Zacks Small-Cap Research

March 19, 2015

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VolitionRx Ltd (VNRX-OTC)

VNRX: Upcoming Interim Trial Data Could Push Share Price Even Higher

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	05/07/2013
Current Price (03/19/15)	$4.10
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. Data from ongoing studies is expected to be released on a regular basis. – which should provide further insight into the performance of the technology and provide support to regulatory filings. CE Mark for sale to the clinical market in Europe is anticipated in 2015/2016 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 $6.50/share..

SUMMARY DATA

52-Week High	**$9.28**
52-Week Low	**$1.30**
One-Year Return (%)	**41.54**
Beta	**-4.06**
Average Daily Volume (sh)	**35,547**
Shares Outstanding (mil)	**18**
Market Capitalization ($mil)	**$74**
Short Interest Ratio (days)	**0.41**
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 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**N/A,**
Type of Stock	**N/A**
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 E	$11 E	$21 E	$44 E	$76 E
2016					$1715 E
2017					$4106 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	-$0.10 E	-$0.10 E	-$0.11 E	-$0.10 E	-$0.41 E
2016					-$0.28 E
2017					-$0.19 E

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

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WHAT'S NEW…..

Q4, FY 2014 Results

VNRX filed their 10-K for the period ending December 31, 2014. Operating expenses, as expected, continue to trend higher with the majority of the increase related to R&D activities in support of the various NuQ clinical programs. Aside from slightly higher than modeled OpEx in Q4 and (insignificantly) lower revenue than anticipated in 2014, results continue to come close to our forecasts.

OpEx was $5.9M in 2014, up from $4.2M in the prior year. Net income and EPS were ($8.3)M and ($0.61) in 2014, compared to ($3.7)M and ($0.34) in 2013.

Cash used in operating activities was $4.1M in 2014. In addition VNRX used $303k for purchase of PP&E. Cash balance at close of 2014 stood at $2.1M but subsequent to year-end VNRX raised ~ $11.1M (net) from share issuance.

We have updated our model following the 10-K filing. This includes adjusting our European launch timelines for a NuQ colorectal cancer panel from 2015 to 2016 – pushing back our related revenue estimates. We have also made some downward adjustments to our modeled RUO-related revenue. While we had always anticipated that the RUO channel would provide only very limited revenue opportunity, we think it's likely that the totality of management's focus is the IVD channel and related activities towards eventual commercialization in this market. As such, and combined with the fact that RUO has generated very little to-date, we have trimmed our revenue estimates in the research use only market. We note that these adjustments largely impact our near-term periods with a relatively insignificant effect to our out-years.

The model updates have moved our per-share (DCF-generated) price target, from $7.00 to $6.50. We expect further positive clinical trial data, which has provided a tailwind to the share price over the last several months, to further catalyze market value appreciation. Interim data from the large retrospective colorectal cancer trial is expected in the coming months (or even weeks) which could offer another inflection point opportunity for investors. We continue to believe the shares remain well undervalued and are maintaining our Outperform rating.

Pancreatic Cancer Study Data, New Trial in Ovarian Cancer

There continues to be a regular flow of clinical trial data. The most recent of which was announced in early January which came from a small pilot study in pancreatic cancer patients. The data looks to be highly encouraging and showed impressive accuracy. 60 individuals, including 25 with stage IIa or stage IIb pancreatic cancer, 25 healthy subjects and 10 with other pancreatic non-cancer disorders. NuQ identified 21 of the 25 cancer cases (84% sensitivity) at a 92% specificity among the healthy subjects (i.e. - just two false positives).

Accuracy remained high when patients with non-cancer pancreatic disorders were included in the comparator with NuQ able to identify 19 of the cancer cases (76% sensitivity) from all other (i.e. – healthy and non-cancer pancreatic disorder) patients. There was only one false positive result with a healthy subject and two false positives with non-cancer pancreatic disorders.

We note that diagnosis of pancreatic cancer is almost always a death sentence given that no tests on the market than can reliably diagnose 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. We think these initial results indicate NuQ could potentially be an effective diagnostic for pancreatic cancer. VNRX will likely look to move to larger clinical studies in pancreatic cancer.

And VolitionRx just recently initiated its first study in ovarian cancer. This is also VNRX's first study focused solely on an Asian population and the first study that will analyze both blood and tissue. The small pilot study is

expected to include blood and tissue samples from 40 patients (20 with cancer, 20 healthy) and is being done in collaboration with Singapore General Hospital. Researchers will be blinded to the samples which will be analyzed with the NuQ assays. Success with the pilot study would likely mean that VNRX will move to larger ovarian cancer studies.

