Zacks Small-Cap Research

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VolitionRx Ltd (VNRX-NYSE)

VNRX: Several Key Milestones Expected in 2016 Including European Launch

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	05/07/2013
Current Price (03/14/16)	$3.40
Target Price	**$6.50**

OUTLOOK

Data from the various clinical trials continues to be consistently positive. Based on the number of studies anticipated to read out during 2016, this should be a telling year in terms of the potential utility of the NuQ assays in a variety cancers. And 2016 is also expected to include CE Marking of the initial CRC assay, commercial introduction in Europe and more clarity on the U.S. commercialization pathway.

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, 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.

We feel the current market price ($3.40) 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 should further benefit appreciation of the share price towards our target. We are maintaining our Buy recommendation.

SUMMARY DATA

52-Week High	**$5.25**
52-Week Low	**$3.00**
One-Year Return (%)	**-21.35**
Beta	**-1.79**
Average Daily Volume (sh)	**13,553**
Shares Outstanding (mil)	**18**
Market Capitalization ($mil)	**$65**
Short Interest Ratio (days)	**N/A**
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 2016 Estimate	**N/A**
P/E using 2017 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)
2015	$0 A	$0 A	$0 A	$0 A	$0 A
2016	$0 E	$0 E	$0 E	$84 E	$84 E
2017					$1742 E
2018					$4918 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.12 A	-$0.10 A	-$0.16 A	-$0.15 A	-$0.54 A
2016	-$0.16 E	-$0.15 E	-$0.16 E	-$0.15 E	-$0.62 E
2017					-$0.53 E
2018					-$0.41 E

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

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Q4 Results / Operational and Milestones Update:

VNRX reported Q4 financial results and provided an operational and milestones update. On the financials side, results continue to trend within our expectations. We continue to expect negligible revenue in the current year but a more meaningful contribution beginning in 2017 following launch of the initial panel(s) in Europe.

Q4 OpEx was $2.7M, up slightly from the ~$2.4M average through the first three quarters of 2015. We expect operating expenses to trend higher throughout 2016 on additional clinical trial and regulatory activities associated with CE Marking of more assays and the initial panel. VNRX now also expects to begin implementing an FDA-clearance/approval strategy which could include preparations for a U.S.-based study in 2016 to support a potential future 510(k) submission.

Q4 net income and EPS were ($2.7)M and ($0.15), compared to our ($2.3)M and ($0.13) estimates. Cash used in operating activities $2.1M in the quarter and $8.8M for the full year. We expect this to increase going forward with the ramp-up in ongoing studies, the recent commencement of others, regulatory submission activities and pre-launch (Europe) preparations. Cash balance at 2015 year-end was $5.9M. Warrant exercises may provide some additional funding but we continue to expect a capital raise to be in the cards in the near-term - an assumption which had already been incorporated into our model and valuation.

On the operational front – management laid out some expected upcoming milestones on the Q4 call and the 10-K provided additional details. They also provided an update on the U.S. strategy – which now, along with potentially continuing to include the LDT (via CLIA lab) route, may also entail seeking 510(k) de novo clearance as an adjunct to standard of care in symptomatic patients - both leading up to eventual implementation of a PMA approval strategy for use as a colorectal cancer screen. They are considering the 510(k) route (will have more info following meeting with FDA) as it provides another option to getting their assays on the U.S. market prior to the potential long (and more expensive) slog that the PMA pathway will entail and one which may offer more upside (and more control) than that of the LDT route.

Data from the various clinical trials continues to be consistently positive. The most recent of which in colorectal cancer was announced in mid-February. This was in pre-cancerous colorectal adenomas – which are particularly difficult to detect. We view this as particularly encouraging given the increased chance for positive patient outcomes when cancer is identified at its earliest stages. Look for more data in this patient population in 2016.

