Zacks Small-Cap Research

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VolitionRx Ltd (VNRX-NYSE)

VNRX: Large U.S. Study Comes Cheap and Could Support Eventual Asymptomatic FDA Filing

Based on our DCF model which goes out to year 2026 and uses a 9.5% discount rate (based on CAPM) and 2% terminal growth rate, VNRX is valued at $7.50/share. Our model and assumptions will be updated if appropriate based on news flow which could also influence valuation

Current Price (07/31/17)	$3.03
Valuation	**$7.50**

OUTLOOK

VNRX will participate in a large U.S. study that could potentially serve as primary support for an eventual FDA filing seeking U.S. regulatory approval for a NuQ technology-based blood test in the primary diagnosis of colorectal cancer. Such a test would be aimed at the asymptomatic U.S. population - a market size estimated at approximately 90M individuals and, per our estimate, valued at over $4B. Given the relative enormous and valuable market, coupled with drawbacks of currently available non-invasive CRC testing options, eventual FDA approval would likely be a highly substantial value driver. VNRX is required to contribute just $3M (paid in equal quarterly installments over 3 years), with most of the funding borne by the study's main sponsor, the U.S. National Cancer Institute's (NCI) Early Detection Network (EDRN), which is the leading cancer research organization in the U.S. The Great Lakes New England Clinical Validation Center and the University of Michigan are also major participants and, along with EDRN, focused on the pursuit of technologies for the early detection of cancer.

SUMMARY DATA

52-Week High	**$5.86**
52-Week Low	**$2.92**
One-Year Return (%)	**-8.43**
Beta	**-1.55**
Average Daily Volume (sh)	**36,777**
Shares Outstanding (mil)	**27**
Market Capitalization ($mil)	**$80**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**18**
Insider Ownership (%)	**28**
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 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in '000)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	$0 A	$0 A	$0 A	$0 A	$0 A
2017	$0 A	$0 E	$0 E	$0 E	$0 E
2018					$659 E
2019					$3990 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.13 A	-$0.13 A	-$0.15 A	-$0.12 A	-$0.52 A
2017	-$0.13 A	-$0.15 E	-$0.14 E	-$0.15 E	-$0.57 E
2018					-$0.49 E
2019					-$0.38 E

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

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Large U.S. Prospective Trial Could Support Eventual Asymptomatic FDA Filing

VNRX announced that it will participate in a large U.S. study that could potentially serve as primary support for an eventual FDA filing seeking U.S. regulatory approval for a NuQ technology-based blood test in the primary diagnosis of colorectal cancer. Such a test would be aimed at the asymptomatic U.S. population - a market size estimated at approximately 90M individuals and, per our estimate, valued at over $4B. Given the relative enormous and valuable market, coupled with drawbacks of currently available non-invasive CRC testing options - including low accuracy, required fecal-handling, dietary restrictions and high cost, eventual FDA approval would likely be a highly substantial value driver.

VNRX is required to contribute just $3M (paid in equal quarterly installments over 3 years), with most of the funding borne by the study's main sponsor, the U.S. National Cancer Institute's (NCI) Early Detection Network (EDRN), which is the leading cancer research organization in the U.S. The Great Lakes New England Clinical Validation Center and the University of Michigan are also major participants and, along with EDRN, focused on the pursuit of technologies for the early detection of cancer.

While complete details of the study have yet to be made public (although we think the study design may be publicly available later this year), we do know the following:

- will include ~13.5k asymptomatic screening samples from subjects $\geq$ 50 years of age who have not previously undergone colonoscopy or CRC screening. This "non-adherent" (to CRC screening guidelines) population is at particular risk and a focus for organizations such as EDRN in improving screening compliance
- 4,677 samples have already been collected (retrospective collection). The remainder (~8.8k) will be prospectively collected at multiple sites prior to participants undergoing colonoscopy
- 2 to 3 years is the expected timeframe for collection to be completed
- samples will be tested with a panel of NuQ colorectal cancer assays
- samples will also be tested with other (non-VNRX) diagnostics - while specifics were not provided, this could presumably include traditional FIT/gFOB (i.e. fecal) tests as well as potentially more recently commercialized diagnostics such as Exact Sciences' ColoGuard stool DNA test. This could provide a unique opportunity for a true head-to-head comparison of results against (potential) competing products from the same study and samples

Given that this is a third-party study in which VNRX is a participant but not the main sponsor, they did not have the benefit of direct consultation with and feedback from FDA relative to the study design. But, management stressed that the study was developed by NCI for the purpose of acting as a pivotal study which could be used as primary support by VNRX for an eventual FDA PMA filing seeking U.S. regulatory clearance for a NuQ-based blood test as a first line CRC screen (i.e. for asymptomatic patients). Whether this study will be 'sufficient' in the eyes of FDA as a pivotal study is something that we may not know for quite some time - VNRX expects their first significant interaction with FDA to be a pre-submission meeting which likely would not be scheduled until after this study is largely completed and initial results are compiled.

