Zacks Small-Cap Research

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VolitionRx Ltd (VNRX-NYSE)

VNRX: Could NuQ Become Next Gold-Standard for Pancreatic Cancer?

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	05/07/2013
Current Price (10/09/15)	$4.40
Target Price	**$6.50**

OUTLOOK

VolitionRx is focused on the development of blood-based cancer detection tests using their NuQ technology which aims to marry high accuracy and reliability typically only achieved with invasive and costly diagnostic methods with the convenience, low-cost and non-invasive nature characteristic of many of the current cancer screening tests. The tests address potentially multi-billion $ markets. Initial clinical data has been very encouraging, showing impressive sensitivity/specificity. Data from ongoing studies is expected to be released on a regular basis and should provide further insight into the performance of the technology and provide support to regulatory filings. CE Mark of a panel of colorectal cancer tests for sale to the clinical market in Europe is anticipated this year. Launch in 2016. Pancreatic cancer data highly encouraging – this could be next test to market. US strategy may entail launch of LDT as pursue PMA. Despite risks such as that VNRX will need to raise significant capital before they reach cash flow positive, we think the shares are very attractive at the current market price. Our DCF model values the stock at about $6.50/share.

SUMMARY DATA

52-Week High	**$5.25**
52-Week Low	**$3.00**
One-Year Return (%)	**9.73**
Beta	**-2.67**
Average Daily Volume (sh)	**41,027**
Shares Outstanding (mil)	**18**
Market Capitalization ($mil)	**$85**
Short Interest Ratio (days)	**0.38**
Institutional Ownership (%)	**5**
Insider Ownership (%)	**33**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in '000)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	$0 A	$0 A	$15 A	$0 A	$15 A
2015	$0 A	$0 A	$0 E	$0 E	$0 E
2016					$205 E
2017					$1641 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.18 A	$0.06 A	-$0.44 A	-$0.07 A	-$0.61 A
2015	-$0.12 A	-$0.10 A	-$0.12 E	-$0.11 E	-$0.45 E
2016					-$0.35 E
2017					-$0.30 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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Pancreatic Panel Shows 92% Sensitivity @ 90% Specificity: Study Published in *Clinical Epigenetics.* Pancreatic Cancer Panel May Be Next Product Introduction, Could It Become The New "Gold Standard"???….

This morning (Oct 12) VNRX announced that results of their pancreatic cancer pilot study were published in the online version of Clinical Epigenetics. The study included 59 individuals; 25 with stage IIa or stage IIb pancreatic cancer (i.e. early-stage, operable cancers), 24 healthy subjects and 10 with other pancreatic non-cancer disorders (i.e. benign pancreatic disease). Blood samples were taken from patients prior to being treated at Skane University Hospital in Lund, Sweden. Healthy samples came from a local blood bank.

In January VNRX announced interim results which showed a five-assay NuQ panel correctly identified 21 of the 25 cancer cases (84% sensitivity) at a 90% specificity among the healthy subjects (i.e. - two false positives). This panel was also able to distinguish 18 of the pancreatic cancer cases from healthy individuals or those with other pancreatic non-cancer disorders with a 72% sensitivity at 90% specificity (three false positive results; one from healthy group and two from benign group).

As we noted in January, we characterized the interim results as highly encouraging given the impressive accuracy seen with the interim data. However, we are even more inspired with the results of the full data set which included, in addition to the initial five-assay panel, a four-NuQ assay panel in combination with a generic CA19-9 ELISA test. Carbohydrate antigen 19-9 (CA 19-9) is considered the current gold-standard diagnostic for pancreatic cancer testing and is used as a benchmark for comparing novel pancreatic cancer diagnostics. This is despite it not being particularly accurate – with reported sensitivity/specificity of 79%/82%.

But when four of the five NuQ assays in the original panel (the least incrementally additive assay was excluded) were combined with CA 19-9, VNRX was able to achieve higher accuracy as compared to both their initial five-assay panel as well as to CA 19-9. This four NuQ panel plus CA 19-9 achieved 92% sensitivity using a 90% specificity (identified 23 of 25 cancer cases) on discriminating cancer versus healthy subjects as well as versus healthy and benign subjects. This is significantly higher than CA 19-9 alone. The table below illustrates the superiority of the four NuQ panel plus CA 19-9 as compared to CA 19-9 alone, the four NuQ assay panel alone and the original five NuQ assay panel. In addition to the high accuracy of the four NuQ panel plus CA 19-9, it is also noteworthy that all of the three false positives were from the benign group, with none coming from the healthy group (i.e. – 100% specificity versus healthy group).

