

May 31, 2012

Market Outperform / Speculative Risk

### Open Road Ahead for VS-507 as FDA Accepts pCR as an Approvable Endpoint

#### MARKET DATA 5/30/2012

Price	\$9.33
Exchange	NASDAQ
Target Price	\$19.00
52 Wk Hi - Low	\$12.24 - \$8.89
Market Cap(MM)	\$196.5
EV(MM)	\$155.4
Shares Out (MM)	21.1
Public Mkt Float (MM)	21.1
Avg. Daily Vol	25,025
Short Interest	393,618

#### BALANCE SHEET METRICS

Cash (MM)	\$47.8
LTD (MM)	\$0.0
Total Debt/Capital	NA
Cash/Share	\$30.67
Book Value(MM)	NA
Book Value/Share	\$5.44

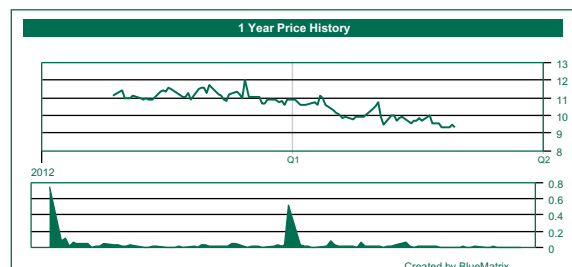
Cash (MM): Includes cash and equivalents, short-term and long-term securities.

#### EARNINGS DATA (\$)

FY - Dec	2011E	2012E	2013E
Q1 (Mar)	--	(0.47)A	--
Q2 (Jun)	--	(0.49)	--
Q3 (Sep)	--	(0.52)	--
Q4 (Dec)	(4.01)	(0.54)	--
Full Year EPS	(10.59)	(2.04)	(1.64)

#### INDICES

DJIA	12,419.9
SP-500	1,313.3
NASDAQ	2,537.4
NBI	1,291.4



FDA published new draft guidance Wednesday supporting the use of pathological complete response as a surrogate endpoint for accelerated approval for developing neoadjuvant therapies intended to treat high-risk early stage breast cancer. Drs. Tanya Prowell of The Sidney Kimmel Comprehensive Cancer Center and Richard Pazdur of FDA provided further commentary on the draft decision in an editorial published in the New England Journal of Medicine yesterday. Both pieces outline FDA's vision for the development of neoadjuvant therapy aimed at shrinking tumors in patients with preoperative localized breast cancer in order to facilitate surgery and ultimately improve survival outcomes. Pathological complete response (pCR) (the absence of invasive cancer cells in the breast and surrounding lymph nodes) has been shown to predict for progression-free and overall survival. As there are currently no approved drugs in the neoadjuvant setting, FDA's acceptance of pCR as a clinical endpoint solidifies a new incentive for drug-developers, offering a shorter time-to-market and reduced initial investment.

While FDA guidance opens the neoadjuvant setting to drug development, emphasis has been placed on addressing patients with triple-negative disease and other sub-types with a high risk of recurrence. According to the proposed guidance, new drugs demonstrating meaningful pCR improvement when combined with a standard adjuvant therapy in a large randomized study (compared to adjuvant therapy alone) would be considered for accelerated approval. In order to satisfy the requirements for full regulatory and continued marketing approval however, drugs would still to demonstrate improvements in PFS or OS, and maintain an acceptable long-term safety profile through matured data. Furthermore, FDA has recommended that trial in the neoadjuvant setting exclude patients with tumors that are ER/PR+, HER2+ or are of lower-grade, who would otherwise derive greater benefit from existing approved therapy, thereby balancing the need for novel early-stage breast cancer therapies with the limited available safety data.

FDA's clarity on the use of pCR is welcome news for VSTM and its lead candidate VS-507. As a reminder, VS-507 is a small molecule Wnt pathway inhibitor directed at specifically killing the cancer stem cell population believed to be responsible for tumor recurrence in patients with in triple negative breast cancer. As VS-507 is currently only in IND tox assessment, the initiation of later-stage trials necessary for regulatory approval remains some time away. That said, the recent announcement from FDA legitimizes VSTM's intended development plans for VS-507, removing considerable uncertainty about the validity of pCR as an approvable endpoint.

