Zacks Small-Cap Research

November 10, 2014

Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

scr.zacks.com

10 S. Riverside Plaza, Ste 1600, Chicago, IL 60606

VolitionRx Ltd (VNRX-OTC)

VNRX: Positive Study Data Provides Runway to CE Mark Filing

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	05/07/2013
Current Price (11/10/14)	$3.99
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 which should help fund the U.S. development program. Despite risks such as that VNRX will need to raise significant capital before they reach cash flow positive, we think the shares are very attractive at the current market price. Our DCF model values the stock at about $7/share..

SUMMARY DATA

52-Week High	**$9.28**
52-Week Low	**$1.25**
One-Year Return (%)	**100.00**
Beta	**-3.59**
Average Daily Volume (sh)	**36,210**
Shares Outstanding (mil)	**13**
Market Capitalization ($mil)	**$54**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**41**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2014 Estimate	**N/A**
P/E using 2015 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in '000)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	$0 A	$0 A	$0 A	$0 A	$0 A
2014					$80 E
2015					$944 E
2016					$4342 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.09 A	-$0.10 A	-$0.08 A	-$0.07 A	-$0.34 A
2014	-$0.18 A	$0.06 A	-$0.44 A	-$0.10 E	-$0.65 E
2015					-$0.34 E
2016					-$0.14 E

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

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WHAT'S NEW…..

Q3 2014
VNRX filed their 10-Q for the third quarter ending September 30, 2014. Operating expenses experienced a substantial uptick on both a yoy and sequential basis. G&A increased mostly from non-cash stock compensation while the jump in R&D relates to ramping up of ongoing clinical studies as well as initiation of the new Danish study.

Excluding $4.1M in non-cash expense related to the revaluation of derivative liability, pre-tax income was ($1.8)M, compared to ($926)k in Q3 2013 and ($1.1)M in Q2 2014. EPS with and without the derivate income was ($0.44) and ($0.13), respectively.

Cash used in operating activities was $864k but excluding changes in working capital, cash used was $1.2M. VNRX exited the quarter with $2.4M in cash and equivalents.

New Data Shows NuQ's Ability to Detect Cancer At All Stages, Including Critical Early Stages:
In September 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 in early October 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.

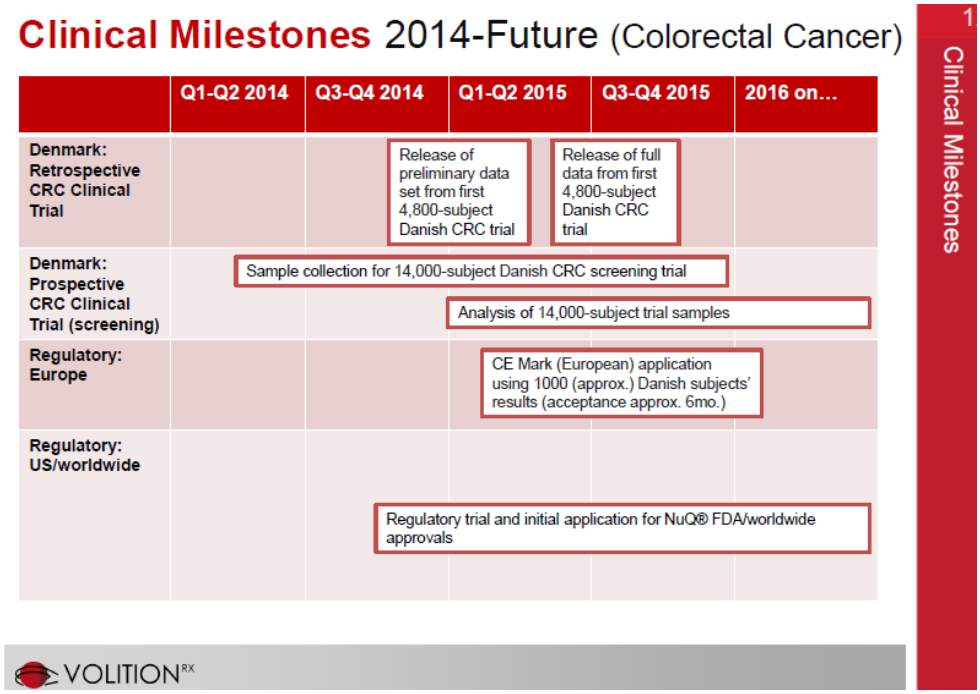
VNRX has indicated that they expect to file for CE Marking by the current year-end. We expect this positive data to-date will be supporting their application. We continue to model launch of a NuQ panel for colorectal cancer to launch in Europe next year.

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

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

Update on Colon Cancer Milestone Timelines

VNRX has presented at several conferences and industry events over the past few months, including the aforementioned Aegis healthcare conference and International Conference of Anticancer Research. Along with the recent clinical trial results the company provided an update on expected milestone timelines and reiterated its commercialization strategy. Below is a slide from the Aegis presentation - these timelines largely reflect our earlier expectations, with some elongation in expected trial completion.



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 noted that they think they may have data on the initial ~3k samples in Q1 2015 and interim data on a somewhat regular basis as they expect to be able to process ~500 sample per month.

Regulatory timelines also remain mostly in-line with our prior 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 early/mid-2015 - which means European launch could still happen prior to 2015 year-end. 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 CLIA lab market can be accessed without FDA approval through selling the tests as analyte specific reagents (ASR) to other in vitro diagnostic test manufacturers and laboratories or through selling the testing service as a laboratory developed test (LDT) from a CLIA lab. And while this may offer an opportunity to begin selling the technology in the U.S. in the near-term, ASRs and LDTs can not be marketed for specific indications and target a relatively small portion of the overall IVD market. As such, FDA approval remains the end-goal.