Management provided updates on expected upcoming milestones. While some have slipped from prior expectations, based on the number of studies anticipated to read out during 2016, this should be a telling year in terms of the potential utility of the NuQ assays in a variety cancers. And 2016 is also expected to include CE Marking of the initial CRC assay and commercial introduction in Europe. Management's expected upcoming milestones include:

- Colorectal Cancer:
    - **4,800** sample retrospective trial expected to have full and final results in 2H 2016. Will be used to support CE Marking of initial panel
    - **14k** sample prospective trial expected to have preliminary data in late 2016. This study is comparing NuQ to FIT test, the market standard for CRC in Europe. Positive results could provide support for NuQ as a CRC screen which could significantly broaden its appeal
    - Additional data from (pre-cancerous) adenomas later in 2016
    - CE Marking – expect to CE Mark additional CRC assays during 2016 and CE Mark the initial panel by year-end. Also expect to launch the panel in Europe in 2016. Hope to have CE Marking for CRC screen in 2017
    - FDA – expect to meet with FDA regarding proposed 510(k) pathway seeking clearance for use as an adjunct to standard of care in high-risk symptomatic patients
        - Hope to begin 510(k) supporting studies in 2016. Initial indication will be CRC
        - Anticipate ~500 patient study at cost of $1M - $1.5M per indication
        - Hope to file for first 510(k) clearance in 2017
        - Follow-on indications in other cancers would follow including potentially lung and pancreatic cancer in 2018
        - PMA – hope to initiate PMA supporting studies in 2016 or 2017 for NuQ as a screening test for CRC. Expect pivotal PMA study to be significantly larger than those for 510(k) clearance – if all goes well VNRX thinks PMA studies would complete in 2018

- LDT – will continue to investigate the CLIA lab route. This could be in lieu of or in parallel with 510(k) pursuit. Management did not provide on update on status of where they are with identifying a third-party CLIA lab or if they intend to certify a lab themselves. As the 510(k) proposal is relatively new, we think it may be that they may have a more defined near-term U.S. strategy following the expected upcoming meeting with FDA

- Pancreatic Cancer:
  - Recently announced data showing pancreatic panel demonstrated 92% sensitivity @ 90% specificity. Study published in Clinical Epigenetics. We view the data as highly encouraging. Follow-on and larger confirmatory trials being planned
  - Assuming further validated in follow-on studies, VNRX thinks they could have CE Mark for pancreatic cancer in early 2017

- Lung Cancer:
  - Expect full analysis of **240-patient** lung cancer study in Q3 2016. As a reminder VNRX announced interim results, on 73 patients (29 with NSCLC, 22 with COPD and 22 healthy controls), in November which showed a panel of four NuQ assays detected 93% of lung cancer cases (27/29) with 91% specificity (2 false positives among 22 healthy controls).
  - The larger **600-patient** lung cancer trial, being conducted at University Hospital in Bonn Germany, is expected to have results this year.
  - May initiate other studies in lung cancer in 2016
  - If all goes well hope to have CE Mark for lung cancer assay/panel in Q2 2017

- Prostate Cancer:
  - Retrospective using **550 blood samples** from hospital patients in collaboration with Surrey Cancer Research Institute (Univ of Surrey, UK). Per the 10-K expect analysis to be done in Q1 2016 – which potentially means results could be available later this year.
  - Prospective **120-patient** study being done by Immune Health. Recruiting patients – shooting to have data completed in Q1 2017
  - May initiate other studies in prostate cancer in 2016

- 27-Cancer (Pan-Cancer): 4,700 patients looking at 27 of the most prevalent cancers. Analysis will be conducted with several (~25) NuQ assays. Expected to complete in 1H 2017

- Non-Cancers: last week VNRX announced the first data from a non-cancer study. Preliminary data showed NuQ was able to detect 86% of patients with Idiopathic Pulmonary Fibrosis (IPF), a fatal lung disease. The study, being conducted at Liege University Hospital in Belgium, included 30 healthy subjects and 47 IPF patients; 21 which had not been treated and 27 which had. Interim data showed NuQ detected IPF in 18 of the 21 non-treated (86%) from the healthy cohort at 80% specificity (6 false positives). VNRX expects to move into a larger study to help confirm results. Data could be available later this year. While IPF affects only about 100k in the U.S., it is usually fatal and diagnosis options are limited and costly. As such, an accurate blood-based IPF test could have real appeal.

CLINICAL TRIAL DETAILS:

- **Prostate Cancer:** feasibility study to assess NuQ in detecting prostate cancer being done in collaboration with Surrey Cancer Research Institute (Univ of Surrey, UK). Retrospective using 550 blood samples from hospital patients. Evaluated groupings will be patients with; aggressive prostate cancer, slow-growth prostate cancer and age-matched healthy individuals (control group). NuQ will also be assessed in ability to distinguish between the different prostate conditions and the controls. We think eventual pursuit of prostate cancer was almost a given based on the relatively high incidence of the disease (~250k U.S. diagnoses each year) and widespread testing despite the poor accuracy of current non-invasive diagnostics.

