Zacks Small-Cap Research

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VolitionRx Ltd (VNRX-NYSE)

VNRX: Triage Clinically Validated, Logistics Validation and Danish Launch Could Be Upcoming

Based on our DCF model which goes out to year 2026 and uses a 9.5% discount rate (based on CAPM) and 2% terminal growth rate, VNRX is valued at $7/share. Our model and assumptions will be updated if appropriate based on news flow which could also influence valuation

Current Price (03/20/17)	$4.36
Valuation	**$7.00**

OUTLOOK

VNRX has done a lot in a relatively little amount of time. In September 2015 they received CE Mark of their first assay - since then they received CE Mark of additional assays and in December 2016 received CE Mark of Triage – expected to launch in European national CRC screening programs. While management had been aiming to launch the test in their initial targeted European territories sometime in the first half of 2017, that will have to wait for completion of a just-commenced logistics study. Goal is now to be included in Danish national CRC screening program beginning in early 2018. Given management's confidence in the supporting clinical data, we do not have meaningful concerns of any surprises at DDW in May. However, given that these logistics studies are also gatekeeper to accessing Denmark's screening programs, we will be eagerly awaiting to hear any updates from these. Danish market is not overly substantial but can still be meaningful to VNRX given that it should require relatively little in the way of sales-spend to capture and gross margins are expected to be significant (we think as high as 90% or more). Also should serve as litmus test as VNRX looks to launch in follow-on EU countries and possibly Asia.

SUMMARY DATA

52-Week High	**$5.86**
52-Week Low	**$3.05**
One-Year Return (%)	**24.51**
Beta	**-1.56**
Average Daily Volume (sh)	**36,855**
Shares Outstanding (mil)	**26**
Market Capitalization ($mil)	**$115**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**18**
Insider Ownership (%)	**30**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

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

ZACKS ESTIMATES

Revenue
(in '000)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	$0 A	$0 A	$0 A	$0 A	$0 A
2017	$0 E	$0 E	$0 E	$0 E	$0 E
2018					$1760 E
2019					$7647 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.13 A	-$0.13 A	-$0.15 A	-$0.12 A	-$0.52 A
2017	-$0.14 E	-$0.14 E	-$0.15 E	-$0.15 E	-$0.58 E
2018					-$0.45 E
2019					-$0.29 E

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

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Q4 Results / Operational and Business Update:

VNRX reported Q4 results and provided an operational and business update. On the financials side, operating expenses were about 12% lower than we had estimated while revenue remained blank, as we had anticipated. While we had previously modeled some (insignificant) top-line contribution to begin in 2017, we have since pushed back initial revenue to early 2018 - this is subject to updating, however, as potential stocking orders from 2018 Danish national CRC screening programs could materialize later this year. Certainly, on the positive front, as we detail below, is that it appears VNRX continues to make meaningful strides towards ticking off the boxes necessary to get Triage included on European CRC screening programs (most importantly of which was CE Marking of Triage, which happened in December).

Q4 OpEx was $3.3M, moderately lower than our $3.8M estimate and down slightly from Q3. We continue to expect operating expenses to trend higher on additional clinical trial and regulatory activities, some initial (moderate) spend on sales, marketing and launch preparations and activities related to initiation of a U.S. regulatory program. But, a partial offset to R&D expense is also now more likely given the VNRX has paused some programs to focus more of their resources on the Triage launch.