Table 3 Performance of cfnucleosome biomarker panels with and without CA 19-9

	CA 19-9		4 NuQ® assays		5 NuQ® assays		4 NuQ® assays + CA 19-9	
Clinical question	AUC	Sensitivity (%) (90 % specificity)	AUC	Sensitivity (%) (90 % specificity)	AUC	Sensitivity (%) (90 % specificity)	AUC	Sensitivity (%) (90 % specificity)
Cancer vs. healthy	0.87	80	0.91	68	0.95	84	0.98	92
Cancer vs. healthy and benign	0.84	72	0.90	64	0.92	72	0.94	92

SOURCE: Bauden et al. Clinical Epigenetics (2015) 7:106

Despite CA 19-9's high risk of false negative results and the American Society of Clinical Oncology discouraging its use, it remains the gold standard for diagnosis of pancreatic cancer. However, its main use has mostly been relegated to determine whether a tumor is secreting carbohydrate antigen 19-9 and to monitor the level following treatment. The results of this small pilot study suggest NuQ assays in combination with CA 19-9 could have more than high enough accuracy as a clinical pancreatic cancer diagnostic and would be the only test able to identify early stage pancreatic cancer with relatively very high sensitivity.

Diagnosis of pancreatic cancer is almost always a death sentence given that no tests currently on the market can reliably identify early-stage pancreatic cancer. Currently only about 6% of people diagnosed with pancreatic cancer survive five years or more. The USPSTF has a grade D recommendation on pancreatic cancer screening, recommending "against routine screening for pancreatic cancer in asymptomatic adults using abdominal palpitation, ultrasonography, or serological markers." The USPSTF notes that they "found no evidence that screening for pancreatic cancer is effective in reducing mortality. There is a potential for significant harm due to the very low prevalence of pancreatic cancer, limited accuracy of available screening tests, the invasive nature of diagnostic tests, and the poor outcomes of treatment. As a result, the USPSTF concluded that the harms of screening for pancreatic cancer exceed any potential benefits."

As such a test that could identify pancreatic cancer at an early stage may allow for more effective clinical intervention and vastly improve mortality rates. If VNRX can demonstrate similar results of this pilot study in larger trials, we think eventual FDA approval would be almost a given and believe it is reasonable that this panel could one day become the new gold standard for pancreatic cancer diagnosis. Importantly, CA 19-9 is a generic ELISA test so it is easily available with no intellectual property protection and, therefore, can be freely combined and commercialized in a VNRX panel.

Next steps likely include at least one more small clinical study which, assuming positive results, will be followed by one or more much larger (500+ subjects) studies. We expect to hear more about VNRX's specific plans in the coming weeks or months but we think it is not unreasonable that larger, pivotal pancreatic cancer studies could be completed sometime next year. If results are confirmed, we expect pancreatic cancer will be VNRX's second (after colorectal cancer) assay commercialized, which could potentially happen by late 2016 or 1H 2017. We note that we do not yet include contribution from a pancreatic cancer assay in our model (or our related valuation) but expect to do so if high accuracy of the panel is maintained over the course of additional clinical trials. And if it is, we expect this will provide another inflection point opportunity for the stock price.

OUTLOOK / VALUATION / RECOMMENDATION

VNRX continues to make progress with an initial CE Mark filing. Initial CE Mark, for NuQ X001, came in September. While we had hoped entry into the European market for a colorectal cancer test would come sometime in 2015, slight delays have us now modeling launch in Europe in 2H 2016. With studies ongoing in several other cancer types, including pancreatic and breast, among several others, subsequent CE Marking in other cancers could potentially come in fairly short order. We also expect VNRX will look to continually enhance the performance of their commercialized panels. Ongoing study data will also be used to support reimbursement.

Relative to the U.S. market, we think VNRX's current game-plan – that is, to initially tap the LDT channel via licensing agreement(s) with established CLIA lab(s), makes a lot of sense. Not only is this an earlier revenue opportunity in the U.S. as the company continues to pursue FDA approval, it also provides additional and valuable clinical experience and awareness benefits.