We maintain our Market Outperform rating for VSTM shares and \$19 price target. We derive our price target through a combination of methodologies, including a DCF-based valuation of \$17 and a CAGR valuation of \$22. Risks to our valuation include the risk of clinical failure with VS-507 and/or VS-4718/5095 for reasons of safety or inactivity. In our view, the value of VSTM shares will be primarily milestone-driven over the next six to twelve months, as VS-507 completes IND tox assessment.

**Table 1. Upcoming Milestones**

Milestone	Date
• Peer-review scientific journal publication	2H 2012
• IND filing of VS-507 with FDA and initiation of Phase I trial	2H 2012
• IND filing of VS-4718/VS-5095 with the FDA and initiation of Phase I trial	1H 2013

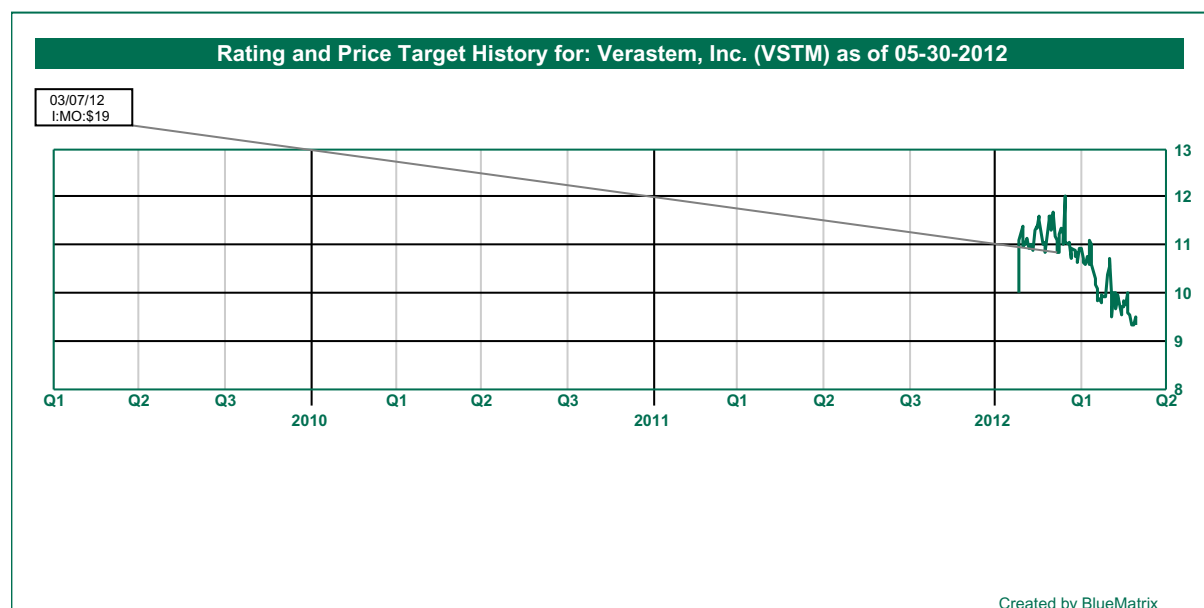
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### RETURN ASSESSMENT

- **Market Outperform (Buy):** The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector, as defined by First Call.
- **Market Perform (Hold):** The common stock of the company is expected to mimic the performance of a passive index comprised of all the common stock of companies within the same sector, as defined by First Call.
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### RISK ASSESSMENT

- **Speculative -** The common stock risk level is significantly greater than market risk. The stock price of these equities is exceptionally volatile.
- **Aggressive -** The common stock risk level is materially higher than market level risk. The stock price is typically more volatile than the general market.
- **Moderate -** The common stock is moderately risky, or equivalent to stock market risk. The stock price volatility is typically in-line with movements in the general market.



### RATING SUMMARY

Distribution of Ratings Table				
Rating	Count	Percent	IB Serv./Past 12 Mos	
			Count	Percent
Market Outperform(MO)	73	63.48%	10	13.70%
Market Perform(MP)	28	24.35%	3	10.71%
Market Underperform(MU)	6	5.22%	0	0.00%
Under Review(UR)	8	6.96%	2	25.00%
Total	115	100%	15	100%

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