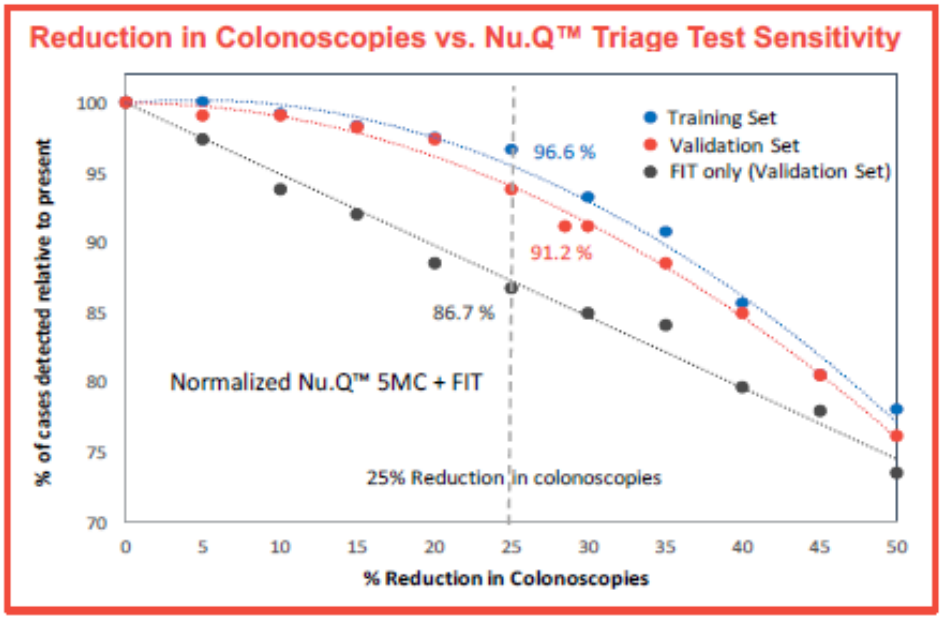
Q4 net income and EPS were ($3.1)M and ($0.12), compared to our ($3.8)M and ($0.15) estimates – some of the difference relates to $335k in grants received. Cash used in operating activities was $2.4M and $9.1M in the three and twelve months ending December 31st. As we have noted in the past, we think the company has done an impressive job with efficient use of cash as evidenced by the reams of clinical data, ongoing studies and CE Marking of several CRC assays as well as of Triage (among other successes) that they have accomplished over the last ~2 years on a cash budget of less than $20M. VNRX exited 2016 with $21.7 M in cash and equivalents.

Triage Update: CE Marked, Clinically Validated, Now in Logistics Studies. Danish Launch Upcoming?
VoltionRx has done a lot in a relatively little amount of time. In September 2015 they received CE Mark of their first assay - since then they received CE Mark of additional assays and in December 2016 received CE Mark of Triage – their initial CRC blood test that is expected to be launch in European national CRC screening programs.

As a reminder, Triage consists of two of the three assays that have already received CE Mark and will be positioned for use following a positive result from a fecal immunochemical test (FIT). As envisioned by VNRX, Triage will be used following positive FIT results which would reduce the number of colonoscopy referrals for people that do not have CRC - this in-turn will reduce bottlenecks and increase throughput of colonoscopy screening for those people that are most likely to have cancer. Being able to reduce the number of unnecessary colonoscopies could be highly appealing to both the individual and the healthcare systems. On the individual level, colonoscopies are invasive, uncomfortable and time consuming - so being able to safely avoid them is a potentially potent message for Triage. And for the healthcare system, Triage may be able to reduce colonoscopy bottlenecks for more of the people that are most likely to benefit from them while possibly reducing overall healthcare costs.

While management had been aiming to launch the test in their initial targeted European territories sometime in the first half of 2017, that will have to wait for completion of a just-commenced logistics study. The goal is now to be included in the Danish national colorectal cancer screening programs beginning in early 2018.

Importantly, management believes they have sufficient supporting clinical data. Data is from their ongoing 14k sample prospective CRC study being conducted in collaboration with Hvidovre Hospital (Denmark). Approximately 8k of the 14k samples are of positive FIT tests (the other 6k are negative FIT tests) – as a reminder, earlier in 2016 VNRX announced that the first 1,906 samples analyzed demonstrated Triage had the potential to reduce colonoscopies by 25% while maintaining a 97% detection rate for CRC. Those results were presented in October 2016 at ESMO. Then at ENDO 2017 in February, data on an additional 1,961 samples were presented – which largely confirmed the prior results (showed 29% reduction in colonoscopies with 91% sensitivity). Results are in the chart below. The full 8k-sample data is expected to be presented at the Digestive Disease Week conference being held in Chicago during the first week of May.



