EDISON

VolitionRx

Earnings update

Gaining more evidence

Pharma & biotech

In May 2017, VolitionRx presented the final data from its 8,000-person clinical validation study of the Nu.Q™ Colorectal Cancer Screening Triage Test. Patients screened with this product would have required 24.5% fewer colonoscopies. The first potential market will be Denmark with feedback expected in about September 2017.

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	0.7	(14.1)	(0.53)	0.0	N/A	N/A
12/18e	2.5	(18.7)	(0.68)	0.0	N/A	N/A

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

Triage test: Successful 8,000-person clinical trial

VolitionRx presented data from the validation portion of the Nu.Q™ Colorectal Cancer Screening Triage Test clinical trial. This portion of the trial was prospective and examined 4,076 patients with a positive fecal immunochemical test (FIT) result. It found that it could eliminate 22% of these FIT-positive patients from needing a colonoscopy while identifying 95% of colorectal cancer (CRC) cases. When combined with the patients from previous portions, the total result would be a 24.5% reduction in colonoscopies, which is remarkably close to the 25% the test was designed for.

US trial being designed: 10,000 undiagnosed

The company announced on the Q117 conference call that it is in the design stages for a 10,000 undiagnosed person trial in the US for the frontline CRC screening test. This is approximately the same size of trial that was performed by Exact Sciences to support Cologuard. We believe the Nu.Q™ trial may have similar endpoints of 65% sensitivity for CRC and 85% specificity for advanced neoplasias.

Outlook: $2.5m to $3.0m burn per quarter

The company provided guidance on spending for 2017 of approximately $2.5m to $3.0m per quarter, which is indicative of the company's continued cost control. Q117 spending was higher ($3.2m) due to $875,000 invested in a new Belgian R&D facility. We expect this facility to enable the continued development of the frontline CRC, lung cancer, and pancreatic cancer programs.

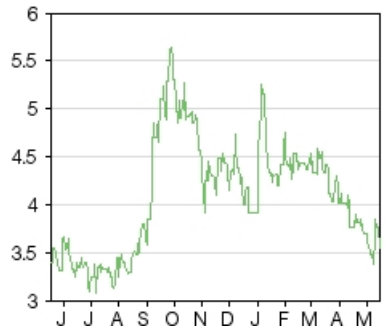
Valuation: Unchanged at $272m

Our valuation of VolitionRx remains unchanged at $272m, although it has decreased slightly on a per-share basis to $10.32 per basic share from $10.40 per basic share. We have increased the probability of success for the Nu.Q™ colorectal triage test to 50% (from 30%) following the data from the validation study. However, this was offset by a reduction in the value for the CRC frontline test due to delaying the launch of the product to 2018. VolitionRx ended Q117 with $17.7m in net cash, and we expect it to require $45m in additional cash to reach profitability in 2021.

16 May 2017

Price	**US$3.55**
Market cap	**US$94m**
Net cash ($m) at end Q117	17.7
Shares in issue	26.4m
Free float	73%
Code	VNRX
Primary exchange	NYSE MKT
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(10.6)	(20.2)	3.8
Rel (local)	(13.3)	(22.0)	(11.6)
52-week high/low		US$5.6	US$3.1

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 recently received a CE mark, allowing for commercialization in Europe.

Next events

Danish CRC screening steering committee meeting	September 2017

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Edison profile page

Triage test validation data reported

As part of the clinical development of the Nu.Q™ Colorectal Cancer Screening Triage Test, VolitionRx has completed an 8,000-person prospective clinical trial of patients with a positive FIT result. These patients presented at Hvidovre Hospital in Copenhagen after being identified by the country's CRC screening program and were followed up with colonoscopy. The trial was broken into three sections: a 2,000-person training set in which the parameters of the test were set, and 2,000- and 4,000-person validation sets. The company set a target of a 25% negative test rate (meaning a potential 25% reduction in colonoscopies), and the validation data can be considered a success if it can replicate these data. The company presented data from the final 4,000-person validation cohort and provided an overview of the full 8,000-person data set at the Digestive Disease Week conference in May 2017. It found that 22% of patients were negative for the Nu.Q™ test in the new validation set, and 24.5% overall for the full 8,000-person trial. This is exceptionally close to the 25% target and based on this we can consider that the tests perform as expected in a real-world CRC-screening setting.

