Zacks Small-Cap Research

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VolitionRx Ltd (VNRX-OTC)

VNRX: 938-Sample Set Supports Earlier Findings of High Accuracy in Colon Cancer Detection

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	05/07/2013
Current Price (09/11/14)	$2.30
Target Price	**$7.00**

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. Larger studies have since been initiated. Data from ongoing studies is expected to be released on a regular basis. – which should provide further insight into the performance of the technology. Tests are now for sale for RUO. CE Mark for sale to the clinical market in Europe is anticipated in late 2014 or early 2015 which should help fund the U.S. development program. 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 $7/share..

SUMMARY DATA

52-Week High	**$3.25**
52-Week Low	**$1.25**
One-Year Return (%)	**-18.75**
Beta	**-0.46**
Average Daily Volume (sh)	**13,859**
Shares Outstanding (mil)	**13**
Market Capitalization ($mil)	**$31**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**41**
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 2014 Estimate	**N/A**
P/E using 2015 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)
2013	$0 A	$0 A	$0 A	$0 A	$0 A
2014					$79 E
2015					$944 E
2016					$4342 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.09 A	-$0.10 A	-$0.08 A	-$0.07 A	-$0.34 A
2014	-$0.18 A	$0.06 A	-$0.09 E	-$0.09 E	-$0.28 E
2015					-$0.31 E
2016					-$0.14 E

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

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WHAT'S NEW…..

Data From Largest Sample Base To-Date Supports Earlier Findings of NuQ Utility for Colon Cancer:
As we noted in our previous update, we had anticipated that announcement of data from the initial 1,000 patients in the retrospective colon cancer study being done at Hvidovre Hospital (Denmark) would be forthcoming. That announcement came this morning (9/11/14) and was presented at the Aegis Capital Healthcare Conference with results supporting earlier findings in studies with much smaller sample bases. The data continues to show high specificity and sensitivity of VNRX's NuQ technology in the detection of colorectal cancer.

And while over the prior 18 to 20 months at least three separate studies had indicated potential real utility of NuQ in colon cancer detection, these studies were relatively small. These included;

> In late 2012 results from a small internal study were announced. The study included 105 patients including 31 healthy patients and those with cancer of the colon(n=25), breast(n=25), and lung(n=24). In the colorectal cancer cohort the NuQ assay had a 76% sensitivity (19 of 25 patients detected), 90% specificity (3 of 31 healthy samples false positive).

> In November 2013 results from the Bonn University study were announced and presented at CNAPS. Data was presented from 90 patients (24 colorectal cancer (CRC), 10 benign colorectal diseased (BCD), and 56 healthy controls (HC)) tested with VolitionRx's NuQ-5m assay for colorectal cancer. Results were encouraging and showed the assay was able to detect 75% of patients with colorectal cancer with a 70% specificity. These findings were confirmed on a second set of 113 patients (49 CRC, 26 BCD, 38 HC). The assay detected significantly (at 95% CI) lower levels of NuQ-5mc in CRC and BCD compared to HC although no differences were found between CRC and BCD. Relative to differentiation of CRC from HC, sensitivities improved from 33% at a 95% specificity to 75% at a 70% specificity.

> In December 2013 preliminary results from a prospective longitudinal study (done at Biobank of CHU UCL Mont-Godinne, an academic hospital in Yvoir, Belgium) which monitored patients as they progressed through diagnosis and treatment of colorectal cancer were announced. Enrollment included patients with a potential digestive pathology such as suspected colorectal cancer, polyps, Crohn's disease and colitis. The goal of the study was for VNRX's NuQ to be able to distinguish between patients with cancer and those with digestive conditions that indicate similar symptoms. The preliminary results from 39 patients showed that when two of the NuQ tests were combined and used together, they were able to detect 85% of cancers with an 85% specificity. The combination test was also able to detect more than 50% of precancerous polyps.

The preliminary results announced this morning come from the analysis of 938 patients from the ~4,800-patient retrospective colon cancer study being done in collaboration with Hvidovre Hospital at the University of Copenhagen in Denmark under the direction of Professor Hans Jorgen Nielsen (Professor of Surgical Oncology at the Department of Surgical Gastroenterology). The study includes samples from patients over 50 years of age which are symptomatic of colorectal cancer. Analysis supported findings from the earlier, smaller studies and showed the three-panel NuQ tests were able to detect 84% of colorectal cancers (60% of polyps) at 78% specificity. Importantly, the NuQ panel was able to detect cancers at various stages including those at an early stage. Given that colorectal cancer is more effectively treated and has a much higher survival rate if found early, the ability of a diagnostic to detect the disease at the earliest stages is critical to maximize chances for patient long-term survival. The preliminary results did not provide specifics in terms of breakdown of positive samples by cancer stage, although management did note in the presentation that the 84%/78% accuracy was roughly similar across early/mid/late stage cancers. The company expects to announce data from the full 4,800-sample set in 2015.