  There's significant debate about the benefits of prostate cancer testing as onset of the disease mostly occurs in older age, it is relatively slow-growing and usually is not the cause of death. Prostate serum antigen (PSA) tests are the most widely used front-line diagnostic with ~20 million tests performed each year in U.S. and ~45 million worldwide. But PSA is fraught with accuracy issues as studies have shown that PSA testing has a sensitivity and specificity of approximately 85% and 30%, respectively, indicating that while it is fairly good at

detecting cancer (detects 85% of cases) it is very poor at differentiating between what is, and what is not cancer (i.e. - very low specificity, resulting in high false-positive rate).

PSA's lack of accuracy in detecting prostate cancer as well as its effectiveness in reducing mortality (the ultimate goal) is highly controversial and has recently come under increasing scrutiny. In fact the USPSTF recommends that healthy men without any symptoms of prostate cancer not receive a PSA test with the USPSTF chairwoman at the time of the decision noting that, "Unfortunately, the evidence now shows that this test does not save men's lives. This test cannot tell the difference between cancers that will and will not affect a man during his natural lifetime. We need to find one that does." This 550-sample feasibility study may provide some insight into if NuQ could be the test that USPSTF is looking for.

VNRX is also working with the MD Anderson Cancer Center on a retrospective study to determine NuQ's ability to distinguish anaplastic prostate cancer, a particularly aggressive form of the disease, from typical castration resistant prostate cancer.

- **Colorectal Cancer:**

  - **Hvidore Retrospective**: in September 2015 VNRX reported additional positive interim data. The presentation supports earlier 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) – we discuss more fully below. While VNRX had previously guided for full data from 4,800-patient retrospective colorectal cancer study to be released in Q4 2015 of this year, this has been pushed back to 2H 2016. The reason is they have been working on the subset population of early-stage pre-cancerous lesions. The full data will be run with ten or more assays – which will help to narrow towards an initial panel consisting of ~4 – 6 assays. This data will be used to support CE Marking of the first CRC panel – which is expected to happen by year end
  - **Hvidore Prospective**: the timeline for release of the initial data from the 14,000 sample prospective colorectal cancer study has also slipped – VNRX had previously hoped this to be a Q1 2016 event but this is now expected in late 2016. 2,500 samples have already been run and VNRX will finish another 2,500. Initial data announcement may include the first batch or both, depending on timing of analysis. This study is comparing NuQ to FIT test, the market standard for CRC in Europe. Positive results could provide support for NuQ as a CRC screen which could significantly broaden its appeal

  - **Pre-Cancerous Colorectal Study:** a subset of the Hvidore retrospective study included patients with precancerous lesions, or adenomas. NuQ was able to detect 60% of these lesions. This prompted VNRX to initiate a study, which will is also being conducted at Hvidore Hospital, for the detection of precancerous polyps. Data was announced in mid-February which showed highly promising accuracy in this difficult to diagnose population. The double-blinded trial was and designed to detect adenomas before they become cancerous, as well as early stage colorectal cancer. It included 430 samples who either had symptoms of colorectal cancer or were at high risk. This included 42 with stage I CRC, 46 with stage II CRC and 181 with adenomas. The healthy cohort included 160 patients. A panel of five NuQ assays detected 75% of adenomas and 86% of stage I CRCs at 78% specificity. VNRX may include additional assays in this other early stage CRC studies in order to try and further improve on accuracy. The company expects to release additional data from this study later this year. The current thinking is that an adenoma assay/panel could be layered into a colorectal cancer assay or as a stand-alone product. As precancerous polyps have proven difficult to detect, relatively high accuracy in this indication could be a meaningful differentiator compared to other colon cancer tests such as Cologuard and Epi proColon. Epi proColon (Epigenomics) showed sensitivity of just 20% with small polyps and Cologuard 42% with precancerous lesions

  - **CHU Dinant Godine Colon Cancer Study:** NuQ continues to show high accuracy in colon cancer trials. Some of the most recent data comes from a small study conducted at the university hospital, CHU Dinant Godinne - UCL Namur, in Belgium. 121 patients which either had symptoms of colon cancer or were at high risk were given a colonoscopy and 23 were found to have colon cancer. The same subjects' blood samples were tested with a panel of four NuQ tests which detected 90% of colon cancer cases at 90% specificity and 67% of precancerous polyps. The panel was able to detect cancer at all stages. The results (below) are inline with earlier findings (and larger studies) which have shown NuQ to be able to detect colon cancer at specificity of at least 80% and in some cases, better than 90% and precancerous polyps at 60% or better. Additional data from VNRX's two large colon cancer studies being conducted at Hvidore hospital which combined includes almost 20k

samples as well as an 800-sample precancerous polyp study, are expected to be released in 2H 2016. These data announcements should provide even greater insight into the detection ability of NuQ in colon cancer.

