

VolitionRx

Q4 update

Something innovative in the state of Denmark

Pharma & biotech

VolitionRx recently announced the initiation of a two-phase logistical study for its Nu.Q™ Triage test for colorectal cancer (CRC) in Denmark, which may enable the inclusion of the test in the country's national screening program in conjunction with the standard fecal immunochemical test (FIT). The study is expected to take six months to complete with the potential for a decision by the national screening committee by the end of the year. If included, the Nu.Q™ Triage test would be the first blood-based cancer diagnostic as part of a national screening program for CRC.

| Year end | Revenue (\$m) | PBT* (\$m) | EPS* (\$) | DPS (\$) | P/E (x) | Yield (%) |
|----------|---------------|------------|-----------|----------|---------|-----------|
| 12/15 | 0.0 | (9.7) | (0.54) | 0.0 | N/A | N/A |
| 12/16 | 0.0 | (12.3) | (0.53) | 0.0 | N/A | N/A |
| 12/17e | 1.6 | (15.3) | (0.58) | 0.0 | N/A | N/A |
| 12/18e | 4.1 | (19.6) | (0.71) | 0.0 | N/A | N/A |

Note: *PBT and EPS are normalised, excluding amortization of acquired intangibles, exceptional items and share-based payments.

Unnecessary colonoscopies mar screening programs

Current screening methodologies, such as the FIT test, lead to a large number of false positives. According to data from national screening programs that use FIT, there are around 20 false positives for every true positive, leading to a large number of unnecessary colonoscopies, which tax the health system.

Recent data illustrates the test's potential

At the 2017 World Congress of GI Endoscopy, VolitionRx presented data based on 3,868 samples of the Nu.Q™ Triage test combined with FIT, which indicated the potential to reduce colonoscopies by 28.6% by reducing the number of false positives. Updated data from around 8,000 samples will be presented at Digestive Disease Week (May 6-9 in Chicago).

Denmark may be first country to validate approach

Once the two-phase study is completed in Denmark later this year, Nu.Q™ could potentially be included in the national screening program starting in January. Besides the revenue from that 20,000-40,000 test order (we assume €50 per test), it would provide validation to the approach and may make inclusion in other national screening programs more likely.

Valuation: \$272m or \$10.40 per basic share

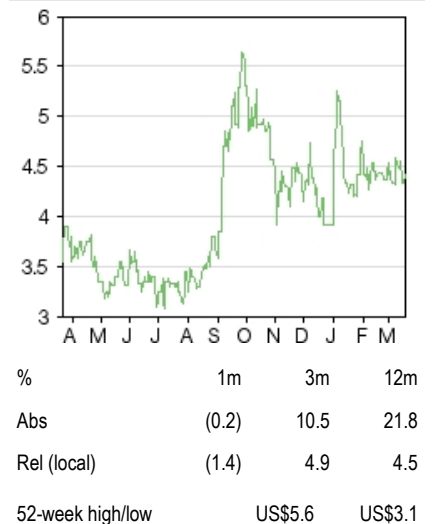
We have increased our valuation slightly to \$272m or \$10.40 per basic share, from \$267m or \$10.23 per basic share. This is mainly due to rolling our NPVs to 2017 and was mitigated by a lower cash balance. Due to continued expense control we have also lowered our operating expense estimates, so that we now expect the company to be slightly cash flow positive in 2020 (previously 2021). We continue to expect VolitionRx to need \$45m in cash prior to profitability.

20 March 2017

Price **US\$4.42**
Market cap **US\$116m**

| | |
|----------------------------|----------|
| Net cash (\$m) at end Q416 | 21.2 |
| Shares in issue | 26.1m |
| Free float | 74% |
| Code | VNRX |
| Primary exchange | NYSE MKT |
| Secondary exchange | N/A |

Share price performance



Business description

VolitionRx is a diagnostics company focused on developing blood-based cancer diagnostics using its proprietary Nu.Q™ technology. Its lead program is in colorectal cancer, which recently received a CE Mark, allowing for commercialization in Europe.