VNRX Looking at Prostate Cancer

VNRX continues to expand the potential indications for its NuQ technology and in early October 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.

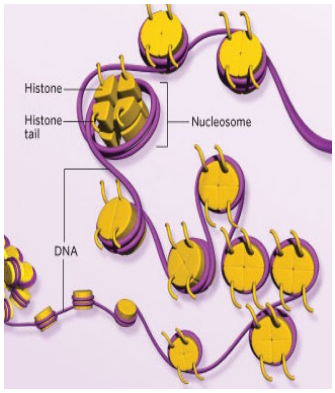
While the accuracy of Cologuard clearly stacks up strongly to NuQ (to-date), Cologuard has certain disadvantages including that it is a stool test, which can suffer from low compliance due to dislike of handling stool, and the relatively high price point. As NuQ is a blood test, there is no stool handling 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.

BACKGROUND

Epigenetics: Relatively New Role In Cancer Detection…

VNRX's test technology is based on the field of epigenetics. Epigenetics refers to functional changes in the genome, or the switching on and off of genes, which are caused by something other than changes in the underlying DNA sequence (see Appendix for more in-depth explanation of epigenetics). An example is histone (proteins that order DNA into nucleosomes) modification which regulate gene expression but does not change the underlying DNA sequence. Nucleosomes are the basic unit of DNA packaging, which consists of 146 base pairs of DNA wound around a four histone protein core.

Nucleosome: DNA Wound Around Histone



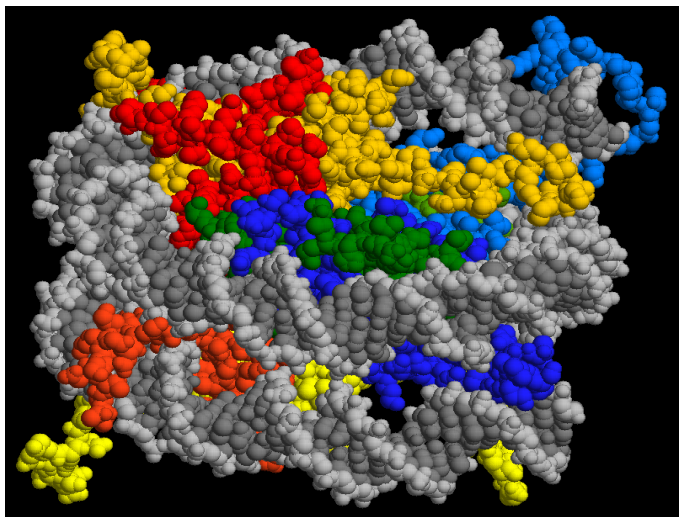
SOURCE: the-scientist.com / Stefan Kubicek

Epigenetics' role in detecting cancer is relatively new with the first real discoveries not culminating until around the mid-1990's. Research has accelerated since, facilitated in part by better DNA sequencing technologies. One of the most significant recent discoveries of epigenetic's role in cancer was how certain epigenetic changes in the GSTP1 gene are a marker for prostate cancer.

The structure of nucleosomes in cancer cells is different than that of healthy cells and it also appears that the structure of nucleosomes is different among types of cancers (e.g. colon vs. breast). VNRX's tests are designed to identify cancer by detecting the level and structure of nucleosomes in the blood. Cancer results in accelerated cell growth and death - when the cells die the nucleosomes are released into the blood and recycled into the body. VNRX's tests have been developed to identify the presence of cancer and also to identify the type of cancer from the levels of nucleosomes in the blood well as the different structure of nucleosomes.

And while VNRX's main focus is on cancer (and particularly colon cancer, at least initially), potential derivative applications include diagnosis of other conditions where elevated blood nucleosomes have also been shown to be present. These include autoimmune diseases (e.g. - rheumatoid arthritis, Crohn's disease, etc), sepsis, and inflammatory-related diseases. Patients with some of these derivative-type conditions (along with healthy and cancer patients) will be included in the planned and ongoing clinical trials. And specific to research related to inflammatory disease, in September 2013 VNRX, along with Alcyomics, were awarded a European grant which is aimed at promoting development of new products from small and medium sized companies. The EUREKA Eurostars grant, worth about $1 million total and about $560k of which is expected to be received by VNRX, will help fund Volition's research for its technology in inflammatory disease. We view this as a small, yet meaningful step towards expanding potential applications outside of cancer.

Structure of Nucleosome



Histones - Red/Blue/Orange/Yellow
DNA - Grey

SOURCE: Protein Data Bank

PATENT PROTECTION / INTELLECTUAL PROPERTY

VNRX product candidates are covered by eight families of patents which the company either authored themselves or licenses from research institutions including from Imperial College, London and the European Molecular Biology Laboratory. As VNRX is possibly the only (or at least one of very few) company in the world pursuing nucleosomes

in the blood for cancer detection, they have been able to rapidly build a patent-moat around their technology and intended applications. Most of the current patents were applied for in 2011, with patent protection afforded through 2031. In addition to the current patents (listed below), the company recently (April 2013) filed for two new patent applications (including one using their technology in personalized medicine as a predictor of the efficacy of cancer treatment) and expects to continue to broaden the intellectual property base and further fortify and lengthen the patent protection of their products and pipeline via ongoing patent filings. Current patent protection encompasses (per company public documents);

