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Zacks Small-Cap Research

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VolitionRx Ltd (VNRX-NYSE)

Capital Markets Day Update: entry into China, Taiwan large lung cancer study and formation of animal diagnostics sub

Based on our DCF model which goes out to year 2028 and uses a 9.5% discount rate (based on CAPM) and 2% terminal growth rate, VNRX is valued at $6.50/share. Our model and assumptions will be updated if appropriate based on news flow which could also influence valuation

Current Price (04/24/19)	$3.34
Valuation	**$6.50**

OUTLOOK

Following reporting of Q4 earnings in mid-March, VolitionRx had a spate of news leading up to their 'Capital Markets Day on April 9th at the New York Stock Exchange. The news is an extension of the product development related updates provided during the Q4 earnings call, which as a reminder, included new (i.e. initial) 'proof-of-concept' study data from the first round of 'product grade' assays in colorectal and lung cancers, potential firming up of a canine cancer diagnostic program (in collaboration with Texas A&M University) and Nu.Q Capture, a new project using magnetic beads to enrich nucleosomes.

SUMMARY DATA

52-Week High	**$3.55**
52-Week Low	**$1.44**
One-Year Return (%)	**69.27**
Beta	**0.66**
Average Daily Volume (sh)	**109,922**
Shares Outstanding (mil)	**38**
Market Capitalization ($mil)	**$127**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**7**
Insider Ownership (%)	**27**
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 2019 Estimate	**N/A**
P/E using 2020 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med-Tech/Diagnostic**

ZACKS ESTIMATES

Revenue
(in millions)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2019	$0.0 E	$0.0 E	$0.1 E	$0.1 E	$2.0 E
2020					$7.8 E
2021					$15.3 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.17 A	-$0.15 A	-$0.14 A	-$0.12 A	-$0.56 A
2019	-$0.13 E	-$0.13 E	-$0.12 E	-$0.13 E	-$0.51 E
2020					-$0.37 E
2021					-$0.27 E

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

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Capital Markets Day update

Following reporting of Q4 earnings in mid-March, VolitionRx had a spate of news leading up to their 'Capital Markets Day on April 9th at the New York Stock Exchange. The news is an extension of the product development related updates provided during the Q4 earnings call, which as a reminder, included new (i.e. initial) 'proof-of-concept' study data from the first round of 'product grade' assays in colorectal and lung cancers (details below), potential firming up of a canine cancer diagnostic program (in collaboration with Texas A&M University) and Nu.Q Capture, a new project using magnetic beads to enrich nucleosomes.

We now more about VNRX's plans for development and commercialization of their cancer assays in Asia – a market which have always viewed as holding significant potential value for blood-based cancer diagnostics (given a cultural aversion to fecal handling and relatively high rates of lung cancer in certain areas of that continent). In late-March VNRX announced that they signed a memorandum of understanding (MOU) with Shanghai Fosun Long March Medical Science Co, Ltd, a diagnostics division of Chinese pharmaceutical company, Shanghai Fosun Pharmaceutical (Group) Co., Ltd. Per the MOU (and following consummation of a formal agreement), Fosun is expected to be instrumental in the development and subsequent regulatory activities and commercialization of the company's colorectal cancer assays in China. Initially this will include conducting clinical studies in colorectal, lung and ovarian cancers in China. Per the press release, it will also include evaluating the development of NuQ assays on Fosun's existing chemiluminescence platform ("LUMIART-II Automated Chemiluminescence Immunoassay System"). The fully-automated, high throughput system is commercialized in China.

VNRX is also making further inroads in Taiwan and following compelling initial proof-of-concept data from the first product-grade assay for lung cancer, the company recently entered an MOU to extend their agreement with National Taiwan University to now include the first large-scale lung cancer study. The study will include 1,200 participants receiving low-dose CT scan, 1,000 of which have lung cancer.

The study could provide the first statistically-powered evidence of the potential utility of NuQ diagnostics as a screen for lung cancer or as an adjunct/triage test for low-dose CT. LDCT, currently the only recommended screening test for lung cancer, has drawbacks including its relatively high cost, patient exposure to radiation, overdiagnosis and a potential for meaningful rates of false-positives. As such, an adjunct or triage test that could improve accuracy of lung cancer screening and/or reduce the need for LDCT (without compromise to diagnosis) could have massive appeal, in our opinion. VNRX currently expects to announce preliminary data from the first 600 samples from this study in Q1 2020.

As a reminder, VolitionRx already has a relationship with National Taiwan University. VNRX previously finalized agreements with NTU to conduct two large CRC studies; 5k-sample asymptomatic screening study and a 2k-sample symptomatic study.

VNRX also revealed a little bit more about their plans for development of a canine cancer assay. On April 9th VolitionRx announced that they signed an MOU with Texas A&M University related to the formation of a new U.S. subsidiary, "Vetco", with a focus on the veterinarian diagnostics market. It is envisioned that Texas A&M University would have an equity interest in Vetco.

As a reminder, management previously indicated that they think a canine cancer test could be a relatively fast moving program given the less-stringent U.S. regulatory pathway for animal diagnostics (via USDA versus FDA's PMA or 510k)k)). Canine cancer also represents a sizeable market. In fact, management noted that 4.2M cases of canine cancer are diagnosed each year in the U.S., or nearly 2.5x as many human cancers. And, given a similar price point as a human Nu.Q test (~$100), the canine cancer opportunity could be in the many hundreds of millions of dollars.

