Zacks Small-Cap Research

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VolitionRx Ltd (VNRX-NYSE)

VNRX: Closing In On E.U. Launch, Asia Could Be Next. Update On U.S. Strategy

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 (05/22/17)	$3.43
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 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, the latter which has recently come to the fore-front as possible initial launch territories.

SUMMARY DATA

52-Week High	**$5.86**
52-Week Low	**$3.05**
One-Year Return (%)	**3.63**
Beta	**-1.85**
Average Daily Volume (sh)	**27,321**
Shares Outstanding (mil)	**26**
Market Capitalization ($mil)	**$89**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**18**
Insider Ownership (%)	**16**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

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

ZACKS ESTIMATES

Revenue
(in '000)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	$0 A	$0 A	$0 A	$0 A	$0 A
2017	$0 A	$0 E	$0 E	$0 E	$0 E
2018					$1456 E
2019					$5799 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.13 A	-$0.13 A	-$0.15 A	-$0.12 A	-$0.52 A
2017	-$0.13 A	-$0.14 E	-$0.14 E	-$0.15 E	-$0.56 E
2018					-$0.46 E
2019					-$0.34 E

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

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Q1 Results / Operational and Business Update: Closing In On E.U. Launch, Is Asia Next?

VNRX reported Q1 results and provided an operational and business update. Relative to the financials, operating expenses were more moderate than what we had expected for the second consecutive quarter. And while VNRX is gearing up for additional development-related activities including the second iteration of pre-commercialization studies in certain parts of Europe, guidance is for expenses to remain flattish as VNRX maintains their diligence on expense and cash control. We continue to model no revenue until 2018 – although if all the pieces fall squarely in place relative to completing these studies and tying up any other loose ends, it is not unreasonable that VNRX could recognize initial Triage-related revenue in the current year.

Q1 OpEx was $3.4M, compared to our $3.7M estimate and roughly flat from Q4 2016. Net income and EPS were ($3.3)M and ($0.13), compared to our ($3.7)M and ($0.14) estimates. Cash used in operating activities was $2.7M. Another $875k was used in upfitting the new R&D facility. Management is guiding for near-term burn (operating and investing) of ~$2.5M - $3.0M per quarter. Cash balance at quarter end was $18.5M

Relative to the **operational update**, there were some notable items. This includes management's current thoughts on (a bolder vision?) and additional activity related to a U.S. program, indication that Asia is now one of the potential front-runners in terms of initial market launches and recent executive level hires tasked with leading validation and commercialization activities in both of those regions. Relative to Europe, the pre-commercialization logistics studies are wrapped up and design pathway studies are on-deck, with launch via certain national CRC screening programs still a possibility before year-end. A manuscript of the study supporting the accuracy and utility of Triage in detection of CRC was published in May in the journal Clinical Epigenetics. And finally, as it relates to recent operational highlights, VNRX's new R&D facility is operational which is expected to substantially increase support-capacity of clinical trials, affording higher throughput and providing additional bandwidth to potentially accelerate current programs and expand into other cancers.

- **Asia**: while Europe has been considered to be where the bulk of the near-term opportunity lies, based on comments on the Q1 call (which we missed due to a timing conflict) and language in the 10-Q, parts of Asia, most notably Taiwan and Singapore, now seem to also be on the short-list of possible initial launch territories. Asia was barely a mention six months ago. Since then VNRX hired a V.P. to lead efforts in that region of the world and commenced clinical evaluation of Triage in Taiwan and are also pursuing regulatory clearance in Singapore. Per VNRX, approval in Singapore would also open up sale of the test to nine other S.E. Asian countries. These studies are simply to confirm Triage has acceptable performance among these populations. Pursuit of regulatory clearance in other Asian countries including China, India and Japan could follow - granting of which would open up sale of the test to relatively enormous populations. And while much of these parts of the world remain economically emergent, that may actually play in VNRX's favor given what they have indicated is expected to be a relatively low cost of production and processing of their tests (and related ability to keep pricing highly competitive). Based on management's comments, the first of the Asia-related regulatory approvals could come in 1H 2018. While we have yet to model any revenue contribution from Asia, this is subject to updating based on development, validation and regulatory-related progress.