Nucleosomics IP

- Exclusive license from Chroma Therapeutics: Nucleosomics WO2005019826 – Detection of histone modifications in cell-free Nucleosomes. Patent granted in Europe, pending in USA *(Patent that underlies the NuQ-M tests)*
- Worldwide exclusive license in the field of cancer diagnosis and cancer prognosis from the European Molecular Biology Laboratory: EMBL Variant Patent WO2011000573 – Diagnostic method for predicting the risk of cancer recurrence based on macroH2A isoforms. Patent pending worldwide
- Volition-authored application: NuQ Patent UK1115099.2 & US61530300 – Method for Detecting Nucleosomes. Patent pending worldwide *(Patent that underlies the Nucleosomics assay technology)*
- Volition-authored application: NuQ-X Patent UK1115095.0 & US61530295 – Method for Detecting Nucleosomes Containing Nucleotides. Patent pending worldwide *(Patent that underlies the NuQ-X technology).*
- Volition-authored application: NuQ-V Patent UK1115098.4 & US61530304 – Method For Detecting Nucleosomes Containing Histone Variants. Patent pending worldwide. *(Patent that underlies the NuQ-V technology)*
- Volition-authored application: NuQ-A Patent UK1121040.8 and U.S. 61568090: Method for detecting Nucleosome Adducts. Patent pending worldwide. *(Patent that underlies the NuQ-A technology)*

HyperGenomics IP

VNRX had previously licensed a patent from Imperial College, London for HyperGenomics technology. However, in late 2013 it was discovered that an unrelated entity had already filed a similar patent. The company noted in its 2013 10-K that they hope to file a methodology patent for HyperGenomics in the first half of 2014.

Endometriosis IP

Volition-authored application: Endometriosis Diagnostic UK1012662.1 – Method for detecting the presence of a gynecological growth. Patent pending worldwide

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CLINICAL DEVELOPMENT

Clinical Data To-Date Is Highly Promising…

VNRX initiated clinical testing in 2012 with a small internal study, positive results from which were announced in November of that year. Since then the company has announced several more studies including two colorectal cancer studies through collaborations with University of Copenhagen, a colorectal cancer study at CHU-UCL Mont-Godinne Hospital in Belgium, three studies in collaboration with the University Hospital Bonn in Germany, and a larger (800-patient) internal study being done in collaboration with Wales Cancer Bank. Data continues to be positive, including recent data released from the Bonn University and Mont-Godinne studies. But the most compelling and positive data to-date came in September and October of this year from the Danish retrospective colon cancer study. Below is a synopsis of some of the various clinical studies that VNRX's technology has been evaluated in and a discussion of the trial data to-date, including the particularly compelling recent data from the large Danish-based colon cancer study.

Bonn University Hospital

In mid-2012 VNRX entered a collaboration with Bonn University Hospital in Germany (Rheinische Friedrich-Wilhelms-Universitat Bonn) to perform clinical trials in the evaluation of Volition's NuQ assays for cancer diagnosis and in other diseases. Lead investigator of the trials is Dr. Stefan Holdenrieder of the Institute of Clinical Chemistry and Clinical Pharmacology at University Hospital Bonn who is considered a world-renowned expert in the field of circulating nucelosomes and has authored over 70 journal papers.

The collaboration includes a large multi-year prospective study in which blood samples will be collected from patients at U of Bonn Hospital. The study was initially expected to commence in July 2012 but this timeline was

pushed back in order for the initial validation studies to complete. With positive results from these initial studies, VNRX is now enrolling for this larger study. Anticipated that blood samples will be taken from at least 4,000 patients including those that are; healthy, those that have cancer (including 20 of the most prevalent cancers at various stages of disease), and those that have conditions other than cancer such as organ-related benign diseases, metabolic diseases (ie - renal failure, autoimmune diseases), acute diseases (ie - sepsis, inflammation, trauma, stroke), and chronic degenerative diseases. The study will evaluate the NuQ tests in diagnosis of cancer as well as derivate application such as with the other diseases and conditions listed above. Holdenreider is also expected to conduct a 100-patient lung cancer monitoring trial.

In early November 2013 VolitionRx announced data from 90 patients (24 colorectal cancer (CRC), 10 benign colorectal diseased (BCD), and 56 healthy controls (HC)) tested with its NuQ-5m assay for colorectal cancer. Results, which were presented by Dr. Holdenrieder at the 8th Circulating Nucleic Acids in Plasma and Serum (CNAPS) congress in Baltimore, were encouraging and showed the assay was able to detect 75% of patients with colorectal cancer with a 70% specificity. These findings were confirmed on a second set of 113 patients (49 CRC, 26 BCD, 38 HC). The assay detected significantly (95% CI) lower levels of NuQ-5mc in CRC and BCD compared to HC although no differences were found between CRC and BCD. Relative to differentiation of CRC from HC, sensitivities improved from 33% at a 95% specificity to 75% at a 70% specificity. In April 2014 these results were published in the online version of the peer-reviewed journal, Anticancer Research, in an article titled "Novel Serum Nucleosomics Biomarkers for the Detection of Colorectal Cancer".

Dr. Holdenreider's study results and comments are clearly encouraging in terms of what they indicate for utility and accuracy of the test. Following publication of the recent data, Holdenreider decided to be directly involved in the performance evaluation of the NuQ assays for CE Marking purposes for colon cancer. He will be conducting a confirmatory trial using samples from the Hvidore sample base for the CE Mark performance evaluation.

The Bonn collaboration may also include a study for the validation of the tests as a predictor of the performance and therapy monitoring of chemotherapy. Expected to enroll ~300 patients with a variety of cancers. The samples will be collected before each of the 6 to 8 therapy cycles and will be correlated with the radiological response evaluation. For both clinical scenarios, the NuQ tests will be compared with already established tumor markers to see their specific use in the clinical application.