Next events

8,000 subject data at Digestive Disease Week Annual Meeting May 2017

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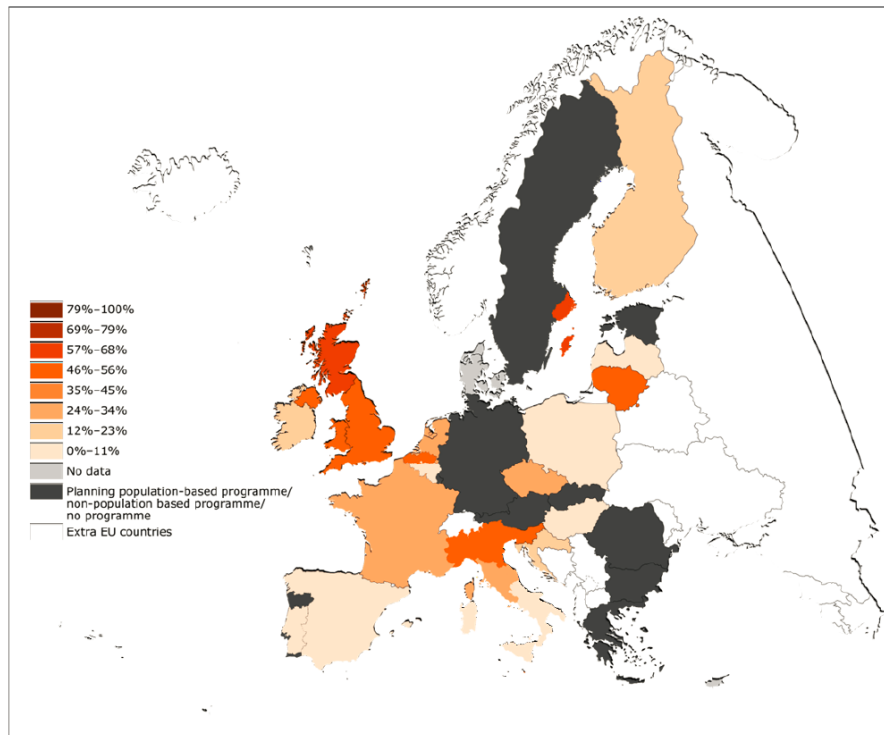
Starting the process in Denmark

In collaboration with Hvidovre Hospital and the Danish Research Group on Early Detection of Colorectal Cancer, Volition has initiated a two-phase logistical study to study some of the practical aspects of including the Nu.Q™ Triage test in the national screening program as an additional layer of screening on top of the standard FIT test. The first phase started in early March in the Capital Region of Denmark and involves three local screening centers and up to 250 subjects. The objective is to evaluate the logistics of collecting and processing the blood samples at a local screening center and then shipping them to a central laboratory in Denmark. The second phase will involve five centers and up to 500 subjects to assess the time that it will take to collect, analyze and deliver results. The results will be delivered directly to the national screening committee with the hope of inclusion in the full screening program, which is slated to start in January 2018.

If it is included, VolitionRx would need to be notified in Q4 in order to provide the estimated 20-40,000 tests required. It would also position the Nu.Q™ Triage test as the only blood-based cancer diagnostic for colorectal cancer to be validated through inclusion in a national screening program. Currently, countries have been generally slow to rollout national screening programs partly due to the fear of the wave of colonoscopies that it would create, leading to low coverage across much of the EU (see Exhibit 1). A positive experience in Denmark could pave the way to increased acceptance into other national screening programs.