But, we think that there are certain aspects that should play in VNRX's favor in that regard. Most notably is the large size of the study - 13.5k samples, including ~9k collected prospectively. This compares to ~10k total (prospective) samples for Exact Sciences' ColoGuard pivotal FDA study. And as it relates to the inclusion criteria of non-compliant subjects - we think that is another (positive) key point as the goal for VNRX will be to demonstrate that their test can improve screening compliance (National Colorectal Cancer Roundtable is leading an initiative to improve compliance to 80% by 2018). The lack of an appropriate study population (i.e. enrollment was not confined to only non-compliant subjects) ultimately created an issue for Epigenomics in their FDA studies with Epi proColon - this resulted in FDA requesting an additional clinical study and delayed U.S. approval by ~2 years. Another aspect that we think bodes well for VNRX is the reputation and expertise of NCI, EDRN and Great Lakes and their focus on facilitating the development (and eventual commercialization) of cancer detection technologies - clearly the most efficient way to do that would be to design their studies to meet anticipated FDA requirements and protocol.

The most significant benefit of participating in this study versus designing their own study (in which case they would have pre-study interaction with FDA) is cost. VNRX contributes just $3M over three years and will have access to over 13k blood samples for validation - that compares to management's estimates of $30M to $40M (cost of Exact's pivotal study as a proxy) that it would cost to design and conduct their own study. The valuable

data and ~$30M or more that they will save by participating in this NCI study, in our opinion, is more than worth the risk that they will need to conduct additional clinical work to support an eventual FDA filing.

Additional Salient Points…

Below we discuss what we think are some of the most salient points relative to VNRX's potential opportunity in the U.S. in the context of the current environment of screening and diagnosis of CRC including available non-invasive methods/modalities and the opportunity to address unmet needs.

- **Non-Compliance Provides Opportunity**: The United States Preventive Services Task Force (USPSTF) recommends screening for CRC beginning at age 50 and until age 75. Currently, only about 65% of screening-age Americans adhere to recommended CRC screening guidelines. A consortium of healthcare and other organizations have a goal of increasing that to 80% by the year 2018, which they estimate will prevent 277k new cases of CRC and 203k deaths within 20 years. With approximately 90M Americans of screening age, that means over 30M are non-compliant. While organizations such as USPSTF and FDA are not part of this consortium, they are undoubtedly aware of the benefits of improving compliance.

  The reasons for lack of adherence to screening guidelines vary and include a lack of access to care, concerns specific to the testing modality such as risks associated with invasive screening methods (such as risk of bowel perforation during colonoscopy) or handling feces with gFOB/FIT tests, cultural barriers, lack of insurance or financial resources and general lack of awareness of the benefits of screening. Additional screening options, such as what VNRX hopes to bring market, have the potential to address some of these barriers, particularly as they relate to concerns of other modalities such as colonoscopy and FIT/gFOB but also, possibly, as they relate to other factors such as cost.

  Noteworthy is evidence which has indicated that screening by any available means is more important than the specific screening modality in reducing rates of CRC. To this point, USPSTF mentions in their CRC guidelines that screening with Hemoccult II, compared with no screening, consistently resulted in a 9% to 22% reduction in CRC-specific mortality. This is despite the fact that Hemoccult II, a guaiac-based FOBT test, is relatively very inaccurate (sensitivity between 13% and 50%) - in fact it is no longer recommended as a CRC screening test. We think this may also provide some context for how motivated (and potentially lenient) U.S. regulators may be in improving CRC screening compliance.

- **Refine Panel**: the 2+ year collection time and large ongoing (and upcoming) OUS clinical trials provides VNRX with the ability to further refine the accuracy of their technology (actual testing, once the specific biomarkers have been chosen and the panel developed, can be done in only a matter of months). All else equal, the higher the sensitivity/specificity, the greater the chance of eventual FDA approval, inclusion as a recommended CRC screening option, reimbursement and for uptake of the test. And while we have not included colonoscopy in our review of alternative screening methods as it is (today) considered as a definitive diagnosis, level of sensitivity/specificity (across all cancer stages) could also determine how potentially competitive VNRX's test could be against invasive modalities.