Colorectal Cancer Study

In August 2012 VNRX announced an agreement with Biobank of CHU UCL Mont-Godinne, an academic hospital in Yvoir, Belgium for a prospective longitudinal study with ~ 250 patients as they progress through diagnosis and treatment of colorectal cancer. This is the first trial using VNRX tests focused on a single cancer (colorectal). Enrollment will include patients with a potential digestive pathology such as suspected colorectal cancer, polyps, Crohn's disease and colitis. The goal of the study is for VNRX's NuQ to be able to distinguish between patients with cancer and those with digestive conditions that indicate similar symptoms. Patient sampling is occurring at CHU UCL Mont-Godinne and Volition will analyze the samples at their lab in Belgium.

Preliminary results from 39 patients, announced in December 2013 at the Clinical Genomics and Informatics Europe Conference in Portugal, showed that when two of the NuQ tests are combined and used together, they were able to detect 85% of cancers with an 85% specificity. The combination test was also able to detect more than 50% of precancerous polyps.

Hvidovre Hospital, University of Copenhagen

In late May 2013 VNRX announced they signed an agreement with Hvidovre Hospital at the University of Copenhagen in Denmark whereby VNRX would obtain ~10,800 patient blood samples for analysis with VolitionRx's NuQ tests. This sample base was subsequently increased to ~15,800.

4,800 of the samples were collected by Hvidovre Hospital under the direction of Professor Hans Jorgen Nielsen (Professor of Surgical Oncology at the Department of Surgical Gastroenterology) from 2010 - 2012. These patients had colorectal cancer as well as other diseases. They also underwent colonoscopies, which along with a plethora of patient background, treatment and follow-up data, makes for a very robust set of data for VolitionRx to use in their analysis of the samples with their NuQ tests which will initially use the samples for detection of colorectal cancer. Not only is the sample and data set high quality and comprehensive, it comes at almost no cost to VNRX with Professor Nielsen offering the samples for free in the hopes it will advance VNRX's efforts in bringing an early cancer detection test to market.

Analysis of the first 1,000 samples commenced in June 2013 and was presented at the Aegis Healthcare conference in September (see our discussion below). This data is expected to be included in the CE Mark

submission, which is now anticipated to happen in early/mid-2015. Dr. Holdenrieder, who is conducting the Bon Hospital studies and is leading the CE Mark performance evaluation process, will be conducting a confirmatory trial using patient samples from Hvidore. We continue to look for CE Mark to be granted in 2015.

The other ~11,000 samples are being collected in a prospective trial which is being jointly funded by VNRX, the University of Copenhagen and a "top ten global diagnostics company." The samples are being collected at the University of Copenhagen under the direction of Professor Nielsen. Collection has commenced and could be completed by the end of 2015. The samples are provided to VNRX blinded and randomized. VNRX anticipates they will spend only about $1.8 million for collection of these samples.

We view this agreement a significant positive for moving VNRX's development programs forward. This provides the company with a very large, high quality sample and data set for a fraction of the cost that they would have had to spend had they run prospective studies on their own (which could have easily cost $10 million - $25 million) and also now puts a more definitive timeline on when CE Mark application could happen. The data from these studies are also expected to be used to help support an eventual FDA filing.

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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.

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

CURRENT CANCER DIAGNOSTICS / SCREENING METHODS

Current cancer diagnosis and screening methods leave a substantial room for improvement in terms of accuracy, cost, patient comfort, and in finding cancers at an earlier, more treatable stage. In general, the more definitive diagnostic methods are more invasive, more time consuming and more costly (such as colonoscopy for colon cancer) while the less invasive and less expensive methods, which are often used for screening and more convenient and patient-friendly, can be unreliable and in some cases, cause more harm than good - yet many are still widely used by healthcare practitioners (see Appendix which highlights the issues with PSA testing for prostate cancer). VNRX's NuQ technology 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.

Below we discuss some of the current diagnostic and screening methods and related drawbacks used for the four cancers that VNRX has indicated will be part of their initial focus. While this is not an exhaustive list of cancers that the NuQ technology could be used for, particularly given that VNRX has a platform technology that could be expanded to dozens of cancers (as well as potentially to other conditions that are related to elevated nucleosomes), we think it provides insight into the dearth of reliable, accurate, low-cost and patient-friendly diagnostics and screens for cancer and opens up a significant potential opportunity for a more effective screening test or method - which we think VNRX could potentially exploit with their NuQ panel.

Colon Cancer

The most effective diagnostic for colon cancer is invasive colonoscopy or flexible sigmoidoscopy. Definitive diagnosis is done with biopsy of suspicious polyps which are removed during colonoscopy/sigmoidoscopy. CT scan is then used to determine the extent of the cancer to determine if and how far it has spread. Colonoscopy screenings are recommended every ten years beginning at the age of 50. Colonoscopy has shown to be an effective diagnostic in finding colon cancer, with published reports indicating a 50% or greater risk reduction in developing early or late stage cancer with recommended screenings. However, there are significant drawbacks of colonoscopies, namely, at about $1,000 per procedure, it’s a relatively high cost screening tool (particularly compared to VNRX's relatively inexpensive testing option) and it's very invasive, uncomfortable and time consuming, requiring the patient to be sedated as a fiber optic camera is threaded through the interior walls of the rectum and colon. Approximately 3.1 million colonoscopies are performed in the U.S. every year (and about 4.1

million done in Europe) which indicates that despite the drawbacks, there's a very substantial market for colon cancer screening - which would presumably expand even further with the availability of an accurate, easy to use, inexpensive and non-invasive screening test such as NuQ.