	4 NuQ® biomarker assays*		5 NuQ® biomarker assays**	
	% detected	Number cases	% detected	Number cases
CRC (all stages)	91%	21 of 23 cases	87%	20 of 23 cases
CRC stage I	100%	4 of 4 cases	75%	3 of 4 cases
CRC stage II	83%	5 of 6 cases	83%	5 of 6 cases
CRC stage III	86%	6 of 7 cases	86%	6 of 7 cases
CRC stage IV	100%	4 of 4 cases	100%	4 of 4 cases
CRC unknown stage	100%	2 of 2 cases	100%	2 of 2 cases
Dysplastic pre-cancers	67%	6 of 9 cases	67%	6 of 9 cases
At 90% specificity against healthy subjects.				
*age adjusted				
**not age adjusted				

- **Lung Cancer:** In December 2014 VNRX announced that they were pursuing a larger lung cancer study, which followed positive data from a pilot study, announced in November of that year. 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.

  VNRX since initiated a larger prospective study – which includes 240 patients and is being conducted at Liege University Hospital in Belgium. Interim results, on 73 patients (29 with NSCLC, 22 with COPD and 22 healthy controls), were announced in November 2015 which showed a panel of four NuQ assays detected 93% of lung cancer cases (27/29) with 91% specificity (2 false positives among 22 healthy controls). VNRX expects the full data set from this trial to be available later this year as well as interim data from the company's larger 600-patient lung cancer trial being conducted at University Hospital in Bonn Germany. We think if NuQ can confirm accuracy at this 90%+ level in larger studies, particularly in early-stage cancers, that this should be a catalyst to the stock price given the dearth of reliable testing options, high mortality of lung cancer and significant incidence of the disease. If all goes well, VNRX thinks they can have CE Mark for lung cancer assay/panel in Q2 2017

- **27-Cancers Study**: 4,700 patients looking at 27 of the most prevalent cancers at the U of Bonn. VNRX had previously said that they hoped to have the first of the data may be available in Q1 2016, although that timeline has slipped. May have some interim data in 2016. Now expect to complete the study in 1H 2017. The study has the potential to produce an enormous amount of data given the number of assays (~25) that may be included as well as the diverse sample set. It is still a question mark as to how the output will applied, although if the data supports it, a home-run would be eventual development of an assay/panel that could detect and differentiate between several cancer types

- **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"???….*

In mid-October 2015 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 2015, 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.

And additional data, from a separate study, further supported the findings of high accuracy of NuQ in detection of pancreatic cancer. Later in October 2015 VNRX announced that NuQ was able to correctly detect 19 of 20 (**95% sensitivity**) pancreatic cancers with an **84% specificity** in patients from their 4,800-sample retrospective colorectal cancer study (while it is a colorectal cancer study, it also picked up patients with other cancers, including 20 with pancreatic cancer). Two NuQ assays along with carcino-embryonic antigen (CEA) test were used in the analysis.

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 may include one or more small clinical studies or potentially going straight to 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.