Exhibit 1: Nu.Q™ Colorectal Cancer Screening Triage Test 4,000-person validation set

Result by colonoscopy	n	Nu.Q™		
		Pos	Neg	% Neg
No disease	1,838	1,292	546	30%
Adenoma	2,039	1,683	356	17%
Low risk	838	652	186	22%
Medium risk	698	579	119	17%
High risk	503	452	51	10%
CRC	199	191	8	4%
1	99	94	5	5%
2	41	40	1	2%
3	43	41	2	5%
4	13	13	0	0%
unknown	3	3	0	0%
Total	4,076	3,166	910	22%

Source: VolitionRx

A key comparator for this study was with a "high threshold" FIT. All patients on the study were FIT positive at the standard lower threshold, and a potentially reasonable way of reducing colonoscopies is raising this threshold. The high threshold FIT reduced the number of positive patients by 36%, but at the cost of missing 9% of patients with cancer. By comparison, the Nu.Q™ triage test missed approximately half as many (4% in the 4,000-person set, 5% in the full trial) of the real cancer patients compared to high threshold FIT. Similarly, the Nu.Q™ test was much better at identifying patients with high-risk adenoma (90% sensitivity in the 4,000 person set, 88% in the full trial) compared to high threshold FIT (75%).

These results set up the triage test as an attractive prospect for national cancer screening programs. The company performed the trial in part to validate the test's utility to the Danish government, which will be the first region targeted. The company previously met with the steering group in charge of the Danish CRC screening program in September 2016, and the earliest we expect feedback on the potential adoption of Nu.Q™ in the country will be at the group's next meeting in September 2017.

US clinical trial in the works

The company announced on the Q117 earnings call that it is in the design stages for a 10,000-person trial in the US for the frontline CRC screening test. The company has formed a US

subsidiary (Volition America, Inc.) to perform the trial. This is approximately the same size as a clinical trial used by Exact Sciences to support approval of Cologuard. The company has not provided any more detail on the trial's design, or provided a timeline for its initiation, although we expect details to be forthcoming. Both the Cologuard pivotal trial and the pivotal trial for Epi proColon from Epigenomics had the same two primary endpoints: 65% or higher sensitivity for CRC and an 85% or higher specificity for advanced neoplasias (meaning that 85% of patients without CRC or high-grade adenomas were correctly identified). We believe a similar target may be required for the VolitionRx study. Previous Nu.Q™ panels have produced CRC sensitivity ratings in the range of 81-91%, although these studies were largely retrospective in nature. Additionally we do not have good data on specificity of the test for advanced neoplasias, although the sensitivity for adenomas of approximately 75% has historically been one of the highest among non-invasive tests. The company will have some leeway in determining the correct test parameters to optimize for these two clinical endpoints, as well as additional data gained over years of testing different Nu.Q™ panels that can be optimized. We look forward to hearing more about the clinical trial design in the coming months.

Valuation

Our valuation of VolitionRx remains unchanged at $272m, although it has decreased slightly on a per share basis to $10.32 per basic share from $10.40 per basic share due to an increase in total shares (26.4m from 26.1m). Some of the underlying assumptions for our valuation have changed, although these have coincidentally balanced to no net effect. We have delayed the first sales of the front-line CRC screening test to 2018 (from late 2017), which has decreased its rNPV to $170m from $180m. Additionally we have adjusted for lower net cash ($17.7m from $21.2m) at Q117. These effects were offset by an increase in the probability of success for the triage test (to 50% from 30%) based on the validation trial. We expect to update our valuation in the future with new clinical results as well as any regulatory decisions regarding the triage test rollout.

Exhibit 2: VolitionRx valuation table

Product	Main indication	Status	Prob. of commercial success	Launch year	Peak sales ($m)	Patent protection	Economics	rNPV ($m)
Nu.Q™	Colorectal	Development	30%	2018	$404	2034	56% peak margin	$170
	Colorectal triage	Pre-commercialization	50%	2017	$42	2034	50% peak margin	$29
	Lung	Development	30%	2018	$145	2034	61% peak margin	$44
	Pancreatic	Development	30%	2018	$37	2034	58% peak margin	$11
Total								**$254**
Cash and cash equivalents (Q117) ($m)								$17.7
Total firm value ($m)								**$272**
Total basic shares (m)								26.4
Value per basic share ($)								**$10.32**
Warrants and options (3/2017, m)								2.1
Weighted average exercise price ($)								$2.40
Cash on exercise ($m)								$5.1
Total firm value ($m)								$277
Non-warrant options (3/2017, m)								3.1
Total number of shares (m)								31.6
Diluted value per share ($)								$8.76

Source: VolitionRx reports, Edison Investment Research

Financials

The company ended Q117 with $17.7m in net cash, and had cash outflows of $3.2m for the quarter, which included $875,000 spent on building the new research facility in Belgium. The company guided to a burn rate of $2.5m to $3.0m per quarter for the rest of the year. We have pushed back our launch timing for the front-line CRC test slightly to 2018, which enables this burn rate. We currently model a small number of sales of the Nu.Q™ Colorectal Cancer Screening Triage Test at the end of 2017 for the Danish screening program totaling $693,000. We expect that the company will need $45m in additional cash to reach profitability in 2021, which we currently include as illustrative debt ($15m in each of 2017, 2018, and 2019).

