Zacks Small-Cap Research

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VolitionRx Ltd (VNRX-NYSE)

VNRX: Initial Product Will Be Complement To Current CRC Screens

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 (09/07/16)	$4.16
Valuation	**$7.00**

OUTLOOK

Data from the various clinical trials continues to be consistently positive. Based on the number of studies anticipated to read out over the near term, this should be a telling year in terms of the potential utility of the NuQ assays in a variety cancers. Still expect CE Marking of the initial CRC assay, Nu.Q Triage Colorectal Cancer Screening Test, this year. Commercial introduction in Europe slated for early 2017. Triage will be positioned as complement to widely used FIT test in Europe. VNRX to announce data supporting the test at ESMO in October, additional branding/mktg plans in coming months. Triage could be a big winner, but early success will be predicated on adoption into EU screening programs - expect this to be a fluid situation throughout 2017. Also eagerly awaiting additional clinical data in several cancers which could prompt upward revisions to our modeled revenue and related valuation. For example, we have yet to model any contribution from a potential pancreatic cancer panel but will likely do so if high accuracy of the diagnostic is maintained in subsequent studies including recently initiated 750-patient study. Success of Triage and additional positive clinical data could further benefit appreciation of the share price.

SUMMARY DATA

52-Week High	**$5.25**
52-Week Low	**$3.05**
One-Year Return (%)	**-0.24**
Beta	**-1.58**
Average Daily Volume (sh)	**35,390**
Shares Outstanding (mil)	**24**
Market Capitalization ($mil)	**$98**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**13**
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 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

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

ZACKS ESTIMATES

Revenue
(in '000)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	$0 A	$0 A	$0 A	$0 A	$0 A
2016	$0 A	$0 A	$0 E	$84 E	$84 E
2017					$1742 E
2018					$4918 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.12 A	-$0.10 A	-$0.16 A	-$0.15 A	-$0.54 A
2016	-$0.13 A	-$0.13 A	-$0.14 E	-$0.15 E	-$0.55 E
2017					-$0.55 E
2018					-$0.43 E

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

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Launch Plan Update: Will Launch With Single "Normalized' Assay, a Complement to Current CRC Screens…

When VNRX announced Q2 results less than 30 days ago the company reiterated their expectation of receiving CE Mark for their initial CRC panel, expected to be composed of 4 - 5 individual assays, later in 2016 with launch anticipated early next year. The company also had indicated they had already identified which assays would be included in the panel and would provide an update, including technical details such as accuracy, in the September/October timeframe. Since then the plan changed, at least to a certain degree.

Yesterday (9/6) VNRX announced that their first commercialized test is instead expected to be a single 'normalized' assay - consisting of two of the three assays that have already received CE Mark - called Nu.Q Triage Colorectal Cancer Screening Test. VNRX expects Nu.Q Triage, which will be positioned for use following a positive result from a fecal immunochemical test (FIT), to be CE Marked later this year and launch in certain areas of Europe and in national screening programs in early 2017.

Management indicated the recent change in plans regarding the composition of their initial CRC test was opportunity-based, made after significant market analysis and provides the fastest route towards generating significant initial revenue. The company points to market feedback that indicates the greatest current unmet need in CRC screening is to reduce bottlenecks in colonoscopy screening (up to 14 weeks in some places) in parts of Europe caused in part by the high false positive rates of FIT - which are often used as a first-line diagnostic, positive results of which are then referred for colonoscopy.

As envisioned by VNRX, Triage would 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.

Per VNRX, Triage has demonstrated the potential to reduce colonoscopies by 25% with 97% sensitivity. While it's not exactly clear how the 25% reduction assumption is calculated, the data presentation at ESMO in October should provide further insight. VNRX noted that the data is from the initial samples of their 14k prospective CRC study.

But we think VNRX's unexpected shift from a first-line CRC screen to Triage may also imply that timing of CE Mark of the first panel (i.e. 4 - 5 assays) will be more drawn out then recently anticipated - however, the plan to launch follow-on tests has not changed and as such, a higher accuracy CRC screen, as well as other CRC related tests (and for other cancers) may still be a possible 2017 event.

