EDISON

VolitionRx

Clinical update

Results from asymptomatic CRC trial reported

Pharma & biotech

VolitionRx recently announced the initial results from a 680-sample study taken from asymptomatic colorectal cancer (CRC) patients. The study demonstrated 80% sensitivity against stage 1 CRC and 66% against high-risk adenomas (at 78% specificity). The company has stated that it is moving on to the 4,300-sample study to determine the final test panel for European launch (results in Q218). This will be followed by a 12,000+ sample blinded study which is expected to complete in H218.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/16	0.0	(12.5)	(0.54)	0.0	N/A	N/A
12/17	0.0	(15.1)	(0.57)	0.0	N/A	N/A
12/18e	0.1	(18.9)	(0.60)	0.0	N/A	N/A
12/19e	1.3	(22.1)	(0.67)	0.0	N/A	N/A

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

Data similar to previous results

The reported sensitivity and specificity for adenomas and stage 1 CRC reported in this study are similar to previous reports, in both symptomatic and asymptomatic patients. The company did not release data on detecting CRC as a whole. The panel in the study outperformed Epi proColon (62% sensitivity/81% specificity), but is difficult to compare to the widely used fecal immunochemical test (FIT), because FIT has substantially higher specificity (65% sensitivity/97% specificity).

Three tests on this panel, total of 30 to be tested

The data from these most recent results comes from a panel of three ELISA tests, two of which utilized the Nu.Q™ technology. The company stated that is continuing to evaluate up to 30 tests in this study and the ongoing 4,300-sample training study, of which 17 are in process or completed. The company is targeting a panel of five or six tests for the final product, potentially with other adjustments (eg age).

FY17 results: $15.0m operating loss

The company reported an operating loss of $15.0m for FY17, the majority of which was attributable to R&D ($8.9m). Operating losses increased over FY16 ($12.4m) and we expect a continued steady increase in losses with progress toward a European launch ($18.9m in 2018). The company ended the year with $10.1m ($8.5m net) or approximately six months in cash. We expect VolitionRx will require $90m in additional capital (up from $82m previously).

Valuation: $212m or $6.93 per basic share

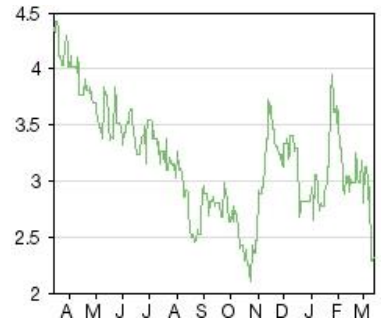
We have increased our valuation to $212m from $200m, but it is lower on a per basic share basis: $6.93 compared to $7.55. We have not made significant adjustments to our assumptions on the back of these clinical results because of their similarity to previous results and limited scope, but we expect to update our valuation with more data from the upcoming trials. This increase is driven by rolling forward our NPVs and higher net cash following the March 2018 offering.

13 March 2018

Price	**US$2.31**
Market cap	**US$70m**

Estimated net cash ($m) (YE17 + offering + greenshoe)	17.4
Shares in issue	30.3m
Free float	69%
Code	VNRX
Primary exchange	NYSE American
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(20.3)	(29.1)	(48.6)
Rel (local)	(24.0)	(32.2)	(56.1)

52-week high/low	US$4.5	US$2.1

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 is being advanced for both triage and frontline testing in Europe and the US.

Next events

4,300 sample training study complete	Q218
Triage test finalized	Q218
12,000+ sample blinded study initiation	H218

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Edison profile page

Preliminary results from 680-sample asymptomatic trial

On 16 February 2018, VolitionRx reported preliminary results from the ongoing 680-sample trial to identify colorectal cancer (CRC) in asymptomatic individuals using the company's Nu.Q technology. The goal of this trial was to validate the technology for progression into the planned larger 4,300-sample asymptomatic trial as part of the company's European approval strategy. Previous studies generally used blood samples from patients that presented at hospitals with bowel symptoms and while these studies were useful in validating the technology, they were limited in that the patients did not accurately represent the asymptomatic screening population, which is the company's target market.

The results as stated by the company are:

> *The interim results demonstrated that a small panel of three ELISA assays, when considered with the subjects' ages and smoking histories, produced an area under the curve (AUC) of 83% and was able to detect 80% of Stage I CRC cases and 66% of High-Risk Adenomas (HRA) at 78% specificity, respectively.*

The interim results provided in this release were limited in scope. First, these results are a panel of only three tests and on the conference call the company provided additional color that only two of the three tests use Nu.Q technology. The remaining assay is a so-called non-proprietary test that uses already available technology such as hypothetically CEA (carcinoembryonic antigen). The study also included adjustments for the patient's age and smoking history. Previous results detailing the sensitivity and specificity of the Nu.Q technology generally included four or five Nu.Q assays. It is unclear at this time if the company performed additional tests and opted not to include them in results presented here, or if the other available Nu.Q tests were simply not complete when the data was analyzed. Moreover, the inclusion of smoking history in the algorithm is new and potentially problematic, as smoking histories are frequently unavailable or falsified. The company has stated that it is moving forward with the 4,300-sample trial which will test at least nine Nu.Q tests, so it is unclear at this time the degree to which these results will be predictive of future performance.