In terms of the road towards eventual FDA approval – which is the ultimate quest and one which we think could rapidly steepen VNRX's revenue curve – this could be a years-long process and require U.S.-based clinical studies. If, however, FDA discussions reveal that a bridge study complementing data from already ongoing studies is sufficient, it's possible the PMA pathway could be more abbreviated.

In terms of the accuracy hurdle that a PMA filing may have to clear - one yardstick that may be relevant to look at is that an FDA advisory panel recently recommended PMA approval of Epigneomics' Epi proColon colorectal cancer test which in a pivotal trial versus FIT showed sensitivity of 79% and specificity of 68%. This compares to VNRX's interim data from the Danish retrospective study, which showed the four-panel NuQ tests were able to detect 81% of colorectal cancers (63% of polyps) at 78% specificity. Epi proColon has also shown relatively low sensitivity (20%) in precancerous polyps – which is another potential indication that NuQ could demonstrate superior accuracy. In addition, we think there is a very real possibility that the additional of more than four assays to the panel will improve the accuracy of VNRX's technology even further.

Valuation Remains Attractive…

Based on our DCF model which goes out to year 2025 and uses a 9.5% discount rate (based on CAPM) and 2% terminal growth rate, VNRX is valued at $6.28/share (which we round to $6.50). Our model and assumptions will be updated if appropriate based on news flow which could also influence valuation. We will be eagerly awaiting additional clinical data in several cancers which, assuming positive, could prompt upward revisions to our modeled revenue and related valuation. For example, as we noted, we have yet to model any contribution from a potential pancreatic cancer panel but will likely do so if high accuracy of the diagnostic is maintained in subsequent studies.

As it is now, we value VNRX at $6.50/share. We feel the current market price ($4.40) remains cheaper than warranted and undervalues the company. We recommend accumulating the stock up towards our $6.50 price target. We think additional and ongoing positive clinical data, including the near-term release of results from the retrospective and prospective colorectal cancer studies, should further benefit appreciation of the share price towards our target. We are maintaining our Buy rating.

FINANCIAL MODEL

VolitionRx Ltd.

	2014 A	Q1 A	Q2 A	Q3 E	Q4 E	2015 E	2016 E	2017 E	2018 E
Revenue	$14.8	$0.0	$0.0	$0.0	$0.0	$0.0	$205.6	$1,640.5	$4,274.1
YOY Growth	-	-	-	-	-	*-100.0%*	-	*698.0%*	*160.5%*
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$42.0	$438.7	$1,177.0
Gross Income	$14.8	$0.0	$0.0	$0.0	$0.0	$0.0	$86.3	$557.8	$1,290.8
Gross Margin	*100.0%*	-	*100.0%*	*100.0%*	*100.0%*	*#DIV/0!*	*58.0%*	*66.0%*	*69.8%*
SG&A	$1,908.2	$1,139.1	$660.6	$812.0	$722.0	$3,333.7	$3,751.0	$3,888.0	$5,100.0
%SG&A	-	-	-	-	-	-	*1824.5%*	*237.0%*	*119.3%*
R&D	$4,044.1	$1,210.8	$1,357.0	$1,321.0	$1,344.0	$5,232.8	$4,455.0	$4,215.0	$3,988.0
% R&D	-	-	-	-	-	-	*2166.9%*	*256.9%*	*93.3%*
Asset Impairment	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($5,937.5)	($2,349.9)	($2,017.6)	($2,133.0)	($2,066.0)	($8,566.5)	($8,119.7)	($7,545.2)	($7,797.2)
Operating Margin	-	-	-	-	-	-	-	*-459.9%*	*-182.4%*
Total Other Expense (Income)	$2,275.7	($339.7)	($146.8)	$0.0	$0.0	($486.6)	$0.0	$0.0	$0.0
Pre-Tax Income	($8,213.2)	($2,010.1)	($1,870.8)	($2,133.0)	($2,066.0)	($8,079.9)	($8,119.7)	($7,545.2)	($7,797.2)
Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
FX translation	$44.1	$0.0	($45.3)	$0.0	$0.0	($45.3)	$0.0	$0.0	$0.0
Net Income	($8,257.2)	($2,010.1)	($1,825.5)	($2,133.0)	($2,066.0)	($8,034.6)	($8,119.7)	($7,545.2)	($7,797.2)
Net Margin	-	-	-	-	-	*#DIV/0!*	*-3949.4%*	*-459.9%*	*-182.4%*
EPS	($0.61)	($0.12)	($0.10)	($0.12)	($0.11)	($0.45)	($0.35)	($0.30)	($0.28)
YOY Growth	-	-	-	-	-	-	-	-	-
Diluted Shares O/S	13,435	16,462	17,946	18,250	18,418	17,769	23,000	25,000	28,000