VNRX's larger 14k sample (recently increased from 11k samples) prospective study is also now underway. This is also being done in collaboration with Hvidovre Hospital. Patients will be screened with a fecal immunological test (FIT) as part of the Danish national screening program. Patients (both FIT-negative and positive) will then tested using VNRX's NuQ assay panel. These results will then be confirmed by colonoscopy. Sample analysis is expected to commence in 2015 which should provide even more insight into the utility of NuQ.

We view the results announced this morning, particularly in consideration of the totality of the positive data from earlier studies, as highly encouraging in terms of the utility of the NuQ technology for the detection of colorectal cancer. This also adds clear support for the potential approvability of NuQ. As a gauge, 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%.

VNRX has indicated that they expect to file for CE Marking by the current year-end. We expect this positive data to-date will be supporting their application. We continue to model launch of a NuQ panel for colorectal cancer to launch in Europe next year.

As we have noted in our ongoing coverage of VNRX, we think there would be ample demand for a cancer screening method that didn't suffer the drawbacks of the current techniques - that being the high cost and patient discomfort of colonoscopy and the high rate of false positives of fecal occult blood tests. With expected pricing under $100 per test and sampling using roughly just one drop of blood, combined with what looks to be (so far) high accuracy, we think VNRX s NuQ tests may offer an option that is competitive to colonoscopy in terms of accuracy but with all the convenience and low cost of fecal occult blood tests.

The issues inherent in current colon cancer detection methods may be a contributing factor to the significant percentage of the at-risk population not meeting colon cancer screening guidelines. According to the CDC, as reported in the November 5, 2013 issue of Morbidity and Mortality Weekly Report, one-third of U.S. adults aged 50-75 who should be screened for colon cancer are not being screened. The USPSTF recommends regular screening for colon cancer using fecal occult blood testing, sigmoidoscopy or colonoscopy beginning at age 50 and continuing to age 75.

We are maintaining our Outperform rating and $7/share price target.

FINANCIAL MODEL

VolitionRx Ltd.

	2013 A	Q1A	Q2A	Q3E	Q4E	2014 E	2015 E	2016 E	2017 E
Revenue	$0.0	$0.0	$0.0	$13.1	$65.6	$78.8	$944.4	$4,341.7	$7,820.1
YOY Growth	*-100.0%*	-	-	-	-	-	*1099.2%*	*359.8%*	*80.1%*
Cost of Goods Sold	$0.0	$0.0	$0.0	$2.0	$9.8	$11.8	$126.7	$522.1	$945.8
Gross Income	$0.0	$0.0	$0.0	$11.2	$55.8	$66.9	$817.7	$3,819.7	$6,874.4
Gross Margin	*#DIV/0!*	-	*#DIV/0!*	*85.0%*	*85.0%*	*85.0%*	*86.6%*	*88.0%*	*87.9%*
SG&A	$1,722.2	$367.7	$259.1	$470.0	$530.0	$1,626.9	$1,850.0	$2,750.0	$3,200.0
%SG&A	-	-	-	-	-	*2065.8%*	*195.9%*	*63.3%*	*40.9%*
R&D	$2,503.7	$870.5	$791.3	$775.0	$855.0	$3,291.8	$4,685.0	$3,850.0	$3,850.0
% R&D	-	-	-	-	-	*4180.0%*	*496.1%*	*88.7%*	*49.2%*
Asset Impairment	$350.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($4,575.9)	($1,238.2)	($1,050.4)	($1,233.8)	($1,329.2)	($4,851.7)	($5,717.3)	($2,780.3)	($175.6)
Operating Margin	-	-	-	-	-	-	-	-	*-2.2%*
Total Other Expense (Income)	($865.6)	$956.3	($1,867.2)	($50.0)	($75.0)	($1,036.0)	($290.0)	$0.0	$0.0
Pre-Tax Income	($3,710.3)	($2,194.4)	$816.8	($1,183.8)	($1,254.2)	($3,815.7)	($5,427.3)	($2,780.3)	($175.6)
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	$25.5	$4.2	$9.6	$0.0	$0.0	$13.8	$0.0	$0.0	$0.0
Net Income	($3,735.8)	($2,198.6)	$807.2	($1,183.8)	($1,254.2)	($3,829.5)	($5,427.3)	($2,780.3)	($175.6)
Net Margin	-	-	-	-	-	-	*-574.7%*	*-64.0%*	*-2.2%*
EPS	($0.34)	($0.18)	$0.06	($0.09)	($0.09)	($0.28)	($0.31)	($0.14)	($0.01)
YOY Growth	-	-	-	-	-	-	-		
Diluted Shares O/S	10,832	12,246	13,888	13,700	14,200	13,509	17,500	19,500	21,500