The company also made the decision to present only a portion of the data available from this study. Sensitivity and specificity were only given for stage 1 CRC and high-risk adenomas. The absence of sensitivity and specificity measurements for other stages or for CRC as a whole is conspicuous. Generally, early stage disease and adenomas are the hardest to detect, so one would expect the data from later stages to be better. Given that this sample set was drawn from asymptomatic patients, the number in later stages could be limited, but the company did not provide any breakdown of patient numbers. Moreover, there should not be a limitation on analyzing all CRC samples as a whole as the total sample size is by definition larger than just stage 1. That said, the sensitivity and specificity presented here were in line with previous results from the company (Exhibit 1), although it should be noted that each of these studies uses different combinations of Nu.Q tests, non-proprietary tests and other adjustments in each case. Sometimes results from multiple panels are reported from the same study with different panels used for adenomas and cancer. The most recent results appear superior to Epi proColon, but are difficult to compare to FIT given the latter's significantly higher specificity.

Exhibit 1: Adenoma and stage 1 CRC detection rates

Study	Total n	High-Risk Adenomas		Stage 1 CRC		Specificity	Notes
		Sensitivity	n	Sensitivity	n		
VolitionRx 1	530	67%	246	78%	49	80%	symptomatic, different panels for adenomas and stage 1
VolitionRx 2	430	75%	N/R	86%	N/R	78%	symptomatic
VolitionRx 3	58	62%*	16	75%	4	90%	asymptomatic, different panels for adenomas and stage 1
Current study	680	66%	N/R	80%	N/R	78%	asymptomatic
Epi proColon	290	**	**	62%	26	81%	from Epi proColon physician brochure
FIT	290	**	**	65%	26	97%	from Epi proColon physician brochure
Cologuard	9198	69%	39	90%	29	87%	From Cologuard physician brochure

Source: VolitionRx, Epi proColon physician brochure. Note: *includes low-risk adenomas, **n too small for comparison, N/R=not released.

The company also provided an area under the curve (AUC) from the receiver operating characteristic (ROC) plot of 0.83 for the detection of stage 1 cancer. This statistic provides a measure for the performance of a diagnostic test without the need to define a threshold for determining positives and negatives. A score of 1.0 represents a perfect test, whereas 0.5 represents no diagnostic value. It is difficult to interpret these values in isolation because the shape of the curve is important and in many cases determines the trade-off between sensitivity and specificity. It is difficult to provide comparisons for this statistic, because typically it is released for the detection of CRC as whole, whereas in this case it refers to just stage 1 cancer. On this basis, Epi proColon (Epigenomics) has an AUC of 0.82, and the fecal immunochemical test (FIT), has an AUC of 0.86 (as reported in the FDA assessment of Epi proColon), whereas Exact Sciences' Cologuard has an AUC of 0.93 (from FDA assessment).

Other news

The company presented slightly updated guidance for its Europe registration program: results for the 4,300-sample study are expected in Q218 (previous guidance was for study completion by 31 March 2018). The company is now guiding to at least 12,000 samples in the blinded European registration study (up from at least 10,000), and a H218 start date (from Q218) with data expected at the end of 2018. The company announced that it expects to have a finalized product specification for the triage test in Q218. Finally with regards to the US trial, the company stated that it would select a panel for screening over the coming 18 months, concurrent with sample collection.

Valuation

We have increased our valuation to $212m from $200m, although it is lower on a per share basis ($6.93 per basic share compared to $7.55). Our assumptions regarding the development program remain virtually unchanged. We have reduced 2018 revenue estimates based on the new timing guidance, but the effect is insignificant. The increase is driven by advancing our NPVs and new cash from the March 2018 offering. We include the greenshoe option in our cash estimates (although it has not closed yet) and deduct 6% offering fees.

We have chosen not to change our assumptions regarding the CRC program following the most recent results because of their limited scope and similarity to previous results. However, we expect to update our assumptions significantly with the release of data from the upcoming European clinical trials.

