NanoString Technologies, Inc.
NanoString Technologies provides life science tools for translational research and molecular diagnostic products. The company's nCounter® Analysis System, which has been employed in basic and translational research since it was first introduced in 2008 and cited in more than 240 peer-reviewed publications, has also now been applied to diagnostic use as the nCounter Dx Analysis System. The company's technology offers a cost-effective way to easily profile the expression of hundreds of genes, miRNAs, or copy number variations, simultaneously with high sensitivity and precision. The company's technology enables

a wide variety of basic research and translational medicine applications, including biomarker discovery and validation. The nCounter-based Prosigna™ Breast Cancer Prognostic Gene Signature Assay is the first *in vitro* diagnostic assay to be marketed through the company's diagnostics business.

For more information, please visit www.nanostring.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the growth opportunity Prosigna represents, the potential throughput of nCounter Dx Analysis Systems running the Prosigna Assay, the timing of the U.S. commercial launch of Prosigna and the impact of the Prosigna launch on the company's business. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: risks associated with keeping pace with rapidly changing technology and customer requirements; risks regarding our ability to successfully introduce new products; risks that new market opportunities may not develop as quickly as expected; risks associated with competition in marketing and selling products; risks of increased regulatory requirements; as well as the other risks set forth in the company's filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof. NanoString Technologies disclaims any obligation to update these forward-looking statements.

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