SOURCE: ENDO Poster Presentation March 2017

So with what management believes is sufficient clinical data supporting the utility of Triage, they are now in a **logistics and pathway study** – which is required to demonstrate that Triage is logistically practical for Denmark's national screening program. The study is being done in collaboration with Hvidovre Hospital and the The Danish Research Group on Early Detection of Colorectal Cancer. It has two phases. Phase I, which started in early March includes three sites and approximately 250 subjects – the goal is to assess the logistics of collecting and processing blood samples at local sites and shipping them to a central lab in Demark. Phase I is expected to be completed in two months (i.e. early/mid-May). Phase 2, commencement of which requires Ethical Approval, involves five sites and ~500 subjects. This assesses the time it takes between blood collection and for analysis and results. Both phases are expected to be completed within six months (i.e. ~end of September 2017).

Management noted on the Q4 call that results of these logistics studies goes directly to the Danish national screening committee. So, if all goes well, it's possible that Triage could be included on the Danish national CRC screening program for 2018. If that ends up being the case, VNRX may see some stocking orders later this year – although we model initial contribution in 2018.

Given management's confidence in the supporting clinical data, we do not have meaningful concerns of any surprises at DDW in May. However, given that these logistics studies are also a gatekeeper to accessing Denmark's screening programs, we will be eagerly awaiting to hear any updates and, eventually results, from these.

Danish Market Is Small But Could Serve As Litmus Test As VNRX Prepares For Follow-On Launches…
The population of Denmark is roughly 5M people – about 1.5M of which we estimate are of CRC screening age. We estimate that approximately 6% of FIT tests are positive and reasonably think that approximately 65% of the screening-age population will actually be screened. Screening guidelines typically recommend CRC testing once every two years. Further assuming revenue to VNRX of ~$50/test, this means Denmark represents a total annual market of approximately $1.5M (or ~30k tests). While not overly substantial, it can still be meaningful to VNRX given that it should require relatively little in the way of sales-spend to capture and gross margins are expected to be significant (we think as high as 90% or more). Additionally, if Triage is accepted into the Danish screening program, it could mean VNRX gets the entire annual market (i.e. not a slow ramp over time) – which means VNRX's initial order, as management indicated on the Q4 call, could be in the tens-of-thousands in volume.

And maybe more importantly, Denmark could serve as the initial litmus test for other countries which could potentially come onboard in the near-term. In addition to certain parts of Asia which VNRX is now looking at, the other initial four EU countries represent an additional ~$30+ million in potential annual revenue (~600k annual tests). So while Denmark is expected to the first launch territory, follow-on launches in other countries could follow. The other countries in Europe that the company has previously indicated are on their initial list (along with our estimated annual potential revenue of each) include Ireland ($1.5M), Scotland ($1.5M), the Netherlands ($5M)

and France ($19M). Other countries may require logistics studies similar to that being done in Denmark in order to be granted access to their respective national screening programs.

Expect regular flow of clinical data…
Meanwhile, we expect a fairly regular flow of clinical data in CRC will continue to be announced from the various studies that the company has ongoing. In addition to the 14k subject prospective study, this includes the largest study started to-date – a prospective seven year study in collaboration with Hvidovre Hospital which was announced in November 2016. A total of 90k blood samples will be taken from 30k patients that tested negative in national fecal colorectal cancer screening test. Samples will be taken at three timepoints, two years apart. Study will determine how early NuQ can detect cancer prior to a definitive diagnosis. In addition, up to 120 points of data will be collected including risk factors such as smoking, obesity, etc. This could provide a massive amount of information relative to utility of NuQ in different population subsets as well as how soon the technology can detect cancer. Initial data could be available by the end of 2018.

VNRX acquired a larger facility for office and lab space which is expected to expansion of the scientific team, greater R&D capabilities and help expedite commercialization of Triage and follow-on products. VNRX expects the facility to be fully operational by Q2 2017. The additional resources and space are expected to facilitate additional programs for further validation of the technology.

Relative to the U.S., VNRX expects to begin the 510(k) process in 2017 – as a reminder, they hope to initially bring a CRC test to the U.S. for symptomatic patients in combination with other tests. VNRX currently expects this program to cost approximately $1.5M - $2M, begin this year and complete in 2018.