Other colon cancer diagnostics / screens include;

- Double-contrast barium enema: patient receives an enema with barium sulfate, a contrast agent, followed by x-rays of the colon and rectum. Weakness of double-contrast enemas are that they are moderately invasive, can miss small polyps and false positives can be a serious issue
- Fecal occult blood tests: checks for blood in the feces which may be indicative of cancer. Commonly used as a first-line screen for colon cancer. Drawbacks include stool handling, significant potential for false positives, results can be influenced by diet, and lower sensitivity (as low as 30% in some studies). Despite these drawbacks fecal occult blood tests are widely used with approximately 140 million of these tests performed worldwide every year

Lung Cancer

There's been some debate about the merits of screening for lung cancer given the lack of consistently reliable evidence that lung cancer screening programs provide a definitive benefit relative to improving earlier detection of the disease. Unlike colon and breast cancer, which have their respective gold-standard (albeit not necessarily very effective 'gold-standards', particularly with mammography) screening tests/methods, lung cancer does not have a leading screening test or method. While some medical organizations such as the American College of Chest Physicians recommend against routine lung cancer screening, others such as the National Comprehensive Cancer Network, which issued its guidelines in 2012, are in favor of a process for screening higher-risk individuals. The U.S. Preventative Services Task Force (USPSTF), recommendations from which often influence public and private insurance reimbursement policy and decisions, recommends annual screening with CT for those 55 – 85 years old with a 30 pack/yr smoking history or those who have quit within the last 15 years (i.e. – high risk individuals). Most recommendations that are in favor of lung cancer screening are aimed at symptomatic and high-risk individuals such as smokers as smoking causes about 90% of lung cancers.

Lung cancer diagnostics / screens include;

- Chest radiographs (with or w/o sputum cytology): advantages of a chest x-ray is it's non-invasive, relatively fast and has been shown to be at least somewhat effective in finding lung cancer, even at early-stages. Drawbacks are that some studies have shown a low sensitivity and not effective in reducing mortality of lung cancer
- Low-dose computed tomography (LDCT): advantages are CT may be more effective in finding lung cancer than chest x-rays. CT scans have shown some promise in detecting even early-stage lung cancers in some studies but its effectiveness has not been consistently confirmed in other studies. Disadvantages are CT scans are relatively expensive and have shown a high false positive rate in studies with high-risk patients, which have ranged from 5% to 50%

Breast Cancer

Mammography remains the number one screening tool for breast cancer with about 40 million mammograms done every year in the U.S. In Europe the use of mammograms is even higher than that in the U.S. Advantages are that it's relatively fast and is non-invasive. Disadvantages are that it's arguably (depending on the study cited) ineffective at reducing breast cancer mortality, has a substantial false positive rate (7% - 15%), is even less effective in women with dense breasts and has even been implicated as causing more harm than good. For a variety of these reasons, mammography is not recommended for asymptomatic women under 50. For women over 50 the USPSTF recommends a mammography every two years.

Other breast cancer diagnostics / screens include;

- MRI: advantages are its non-invasive and has demonstrated higher sensitivity than mammography, can check multiple tumor locations, and analyze tumor growth in dense tissue. MRI suffers some significant weaknesses, however, including low specificity (~30% rate in some studies) which, along with a higher cost than mammography, has confined its use mostly to high-risk patients. Unlike mammography which is used both as a screening and diagnostic tool, breast MRI is largely only used for diagnosis.
- BRCA1 / BRCA2 gene mutations: these gene mutations may indicate an individual is at higher risk of developing breast and ovarian cancer. Advantages are ease and low cost of testing (done using a blood sample). Weakness is that this does not detect cancer, it only indicates a higher risk of developing it, and only about 5% - 10% are linked to these genes

Pancreatic Cancer

There are currently no tests on the market than can reliably diagnose early-stage pancreatic cancer. 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."

Pancreatic cancer diagnostics / screens include;

- CA19-9 Marker test: cancer antigen 19-9 is considered the best tumor marker test in identifying pancreatic cancer. The advantages are it's an easy to perform blood test. The weaknesses are many, however, and include a high rate of both false negatives and false positives and it is generally not reliable in detecting early stage cancer (which is particularly important with pancreatic cancer)
- Endoscopic Ultrasound: involves the insertion of an endoscopy combined with ultrasound. Advantages are that it's been found to have a relatively high sensitivity in detecting pancreatic cancer in symptomatic patients. Disadvantages are it's invasive and may not be very effective in finding early stage cancer
- Imaging (CT/MRI/PET): mostly used to determine staging (i.e. - how far it's spread) of the disease. Generally ineffective as a screening tool or for early diagnosis

OUTLOOK / VALUATION / RECOMMENDATION

VNRX's current plan relative to commercialization is to initially promote to the research market which potentially provides the company with an opportunity to build awareness about the products as well as expands the validation experience of their technology. The company recently brought on a director of sales and marketing to lead the RUO sales effort and also signed distribution agreements for RUO products for the U.S., Europe, Japan, Thailand, Indonesia and Singapore. The RUO market, which consists of selling to research-oriented institutions such as medical universities for uses outside of patient diagnosis, likely offers only a fraction of the revenue opportunity compared to the commercial clinical market, however.

In the meantime, VNRX will pursue CE Mark in order to sell the tests to the clinical market in Europe (which could happen in 2015) and FDA approval for the U.S. market (which is likely at least two years away). Key to increase chances of successfully gaining regulatory approvals (Europe and U.S.) will be to demonstrate high enough accuracy (sensitivity = true positive cancer rate, specificity = true negative cancer rate). The lingering question is 'how high is high enough?' - which is very difficult to determine at this point. The hurdle for CE Mark may be lower in that regard than for FDA approval. The current lack of a consistently reliable, low-cost, non-invasive cancer diagnostic means that the bar may be at a very achievable level.

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.