  In May 2017 VNRX announced results of a small (n = 58) study which showed a panel of four NuQ assays detected 74% of all stages of CRC cancer at a 90% specificity. When incorporating an age-adjusted scoring system, 91% of CRC's were detected at a 90% specificity. Detection of early-stage cancers was also high, with 62% of pre-cancer polyps detected at 90% specificity. While the study was too small to presume replicability of detection at these levels, VNRX will be working to bring the highest performing test into this large NCI study.

- **Sensitivity / Specificity Threshold**: the threshold that may be required for FDA approval can be gleaned from Epigenomics' pivotal trial data. The FDA PMA filing for Epigenomics' Epi proColon blood-based (Septin 9) DNA test was supported by two clinical studies (n = ~2k in aggregate) which demonstrated sensitivity / specificity in detection (across all levels) of CRC of 68.2% / 78.8% in one study and 72.2% / 80.8% (versus FIT sensitivity of 68.0% at 97.4% specificity) in the other. The data was less then overwhelming, resulting in an adverse vote (5 in favor, 6 against) by an FDA advisory panel relative to the question of effectiveness of the test which ultimately required Epigenomics to conduct another clinical trial - this one aimed at assessing how their test would be received in a real-world situation (i.e. could the test improve adherence to CRC testing). Epi proColon finally received FDA approval in April 2016 but as a result of the less than compelling clinical data, it came with a relatively narrow label (discussed below). So while we think the Epi proColon pivotal trial data provides a goal for FDA approval purposes, meaningful adoption, competitiveness and ability to increase compliance of CRC screening may require VNRX to demonstrate a level of sensitivity / specificity that is more in-line with that of FIT and Exact's ColoGuard (FIT-DNA).

- **Target Market**: we think certain characteristics of VNRX's test may appeal differently to two somewhat distinct U.S. target markets; the non-compliant population (~30M people) and the compliant population (~60M people).

Assuming $50 per test and recommended annual testing, this values the non-compliant and compliant U.S. markets at approximately $1.5B and $3B per year, respectively. We suspect that the non-compliant market may be less concerned with superior accuracy than aspects such as cost or concerns over exposure to feces handling or risks of invasive screening methods. And while these potential benefits (i.e. lower cost, lack of exposure to feces and invasive risks) may also appeal to a certain portion of the compliant population, relative sensitivity/specificity will undoubtedly be a significant determinant in choice of screening modality for these people and their physicians. The design of this NCI study clearly focuses on improving non-adherence, although should also provide insight into competitiveness versus current, non-invasive screening methods, which we discuss below.

- **Epi proColon**: labeling was ultimately restricted to a relatively narrow indication - that is, for only those individuals (average risk, age 50 years and older) who are first offered, and decline, a USPSTF-recommended screening test (such as FIT/gFOB or colonoscopy). It is contraindicated as a replacement for (guideline-recommended) CRC screening tests. While Epi proColon was not included in the updated (2016) USPSTF recommended CRC screening guidelines, that may have to do with (inferior) data from a prior version of the test being used in the determination. Updated clinical and longitudinal data as well as evidence supporting an increase in screening compliance could be favorably for inclusion in future USPSTF updates. Nonetheless, as Epi proColon is not currently covered by Medicare (although legislation has been introduced in the U.S. House for Medicare coverage of FDA-approved blood-based CRC screening tests) and its label essentially relegates it to a second-line option to FIT/FOB (which are covered by Medicare and included as recommended CRC screens), we think its competitiveness and ability to meaningfully address the non-compliant population are compromised. Epigenomics was taken private earlier in 2017 and information relative to the market performance of Epi proColon since its launch is largely unavailable.

