NanoString Technologies Inc
Form 8-K
September 09, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the

Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 9, 2013

NanoString Technologies, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-35980**	**20-0094687**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

530 Fairview Avenue North, Suite 2000

Seattle, Washington 98109

(Address of principal executive offices, including zip code)

(206) 378-6266

(Registrant s telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On September 9, 2013, NanoString Technologies, Inc. (the Company) issued a press release announcing 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 (Prosigna), which provides a patient s risk of distant recurrence of breast cancer.

Prosigna is intended for use as a prognostic indicator for distant recurrence-free survival at 10 years in patients who are treated with adjuvant endocrine therapy when used in conjunction with other clinicopathological factors. Prosigna is indicated in female breast cancer patients who have undergone surgery in conjunction with locoregional treatment consistent with standard of care. The indicated patients are post-menopausal women with hormone receptor-positive breast cancer that is either Stage I or II lymph node-negative, or Stage II lymph node-positive with one to three positive nodes. Prosigna is not intended for patients with four or more positive nodes, or for diagnosis, to predict or detect response to therapy, or to help select the optimal therapy for patients.

In the United States, Prosigna s test output will be a patient-specific report that includes both a risk category and an integer risk score, called the Prosigna score, ranging from zero to 100. The Prosigna score relates to an individual patient s probability of distant recurrence within 10 years and is identical to the risk of recurrence (ROR) score referred to in scientific publications and in the Company s CE-marked version of Prosigna. Patients with lymph node-negative disease are categorized into one of three risk groups (low, intermediate or high). Patients with one to three positive lymph nodes are categorized into one of two risk groups (low or high). Node-positive breast cancer patients with Prosigna scores of greater than 80 are automatically considered high risk and their specific scores are reported as greater than 80. The report notes that results apply to patients treated for five years with endocrine therapy as in the patient population tested in the clinical validation study.

Laboratories administering the Prosigna assay will require the Company s nCounter Dx Analysis System, related software and the Prosigna assay kits. The Company s nCounter Dx Analysis System can run up to 10 patient samples in a single run and complete three runs (or 30 patient samples) in an eight hour workday. Assuming a single nCounter Dx Analysis System runs five days per week, approximately 7,500 Prosigna assays can be processed per year. The Company estimates that in 2012 between 65,000 and 75,000 genomic breast cancer assays were run in the United States.

Prosigna-enabled nCounter Dx Analysis Systems are expected to be available for shipment to initial U.S. clinical laboratory customers late in the fourth quarter of 2013 and Prosigna testing services are expected to be available through qualified U.S. clinical laboratories beginning in the first quarter of 2014. To support the commercial launch, the Company is taking multiple steps, including working to incorporate final input from the FDA into the Prosigna software and labeling, building an inventory of nCounter Dx Analysis Systems and the 510(k)-cleared Prosigna kits, preparing materials to support reimbursement of Prosigna and recruiting additional personnel to support the commercial launch.

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are identified by such words as believe, expect, anticipate, estimate, plan, may and words of similar import and are based on current expectations that involve risks and uncertainties, such as our plans, objectives, expectations and intentions. All statements other than historical or current facts, including, without limitation, statements about our plans for the U.S. commercial launch of Prosigna, the potential throughput of nCounter Dx Analysis Systems running the Prosigna assay and the estimated number of breast cancer assays run in the United States. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. These statements, like all statements in this report, speak only as of their date.

Item 9.01 Financial Statements and Exhibits.
(d) Exhibits.

Exhibit Number	Description
99.1	Press release dated September 9, 2013.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

NanoString Technologies, Inc.

By: /s/ R. Bradley Gray
R. Bradley Gray
President and Chief Executive Officer

Date: September 9, 2013

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated September 9, 2013.