Brian Marckx, CFA

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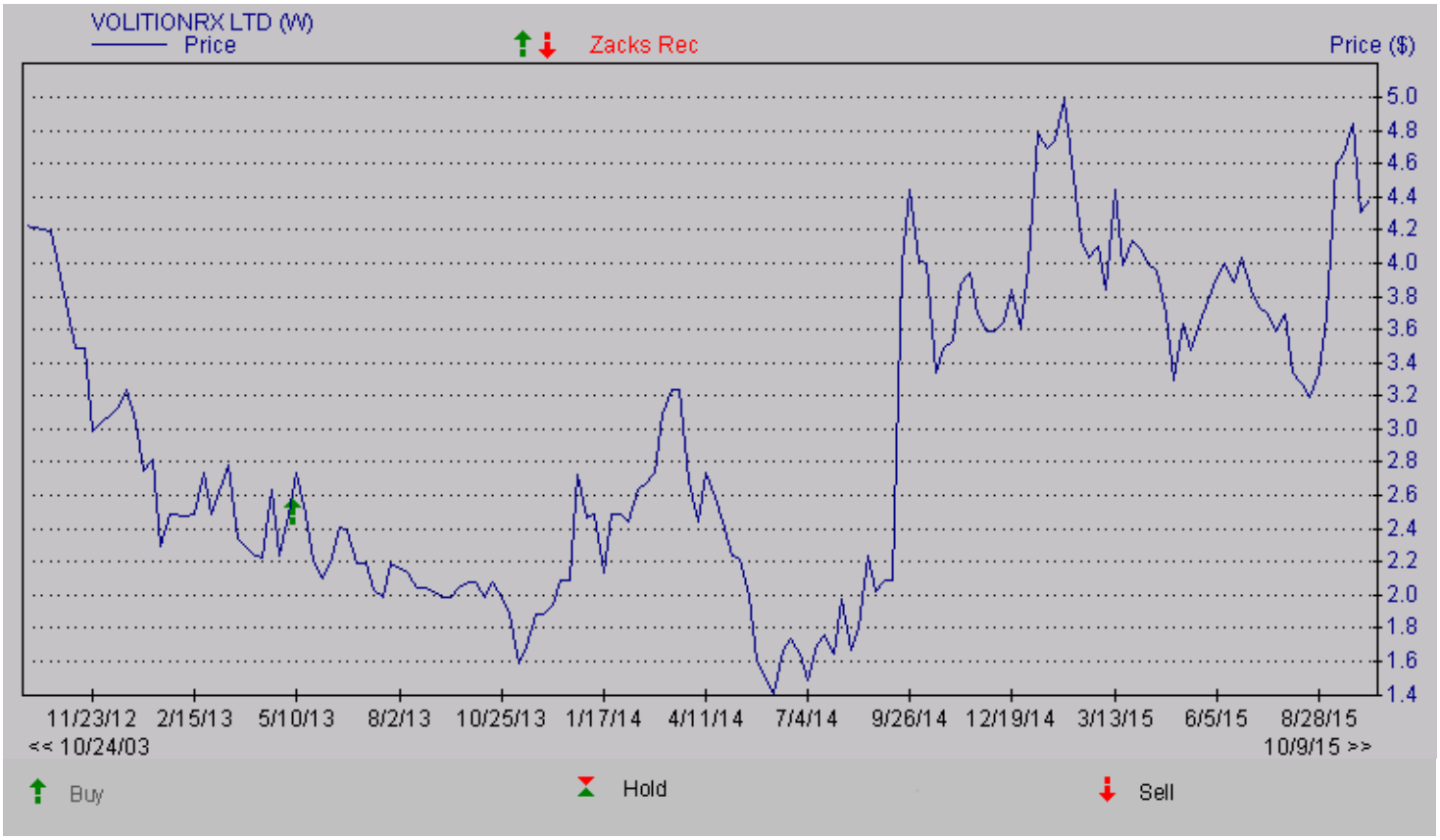

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