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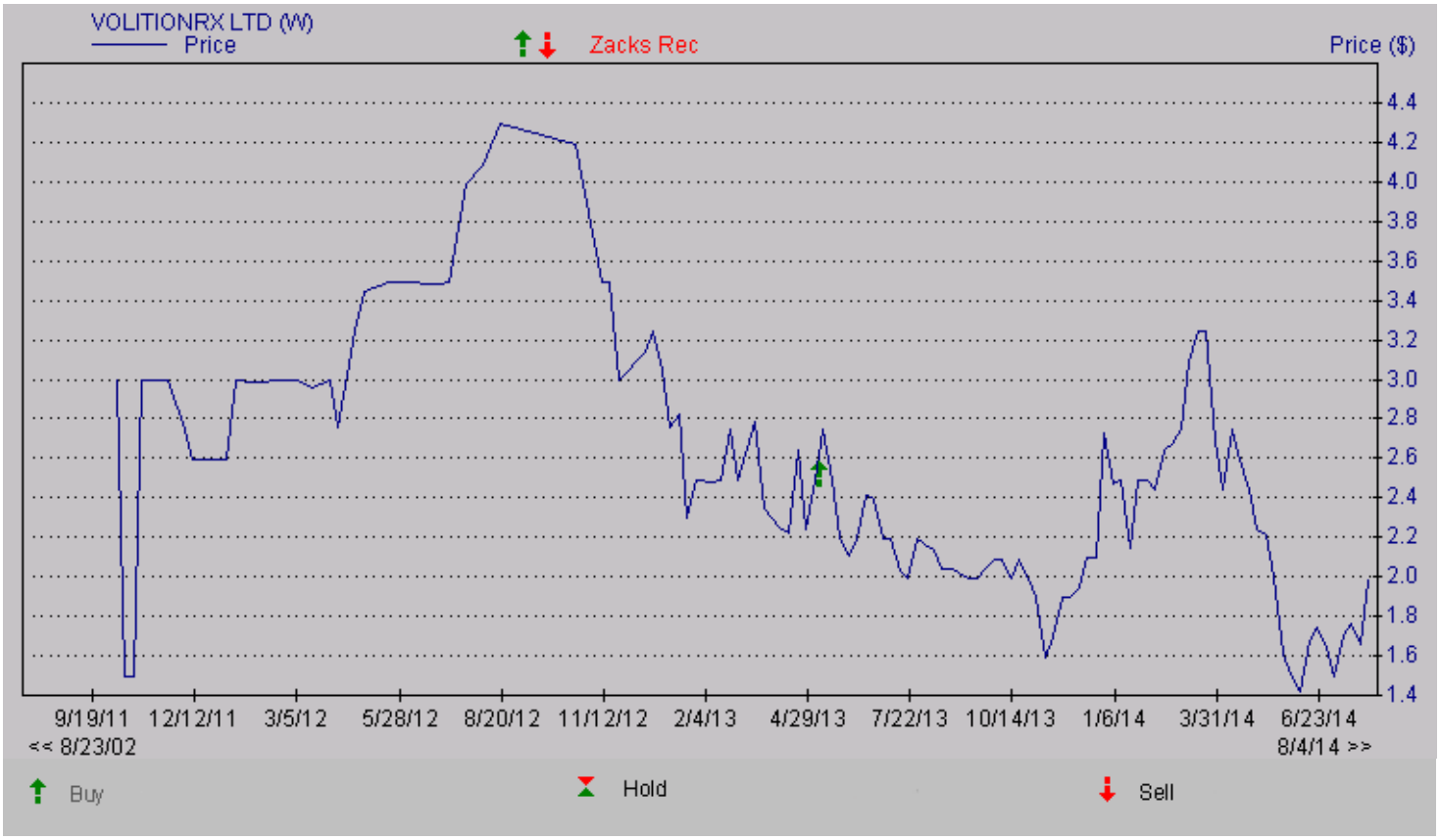

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