Exhibit 1: Percent of populations participating in national CRC screening programs

Figure 4.3. Colorectal cancer screening programmes in the EU (women and men, any test): examination coverage by programme specific age-range (table 4.14)*



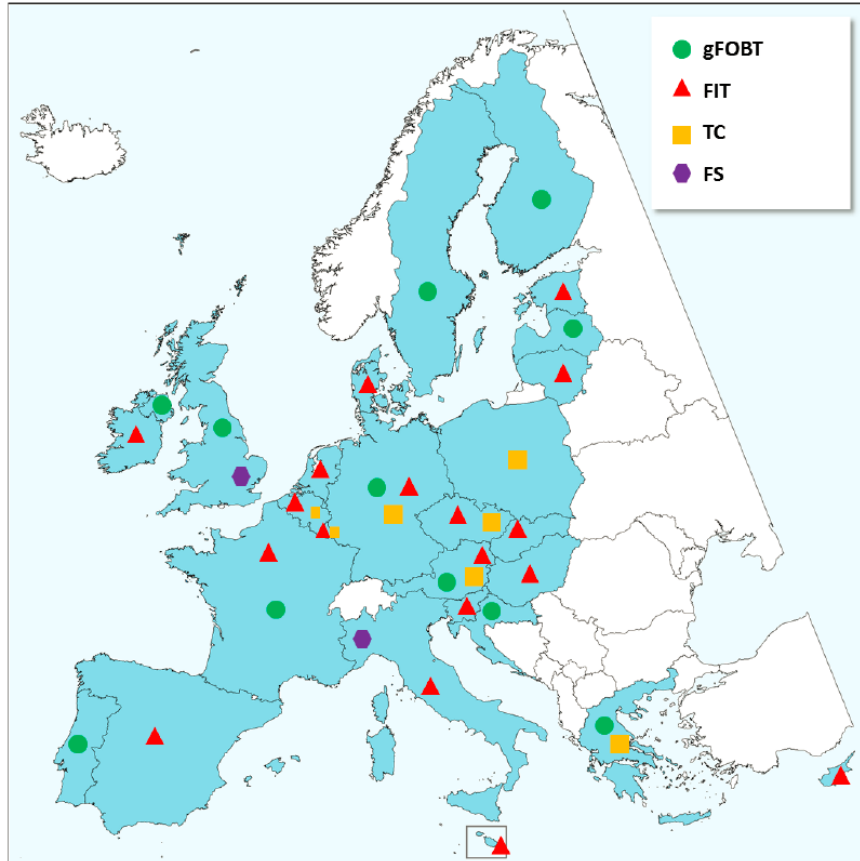
Source: Cancer Screening in the European Union (2017) by the International Agency for Research on Cancer

According to the [International Agency for Research on Cancer](#), the positive predictive value for the fecal FIT test is 4.4%, meaning there are approximately 20 false positives for every true positive in national screening programs that use it (see Exhibit 2). Importantly, at the 2017 World Congress of GI Endoscopy, VolitionRx presented data based on 3,868 samples of the Nu.Q™ Triage test

combined with FIT, which indicated the potential to reduce colonoscopies by 28.6% by reducing the number of false positives.

Exhibit 2: Type of tests used for CRC screening

Figure 3.4. Tests used for colorectal cancer screening in the EU member states in 2016



Legend - gFOBT: Guaiac Fecal Occult Blood Test; FIT: Fecal Immunochemical Test; FS – Flexible Sigmoidoscopy; TC – Total Colonoscopy.

Source: Cancer Screening in the European Union (2017) by the International Agency for Research on Cancer

With regards to the United States, the company has recently founded a US subsidiary, Volition America, to focus on the efforts of obtaining first a 510(k) and then a PMA approval for Nu.Q™. The company is hoping to announce details on the US approval efforts in the next quarter or two.

Valuation

We have increased our valuation slightly to \$272m or \$10.40 per basic share, from \$267m or \$10.23 per basic share. This is mainly due to rolling our NPVs to 2017 and was mitigated by a lower cash balance. We expect to revise our valuation following updates on the company's US strategy, as well as updates on the process for Nu.Q™ Triage inclusion into national screening programs.