And while the shift in initial strategy was a surprise, Triage may provide for easier entry into and less disruption to existing CRC screening programs as compared to a first-line screen. This is because Triage is not replacing another current test (such as FIT) and therefore is not asking clinicians and screening programs to make an either/or decision, like a NuQ first line screen might. So it may allow easier foot-in-the-door opportunity. And if Triage can provide foot-in-the-door opportunity, it may help facilitate entry of VNRX's expected follow-on CRC tests, including those for symptomatic populations and a stand-alone first-line screen.

On the potential negative side is that Triage will add incremental cost (i.e. in addition to FIT) to screening programs (although management indicated on the call incremental cost may be minimal), where as cost of a NuQ front-line screen may be offset by cost of the test it is replacing. But certainly in a bigger-picture view, Triage has the potential to reduce overall cost of colorectal cancer diagnosis and care if it reduces the number of unnecessary colonoscopies and improves detection, particularly at the more treatable early stages of the disease.

VNRX continues to expect effective marketing can be done with a fairly bare-bones program given that European CRC screening programs are largely nationalistic in nature. Targeting KOL's (influential clinicians and screening program leaders) in each of the targeted countries will be a major part of the effort. Decideum, VNRX's market access consultants, will be advising the company on initial target countries and penetration strategies. While the test may be appropriate for the ~148M people in E.U. countries of screening age, management indicated they are

currently looking at a large handful of E.U. countries which either currently have a FIT CRC screening program in place or are expected to do so in the near term as potential initial market entry territories. VNRX expects to reveal more about their marketing and branding strategy in the coming months.

While it is still unclear how difficult (or easy) it may be for Triage to be included in some of the European countries' screening programs, inclusion in European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis may not be a necessary perquisite. Management indicated that they believe the unmet demand for improvements in the screening systems (including colonoscopy bottlenecks and high false positive rates of FIT) as was borne out from their market analysis, suggests clinicians and screening programs may be receptive to using their test. Just how receptive, will likely have significant influence on the company's financial results beginning next year. We expect this may be a very fluid situation in 2017 - as of now, we are maintaining our prior financial outlook which is subject to near-term updating.

FINANCIAL MODEL

VolitionRx Ltd.

	2015 A	Q1 A	Q2 A	Q3 E	Q4 E	2016 E	2017 E	2018 E	2019 E
Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1,741.9	$4,918.8	$12,896.0
YOY Growth	-	-	-	-	-	-	*#DIV/0!*	*182.4%*	*162.2%*
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$873.7	$2,213.4	$5,273.9
Gross Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$868.2	$2,705.3	$7,622.1
Gross Margin	-	-	-	-	*#DIV/0!*	*#DIV/0!*	*49.8%*	*55.0%*	*59.1%*
SG&A	$3,903.8	$1,029.8	$1,183.2	$1,284.0	$1,347.0	$4,844.0	$5,860.0	$6,510.0	$7,525.0
%SG&A	-	-	-	-	-	*#DIV/0!*	*336.4%*	*132.4%*	*58.4%*
R&D	$6,101.7	$1,462.8	$1,792.1	$2,025.0	$2,215.0	$7,494.9	$9,250.0	$9,400.0	$9,200.0
% R&D	-	-	-	-	-	*#DIV/0!*	*531.0%*	*191.1%*	*71.3%*
Asset Impairment	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($10,005.5)	($2,492.6)	($2,975.3)	($3,309.0)	($3,562.0)	($12,338.9)	($14,241.8)	($13,204.7)	($9,102.9)
Operating Margin	-	-	-	-	-	-	*-817.6%*	*-268.5%*	*-70.6%*
Total Other Expense (Income)	($502.2)	$0.0	($25.9)	$0.0	$0.0	($25.9)	$0.0	$0.0	$0.0
Pre-Tax Income	($9,503.3)	($2,492.6)	($2,949.4)	($3,309.0)	($3,562.0)	($12,313.0)	($14,241.8)	($13,204.7)	($9,102.9)
Taxes (benefit)	($4.6)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
FX translation	$12.0	($18.4)	$67.4	$0.0	$0.0	$49.0	$0.0	$0.0	$0.0
Net Income	($9,510.6)	($2,474.2)	($3,016.8)	($3,309.0)	($3,562.0)	($12,362.0)	($14,241.8)	($13,204.7)	($9,102.9)
Net Margin	*#DIV/0!*	-	-	-	-	*#DIV/0!*	*-817.6%*	*-268.5%*	*-70.6%*
EPS	($0.54)	($0.13)	($0.13)	($0.14)	($0.15)	($0.55)	($0.55)	($0.43)	($0.27)
YOY Growth	-	-	-	-	-	-	-	-	
Diluted Shares O/S	17,734	19,289	23,412	23,550	23,800	22,513	26,000	31,000	34,000