- **ColoGuard**: ColoGuard was the first technology approved through the FDA-CMS parallel review program - resulting in FDA approval and Medicare coverage coming on the same day in August 2014. It is indicated for the screening of individuals 50 years and older at average risk of CRC. Pivotal study (n = 10k) demonstrated 92.3% sensitivity and 86.6% specificity in CRC. ColoGuard was included in USPSTF's updated (2016) CRC screening guidelines although does note that while single-test sensitivity of ColoGuard is higher than that of FIT, specificity is lower, resulting in more false positives. Medicare reimburses ColoGuard at a rate of approximately $500 every 3 years for those 50 - 85 years old who do not have symptoms of CRC and who are not at increased risk of CRC. ColoGuard sales have ramped quite rapidly since its launch in late 2014. Approximately 10k tests were sold during the first full quarter (Q1 2015) on the market and this has grown at an average quarterly rate of almost 34%. In the most recent quarter (Q2 2017) 135k tests were completed. We think the relatively strong market performance of ColoGuard may be the product of a number of factors including; reimbursement at time of launch, relatively high accuracy, inclusion in USPSTF guidelines and a robust direct-to-consumer marketing campaign. And while fecal handling is a widely cited headwind to FIT adoption, that may be somewhat offset by the convenience of at-home sample collection (which is then shipped directly to the lab). In addition to (USPSTF's citing of risk of false positives), the high cost is a drawback, particularly for the uninsured or under-insured.

- **FIT:** USPSTF recommends fecal immunochemical testing every year. Medicare reimburses FIT at a rate of approximately $25 every 12 months. Given the various FIT test choices available by different manufacturers there is a lot of heterogeneity among performance. In evaluating FIT for their guidelines, USPSTF focused on those tests that had available data from at least two clinical studies. Among three clinical studies (encompassing ~26k samples) of OC-Light, a qualitative test, and five studies (encompassing ~13k samples) of OC FIT-CHEK, a quantitative test, the lowest sensitivity was 73% at 96% specificity while the highest sensitivity was 88% with 92% specificity. In the largest study (n = 9,989), sensitivity was 74% at 93% specificity – this was also the FIT (OC FIT-CHEK) comparator arm of ColoGuard's pivotal study.

  One of the drawbacks of stool-based test is fecal handling which can affect compliance – although evidence of rates of compliance varies widely depending on the source. Two separate studies[1,2] indicated FIT compliance between 60% and 62%, while (3 stool-sample) gFOB compliance was between 47% and 50% . Those rates are much higher than results from a retrospective study sponsored by Exact Sciences which

[1] van Rossum LG, et al. Random comparison of guaiac and immunochemical fecal occult blood tests for colorectal cancer in a screening population. Gastroenterology. 2008 Jul;135(1):82-90. doi: 10.1053/j.gastro.2008.03.040. Epub 2008 Mar 25.

[2] Hol L, et al. Screening for colorectal cancer: randomised trial comparing guaiac-based and immunochemical faecal occult blood testing and flexible sigmoidoscopy. Gut. 2010 Jan;59(1):62-8. doi: 10.1136/gut.2009.177089.

used claims data from over 150k patients and found a compliance rate of just 0.3% (i.e. compliance in 3 of 1,000) using either FIT or FOB.[3]

- **gFOB**: similar to FIT, USPSTF recommends guaiac-based fecal occult blood testing annually. While legacy gFOB tests suffered from low sensitivity, this has improved with the next generation (such as Hemoccult SENSA) which have demonstrated in clinical studies to have a sensitivity of between 62% and 79% and specificity of 87% to 96%. In addition to fecal handling, other drawbacks of gFOB testing is it require sample collection of three consecutive stools (which can result in low compliance), generally considered to be less accurate than FIT and may require dietary restrictions.

USPSTF List of CRC Screening Strategies: 2016 Final Update

Table. Characteristics of Colorectal Cancer Screening Strategies[a]

Screening Method	Frequency[b]	Evidence of Efficacy	Other Considerations
Stool-Based Tests			
gFOBT	Every year	RCTs with mortality end points: High-sensitivity versions (eg, Hemoccult SENSA) have superior test performance characteristics than older tests (eg, Hemoccult II)	Does not require bowel preparation, anesthesia, or transportation to and from the screening examination (test is performed at home)
FIT[c]	Every year	Test characteristic studies: Improved accuracy compared with gFOBT Can be done with a single specimen	Does not require bowel preparation, anesthesia, or transportation to and from the screening examination (test is performed at home)
FIT-DNA	Every 1 or 3 y[d]	Test characteristic studies: Specificity is lower than for FIT, resulting in more false-positive results, more diagnostic colonoscopies, and more associated adverse events per screening test Improved sensitivity compared with FIT per single screening test	There is insufficient evidence about appropriate longitudinal follow-up of abnormal findings after a negative diagnostic colonoscopy; may potentially lead to overly intensive surveillance due to provider and patient concerns over the genetic component of the test
Direct Visualization Tests			
Colonoscopy[c]	Every 10 y	Prospective cohort study with mortality end point	Requires less frequent screening Screening and diagnostic follow-up of positive findings can be performed during the same examination
CT colonography[e]	Every 5 y	Test characteristic studies	There is insufficient evidence about the potential harms of associated extracolonic findings, which are common
Flexible sigmoidoscopy	Every 5 y	RCTs with mortality end points: Modeling suggests it provides less benefit than when combined with FIT or compared with other strategies	Test availability has declined in the United States
Flexible sigmoidoscopy with FIT[c]	Flexible sigmoidoscopy every 10 y plus FIT every year	RCT with mortality end point (subgroup analysis)	Test availability has declined in the United States Potentially attractive option for patients who want endoscopic screening but want to limit exposure to colonoscopy

