Zacks Small-Cap Research

June 28, 2017
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VolitionRx Ltd (VNRX-NYSE)

VNRX: Replacing Triage Assays: May Only Result in Relatively Short Delay - Could Be a Non-Event

Based on our DCF model which goes out to year 2026 and uses a 9.5% discount rate (based on CAPM) and 2% terminal growth rate, VNRX is valued at $6.75/share. Our model and assumptions will be updated if appropriate based on news flow which could also influence valuation

Current Price (06/28/17)	$3.46
Valuation	**$6.75**

OUTLOOK

The expected short-term delay caused by redevelopment and validation of the Triage assays is a disappointment but if that (i.e. a short-term delay) is the only meaningful consequence of having to redevelop these assays, it is effectively a non-event - or possibly even a positive event given the possibility that Triage performance is further bolstered. We had previously modeled initial revenue contribution beginning in early 2018 - we have since incorporated a six-month delay. Although given that we had previously expected relatively insignificant revenue for the full year 2018 and model the delay to have virtually no long-term related impact, it has a largely immaterial effect on our DCF-generated price target. Our per-share price target has moved from $7.00 to $6.75.

We hope to hear more about the status of development of the assays as well as management's expectations of timelines relative to regulatory and launch on the Q2 earnings call (which we expect ~mid-August), if not earlier.

SUMMARY DATA

52-Week High	**$5.86**
52-Week Low	**$2.92**
One-Year Return (%)	**0.64**
Beta	**-1.54**
Average Daily Volume (sh)	**32,208**
Shares Outstanding (mil)	**26**
Market Capitalization ($mil)	**$91**
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 A	$0 E	$0 E	$0 E	$0 E
2018					$659 E
2019					$3990 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	-$0.15 E	-$0.14 E	-$0.15 E	-$0.57 E
2018					-$0.49 E
2019					-$0.38 E

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

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Replacing Triage Assays: May Only Result in Relatively Short Delay - Could Be a Non-Event

In a brief June 27th press release VNRX noted that the company's proprietary blood assays incorporated into Triage would be replaced. Both assays, as indicated in the release, were found to have high p-values during an additional analysis of the validation data that showed Triage has the potential to prevent 24.5% of colonoscopies and detect almost 95% of colorectal cancers and 88% of (high-risk) adenomas. Given the brevity and seemingly serious potential implications of the announcement, we talked to management for additional clarity on exactly what this might mean in terms of development timelines as well as the overall feasibility of actually bringing Triage to market. While we came away with some still unanswered questions, overall we feel that this may not be a particularly serious issue but (hopefully) only result in a short-term delay to initial commercialization in Europe. In fact in the end, it could even end up being a positive development.

These are the key takeaways from our conversation with management (some of which are based on interpretation given that management could not provide specific answers to all of our questions):

- Triage validation, that is: able to prevent 24.5% of colonoscopies and detect 95% of colorectal cancers and 88% of high-risk adenomas, remains valid. Although this may actually improve with the new assays
- Bullet-proof the data. We suspect the decision to re-develop the two assays was to bullet-proof the data and avoid risk of claims of "correlation does not imply causation", particularly as additional manuscripts are expected to be submitted to peer-reviewed journals
- Short delay? Our interpretation is that validation with the two new assays is expected to be accomplished in relatively short-order and done using a portion of the 8k samples utilized for the initial assays. Given the higher throughput and capacity, we think VNRX should be able to run the samples relatively very quickly. Timelines for CE Marking of the assays and the panel may require a little more guesswork although experience gleaned from the first time around and that fact that CE Marking, in general, is a relatively short process, could mean that all of this might be accomplished as soon as current year-end or shortly thereafter. We hope to know more relative to potential timelines as VNRX provides future updates.
- Improved performance? Again, based on our interpretation from management's comments, we think the re-development may result in assays that outperform those they are replacing. Clearly the goal is to get the p-value down which, all else equal (the other components of Triage, age adjustment and FIT score remain unchanged), should result in a higher performing panel. As such, the 24.5% (colonoscopy reduction), 95% (CRC detection) and 88% (high-risk adenoma detection) cited above may be improved upon. If that is the case, demand for and utility of the test in national CRC European screening programs would likely be further enhanced.
- Pathway design studies continue in Denmark. These should be completed by the time the new assays are CE Marked.

Our comments:

The delay is a disappointment but if that (i.e. a short-term delay) is the only meaningful consequence of having to redevelop these assays, it is effectively a non-event - or possibly even a positive event given the possibility that Triage performance is further bolstered. We had previously modeled initial revenue contribution beginning in early 2018 - we have since incorporated a six-month delay. Although given that we had previously expected relatively insignificant revenue for the full year 2018 and model the delay to have virtually no long-term related impact, it has a largely immaterial effect on our DCF-generated price target. Our per-share price target has moved from $7.00 to $6.75. We hope to hear more about the status of development of the assays as well as management's expectations of timelines relative to regulatory and launch on the Q2 earnings call (which we expect ~mid-August), if not earlier.

