NanoString

Prosigna Gains FDA Approval; On Track for Early 2014 Commercial Ramp - ALERT

Overweight

NSTG, NSTG US
Price: $8.78 (intraday - 09:35 AM)

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On Monday, after the market close, Nanostring (NSTG) announced the Prosigna Breast Cancer assay had received 510(k) approval, removing a slight overhang for the stock, although we believe approval before year-end had been largely anticipated. On the investor call this morning, management reiterated plans to commercially launch the assay in 1Q14 with an initial launch to higher volume labs possible in late 2013. We view this announcement positively, as NSTG hit the company's first key timeline since becoming a public company, and we reiterate our Overweight rating.

- **Prosigna gains FDA approval.** NSTG announced that the FDA granted 510(k) clearance for the Prosigna assay with the timing in line to slightly ahead of expectations. As a reminder, Prosigna provides an assessment of a patient's risk called the Prosigna Score (the Risk of Recurrence score was renamed), which is a prognostic score that predicts the probability of cancer recurrence over ten years. For a deeper dive on Nanostring and Prosigna, our recent initiation report can be found here.

- **Label in line with expectations.** On the call, management discussed the Prosigna label, which they negotiated with the FDA, and there were no surprises or follow-up studies required (although intrinsic sub-typing will require an additional PMA). We note that node positive patients will be classified as low or high risk compared to node negative patients, which have three categories (low, intermediate, high risk), although we do not believe this is significant as physicians and patients will have the Prosigna Score of 1-100.

- **Next steps are reimbursement and inclusion in guidelines.** Management commented that now that approval is attained, the company's focus will shift to getting Prosigna included in guidelines and securing reimbursement. The earliest Prosigna will be included in any guidelines is 2014, while the next cycle for a specific code for Prosigna will be 2014, which would establish the code in early 2015. Until the unique code is established, management does not expect reimbursement to be an issue due to the compelling studies that have been published on Prosigna.

- **Remain Overweight.** Following the anticipated FDA approval, we are not making any adjustments to our model and reiterate our Overweight rating and our DCF-based December 2014 price target of $14.

See page 2 for analyst certification and important disclosures.

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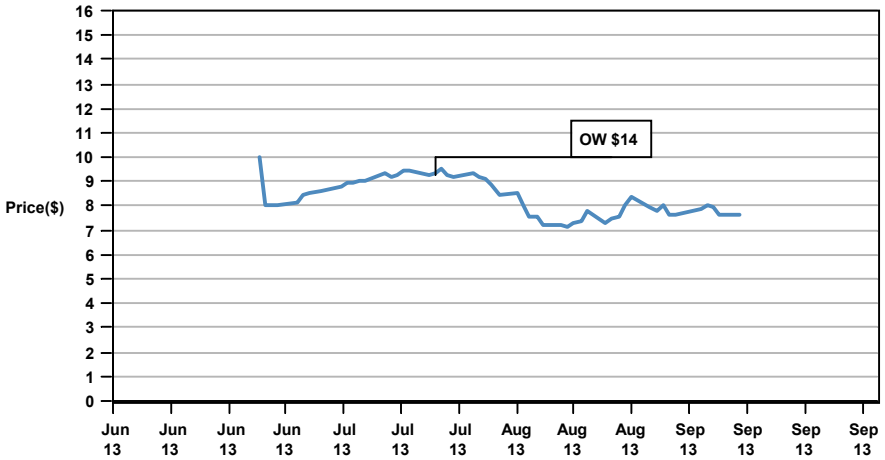
NanoString (NSTG, NSTG US) Price Chart



Date	Rating	Share Price ($)	Price Target ($)
22-Jul-13	OW	9.27	14.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Jul 22, 2013.

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