Exhibit 2: Valuation of VolitionRx

Product	Main Indication	Status	Prob. of commercial success	Launch year	Peak sales ($m)	Patent protection	Economics	rNPV ($m)
NuQ	Colorectal	Development	30%	2018	$404	2034	56% peak margin	$145
	Colorectal triage	Development	40%	2018	$42	2034	50% peak margin	$14
	Lung	Development	20%	2020	$132	2034	61% peak margin	$28
	Pancreatic	Development	20%	2020	$42	2034	58% peak margin	$7
Total								$194
Cash and cash equivalents (YE17 + offering + greenshoe) ($m)								$17.4
Total firm value ($m)								$212
Total basic shares (m)								30.6
Value per basic share ($)								$6.93
Warrants and options (m)								4.7
Weighted average exercise price ($)								$3.45
Cash on exercise ($m)								$16.1
Total firm value ($m)								$228
Total number of shares								35.2
Diluted value per share ($)								$6.47

Source: VolitionRx reports, Edison Investment Research

Financials

The company reported an operating loss of $15.0m for 2017, compared to $12.4m for 2016 (restated from $12.3m). We expect this value to continue to increase in 2018 to $18.9m with the associated expenses of developing and launching the two CRC tests in Europe. The 2017 operating loss was slightly higher than expected ($14.0m) and we have carried our adjustments through to later years. We do not expect the company to be profitable until 2023 and we expect it to require additional capital to finance operations.

The company raised approximately $8.4m gross (3.5m shares at $2.40) in March 2018. However, given the increase in our expected spending, this has only slightly reduced our financing requirement to $82m from $83m before profitability in 2023. We currently project that the company will need an additional $7m in 2018 followed by $15m in 2019, $30m in 2020 and $30m in 2021, which we record as illustrative debt.

Exhibit 3: Financial summary

$'000s	2016	2017	2018e	2019e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS				
Revenue	0	0	71	1,329
Cost of Sales	0	0	(14)	(170)
Gross Profit	0	0	57	1,160
Research & Development	(7,905)	(8,906)	(10,242)	(10,856)
Sales, General & Administrative	(4,525)	(6,140)	(8,673)	(11,756)
EBITDA	(12,430)	(15,046)	(18,857)	(21,453)
Operating Profit (before amort. and except.)	(12,430)	(15,046)	(18,857)	(21,453)
Intangible Amortisation	0	0	0	0
Other	0	0	0	0
Exceptionals	0	0	0	0
Operating Profit	(12,430)	(15,046)	(18,857)	(21,453)
Net Interest	(20)	(73)	(90)	(643)
Other	436	414	0	0
Profit Before Tax (norm)	(12,450)	(15,119)	(18,947)	(22,096)
Profit Before Tax (FRS 3)	(12,014)	(14,705)	(18,947)	(22,096)
Tax	0	0	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(12,450)	(15,119)	(18,947)	(22,096)
Profit After Tax (FRS 3)	(12,014)	(14,705)	(18,947)	(22,096)
Average Number of Shares Outstanding (m)	23.0	26.4	31.8	33.0
EPS - normalised (c)	(54.02)	(57.29)	(59.62)	(66.85)
EPS - FRS 3 ($)	(0.52)	(0.56)	(0.60)	(0.67)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	2,721	4,057	3,222	2,601
Intangible Assets	602	576	576	576
Tangible Assets	2,119	3,481	2,646	2,024
Other	(0)	(0)	(0)	(0)
Current Assets	21,846	10,319	11,709	8,182
Stocks	0	0	1	8
Debtors	0	0	13	237
Cash	21,679	10,116	11,494	7,735
Other	167	202	202	202
Current Liabilities	(2,033)	(2,290)	(3,278)	(3,790)
Creditors	(2,003)	(1,847)	(2,834)	(3,346)
Short term borrowings	(31)	(444)	(444)	(444)
Long Term Liabilities	(1,524)	(2,376)	(9,376)	(24,376)
Long term borrowings	(432)	(1,313)	(8,313)	(23,313)
Other long term liabilities	(1,092)	(1,063)	(1,063)	(1,063)
Net Assets	21,009	9,709	2,277	(17,383)
CASH FLOW				
Operating Cash Flow	(8,865)	(12,193)	(14,702)	(18,745)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(415)	(1,425)	(1)	(13)
Acquisitions/disposals	0	0	0	0
Financing	25,302	998	9,080	0
Dividends	0	0	0	0
Other	(553)	(136)	0	0
Net Cash Flow	15,470	(12,756)	(5,623)	(18,759)
Opening net debt/(cash)	(5,916)	(21,216)	(8,360)	(2,737)
HP finance leases initiated	0	0	0	0
Exchange rate movements	146	(89)	0	0
Other	-316	-12	0	0
Closing net debt/(cash)	(21,216)	(8,360)	(2,737)	16,022

Source: Company accounts, Edison Investment Research

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