Relative to FDA approval, given that there are no tests currently on the market that would likely be considered "predicate devices" and with cancer tests considered Class III medical devices, we think it's probable that FDA approval would need to follow the PMA pathway. This will almost certainly require U.S.-based clinical studies, potentially including several thousands of patients and taking a number of years to complete. If, however, U.S. marketing approval can be obtained with the much simpler 510(k) pathway - possibly using the tests as an adjunct to current cancer diagnostic methods - this would likely significantly reduce time to the U.S. market launch. As it is now, we model a launch to the clinical lab market in the U.S. in 2017 - which could end up being conservative, particularly if 510(k) clearance is deemed sufficient to sell to the clinical market. However, as VNRX pursues FDA approval they also hope to launch their tests to the U.S. CLIA labs market. The CLIA lab market can be accessed without FDA approval through selling the tests as analyte specific reagents (ASR) to other in vitro diagnostic test manufacturers and laboratories or through selling the testing service as a laboratory

developed test (LDT) from a CLIA lab. And while this may offer an opportunity to begin selling the technology in the U.S. in the near-term, ASRs and LDTs can not be marketed for specific indications and target a relatively small portion of the overall IVD market. As such, FDA approval remains the end-goal.

Assuming requisite regulatory approvals, VNRX's commercialization game-plan to tap the clinical lab markets may include either an agreement with another diagnostic company (instrument manufacturer?) or other third-party distribution (clinical lab?) which could allow the company to focus their resources on scaling up production rather than on building a sales force and facing the associated fixed-cost risks of doing so. The European market should afford the opportunity to generate revenue and cash and help fund the U.S. development and regulatory program.

Data from ongoing and future clinical trials should not only provide more insight into the chances of regulatory approval, it should also help determine the potential diagnostic utility of the tests. There may be more insight into this with additional results from the studies using the samples from the University of Copenhagen for colon cancer - initial data has clearly been encouraging.

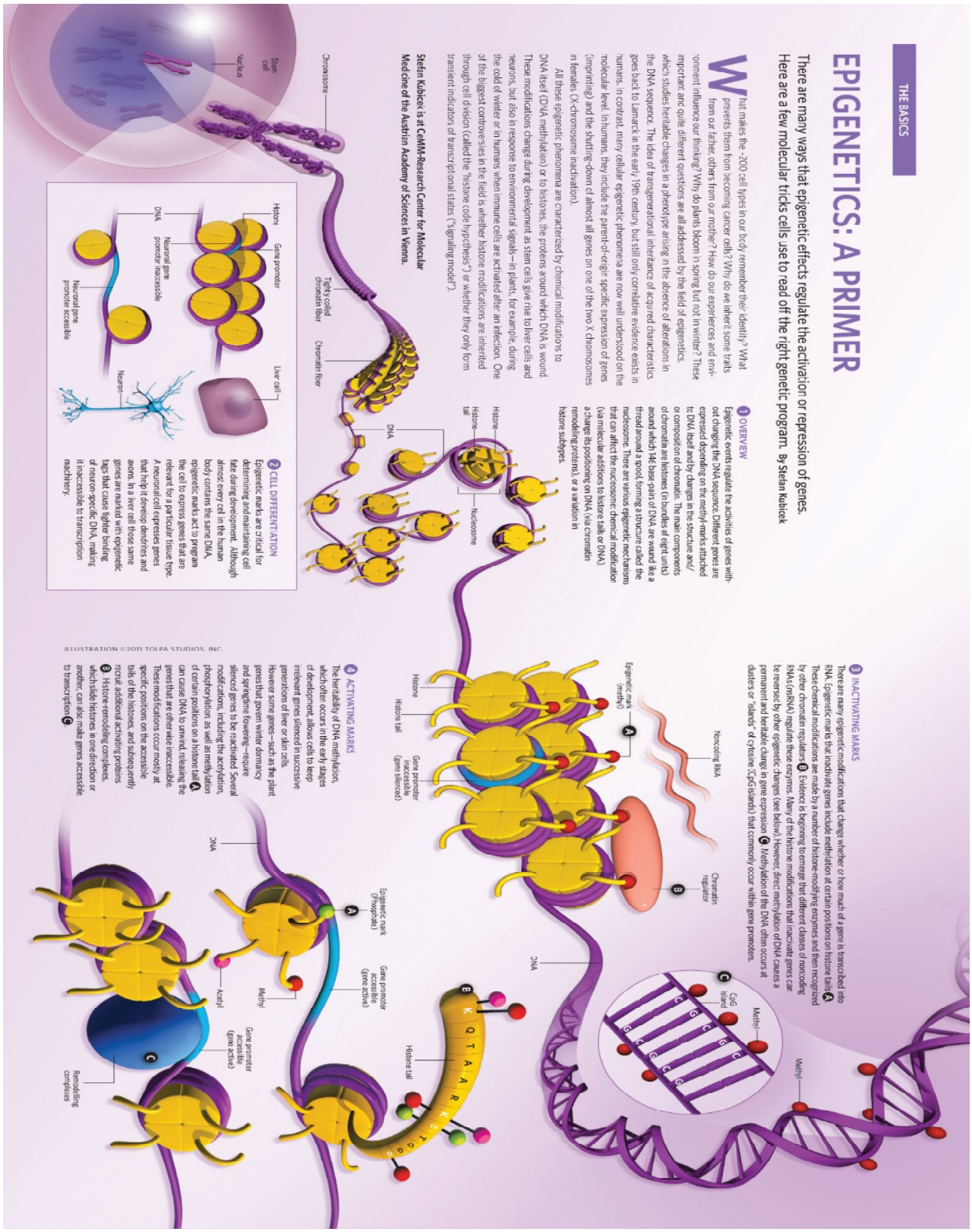
Depending on how strongly healthcare practitioners, third party payers (public and private), and influential medical organizations (such as USPSTF, American Cancer Society, etc.) view the utility of the tests, it's conceivable that VNRX's tests could take share of not only the current IVD cancer market, but also penetrate the markets of other cancer screening and testing methods (e.g. - colonoscopy, mammogram, advanced imaging, etc). These markets are enormous (as we discussed earlier in this report) and many times the size of the current IVD cancer segments. We note that we currently do not incorporate any assumption of penetration into these other diagnostic markets in our model - which, could provide significant upside to our estimates - which will be updated if and when appropriate. As cancer is VNRX's main focus we also do not include commercial contribution from potential future ancillary applications (i.e. - autoimmune diseases, sepsis, inflammatory-related diseases, chemotherapy efficacy, etc) - which also could provide some upside.