Exhibit 3: VolitionRx valuation table

| Product | Main indication | Status | Prob. of commercial success | Launch year | Peak sales (\$m) | Patent protection | Economics | rNPV (\$m) |
|--|-------------------|-----------------------|-----------------------------|-------------|------------------|-------------------|-----------------|----------------|
| NuQ | Colorectal | Development | 30% | 2017 | \$404 | 2034 | 56% peak margin | \$180 |
| | Colorectal triage | Pre-commercialization | 30% | 2017 | \$42 | 2034 | 50% peak margin | \$17 |
| | Lung | Development | 30% | 2018 | \$145 | 2034 | 61% peak margin | \$43 |
| | Pancreatic | Development | 30% | 2018 | \$37 | 2034 | 58% peak margin | \$10 |
| Total | | | | | | | | \$250 |
| Cash and cash equivalents (Q416) (\$m) | | | | | | | | \$21.2 |
| Total firm value (\$m) | | | | | | | | \$272 |
| Total basic shares (m) | | | | | | | | 26.1 |
| Value per basic share (\$) | | | | | | | | \$10.40 |
| Warrants and options (12/2016, m) | | | | | | | | 2.2 |
| Weighted average exercise price (\$) | | | | | | | | \$2.40 |
| Cash on exercise (\$m) | | | | | | | | \$5.2 |
| Total firm value (\$m) | | | | | | | | \$277 |
| Non-warrant options (6/2016, m) | | | | | | | | 2.4 |
| Total number of shares (m) | | | | | | | | 30.7 |
| Diluted value per share (\$) | | | | | | | | \$9.03 |

Source: VolitionRx reports, Edison Investment Research

Financials

The company ended Q416 with \$21.2m in net cash with an operating loss for the quarter of \$3.3m. This loss is a slight decrease over Q3 (loss of \$3.5m), reflecting continued expense control. Due to this, we have lowered our expected operational loss for 2017 from \$16.7m to \$15.4m and now expect the company to become cash flow positive in 2020 (previously 2021). We continue to expect the company to need \$45m in cash prior to profitability.