Lung Cancer Study Initiated
Adding to the now fairly long laundry list of cancer studies is a lung cancer study which VNRX announced in December was in the planning phase. This follows positive data from a pilot study, announced in November. 46 individuals were included in the pilot study, including 21 with non-small cell lung cancer, 12 with COPD and 13 healthy subjects . Both sputum and blood samples were tested. With sputum, NuQ was able to detect 18 of the 21 (85%) lung cancer cases with no false positives for healthy individuals. In addition, NuQ was able to differentiate between lung cancer and COPD.

With blood samples, NuQ identified 76% (16 of 21) patients with lung cancer with only one false positive (1 of 13) of a healthy individual. With blood, NuQ was also able to differentiate between lung cancer and COPD. While this was just a small pilot study, VNRX hopes to confirm the results in a larger trial, which will be performed at the University Hospital of Bonn.

U of Bonn is also conducting VNRX's large 4,000-patient prospective cancer study (includes 20 of the most prevalent cancers at various disease stages) – this lung cancer study will be run as a separate trial in conjunction with the 20-cancer study. Only blood (not sputum) will be used in this confirmatory lung cancer study. Approximately 600 blood samples (~ 400 lung cancer patients, ~100 benign lung disease patients, ~100 healthy patients) will be evaluated in the lung cancer study.

Data Shows NuQ's Ability to Detect Cancer At All Stages, Including Critical Early Stages:
In September 2014 VNRX presented highly encouraging data at the Aegis Capital Healthcare Conference on the initial 938 patients in their retrospective colon cancer study being done at Hvidovre Hospital (Denmark). Then a month later the company announced additional data on 830 of these patients which provided greater support of the ability of the NuQ tests to identify cancer with high accuracy at all stages and also to differentiate between types of cancer.

As a reminder, the preliminary results announced in September came 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. While the September presentation noted that the NuQ panel was able to detect cancers at various stages including those at an early stage, it did not provide a specific breakdown of positive samples by cancer type.

The data announced in October, which was presented at the International Conference of Anticancer Research in Greece, did provide that specific breakdown. 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 has demonstrated in the past. The ability to differentiate is of obvious importance in order to most effectively treat the cancer. As a reminder in March VNRX announced results from a small pilot study which also showed high detection capabilities (80% of prostate cancer) and that NuQ was able to differentiate between colon and prostate cancers.

Of the 59 colorectal cancers presented in October, 35 were colon and 24 rectal - and while the release does not provide quantitative specifics, VNRX does note that their NuQ panel was able to differentiate between the majority of colorectal cancers as being either colon or rectal 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 be 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 preliminary results from the retrospective study which have been announced over the last two months, 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%. While Epigneomics is now commencing another study to address some of the agency's lingering concerns, it is not unreasonable that Epi proColon could receive FDA approval sometime in 2015 - which we would view as a positive event for VNRX given that it may bolster chances of eventual NuQ FDA approval based on the technology's relatively strong clinical data to-date.

