Zacks Small-Cap Research

September 22, 2015

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VolitionRx Ltd (VNRX-AMEX)

VNRX: First Assay Receives CE Mark. Panel Launch Still Expected in 2016.

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	05/07/2013
Current Price (09/22/15)	$4.90
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 tests for sale to the clinical market in Europe is anticipated this year. Launch in 2016. 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	**$5.45**
52-Week Low	**$2.81**
One-Year Return (%)	**13.23**
Beta	**-2.35**
Average Daily Volume (sh)	**47,649**
Shares Outstanding (mil)	**18**
Market Capitalization ($mil)	**$91**
Short Interest Ratio (days)	**1.42**
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	**N/A,**
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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First Assay Receives CE Mark, Launch of Initial Panel Still Expected in 2016:
This morning (Sept 22) VNRX announced that their assay, dubbed NuQ X001S, received CE Marking. This is the company's first assay to receive the European regulatory stamp of approval. While this news was not unanticipated given that management had guided towards expectations that CE Mark of the initial assay(s) would come before current year-end, it is an important milestone nonetheless as this is another substantive step towards initial launch in Europe.

The game plan for initial commercial introduction continues to be that VNRX will launch a panel of assays - likely made up of 4 to 6 tests - following requisite CE Marking of those additional assays. The company recently acquired several Tecans (i.e. - robots) to accelerate analysis of the various studies that are ongoing in colorectal and other cancers - data from which continues to show the NuQ technology is demonstrating excellent sensitivity (including results announced earlier in September - discussed below). We expect a fairly regular flow of additional clinical data over the next several months, which should provide additional insight into the accuracy and potential utility (and demand) of the technology. VNRX is still guiding to launch the initial panel - for colorectal cancer - sometime in 2016.

Add'l Study Data Confirms High Accuracy of NuQ in Detection of Colon Cancer, Even at Early Stages:
Earlier this month (Sept 9) VNRX reported additional compelling data from their 4,800-patient retrospective colon cancer study. The presentation supports previous data that found the NuQ technology has better than 80% sensitivity at 78% specificity with high accuracy at all stages of the disease, including Stage I (i.e. earliest) - this further helps validate the competitiveness of the technology compared to already commercialized blood-based cancer tests. The most recent announcement, which came slightly earlier than expected (we had anticipated this coming sometime in October), provides additional significant support of the utility of the technology in identifying those patients with pre-cancer and cancer.

As a reminder, last year (Sept and Oct 2014) VNRX announced initial data on 938 patients from this 4,800-patient study which showed a three-test NuQ panel was able to detect 84% of colorectal cancers (60% of polyps) at 78% specificity (this prompted initiation of a stand-alone study for adenomas). Of the 59 colorectal cancer cases identified by colonoscopy, the NuQ panel was able to detect 50 (85%). Importantly the test showed high accuracy at all stages of cancer (table below from VNRX's PR). 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.

Stage of Colorectal Cancer	Number of Cancer Cases Identified Accurately by NuQ® Test
Stage I	6 of 8 (75%)
Stage II	19 of 20 (95%)
Stage III	16 of 20 (80%)
Stage IV	9 of 11 (82%)

In addition to high accuracy, the NuQ panel was able to differentiate between types of cancer - something that the technology had also demonstrated in the past. Of the 59 colorectal cancers presented last October, 35 were colon and 24 rectal - and the NuQ panel was able to differentiate between the majority of colorectal cancers as being either colon or rectal cancers.

The data announced about two weeks ago further supports the high accuracy of the technology. While last year's data was from a three assay panel on the first 938 patients, the most recent data (table below) was from a four test panel and included the entire 4,800 sample base. The data showed 81% sensitivity at 78% specificity and importantly, this level of accuracy was consistent with all stages of cancer (i.e. - the high accuracy and utility of the test is not stage-dependent). Furthermore, the panel detected 63% of polyps (slightly higher than the 938-sample set), including 67% of high risk adenomas. The high accuracy, particularly with early stage and pre-cancers, is

particularly impressive and should almost certainly provide a very formidable competitive profile against other blood-based tests, such as Epigneomics' Epi proColon.

Cancer	Sensitivity	N=
Colorectal cancer	81%	401 out of 498
Adenomas	63%	415 out of 655
High risk adenomas	67%	256 out of 383
High neoplasia adenomas	68%	76 out of 111
Villous adenomas	73%	8 out of 11
Serrated adenomas	80%	24 out of 30

And while we think this level of accuracy is more than good enough to have utility as a cancer diagnostic and draw commercial demand (as a gauge Epigneomics' Epi proColon showed sensitivity of 79% and specificity of 68% in its pivotal trial versus FIT), accuracy of the NuQ panel could improve even further. VNRX can run as many as 20 different assays per sample and expects to analyze this 4,800 set with as many as 11 assays - data from which VNRX expects to announce in Q1 2016. As each assay has the potential to provide additional information, combining additional assays into the panel could improve overall accuracy. Once the optimal combination is found, VNRX will then use that as its initial panel to bring to market (expected to be a panel of 4 to 6 assays).