VNRA is working with Texas A&M University's College of Veterinary Medicine to conduct a study of 'Nu.Q Vet'. Specifics in terms of the development and regulatory strategy are expected to be revealed in the near future. If all goes well, management believes they could have a Nu.Q test for the diagnosis of animal cancers (initially canines but potentially also other animals including horses) on the market by next year.

As a refresher of some of the operational-related highlights from VNRX's year-end 2018 earnings release and conference call in mid-March…

There were a few surprises in the Q4/FY2018 earnings release – that includes what appears to be a sooner-than-previously anticipated move towards lung cancer, new (i.e. initial) 'proof-of-concept' study data from the first round of 'product grade' assays in colorectal and lung cancers, potential firming up of a canine cancer diagnostic program (in collaboration with Texas A&M University) and Nu.Q Capture, a new project using magnetic beads to enrich nucleosomes – which is presumably aimed at optimizing the technology for use with high throughput chemiluminescence analyzers.

As it relates to lung cancer, VNRX announced initial proof-of-concept data from an initial Nu.Q product grade assay. In 76 subjects, the assay detected lung cancer, including stage 1 cancer, with an area under the curve (AUC) of 85% as compared to healthy tissue. The same (single) Nu.Q assay, when used in a confirmatory cohort of 152 subjects detected lung cancer with an AUC of 79%.

Up until the Q4 earnings release, lung cancer had largely been considered a back-burner project (as far as we could tell) as the focus was mostly on colorectal cancer (and other cancers including prostate). But, with initial product grade data in lung (as well as CRC) and inbound interest in a lung cancer diagnostic (particularly as it relates to Asia), we think this may now represent one of the lead programs.

As it relates to colorectal cancer, VNRX announced initial proof-of-concept data from an initial Nu.Q product grade assay. In 123 subjects a single Nu.Q assay detected CRC with an AUC of 72%. A two-assay panel, which included this initial product grade Nu.Q assay and an inflammatory biomarker test, had an AUC of 84%.

These are relatively tiny POC studies but the data is certainly encouraging. The goal will be to replicate these results with reproducible product grade assays in larger, fully powered studies.

As it relates to a canine cancer diagnostic, VNRX indicated that they think this could be a relatively fast moving program given the less-stringent U.S. regulatory pathway for animal diagnostics (via USDA versus FDA's PMA or 510k)k)). Canine cancer also represents a sizeable market. In fact, management noted that 4.2M cases of canine cancer are diagnosed each year in the U.S., or nearly 2.5x as many human cancers. And, given a similar price point as a human Nu.Q test (~$100), the canine cancer opportunity could be in the many hundreds of millions of dollars.

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We will be eagerly awaiting updates on all of VNRX's programs, but given the initial POC data, particularly so in their lung and colorectal cancer endeavors. Given the recent highly encouraging data in prostate cancer (and massive unmet need for a PSA replacement/adjunct), we had envisioned that a Nu.Q prostate cancer assay/panel could be a front-runner in terms of possible initial commercialization candidates. Whether that may still be in the cards, we don't know, but will be something we hope to know more about as well. We may know a lot more on April 9th. Stay tuned.

FINANCIAL MODEL

VolitionRx Ltd.

	2018 A	Q1 E	Q2 E	Q3 E	Q4 E	2019 E	2020 E	2021 E
Revenue	$0.0	$0.0	$14.5	$60.0	$125.0	$199.5	$7,805.2	$15,339.4
YOY Growth	-	-	-	-	-	#DIV/0!	3812.4%	96.5%
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1,561.0	$3,313.3
Gross Income	$0.0	$0.0	$14.5	$60.0	$125.0	$199.5	$6,244.1	$12,026.1
Gross Margin	-	#DIV/0!	100.0%	100.0%	100.0%	80.0%	80.0%	78.4%
SG&A	$6,990.8	$1,851.3	$2,019.6	$1,962.7	$2,012.4	$7,845.9	$8,991.6	$10,369.4
%SG&A	-	-	-	-	-	3932.8%	115.2%	67.6%
R&D	$10,906.9	$2,751.5	$2,863.2	$2,701.6	$2,994.8	$11,311.1	$13,874.9	$15,450.8
% R&D	-	-	-	-	-	5669.7%	177.8%	100.7%
Operating Income	($17,897.7)	($4,602.8)	($4,868.3)	($4,604.3)	($4,882.2)	($18,957.5)	($16,622.3)	($13,794.1)
Operating Margin	#DIV/0!	-	-	-	-	-9502.5%	-213.0%	-89.9%
Total Other Expense (Income)	$111.0	$30.2	$27.6	$24.7	$22.9	$105.4	$140.0	$174.0
Pre-Tax Income	($18,008.7)	($4,633.0)	($4,895.9)	($4,629.0)	($4,905.1)	($19,062.9)	($16,762.3)	($13,968.1)
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%	35.0%
FX translation	($352.9)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($17,655.7)	($4,633.0)	($4,895.9)	($4,629.0)	($4,905.1)	($19,062.9)	($16,762.3)	($13,968.1)
Net Margin	-	-	-	-	-	-	-	-
EPS	($0.56)	($0.13)	($0.13)	($0.12)	($0.13)	($0.51)	($0.37)	($0.27)
YOY Growth	-	-	-	-	-	-	-	
Diluted Shares O/S	31,389	36,441	37,850	38,012	38,265	37,642	45,000	52,000

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HISTORICAL STOCK PRICE



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