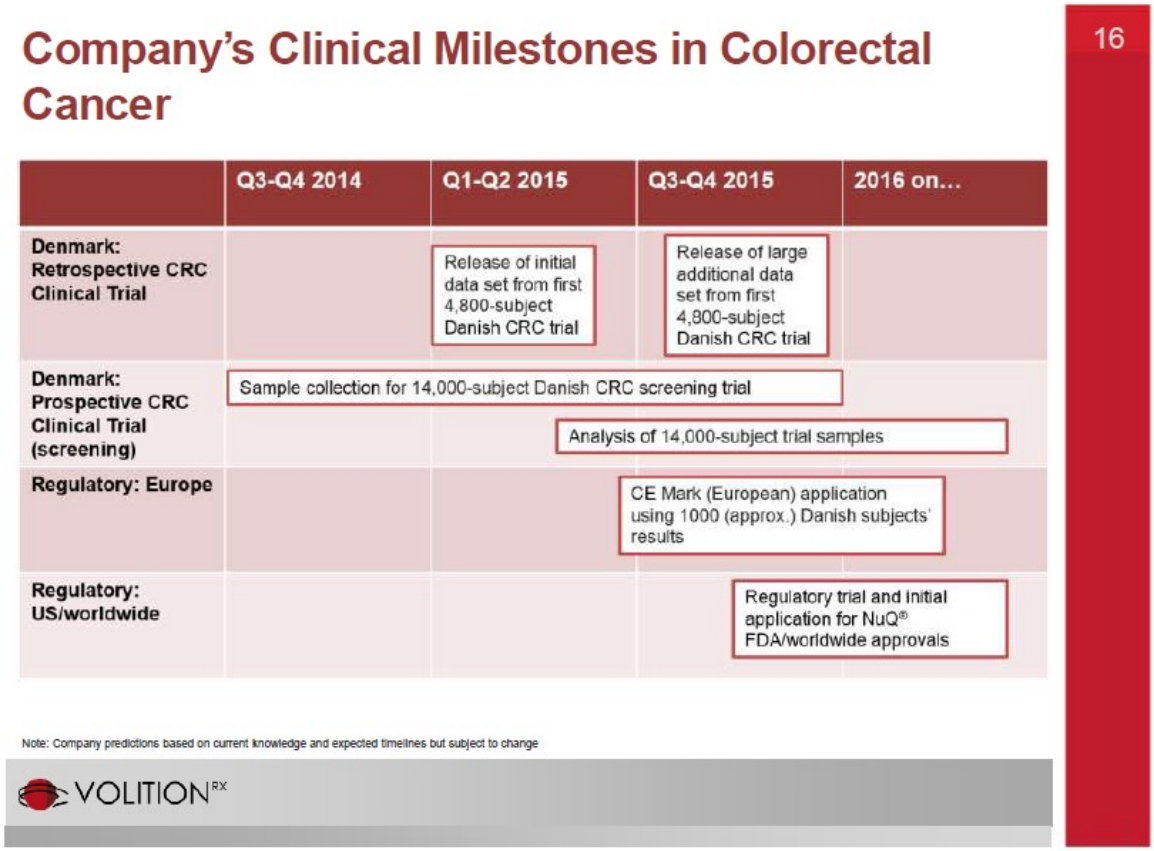
VNRX had previously indicated that they had hoped to file for CE Marking by 2014 year-end. This has been subsequently pushed back and now the company hopes to file by Q2 2015. We expect this positive data to-date will be supporting their application. We had previously modeled launch of a NuQ panel for colorectal cancer to happen in 2015, which we have now pushed back to sometime in 2016.

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.

Update on Colon Cancer Milestone Timelines

Below is a slide from VNRX's March 6, 2015 investor presentation showing expected timelines for its colorectal cancer panel. Some of these timelines have been slightly pushed back from VNRX's prior colorectal cancer clinical milestones timeline which they presented at the Aegis conference in September 2014.



VNRX expects to have additional interim data from the ~4,800-patient retrospective Danish colon cancer study in the coming months and results from the full data set later in 2015. The 14k-sample prospective study is now underway. Management had noted earlier that they thought that they may have data on the initial ~3k samples in Q1 2015 (although this may now not happen until Q2) and interim data on a somewhat regular basis as they expect to be able to process ~500 sample per month.

Regulatory timelines have slipped somewhat slightly from our earlier forecast. CE Mark filing, which we had previously thought might happen in late 2014, will be supported by the compelling interim Danish colon cancer study data and now is expected to happen in mid-2015. We were hoping European launch might happen in 2015 but we think that that is now less likely and are now modeling for a 2016 launch. Initial commercialization is expected to be targeted at national colon cancer screening programs. And with a fairly regular stream of clinical data expected to come from the both Danish colon cancer studies, we think this (assuming continued positive results) has the potential to provide significant support for an accelerated commercial roll-out.

Relative to the U.S. market - VNRX noted in the recent presentations that they now expect to initially tap the domestic market via CLIA labs as they forge towards eventual FDA approval (the latter which will require a U.S.-based study). The IVD market can be accessed without FDA approval through selling the tests as laboratory developed tests (LDTs) through a CLIA certified lab. VNRX envisions its current strategy for the U.S. market to be commercialization with an LDT test and a licensing agreement with a CLIA certified lab. This could get NuQ (colorectal cancer) panel in the U.S. door, although eventual FDA approval would still be VNRX's ultimate goal. FDA approval, as we have noted in our coverage of VNRX, would likely be a years-long process including significant U.S. clinical studies and, as such, is not likely to materialize within the next (at least) two years.

VNRX Looking at Prostate Cancer

VNRX continues to expand the potential indications for its NuQ technology and in early October 2014 announced a collaboration with the high profile MD Anderson Cancer Center at the University of Texas to study the company's technology in the detection of prostate cancer. The retrospective study will assess the NuQ technology in differentiating between anaplastic prostate cancer, a very aggressive form, and castration-resistant prostate cancer, a less aggressive form. The ability to differentiate between the two is important in clinical practice as it can dictate the most appropriate treatment regimen.