Valuation Very Attractive…

Based on our DCF model which goes out to year 2024 and uses an 11% discount rate (based on CAPM) and 2% terminal growth rate, VNRX is valued at $6.71/share (which we round to $7.00). 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 $7.00/share. We feel the current market price ($2.00) substantially undervalues the company and recommend accumulating the stock up towards our $7.00 price target. We are maintaining our Outperform rating.

APPENDIX

A.) Epigenetics



SOURCE: the-scientist.com / Stefan Kubicek

B.) PSA Testing: Widely Used Despite Serious Reliability Issues

According to the National Cancer Institute, it is estimated that ~ 241k men will be diagnosed with and ~34k men will die of prostate cancer in the U.S. The key to improving prostate cancer diagnosis and patient outcomes is being able to accurately (i.e. minimize false-positives/false-negatives and determine the extent of progression) diagnose the disease at an early stage which in-turn will allow physicians to better determine the most appropriate course of treatment (if any) and reduce patient anxiety related to false-positive diagnoses. The current standard screening method for prostate cancer is a digital rectal exam (DRE) along with the prostate-specific antigen (PSA) test, which measures a protein released by prostate cells to determine the presence of cancer.

Despite its widespread use (~20MM PSA tests done every year in North America and ~45MM worldwide, representing markets worth ~$200MM U.S. and ~$500MM worldwide), PSA's 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. Among the evidence that detractors cite as support against the use of PSA is the results of a meta-analysis of clinical trial data on over 400k patients which were published in the British Medical Journal in 2010. The study found that while PSA increases cancer detection, it is not associated with a "significant effect of screening on death from prostate cancer or overall mortality." The authors concluded that, "The existing evidence from randomized controlled trials does not support the routine use of screening for prostate cancer with PSA with or without digital rectal exam."

In a well publicized announcement, based on the results of several large clinical trials in the U.S. and Europe, in late 2011 the U.S. Preventative Services Task Force recommended that healthy men without any symptoms of prostate cancer not receive a PSA test. The recommendation, which was finalized in May 2012, carries significant weight and can determine whether public (including Medicare) and private health insurers will reimburse for the test. Per the chairwoman of the task force relative to the recommendation, "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." The Task Force gave the PSA test its lowest rating, D, noting that it does more harm than good.

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). The heart of the accuracy problem with PSA testing is that levels of the PSA protein can be elevated (and result in the test indicating positive for cancer) under fairly common circumstances when cancer may not actually be present which could result in a false-positive diagnosis. The most common of these is when there is an enlargement of the prostate (called benign prostate hyperplasia or BPH). While the majority of men will experience some enlargement of the prostate as they age, only a very small percentage of them will develop prostate cancer. The correlation between BPH and increased levels of PSA results in only about 30% of positive PSA tests (i.e. PSA elevated beyond what is considered normal, >4ng/ml) actually turning out to be cancer. And of those accurately diagnosed as having cancer (as confirmed by biopsy) with PSA, most have slow-growing cancers that would never become life-threatening. There is also no definitive evidence that the presence of BPH increases the chances of eventually developing prostate cancer.

In the event of a positive PSA test showing, a biopsy will be done to confirm the diagnosis. If cancer cells are found in the tissue a Gleason score is assigned which is a measure of the severity or aggressiveness of the cancer. Prostate cancer biopsy involves the insertion of needles into different regions of the prostate gland to extract tissue which are then examined under a microscope. As a result of the low specificity of the PSA test, almost 75% of biopsies for prostate cancer turn out to be negative for the disease. Consequences of this include unnecessary mental anxiety associated with the thought of having a potentially deadly disease (this mental stress, especially with the elderly, can also result in physical health risks such as heart stress) and the risks inherent with biopsy such as infection. And even if the biopsy comes back negative, there still can be lingering mental anxiety from wondering if the biopsy was wrong and cancer is actually present. Instead of what might be a more appropriate course of action such as watchful-waiting (i.e. monitoring including future follow-up testing), this anxiety can prompt the patient to undergo unnecessary treatments such as surgery, radiation, and hormone-blocking medication which can expose them to further negative side effects such as persistent blood in the semen, impotence, erectile dysfunction, urinary incontinence, bowel dysfunction, and even death (the latter, a result of complications from surgery). The unnecessary mental anxiety and over-treatment associated with PSA testing was a major reason for the recommendation by the U.S. Preventative Services Task Force against use of the test.

FINANCIAL MODEL

VolitionRx Ltd.