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	$658.9	$3,989.9
YOY Growth	-	-	-	-	-	-	-	*505.5%*
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$171.3	$798.0
Gross Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$487.6	$3,191.9
Gross Margin	-	-	-	-	-	-	*74.0%*	*80.0%*
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	-	-	-	-	-	-	*1186.8%*	*217.0%*
R&D	$6,837.6	$1,841.6	$1,936.0	$1,978.0	$2,214.0	$7,969.6	$9,688.0	$9,512.0
% R&D	-	-	-	-	-	-	*1470.3%*	*238.4%*
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)	($3,580.0)	($3,690.0)	($4,102.0)	($14,722.7)	($17,020.4)	($14,980.1)
Operating Margin	-	-	-	-	-	-	*-2583.1%*	*-375.4%*
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)	($3,840.6)	($3,698.0)	($4,110.0)	($14,999.3)	($17,047.4)	($15,007.1)
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)	($3,840.6)	($3,698.0)	($4,110.0)	($14,967.8)	($17,047.4)	($15,007.1)
Net Margin	*#DIV/0!*	-	-	-	-	*#DIV/0!*	*-2587.2%*	*-376.1%*
EPS	($0.52)	($0.13)	($0.15)	($0.14)	($0.15)	($0.57)	($0.49)	($0.38)
YOY Growth	-	-	-	-	-	-	-	
Diluted Shares O/S	23,049	26,129	26,350	26,500	26,700	26,420	35,000	39,000

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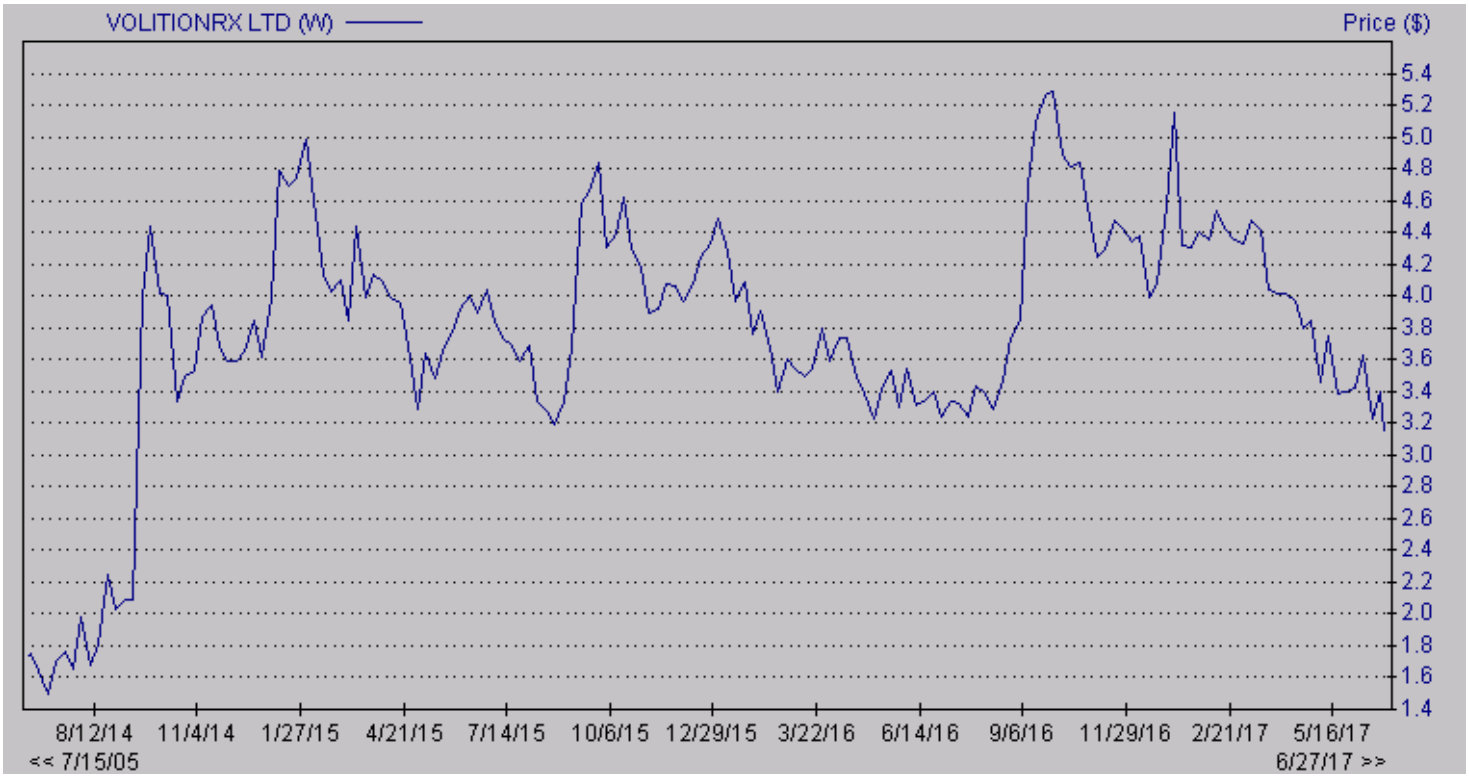

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