CMS Establishes Reimbursement of $502/test For Exact Sciences Cologuard Colon Cancer Stool Test
In early October the Center for Medicare and Medicaid Services (CMS) agreed to reimburse Exact Sciences' Cologuard colon cancer stool test at a rate of $502 per test. Cologuard, which received FDA approval in August of this year, is the first non-invasive DNA screening test for colorectal cancer. Cologuard was evaluated in a 10k-patient pivotal study and showed 92% sensitivity and 87% specificity on detection of colorectal cancer.

While the accuracy of Cologuard clearly stacks up strongly to NuQ (to-date), Cologuard has certain disadvantages including that it is a stool test, which can suffer from low compliance due to dislike of handling stool, and the relatively high price point. As NuQ is a blood test, there is no stool handling and relative to cost, VNRX has indicated that they expect pricing will be in the $40 - $80 range. Insurance reimbursement is typically key to maximize adoption of diagnostics and the fact that CMS has agreed to reimburse for Cologuard may bode well for NuQ's chances for the same if and when it receives FDA approval.

OUTLOOK / VALUATION / RECOMMENDATION

VNRX continues to make progress with an initial CE Mark filing. 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 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.

Relative to the U.S. market, we think VNRX's current game-plan – that is, to initially tap the IVD channel via an LDT and licensing agreement with an established CLIA lab, 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 will likely be a years-long process and require U.S.-based clinical studies. These studies will need to demonstrate satisfactory accuracy of the NuQ technology in identifying cancer. As we have noted in the past, the lingering question in terms of what FDA may require relative to accuracy is 'how high is high enough?'

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 (n = 938) from the Danish retrospective study, which showed the three-panel NuQ tests were able to detect 84% of colorectal cancers (60% of polyps) at 78% specificity. While Epigneomics is now commencing another study to address some of the agency's lingering concerns, it is not unreasonable that Epi proColon could receive FDA approval sometime in 2015 - which we would view as a positive event for VNRX, given that it may bolster chances of eventual NuQ FDA approval given the technology's relatively strong clinical data to-date. Epi proColon is already available in Europe – which also should provide some confidence that CE Mark for VNRX's colon cancer panel will materialize.

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 $6.61/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 ($4.10) 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 interim results from the retrospective colorectal cancer study, should further benefit appreciation of the share price towards our target. We are maintaining our Outperform rating.

FINANCIAL MODEL

VolitionRx Ltd.

	2014 A	Q1 E	Q2 E	Q3 E	Q4 E	2015 E	2016 E	2017 E	2018 E
Revenue	$14.8	$0.0	$11.0	$20.7	$44.1	$75.8	$1,715.1	$4,105.9	$7,431.7
YOY Growth	-	-	-	-	-	*412.7%*	*2162.7%*	*139.4%*	*81.0%*
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$469.3	$1,137.4	$2,072.4
Gross Income	$14.8	$0.0	$11.0	$20.7	$44.1	$75.8	$1,245.7	$2,968.5	$5,359.3
Gross Margin	*100.0%*	-	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*72.6%*	*72.3%*	*72.1%*
SG&A	$1,908.2	$541.0	$574.0	$618.0	$598.0	$2,331.0	$2,750.0	$3,200.0	$5,100.0
%SG&A	-	-	-	-	-	-	*160.3%*	*77.9%*	*68.6%*
R&D	$4,044.1	$1,228.0	$1,284.0	$1,321.0	$1,344.0	$5,177.0	$4,455.0	$4,215.0	$3,988.0
% R&D	-	-	-	-	-	-	*259.8%*	*102.7%*	*53.7%*
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)	($1,769.0)	($1,847.0)	($1,918.3)	($1,897.9)	($7,432.2)	($5,959.3)	($4,446.5)	($3,728.7)
Operating Margin	-	-	-	-	-	-	-	*-108.3%*	*-50.2%*
Total Other Expense (Income)	$2,275.7	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($8,213.2)	($1,769.0)	($1,847.0)	($1,918.3)	($1,897.9)	($7,432.2)	($5,959.3)	($4,446.5)	($3,728.7)
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	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($8,257.2)	($1,769.0)	($1,847.0)	($1,918.3)	($1,897.9)	($7,432.2)	($5,959.3)	($4,446.5)	($3,728.7)
Net Margin	-	-	-	-	-	*-9805.4%*	*-347.5%*	*-108.3%*	*-50.2%*
EPS	($0.61)	($0.10)	($0.10)	($0.11)	($0.10)	($0.41)	($0.28)	($0.19)	($0.14)
YOY Growth	-	-	-	-	-	-	-	-	-
Diluted Shares O/S	13,435	17,951	18,164	18,250	18,418	18,196	21,000	23,000	26,000

