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# Zacks Small-Cap Research

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## VolitionRx Ltd (VNRX-NYSE)

**VNRX: NuQ Shows Compelling Asymptomatic Detection of Pre/Early Cancers**

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 $7.50/share. Our model and assumptions will be updated if appropriate based on news flow which could also influence valuation

| | |
|---|---|
| Current Price (02/27/18) | $3.15 |
| **Valuation** | **$7.50** |

## OUTLOOK

Compelling early-stage CRC detection data from a 680-sample asymptomatic training study indicates that substantive progress has been made towards building a NuQ-based frontline CRC panel. While this is not the first data suggesting relatively high accuracy of NuQ in detecting CRC, we believe it is the most compelling given that it is the first asymptomatic-designed study and showed high detection rates of early-stage disease. In this 680-subject study, a panel of three NuQ assays detected 80% of stage 1 cancers and 66% of high-risk pre-cancer adenomas at 78% specificity. Early-stage detection is critical to maximize survivability although currently marketed non-invasive CRC diagnostics have shown very poor performance with cases of early disease, particularly those that are precancerous. VNRX will look to further improve upon the performance of their asymptomatic screen and hopes to have the final panel chosen, fully validated and launched in the EU by current year-end. If management is able to hit their current anticipated timeline, we think there could be at least two value-inflection opportunities related to this EU CRC asymptomatic screen development program over the next 6 to 9 months.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$4.71** |
| **52-Week Low** | **$2.08** |
| **One-Year Return (%)** | **-29.02** |
| **Beta** | **-1.24** |
| **Average Daily Volume (sh)** | **84,452** |
| **Shares Outstanding (mil)** | **27** |
| **Market Capitalization ($mil)** | **$84** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **17** |
| **Insider Ownership (%)** | **28** |
| **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** | **High,** |
| **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 A | $0 A | $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 | -$0.13 A | -$0.15 A | -$0.16 E | -$0.56 E |
| 2018 | | | | | -$0.51 E |
| 2019 | | | | | -$0.41 E |

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

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**NuQ Compelling Asymptomatic Detection of Pre/Early Cancers:** goal is to refine, validate, launch in EU in 2018

As a reminder, VolitionRx has several colorectal cancer development programs in various stages in different geographies. That includes separate programs for the development of assays and panels targeting symptomatic and asymptomatic populations for use in national colorectal cancer screening programs in certain parts of Europe.

Their initial foray has been with Triage, being developed as an adjunct to traditional stool-based FIT testing (as a way to reduce the number of unnecessary colonoscopies) for use in Denmark's (as well as potentially other countries) national screening programs. Successful completion of a logistics and pathway design study, anticipated to be one of the final pre-commercialization gating items, happened in early February – meaning that Triage might soon enter Denmark's colorectal cancer screening programs. In the meantime, as management explained on their Q3 earnings call in November, they are aggressively pursuing development of an asymptomatic colorectal cancer screen with the hope to also launch it in Europe before current year-end.

While development timelines have slipped a bit from guidance provided on the Q3 call, the compelling early-stage CRC detection data from a 680-sample asymptomatic training study (announced yesterday) certainly indicates that substantive progress has been made towards building a NuQ-based frontline CRC panel. While this is not the first data suggesting relatively high accuracy of NuQ in detecting CRC, we believe it is the most compelling given that it is the first asymptomatic-designed study and showed high detection rates of early-stage disease. Early-stage detection is critical to maximize survivability although the currently marketed non-invasive diagnostics have shown very poor performance with cases of early disease, particularly those that are precancerous.

In this 680-subject study, which includes ~100 with cancer, a panel of three NuQ assays detected 80% of stage 1 cancers and 66% of high-risk pre-cancer adenomas at 78% specificity. Data of the later-stage cases or detection across all cancers was not released, although we expect that more comprehensive data will be included in future announcements.

For context of the performance of some of the leading non-invasive CRC screening diagnostics in detecting pre-cancers; Exact Sciences (stool-based) ColoGuard showed 42% sensitivity in detection of advanced precancerous adenomas at 87% specificity, FIT showed 24% sensitivity in detection of advanced precancerous adenomas at 94% specificity and Septin9 showed 18% sensitivity in detection of advanced precancerous adenomas at 80% specificity. While the differences in specificity of all of the studies makes head-to-head performance comparison difficult, we think this at least provides some insight into the relatively poor pre-cancer detection abilities of currently available non-invasive diagnostics and helps illustrate the unmet need for a more accurate test.

As it relates to performance in detecting CRC (of any stage) published studies showed sensitivity / specificity of these tests at; ColoGuard 92% / 87%, FIT 79% / 94% and Septin9 68% / 80%. Again, we provide this only for some context and also note that, as we have discussed in detail in prior reports, all non-invasive CRC diagnostics suffer from one or more meaningful drawbacks – some of which include low accuracy, high cost and requisite fecal handling.