Abbreviations: FIT, fecal immunochemical test; FIT-DNA, multitargeted stool DNA test; gFOBT, guaiac-based fecal occult blood test; RCT, randomized clinical trial.

[a] Although a serology test to detect methylated *SEPT9* DNA was included in the systematic evidence review, this screening method currently has limited evidence evaluating its use (a single published test characteristic study met inclusion criteria, which found it had a sensitivity to detect colorectal cancer of <50%).[1] It is therefore not included in this table.

[b] Applies to persons with negative findings (including hyperplastic polyps) and is not intended for persons in surveillance programs. Evidence of efficacy is not informative of screening frequency, with the exception of gFOBT and

[c] Strategy yields comparable life-years gained (ie, the life-years gained with the noncolonoscopy strategies were within 90% of those gained with the colonoscopy strategy) and an efficient balance of benefits and harms in CISNET modeling.[2]

[d] Suggested by manufacturer.

[e] Strategy yields comparable life-years gained (ie, the life-years gained with the noncolonoscopy strategies were within 90% of those gained with the colonoscopy strategy) and an efficient balance of benefits and harms in CISNET modeling when lifetime number of colonoscopies is used as the proxy measure for the burden of screening, but not if lifetime number of cathartic bowel preparations is used as the proxy measure.[2]

Valuation Update

Prior to the announcement of the large 13.5k-sample NCI/EDRN study, our DCF-derived valuation calculated fair value of the company at $6.75/share. The question now is, how much incremental value is provided by inclusion in this study?

We have approached that question by estimating the difference between the approximate cost of a U.S. pivotal study if VNRX had gone it alone versus that of this NCI study - we estimate the savings is about $30M over a period of around three years. We then discount that back to present at (our DCF discount rate) 9.5%. We also

[3] Anissa Cyhaniuk, MA, and Megan E. Coombes, MSc. Longitudinal Adherence to Colorectal Cancer Screening Guidelines. AJMC Feb 2016

apply a 25% haircut to reflect what we think fairly represents risk that the study is not sufficient to act as a pivotal study for U.S. regulatory purposes. The result is incremental value of approximately $18M, or $0.70/share. **Our updated valuation is $7.50/share.**

Additional clinical data should help to handicap U.S. regulatory success of a NuQ-based asymptomatic CRC screen, help to compare the potential competitiveness against what is already on the market and aid in modeling U.S. revenue.

FINANCIAL MODEL

VolitionRx Ltd.

	2016 A	Q1 A	Q2 E	Q3 E	Q4 E	2017 E	2018 E	2019 E
Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$658.9	$3,989.9
YOY Growth	-	-	-	-	-	-	-	*505.5%*
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$171.3	$798.0
Gross Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$487.6	$3,191.9
Gross Margin	-	-	-	-	-	-	*74.0%*	*80.0%*
SG&A	$5,429.1	$1,509.1	$1,644.0	$1,712.0	$1,888.0	$6,753.1	$7,820.0	$8,660.0
%SG&A	-	-	-	-	-	-	*1186.8%*	*217.0%*
R&D	$6,837.6	$1,841.6	$1,936.0	$1,978.0	$2,214.0	$7,969.6	$9,688.0	$9,512.0
% R&D	-	-	-	-	-	-	*1470.3%*	*238.4%*
Asset Impairment	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($12,266.6)	($3,350.7)	($3,580.0)	($3,690.0)	($4,102.0)	($14,722.7)	($17,020.4)	($14,980.1)
Operating Margin	-	-	-	-	-	-	*-2583.1%*	*-375.4%*
Total Other Expense (Income)	($361.3)	$0.0	$260.6	$8.0	$8.0	$276.6	$27.0	$27.0
Pre-Tax Income	($11,905.3)	($3,350.7)	($3,840.6)	($3,698.0)	($4,110.0)	($14,999.3)	($17,047.4)	($15,007.1)
Taxes (benefit)	$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%*
FX translation	$109.1	($31.5)	$0.0	$0.0	$0.0	($31.5)	$0.0	$0.0
Net Income	($12,014.4)	($3,319.2)	($3,840.6)	($3,698.0)	($4,110.0)	($14,967.8)	($17,047.4)	($15,007.1)
Net Margin	*#DIV/0!*	-	-	-	-	*#DIV/0!*	*-2587.2%*	*-376.1%*
EPS	($0.52)	($0.13)	($0.15)	($0.14)	($0.15)	($0.57)	($0.49)	($0.38)
YOY Growth	-	-	-	-	-	-	-	
Diluted Shares O/S	23,049	26,129	26,350	26,500	26,700	26,420	35,000	39,000