In tandem they will investigate bringing a CRC test through FDA for asymptomatic patients to be used in U.S. screening programs. This is expected to follow a PMA pathway. VNRX expects this to commence in 2017 and complete in 2019 and notes that PMA approval, depending on the scope of the program, could cost anywhere between $5M and $50M to obtain.

OUTLOOK / VALUATION

We model now model initial revenue contribution in 2018 as a result of inclusion of Triage on Denmark's national CRC screening program. We also model some incremental revenue from stocking orders later than same year related to inclusion in follow-on countries among the initial targeted five EU countries. While all of our assumptions will be updated with relevant news flow, our confidence of inclusion in Denmark was recently bolstered by the additional clinical validation. Further support to our confidence would come if the logistics studies prove successful.

While we think initial introduction in Denmark as an adjunct should provide foot-in-the-door opportunity as well as the chance to build early awareness, follow-on launches in additional countries, particularly those with larger populations (such as France and The Netherlands) would significantly increase VNRX's initial revenue opportunity. We have yet to model any potential contribution from Asia – although given VNRX's moves in that direction, including the recent hiring of an executive to lead their strategy in that part of the world, those assumptions are also subject to a near-term change.

Over the mid-term, broadening the label in Europe to include as a stand-alone CRC test could have the effect of accelerating interest in demand and would certainly significantly increase the size of the indicated population for the test (as a reminder Triage will be used only for positive FIT subjects – which equals only ~6% of the total tested). We continue to expect data from the large CRC studies, including the recently initiated 90k sample study, to provide greater insight into the utility of the assays for CRC.

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 (PMA) 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.

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 $7/share. Our model and assumptions will be updated if appropriate based on news flow which could also influence valuation.

While VNRX recently paused many of its other cancer programs as they focus on the launch of Triage in CRC, eventual continued success in other areas 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 (particularly the recently announced 750-patient Germany-based study).

As it is now, we value VNRX at $7/share. We feel the current market price ($4.36) remains cheaper than warranted and undervalues the company. We think acceptance of Triage into national screening programs (including Denmark's) as well as additional and ongoing positive clinical data should further benefit appreciation of the share price towards our target.

FINANCIAL MODEL

VolitionRx Ltd.

	2016 A	Q1 E	Q2 E	Q3 E	Q4 E	2017 E	2018 E	2019 E
Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1,759.5	$7,646.9
YOY Growth	-	-	-	-	-	-	-	*334.6%*
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$263.9	$764.7
Gross Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1,495.6	$6,882.2
Gross Margin	-	-	-	-	-	-	*85.0%*	*90.0%*
SG&A	$5,429.1	$1,820.0	$1,841.0	$1,876.0	$1,924.0	$7,461.0	$7,820.0	$8,660.0
%SG&A	-	-	-	-	-	-	*444.4%*	*113.2%*
R&D	$6,837.6	$1,871.0	$1,880.0	$1,954.0	$2,120.0	$7,825.0	$9,550.0	$9,400.0
% R&D	-	-	-	-	-	-	*542.8%*	*122.9%*
Asset Impairment	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($12,266.6)	($3,691.0)	($3,721.0)	($3,830.0)	($4,044.0)	($15,286.0)	($15,874.4)	($11,177.8)
Operating Margin	-	-	-	-	-	-	*-902.2%*	*-146.2%*
Total Other Expense (Income)	($361.3)	$1.0	$1.1	$4.0	$3.5	$9.6	$23.2	$23.2
Pre-Tax Income	($11,905.3)	($3,692.0)	($3,722.1)	($3,834.0)	($4,047.5)	($15,295.6)	($15,897.6)	($11,201.0)
Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
FX translation	$109.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($12,014.4)	($3,692.0)	($3,722.1)	($3,834.0)	($4,047.5)	($15,295.6)	($15,897.6)	($11,201.0)
Net Margin	*#DIV/0!*	-	-	-	-	*#DIV/0!*	*-903.5%*	*-146.5%*
EPS	($0.52)	($0.14)	($0.14)	($0.15)	($0.15)	($0.58)	($0.45)	($0.29)
YOY Growth	-	-	-	-	-	-	-	
Diluted Shares O/S	23,049	26,130	26,150	26,200	26,300	26,195	35,000	39,000

Brian Marckx, CFA

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