COMMERCIALIZATION

- **CE Mark / European Commercialization**: NuQ X001S is the first assay to receive CE Mark, which happened in September. Despite some delay in expected release of data from the Hvidore studies, VNRX continues to expect that additional assays and the initial panel will be approved and launch sometime in 2016. Initial panel will be supported by 4,800-sample colorectal cancer study. Follow on CRC screen could also come in 2017 and be supported by 14K-sample study.
    - Follow-ons…: VNRX will then look to strengthen both the clinical support for their technology as well as the performance. Follow-on data from the two large Hvidore studies should provide support for both – as noted, additional data should be available fairly quickly. The 14k sample prospective trial expected to have preliminary data in late 2016. This study is comparing NuQ to FIT test, the market standard for CRC in Europe. Positive results could provide support for NuQ as a CRC screen which could significantly broaden its appeal. The data should help drive development of new and higher performing assays on a regular basis and, combined into panels, can further enhance performance, providing opportunity for the next iteration of CE Marked products. Providers and payers are also interested in seeing as much data as possible to make informed use and reimbursement decisions – so a regular flow of positive trial data will be key to maximizing initial chances of success in the marketplace
    - Commercialization: VNRX does not expect to launch into Europe until they have more supporting data and the full panel CE Marked – which they think can happen in 2016 – we think it's more likely a 2H event than in 1H. And while we model some (immaterial) revenue related to an assumed introduction in Europe in late 2016, it is possible launch slips to 1H 2017. VNRX recently brought on two consulting firms to guide the European commercialization strategy which includes advice on market selection, reimbursement expectations, distribution, etc.
    - More follow-ons…: with the plethora of data expected to come out of the various studies, VNRX hopes to further enhance the performance of their tests and bring further iterations of cancer panels through CE Marking. Clearly the initial focus is colorectal cancer but pancreatic, lung and others could potentially follow in short-order. And possibly, eventually a multi-cancer panel Pancreatic now looks like it will be the second indication. As it is now, VNRX hopes to have CE Mark for pancreatic and lung cancer assays/panels in 2017
    - Our Comments: Epigenomics has had a tough go of it in Europe with their IVD Epi proColon colon cancer blood test. While the test has been available since 2012 product revenue from Europe amounted to roughly $1 million in all of 2014. They cite a difficult reimbursement environment and high barriers to get into the government level screening programs. Part of the difficulty is most likely pricing - as Cameron noted on a prior call, the government programs are tight-fisted and to be competitive pricing needs to be near the EUR 20 – 30 range (~$20 - $30). And if Epigenomics can't or won't come in near there, then it is reasonable they may not qualify. VNRX indicated that they

believe they can meet that price point and maintain reasonable margins. They brought on the two consulting firms (one focused on the U.K. and the other the rest of Europe) to help navigate the intricacies and difficulties – one potentially major one being reimbursement – of the European market. VNRX may also have an advantage in accuracy – the data to-date has suggested NuQ may have superior accuracy as compared to the 79% sensitivity / 68% specificity Epi proColon demonstrated in their PMA-supporting studies. This could be particularly true in pre-cancerous lesions – a much more difficult population to identify but one which NuQ has shown impressive accuracy. If confirmed in larger studies, this could draw particularly strong appeal. As more data is announced, it should provide greater insight.

We think it is reasonable to expect revenue from Europe will not be overly significant in the first year of launch, particularly if initial commercialization does not happen until late in the year. This could improve with further penetration throughout Europe and also depend on reimbursement and inclusion in government screening programs.

- **U.S. Pathway**: initial U.S. introduction is expected to be in the form of licensing rights to the technology to CLIA certified labs to develop LDT tests and/or via 510(k) clearance. Concurrent with that VNRX would work to bring an FDA approved test (i.e. PMA) to market.

  VNRX has brought on another consultant to guide them in their U.S. plans. Timelines for the possible CLIA lab route are uncertain although management indicated on the Q4 call that they will continue to investigate this along with the more recent strategy to potentially pursue 510(k) clearance. They will first meet with FDA regarding proposed 510(k) pathway seeking clearance for use as an adjunct to standard of care in high-risk symptomatic patients. Assuming that route remains feasible, current expectations include;

  - FDA – expect to meet with FDA this year regarding proposed 510(k) pathway seeking clearance for use as an adjunct to standard of care in high-risk symptomatic patients
  - Hope to begin 510(k) supporting studies in 2016. Initial indication will be CRC
  - Anticipate ~500 patient study at cost of $1M - $1.5M per indication
  - Hope to file for first 510(k) clearance in 2017
  - Follow-on indications in other cancers would follow including potentially lung and pancreatic cancer in 2018

  LDT – will continue to investigate the CLIA lab route. This could be in lieu of or in parallel with 510(k) pursuit. Management did not provide on update on the Q4 2015 earnings call on status of where they are with identifying a third-party CLIA lab or if they intend to certify a lab themselves. As the 510(k) proposal is relatively new, we think it may be that they may have a more defined near-term U.S. strategy following the expected upcoming meeting with FDA.

  The 510(k) clearance pathway affords the potentially to market the test on a broader scale and one which VNRX would have control over. As we've noted before, while LDT's offer the opportunity to get the tests into the market, generate earlier revenue and build some front-end awareness about the technology (although the tests would likely be marketed under another brand), they may hold only a fraction of the revenue potential that a PMA approved product would – and quite possibly less than an FDA-cleared (i.e. 510(k) pathway) would.