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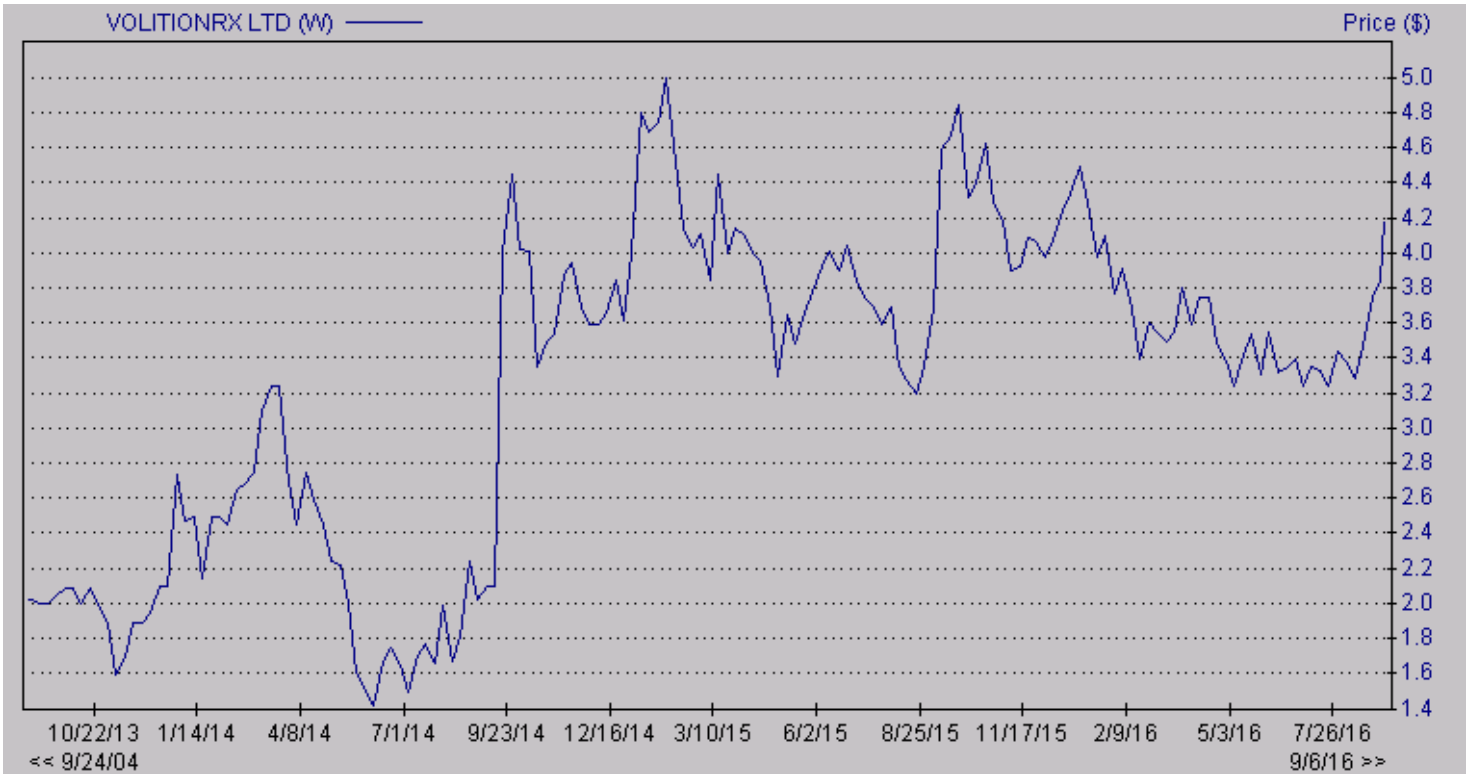

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