Additional data from this retrospective study as well as other studies, including the 14k prospective colon cancer study (initial data on 2,500 samples expected early 2016) and dedicated 800-patient pre-cancerous colorectal study, will provide even more insight into the potential for NuQ in colon cancer. And, as reminder, the technology is being studied in other cancers including (dedicated studies for) lung, ovarian and pancreatic and is in a 4,200-patient study assessing NuQ in 27 of the most prevalent cancers.

We are maintaining our Buy recommendation and $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.

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. As it is now, we value VNRX at $6.50/share. We feel the current market price ($4.90) 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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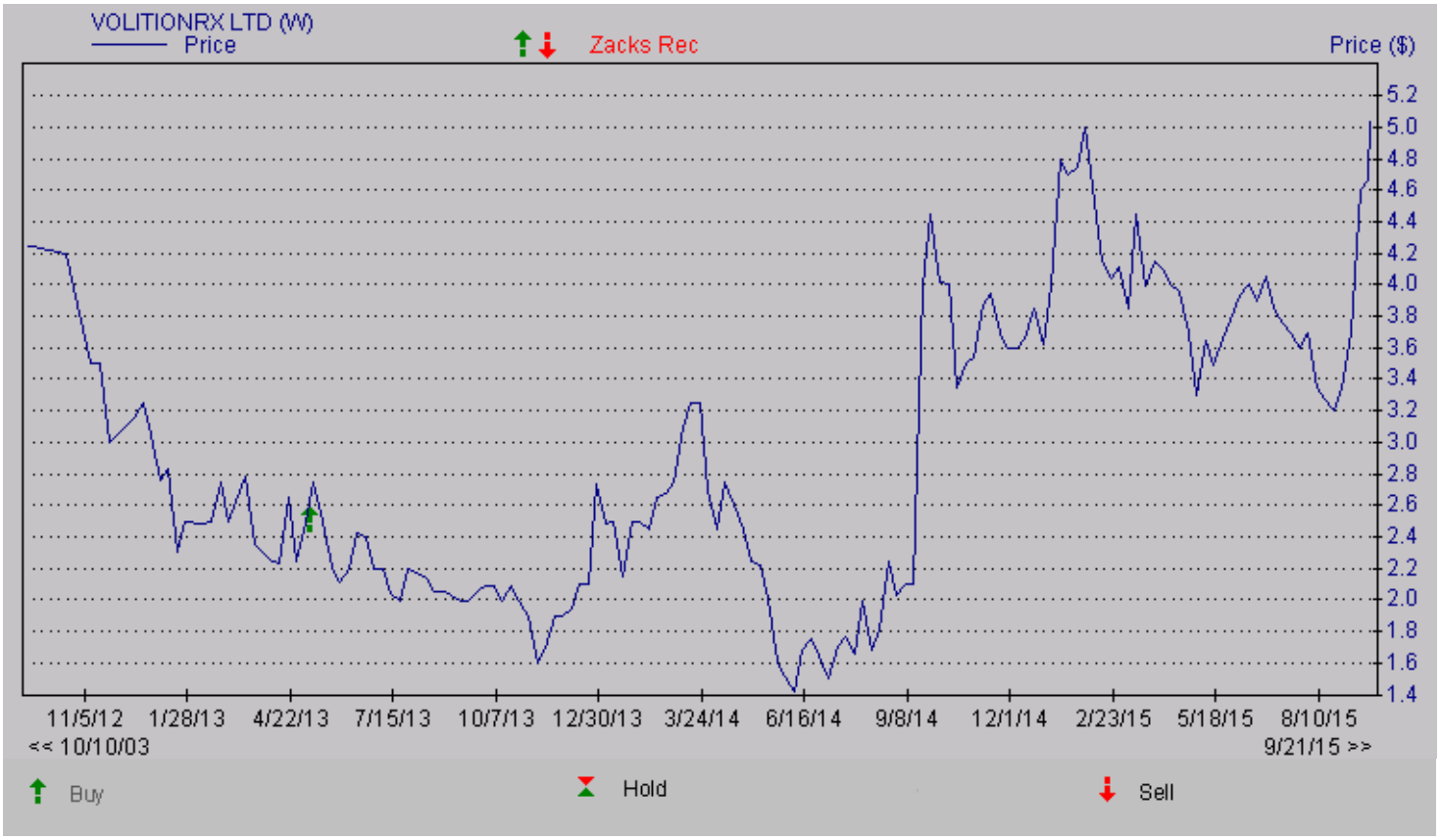

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