Brian Marckx, CFA

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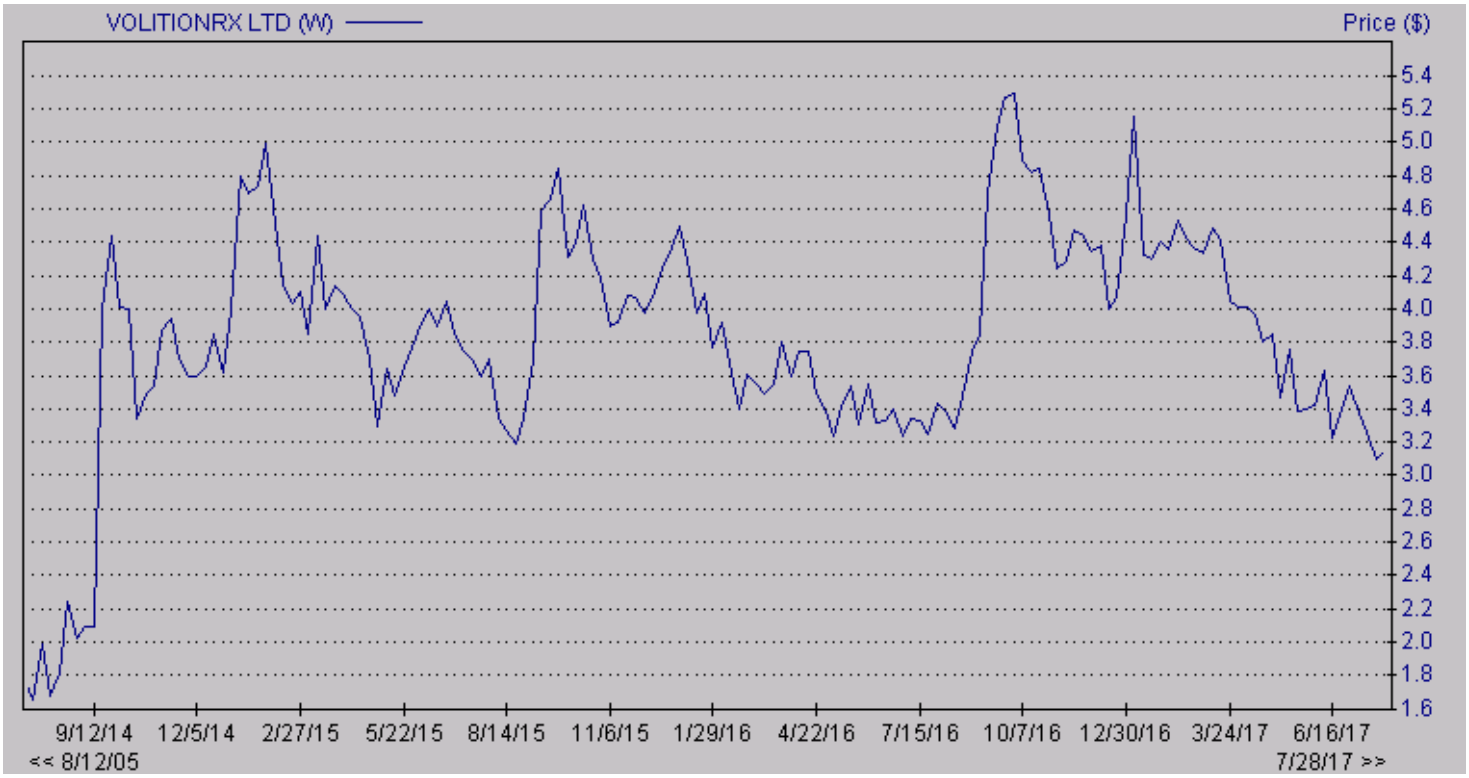

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