- **U.S.:** the U.S. strategy and related regulatory pathway has so far been non-committal as management has been weighing options. Included in the list of possibilities to bring a CRC test to the U.S. market has been as an adjunct to currently available tests targeting symptomatic patients (i.e. likely a 510(k) pathway), an LDT via a CLIA lab partnership, and a much more involved and robust PMA pathway seeking an asymptomatic indication. While the first two (i.e. 510k and/or LDT routes) may still very well be under consideration, management seemed to be leaning at least a little more heavily towards moving directly towards a full-blown PMA-supporting asymptomatic CRC patient study, noting that they "want to do a very serious trial of 10k+ asymptomatic patients" and indicating that they will have more details in the near future. VNRX has previously disclosed that they think even a PMA pathway could be successfully pursued on a budget of only about $5M – they reiterated that on the Q1 call.

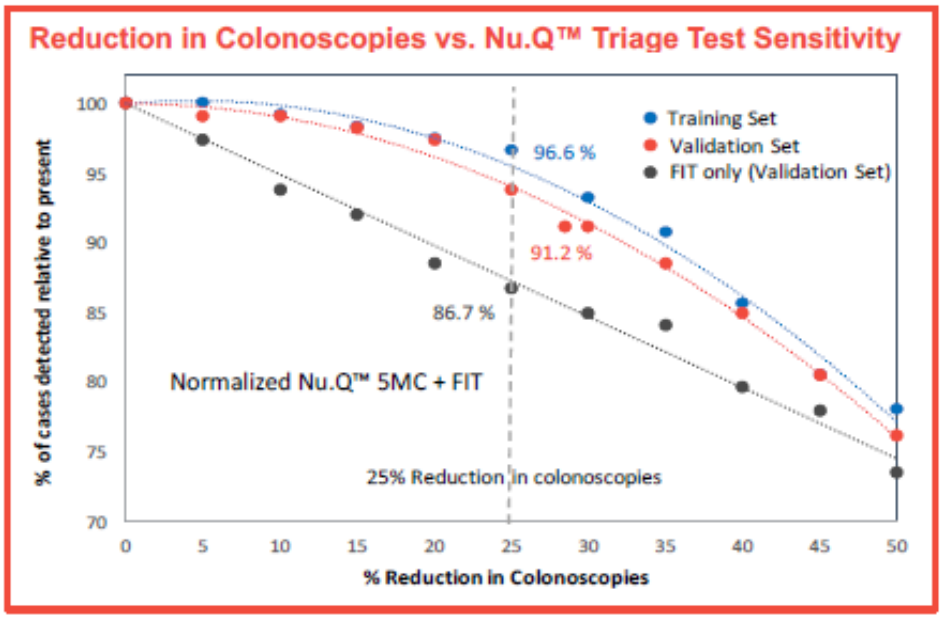
- **Europe:** logistics studies are completed (more background details below) with the first of planned pathway design studies expected to commence in Denmark.

Triage Update: CE Marked in December, Pathway Design Studies Starting. Danish Launch in 2017?
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 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 pathway design studies now that logistics studies have finished. 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 was then presented at DDW 2017 in May which also confirmed earlier results. Specifically, Triage demonstrated the ability to prevent 24.5% of colonoscopies and detect almost 95% of colorectal cancers and 88% of (high-risk) adenomas. The data was published May 2017 in a manuscript titled "Circulating nucleosomes as new blood-based biomarkers for detection of colorectal cancer" in Clinical Epigenetics.



SOURCE: ENDO Poster Presentation March 2017

So with what management believes is sufficient clinical data supporting the utility of Triage and with the logistics portion of the pre-commercialization studies done, they are now about to enter **pathway studies** – which are required to demonstrate that Triage is practical for Denmark's national screening program. The studies are 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 is now concluded started in early March at three sites and approximately 250 subjects – the goal was to assess the logistics of collecting and processing blood samples at local sites and shipping them to a central lab in Demark. Phase 2, commencement of which requires Ethical

Approval (the study recently received approval to begin in Denmark), involves five sites and ~500 subjects. This assesses the time it takes between blood collection and for analysis and results.

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 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 a recent earnings 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 (including Taiwan and Singapore) 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.

Asia Represents Relative Enormous Market
While Europe has been considered to be where the bulk of the near-term opportunity lies, based on comments on the Q1 2017 call and language in the 10-Q, parts of Asia, most notably Taiwan and Singapore, now seem to also be on the short-list of possible initial launch territories. Asia was barely a mention six months ago. Since then VNRX hired a V.P. to lead efforts in that region of the world and commenced clinical evaluation of Triage in Taiwan and are also pursuing regulatory clearance in Singapore. Per VNRX, approval in Singapore would also open up sale of the test to nine other S.E. Asian countries. These studies are simply to confirm Triage has acceptable performance among these populations. Pursuit of regulatory clearance in other Asian countries including China, India and Japan could follow - granting of which would open up sale of the test to relatively enormous populations. And while much of these parts of the world remain economically emergent, that may actually play in VNRX's favor given what they have indicated is expected to be a relatively low cost of production and processing of their tests (and related ability to keep pricing highly competitive). Based on management's comments, the first of the Asia-related regulatory approvals could come in 1H 2018. While we have yet to model any revenue from Asia, this is subject to updating based on development, validation and regulatory-related progress. We ballpark the market opportunity in Taiwan and Singapore at approximately $7.2M and $1.7M, respectively – but, perhaps more important could be that these might represent just the initial foray into Asia which could be a harbinger for eventual introductions into countries with larger populations, including India and China. Noteworthy is that regulatory approval in Singapore would allow sale of Triage in nine other Asian countries – as such, regulatory clearance in that country could be a particularly important milestone for VNRX.

