

NanoString Technologies Inc
Form 8-K
December 11, 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): December 10, 2013

NanoString Technologies, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

001-35980
(Commission

File Number)
530 Fairview Avenue North, Suite 2000

20-0094687
(IRS Employer

Identification No.)

Edgar Filing: NanoString Technologies Inc - Form 8-K

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 7.01 Regulation FD Disclosure.

On December 10, 2013, NanoString Technologies, Inc. (the Company) issued a press release announcing the adoption of its Prosigna Breast Cancer Prognostic Gene Signature Assay (Prosigna) by two comprehensive cancer centers and three commercial laboratories, which currently serve breast cancer patients throughout the United States. These five initial adopters expect to begin providing Prosigna testing services during the first half of 2014, with the first of these laboratories anticipating providing testing services beginning in the first quarter of 2014.

The Company also announced that it has begun building its North American Prosigna sales team by hiring Rick Schirmer as Vice President of North America Diagnostics. Mr. Schirmer joins the Company from Sanofi, where over a 24 year career he rose to the position of Vice President of Customer Engagement for Oncology, Hematology and Transplant, a role in which he was responsible for Sanofi's U.S. oncology sales forces. The Company also has actively begun recruiting sales professionals to build a dedicated sales force to educate medical oncologists about Prosigna. The Company intends to use a phased approach to build its sales force, initially hiring approximately 15 field based oncology-focused sales representatives during the first quarter of 2014, with the expectation that the sales force will grow once milestones related to treatment guideline inclusion and third-party payer reimbursement have been achieved. The Company also intends to build a small team of medical science liaisons to complement the sales force and expects to continue to rely on its existing sales professionals to place nCounter® Dx Analysis Systems in clinical labs.

The U.S. list price for a Prosigna kit is expected to be \$2,080 per test (which is comparable to the pricing in jurisdictions accepting the CE-marked version of Prosigna). The Company plans to sell Prosigna kits to its lab customers, who will be responsible for providing the testing service, contracting and billing payers. The Company plans to sell Prosigna kits to clinical laboratories on a fixed dollars-per-kit basis, which would not expose the Company to direct third-party payer reimbursement risk. However, the Company anticipates providing customary volume discounts, and in some cases, introductory pricing during the period in which third-party payer reimbursement is being established. As a result, the Company expects the average selling price per Prosigna test to be between \$1,500 and \$2,000.

Because the Company's customers are assuming the third-party payer reimbursement risk, the Company expects to record revenue on Prosigna kit sales when they are shipped to the Company's customers; however, the usage and sales of Prosigna kits are expected to be relatively slow in the first few quarters of 2014. Given that the first group of initial adopters will be coming on line during the first half of 2014, the Company does not expect meaningful revenues in the first quarter of 2014. In the second half of 2014, the potential for third-party payer reimbursement, the inclusion of Prosigna in the National Comprehensive Cancer Network's (NCCN) guidelines and positive coverage decisions from major insurance plans are expected to drive uptake. The Company is continuing its efforts to establish third-party payer reimbursement for Prosigna. The Company also plans to apply in the first half of 2014 to have Prosigna included in the NCCN's treatment guidelines. If the application is considered and approved by the NCCN's guideline committee, it is anticipated that Prosigna would be referenced in the NCCN treatment guidelines in the second half of 2014.

Within Europe, the Company is primarily focused on establishing third-party payer reimbursement for Prosigna testing services. Once positive third-party payer reimbursement decisions are achieved in Europe, the Company anticipates an acceleration in sales growth, but until then, the pace of instrument placements and Prosigna kit sales is expected to remain measured. The Company does not expect any major positive third-party payer reimbursement decisions to substantially accelerate Prosigna revenues in Europe until after 2014.

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 projections of the timing and breadth of Prosigna availability in the United States; expectations regarding the Company's ability to work collaboratively with its customers; expectations regarding the size and projected timing of hiring a dedicated oncology sales force; expectations regarding the Company's ability to achieve widespread third-party payer reimbursement for Prosigna and the timing and nature of Prosigna of third-party payer reimbursement-related decisions; plans for and timing of applications and decisions regarding inclusion of Prosigna in treatment guidelines; expectations regarding average selling price of Prosigna; the timing and nature of revenue recognition for Prosigna sales; and expectations regarding the pace of Prosigna sales. 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 December 10, 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: December 11, 2013

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated December 10, 2013.