Brian Marckx, CFA

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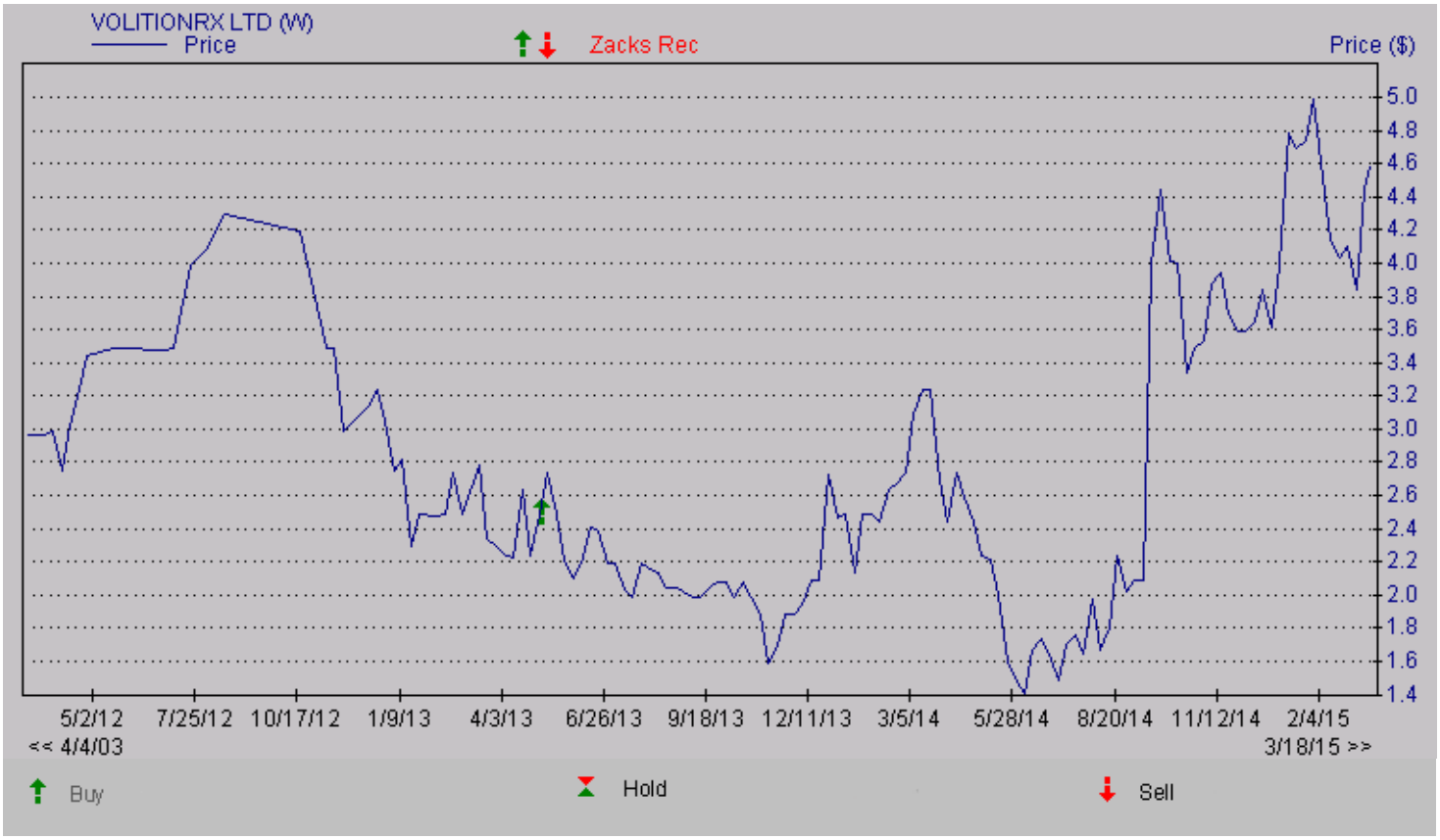
HISTORICAL ZACKS RECOMMENDATIONS



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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 15.2%, Hold/Neutral- 75.0%, Sell/Underperform – 9.0%. Data is as of midnight on the business day immediately prior to this publication.