	2013 A	Q1A	Q2A	Q3A	Q4E	2014 E	2015 E	2016 E	2017 E
Revenue	$0.0	$0.0	$0.0	$14.8	$65.6	$80.4	$944.4	$4,341.7	$7,820.1
YOY Growth	*-100.0%*	-	-	-	-	-	*1074.4%*	*359.8%*	*80.1%*
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$9.8	$9.8	$126.7	$522.1	$945.8
Gross Income	$0.0	$0.0	$0.0	$14.8	$55.8	$70.6	$817.7	$3,819.7	$6,874.4
Gross Margin	*#DIV/0!*	-	*#DIV/0!*	*100.0%*	*85.0%*	*87.8%*	*86.6%*	*88.0%*	*87.9%*
SG&A	$1,722.2	$367.7	$259.1	$706.2	$688.0	$2,021.0	$2,340.0	$2,750.0	$3,200.0
%SG&A	-	-	-	-	-	*2513.4%*	*247.8%*	*63.3%*	*40.9%*
R&D	$2,503.7	$870.5	$791.3	$1,072.0	$888.0	$3,621.7	$4,685.0	$3,850.0	$3,850.0
% R&D	-	-	-	-	-	*4504.1%*	*496.1%*	*88.7%*	*49.2%*
Asset Impairment	$350.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($4,575.9)	($1,238.2)	($1,050.4)	($1,763.4)	($1,520.2)	($5,572.2)	($6,207.3)	($2,780.3)	($175.6)
Operating Margin	-	-	-	-	-	-	-	-	*-2.2%*
Total Other Expense (Income)	($865.6)	$956.3	($1,867.2)	$4,130.6	($75.0)	$3,144.6	($290.0)	$0.0	$0.0
Pre-Tax Income	($3,710.3)	($2,194.4)	$816.8	($5,893.9)	($1,445.2)	($8,716.8)	($5,917.3)	($2,780.3)	($175.6)
Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
FX translation	$25.5	$4.2	$9.6	$19.9	$0.0	$33.7	$0.0	$0.0	$0.0
Net Income	($3,735.8)	($2,198.6)	$807.2	($5,913.8)	($1,445.2)	($8,750.5)	($5,917.3)	($2,780.3)	($175.6)
Net Margin	-	-	-	-	-	-	*-626.6%*	*-64.0%*	*-2.2%*
EPS	($0.34)	($0.18)	$0.06	($0.44)	($0.10)	($0.65)	($0.34)	($0.14)	($0.01)
YOY Growth	-	-	-	-	-	-	-		
Diluted Shares O/S	10,832	12,246	13,888	13,525	14,200	13,465	17,500	19,500	21,500

Brian Marckx, CFA

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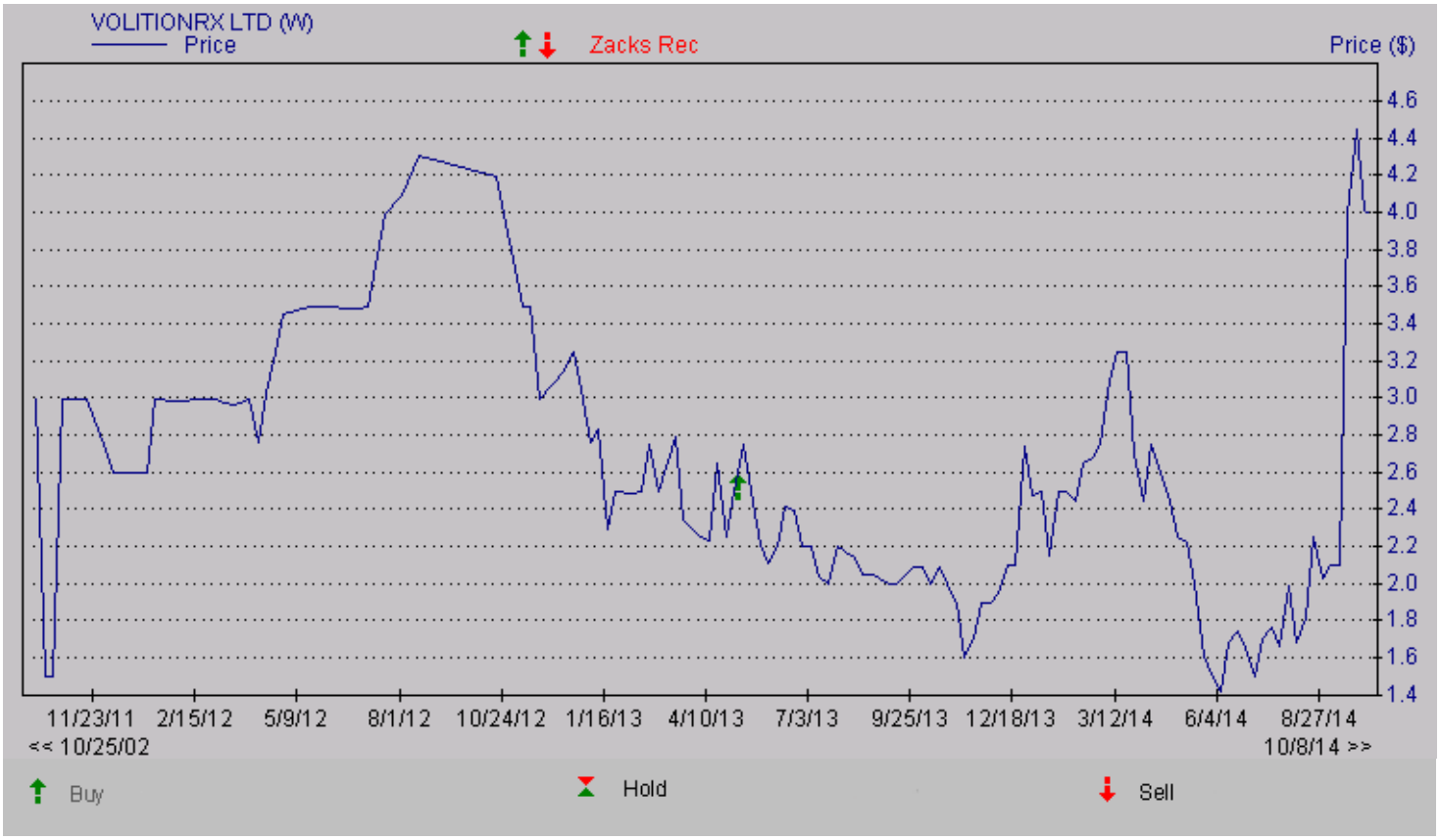

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