  Relative to the FDA PMA-approval process – this is still being refined – initially VNRX was hoping to support a PMA filing with data from the ongoing studies (prospective and retrospective most likely) and then potentially supplement that with a "bridging" study – essentially additional samples from more ethnicities to more represent the broader U.S. population. This, however, is not yet definitive and something that we expect we will hear more about as more info is available. The goal with PMA approval would be to gain FDA approval as a CRC screen – this would be essentially the best possible indication as it would be a first-line diagnosis.

  Timelines for an eventual FDA approved product are highly uncertain right now as there still needs to be clarification from FDA on what they will require to support a filing. VNRX hopes to initiate a PMA-supporting study this year or next and believes that if all goes well the studies could complete in 2018. If that timeline is feasible, the earliest that an FDA approved (i.e. PMA pathway) assay/panel could likely come to the U.S. market is 2019. We think it is not unlikely that it would be later than 2019, however.

OUTLOOK / VALUATION / RECOMMENDATION

We continue to model launch in Europe in late 2016 – although it is quite possible that this could slip until 2017. Broadening the label in Europe to include as a CRC screen could have the effect of accelerating interest in demand. We continue to expect data from the large Danish CRC studies as well as pre- and early-stage cancer to provide greater insight into the utility of the assays for CRC. 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 – as noted, we think pancreatic could emerge as a very formidable indication if larger studies confirm the early highly encouraging data. 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) and/or 510(k), makes a lot of sense. Not only are these earlier revenue opportunities 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.

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 (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. Epi proColon has also shown relatively low sensitivity (20%) in precancerous polyps – which is another potential indication that NuQ could demonstrate superior accuracy.

Valuation Remains Attractive…

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 $6.44/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.

Based on the number of studies anticipated to read out during 2016, this should be a telling year in terms of the potential utility of the NuQ assays in a variety cancers. And 2016 is also expected to include CE Marking of the initial CRC assay, commercial introduction in Europe and more clarity on the U.S. commercialization pathway. 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 ($3.40) 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 should further benefit appreciation of the share price towards our target. We are maintaining our Buy recommendation.

FINANCIAL MODEL

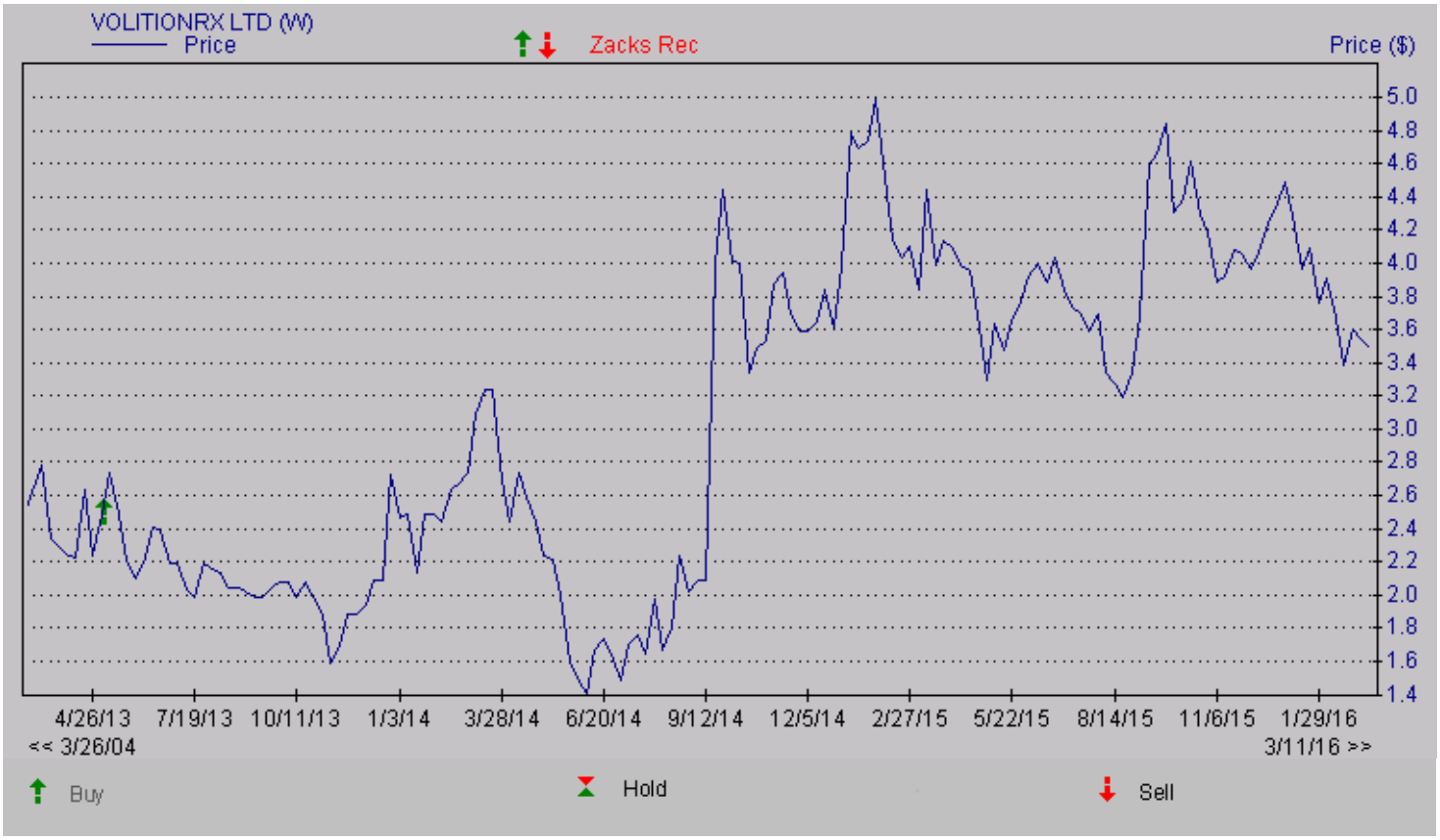
VolitionRx Ltd.