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 and recently held a grand opening of a larger facility for office and lab space which increases clinical trial capacity and R&D capabilities in general to help expedite commercialization of Triage and development of follow-on products including tests for other cancers.

Relative to the U.S…., the U.S. strategy and related regulatory pathway has so far been non-committal as management has been weighing options. Included in the list of possibilities to bring a CRC test to the U.S. market has been as an adjunct to currently available tests targeting symptomatic patients (i.e. likely a 510(k) pathway), an LDT via a CLIA lab partnership, and a much more involved and robust PMA pathway seeking an asymptomatic indication. While the first two (i.e. 510k and/or LDT routes) may still very well be under consideration, management seemed to be leaning at least a little more heavily towards moving directly towards a full-blown PMA-supporting asymptomatic CRC patient study, noting on the Q1 2017 call in May that they "want to do a very serious trial of 10k+ asymptomatic patients" and indicating that they will have more details in the near future. VNRX has previously disclosed that they think even a PMA pathway could be successfully pursued on a relatively meager budget of only about $5M – they reiterated that on the Q1 call.

OUTLOOK / VALUATION

We 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 pathway 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 and pursuit of validation studies in Taiwan and Singapore, 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, given management's non-commitment up to this point, our model reflects no related revenue nor significant development-related expense. While the latest iteration appears to be going directly to an asymptomatic indication via a large prospective study, we hope to hear more about their plans on future calls and will update our assumptions as appropriate. We note that eventual FDA approval – while the ultimate quest and one which we think could rapidly steepen VNRX's revenue curve – could be a years-long process, particularly as a stand-alone test for asymptomatic patients.

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 ($3.43) 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 A	Q2 E	Q3 E	Q4 E	2017 E	2018 E	2019 E
Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1,456.1	$5,789.8
YOY Growth	-	-	-	-	-	-	-	*297.6%*
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$291.2	$926.4
Gross Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1,164.8	$4,863.5
Gross Margin	-	-	-	-	-	-	*80.0%*	*84.0%*
SG&A	$5,429.1	$1,509.1	$1,644.0	$1,712.0	$1,888.0	$6,753.1	$7,820.0	$8,660.0
%SG&A	-	-	-	-	-	-	*537.1%*	*149.6%*
R&D	$6,837.6	$1,841.6	$1,880.0	$1,921.0	$2,074.0	$7,716.6	$9,550.0	$9,400.0
% R&D	-	-	-	-	-	-	*655.9%*	*162.4%*
Asset Impairment	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($12,266.6)	($3,350.7)	($3,524.0)	($3,633.0)	($3,962.0)	($14,469.7)	($16,205.2)	($13,196.5)
Operating Margin	-	-	-	-	-	-	*-1113.0%*	*-227.9%*
Total Other Expense (Income)	($361.3)	$0.0	$260.6	$8.0	$8.0	$276.6	$27.0	$27.0
Pre-Tax Income	($11,905.3)	($3,350.7)	($3,784.6)	($3,641.0)	($3,970.0)	($14,746.3)	($16,232.2)	($13,223.5)
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%*
FXtranslation	$109.1	($31.5)	$0.0	$0.0	$0.0	($31.5)	$0.0	$0.0
Net Income	($12,014.4)	($3,319.2)	($3,784.6)	($3,641.0)	($3,970.0)	($14,714.8)	($16,232.2)	($13,223.5)
Net Margin	*#DIV/0!*	-	-	-	-	*#DIV/0!*	*-1114.8%*	*-228.4%*
EPS	($0.52)	($0.13)	($0.14)	($0.14)	($0.15)	($0.56)	($0.46)	($0.34)
YOY Growth	-	-	-	-	-	-	-	
Diluted Shares O/S	23,049	26,129	26,350	26,500	26,700	26,420	35,000	39,000

Brian Marckx, CFA

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