VNRX will look to further improve upon the performance of their asymptomatic screen. Additional assays and panels will be evaluated in the 680-patient training study. A larger 4.3k subject training study will then afford powering the evaluation of a larger panel – the final panel is expected to include 5 or 6 assays. The next step will then be to validate that panel in a 12k subject study. In the meantime, VNRX will put as many pieces as possible in place towards applying for CE Mark so as to facilitate launch ASAP. If management is able to hit their current anticipated timeline (below), we think there could be at least two value-inflection opportunities (including data read-outs of the panel in the 4.3k and 12k studies) related to this EU CRC asymptomatic screen development program over the next 6 to 9 months. Management's current anticipated timelines are;

- Q2 2018: report results of 4.3k training study
- 2H 2018: commence 12k subject study
- 2H 2018: launch asymptomatic CRC screen in EU

**Other activities…**

Data from the 27-cancer study, which is also expected to be announced later this year, also has the potential to be a major announcement, particularly if it also shows relatively strong performance in early-stage cancers.

**In Asia**… in November VNRX signed an MOU with National Taiwan University to conduct two studies encompassing a total of 7k blood samples related to CRC. The first study will include 5k samples from

asymptomatic individuals while the second is 2k samples from symptomatic CRC patients. These studies are only for marketing/commercialization purposes and not regulatory-related.

**In terms of Triage**…with the successful (although delayed from initial expectations) completion of the logistics and pathway design study, management indicated that they will forge ahead with bringing Triage to market. We may hear more about their intentions and plans as it relates to commercialization plans for Triage on the upcoming Q4 call. However, while we continue to model launch of Triage in 2H 2018, we also think buttoning-up remaining development and CE Marking of Triage may take a backseat to the frontline test, the market for which is significantly larger. As such, we still think this is a "stay tuned" situation.

**Research Use Only Kits**: In September VNRX announced the introduction and first sale of Nu.Q-based RUO kits. The first sale was made to a (unnamed) "large multinational pharmaceutical company". The company noted that the customer requested a customized kit, which is how the initial sale materialized. From our experience, it is almost impossible to judge potential demand for RUO products (at least at initial launch), although management has indicated that they have had meaningful interest, particularly for companion diagnostic development purposes. While it is possible significant and consistent demand could materialize, (particularly if, for example, they were used as a companion diagnostic for a new popular drug), we currently do not model any meaningful related potential contribution. We will update this if appropriate.

## FINANCIAL MODEL

VolitionRx Ltd.

| | 2016 A | Q1 A | Q2 A | Q3 A | 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 | $1,734.5 | $1,825.2 | $1,941.0 | $7,009.9 | $7,820.0 | $8,660.0 |
| *%SG&A* | - | - | - | - | - | - | *1186.8%* | *217.0%* |
| R&D | $6,837.6 | $1,841.6 | $1,728.5 | $2,204.0 | $2,214.0 | $7,988.0 | $10,577.0 | $10,455.0 |
| *% R&D* | - | - | - | - | - | - | *1605.2%* | *262.0%* |
| 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) | ($3,463.0) | ($4,029.2) | ($4,155.0) | ($14,997.9) | ($17,909.4) | ($15,923.1) |
| *Operating Margin* | - | - | - | - | - | - | *-2718.0%* | *-399.1%* |
| Total Other Expense (Income) | ($361.3) | $0.0 | $0.0 | ($136.6) | $8.0 | ($128.6) | $27.0 | $27.0 |
| Pre-Tax Income | ($11,905.3) | ($3,350.7) | ($3,463.0) | ($3,892.7) | ($4,163.0) | ($14,869.3) | ($17,936.4) | ($15,950.1) |
| 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%* |
| FX translation | $109.1 | ($31.5) | ($61.3) | $32.4 | $0.0 | ($60.4) | $0.0 | $0.0 |
| Net Income | ($12,014.4) | ($3,319.2) | ($3,401.7) | ($3,925.1) | ($4,163.0) | ($14,808.9) | ($17,936.4) | ($15,950.1) |
| *Net Margin* | *#DIV/0!* | - | - | - | - | *#DIV/0!* | *-2722.1%* | *-399.8%* |
| EPS | ($0.52) | ($0.13) | ($0.13) | ($0.15) | ($0.16) | ($0.56) | ($0.51) | ($0.41) |
| *YOY Growth* | - | - | - | - | - | - | - | |
| Diluted Shares O/S | 23,049 | 26,129 | 26,383 | 26,512 | 26,515 | 26,385 | 35,000 | 39,000 |

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