	2015 A	Q1 E	Q2 E	Q3 E	Q4 E	2016 E	2017 E	2018 E	2019 E
Revenue	$0.0	$0.0	$0.0	$0.0	$84.3	$84.3	$1,741.9	$4,918.8	$12,896.0
YOY Growth	-	-	-	-	-	-	*1967.1%*	*182.4%*	*162.2%*
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$48.9	$48.9	$873.7	$2,213.4	$5,273.9
Gross Income	$0.0	$0.0	$0.0	$0.0	$35.4	$35.4	$868.2	$2,705.3	$7,622.1
Gross Margin	-	-	-	-	*42.0%*	*42.0%*	*49.8%*	*55.0%*	*59.1%*
SG&A	$3,903.8	$1,141.0	$1,019.0	$1,124.0	$1,087.0	$4,371.0	$4,820.0	$5,470.0	$6,485.0
%SG&A	-	-	-	-	-	*5186.9%*	*276.7%*	*111.2%*	*50.3%*
R&D	$6,101.7	$1,748.0	$1,822.0	$2,025.0	$2,215.0	$7,810.0	$8,800.0	$9,150.0	$9,000.0
% R&D	-	-	-	-	-	*9267.8%*	*505.2%*	*186.0%*	*69.8%*
Asset Impairment	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($10,005.5)	($2,889.0)	($2,841.0)	($3,149.0)	($3,266.6)	($12,145.6)	($12,751.8)	($11,914.7)	($7,862.9)
Operating Margin	-	-	-	-	-	-	*-732.1%*	*-242.2%*	*-61.0%*
Total Other Expense (Income)	($502.2)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($9,503.3)	($2,889.0)	($2,841.0)	($3,149.0)	($3,266.6)	($12,145.6)	($12,751.8)	($11,914.7)	($7,862.9)
Taxes (benefit)	($4.6)	$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	$12.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($9,510.6)	($2,889.0)	($2,841.0)	($3,149.0)	($3,266.6)	($12,145.6)	($12,751.8)	($11,914.7)	($7,862.9)
Net Margin	*#DIV/0!*	-	-	-	-	*-14412.7%*	*-732.1%*	*-242.2%*	*-61.0%*
EPS	($0.54)	($0.16)	($0.15)	($0.16)	($0.15)	($0.62)	($0.53)	($0.41)	($0.25)
YOY Growth	-	-	-	-	-	-	-	-	
Diluted Shares O/S	17,734	18,520	18,800	19,500	21,250	19,518	24,000	29,000	32,000

Brian Marckx, CFA

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