Exhibit 4: Financial summary

| | \$000s | 2012 | 2013 | 2014 | 2015 | 2016e | 2017e | 2018e |
|--|--------|---------|---------|---------|----------|----------|----------|----------|
| Year end 31 December | | IFRS | IFRS | IFRS | IFRS | IFRS | IFRS | IFRS |
| PROFIT & LOSS | | | | | | | | |
| Revenue | | 55 | 0 | 15 | 0 | 0 | 1,622 | 4,086 |
| Cost of Sales | | 0 | 0 | 0 | 0 | 0 | (229) | (537) |
| Gross Profit | | 55 | 0 | 15 | 0 | 0 | 1,393 | 3,549 |
| Research & Development | | (2,843) | (2,504) | (4,044) | (6,102) | (6,838) | (8,621) | (9,483) |
| Sales, General & Administrative | | (1,295) | (2,072) | (1,908) | (3,904) | (5,429) | (8,171) | (12,511) |
| EBITDA | | (4,083) | (4,576) | (5,937) | (10,006) | (12,267) | (15,399) | (18,446) |
| Operating Profit (before GW and except.) | | (4,083) | (4,576) | (5,937) | (10,006) | (12,267) | (15,399) | (18,446) |
| Intangible Amortisation | | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Other | | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Exceptionals | | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Operating Profit | | (4,083) | (4,576) | (5,937) | (10,006) | (12,267) | (15,399) | (18,446) |
| Net Interest | | 0 | 0 | 0 | 0 | 0 | 71 | (1,121) |
| Other | | (39) | 840 | (2,320) | 471 | 252 | 0 | 0 |
| Profit Before Tax (norm) | | (4,083) | (4,576) | (8,358) | (9,666) | (12,267) | (15,327) | (19,567) |
| Profit Before Tax (FRS 3) | | (4,122) | (3,736) | (8,258) | (9,535) | (12,014) | (15,327) | (19,567) |
| Tax | | 0 | 0 | (0) | 5 | 0 | 0 | 0 |
| Deferred tax | | 0 | 0 | (0) | (0) | (0) | (0) | (0) |
| Profit After Tax (norm) | | (4,083) | (4,576) | (8,358) | (9,661) | (12,267) | (15,327) | (19,567) |
| Profit After Tax (FRS 3) | | (4,122) | (3,736) | (8,258) | (9,530) | (12,014) | (15,328) | (19,567) |
| Average number of shares outstanding (m) | | 9.4 | 10.8 | 13.5 | 17.7 | 23.0 | 26.7 | 27.7 |
| EPS - normalised (c) | | (43.62) | (42.24) | (62.08) | (54.49) | (53.22) | (57.51) | (70.60) |
| EPS - FRS 3 (\$) | | (0.44) | (0.34) | (0.61) | (0.54) | (0.52) | (0.58) | (0.71) |
| Dividend per share (\$) | | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| BALANCE SHEET | | | | | | | | |
| Fixed Assets | | 1,522 | 1,065 | 1,097 | 1,489 | 2,721 | 2,243 | 1,890 |
| Intangible Assets | | 1,430 | 1,002 | 809 | 705 | 602 | 602 | 602 |
| Tangible Assets | | 91 | 63 | 289 | 784 | 2,119 | 1,640 | 1,288 |
| Other | | 0 | 0 | (0) | (0) | (0) | (0) | (0) |
| Current Assets | | 416 | 941 | 2,192 | 6,070 | 21,846 | 23,120 | 20,954 |
| Stocks | | 0 | 0 | 0 | 0 | 0 | 11 | 26 |
| Debtors | | 0 | 0 | 0 | 0 | 0 | 289 | 728 |
| Cash | | 376 | 889 | 2,139 | 5,916 | 21,679 | 22,652 | 20,033 |
| Other | | 39 | 53 | 53 | 154 | 167 | 167 | 167 |
| Current Liabilities | | (695) | (957) | (2,713) | (1,120) | (2,033) | (1,478) | (1,848) |
| Creditors | | (695) | (957) | (2,713) | (1,120) | (2,003) | (1,478) | (1,848) |
| Short term borrowings | | 0 | 0 | 0 | 0 | (31) | 0 | 0 |
| Long Term Liabilities | | (635) | (433) | (352) | (548) | (1,524) | (16,524) | (31,524) |
| Long term borrowings | | 0 | 0 | 0 | 0 | (432) | (15,432) | (30,432) |
| Other long term liabilities | | (635) | (433) | (352) | (548) | (1,092) | (1,092) | (1,092) |
| Net Assets | | 607 | 617 | 224 | 5,891 | 21,009 | 7,360 | (10,528) |
| CASH FLOW | | | | | | | | |
| Operating Cash Flow | | (2,315) | (3,084) | (4,141) | (8,766) | (9,056) | (13,966) | (17,578) |
| Net Interest | | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Tax | | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Capex | | (91) | (1) | (303) | (352) | (415) | (30) | (41) |
| Acquisitions/disposals | | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Financing | | 2,576 | 2,828 | 5,627 | 12,498 | 25,302 | 0 | 0 |
| Dividends | | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Other | | 0 | 0 | 0 | 0 | (553) | 0 | 0 |
| Net Cash Flow | | 171 | (257) | 1,183 | 3,379 | 15,279 | (13,996) | (17,619) |
| Opening net debt/(cash) | | (348) | (376) | (889) | (2,139) | (5,916) | (21,216) | (7,220) |
| HP finance leases initiated | | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Exchange rate movements | | (40) | 4 | (44) | 13 | 146 | 0 | 0 |
| Other | | (103) | 765 | 111 | 385 | (125) | 0 | 0 |
| Closing net debt/(cash) | | (376) | (889) | (2,139) | (5,916) | (21,216) | (7,220) | 10,399 |

Source: VolitionRx reports, Edison Investment Research

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