Exhibit 3: Financial summary

$000s	2012	2013	2014	2015	2016	2017e	2018e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS							
Revenue	55	0	15	0	0	693	2,483
Cost of Sales	0	0	0	0	0	(139)	(388)
Gross Profit	55	0	15	0	0	554	2,095
Research & Development	(2,843)	(2,504)	(4,044)	(6,102)	(6,838)	(7,521)	(8,273)
Sales, General & Administrative	(1,295)	(2,072)	(1,908)	(3,904)	(5,429)	(7,131)	(11,431)
EBITDA	(4,083)	(4,576)	(5,937)	(10,006)	(12,267)	(14,098)	(17,609)
Operating Profit (before GW and except.)	(4,083)	(4,576)	(5,937)	(10,006)	(12,267)	(14,098)	(17,609)
Intangible Amortization	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0
Exceptionals	0	0	0	0	0	0	0
Operating Profit	(4,083)	(4,576)	(5,937)	(10,006)	(12,267)	(14,098)	(17,609)
Net Interest	0	0	0	0	0	0	(1,136)
Other	(39)	840	(2,320)	471	252	32	0
Profit Before Tax (norm)	(4,083)	(4,576)	(8,358)	(9,666)	(12,267)	(14,098)	(18,745)
Profit Before Tax (FRS 3)	(4,122)	(3,736)	(8,258)	(9,535)	(12,014)	(14,067)	(18,745)
Tax	0	0	(0)	5	0	0	0
Deferred tax	0	0	(0)	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(4,083)	(4,576)	(8,358)	(9,661)	(12,267)	(14,098)	(18,745)
Profit After Tax (FRS 3)	(4,122)	(3,736)	(8,258)	(9,530)	(12,014)	(14,067)	(18,745)
Average Number of Shares Outstanding (m)	9.4	10.8	13.5	17.7	23.0	26.7	27.7
EPS - normalised (c)	(43.62)	(42.24)	(62.08)	(54.49)	(53.22)	(52.90)	(67.63)
EPS - FRS 3 ($)	(0.44)	(0.34)	(0.61)	(0.54)	(0.52)	(0.53)	(0.68)
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	3,129	2,544
Intangible Assets	1,430	1,002	809	705	602	589	589
Tangible Assets	91	63	289	784	2,119	2,540	1,955
Other	0	0	(0)	(0)	(0)	(0)	(0)
Current Assets	416	941	2,192	6,070	21,846	25,213	25,098
Stocks	0	0	0	0	0	7	19
Debtors	0	0	0	0	0	123	442
Cash	376	889	2,139	5,916	21,679	24,914	24,467
Other	39	53	53	154	167	169	169
Current Liabilities	(695)	(957)	(2,713)	(1,120)	(2,033)	(2,417)	(3,126)
Creditors	(695)	(957)	(2,713)	(1,120)	(2,003)	(2,350)	(3,059)
Short term borrowings	0	0	0	0	(31)	(67)	(67)
Long Term Liabilities	(635)	(433)	(352)	(548)	(1,524)	(16,770)	(31,770)
Long term borrowings	0	0	0	0	(432)	(15,692)	(30,692)
Other long term liabilities	(635)	(433)	(352)	(548)	(1,092)	(1,079)	(1,079)
Net Assets	607	617	224	5,891	21,009	9,154	(7,254)
CASH FLOW							
Operating Cash Flow	(2,315)	(3,084)	(4,141)	(8,766)	(9,056)	(11,229)	(15,421)
Net Interest	0	0	0	0	0	0	0
Tax	0	0	0	0	0	0	0
Capex	(91)	(1)	(303)	(352)	(415)	(875)	(25)
Acquisitions/disposals	0	0	0	0	0	0	0
Financing	2,576	2,828	5,627	12,498	25,302	43	0
Dividends	0	0	0	0	0	0	0
Other	0	0	0	0	(553)	(30)	0
Net Cash Flow	171	(257)	1,183	3,379	15,279	(12,091)	(15,446)
Opening net debt/(cash)	(348)	(376)	(889)	(2,139)	(5,916)	(21,216)	(9,156)
HP finance leases initiated	0	0	0	0	0	0	0
Exchange rate movements	(40)	4	(44)	13	146	(38)	0
Other	(103)	765	111	385	(125)	68	0
Closing net debt/(cash)	(376)	(889)	(2,139)	(5,916)	(21,216)	(9,156)	6,291

Source: VolitionRx reports, Edison Investment Research

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