EDISON

VolitionRx

Q319 company results

Data with product-grade assays expected soon

Healthcare equipment & services

22 November 2019

Price	**US$5.17**
Market cap	**US$212m**
Net cash ($m) at end Q319	17.4
Shares in issue	41.1
Free float	70%
Code	VNRX
Primary exchange	NYSE
Secondary exchange	N/A

According to the latest Q319 update, VolitionRx has made progress with proof-of-concept studies with its upgraded Nu.Q assays and expects to start publishing the data in the coming weeks. After that, it plans to continue working on its lead indications, including colorectal and lung cancers. VolitionRx also reported progress with its newer programmes. Its agreement with the Texas A&M University has been executed to develop cancer tests for animal health. The innovative Nu.Q Capture programme made a breakthrough this summer and could eventually speed up biomarker discovery or potentially bring in licensing revenues from liquid biopsy players. Our valuation is $223m or $5.42/share.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/17	0.0	(15.1)	(0.57)	0.0	N/A	N/A
12/18	0.0	(18.0)	(0.49)	0.0	N/A	N/A
12/19e	0.0	(18.4)	(0.46)	0.0	N/A	N/A
12/20e	0.1	(19.7)	(0.47)	0.0	N/A	N/A

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

Feasibility studies with product-grade assays

Progress on the assay upgrade was one of the main operational goals in 2018, while this year VolitionRx has conducted multiple proof-of-concept studies with the new product-grade Nu.Q assays. During the Q319 presentation, the company mentioned that so far it has tested two new assays in eight separate discovery cohorts across five cancers. VolitionRx has not released all the new proof-of-concept data yet but expects to start this in December 2019 and continue throughout 2020. The proof-of-concept data released earlier this year (in lung and colorectal cancer) were described in our last outlook report.

Large-scale cancer trial to follow

Following the assay upgrade and proof-of-concept studies VolitionRx will focus on its larger programmes. Since its establishment, the company has accumulated a large blood sample bank (Exhibit 2), which means that once the assays are ready, the studies can be performed relatively quickly. Historically, its primary focus has been on colorectal cancer, but lung cancer has gained traction this last year. The new product-grade assays performed well in feasibility studies and the company's partners in Asia also seem to be interested in this indication. Large lung cancer trials are now underway in both China and Taiwan.

Valuation: $223m or $5.42/share

Our valuation of VolitionRx is marginally lower at $223m or $5.42/share (vs $5.50/share previously) after rolling our model forward, which was offset by a lower net cash position (we included the exercised warrants in our previous report). Newsflow expected over the next 12 months includes proof-of-concept data, initial results from the Asian clinical trials, progress in colorectal cancer test development and updates on the animal health venture.

Share price performance

%	1m	3m	12m
Abs	(13.1)	23.1	140.5
Rel (local)	(15.8)	16.0	105.3
52-week high/low	US$6.42		US$1.70

Business description

VolitionRx is a life sciences company developing novel, simple-to-use, blood-based tests to diagnose a range of cancers and conditions by identifying and measuring nucleosomes in the blood stream. The primary focus is to develop the Nu.Q family of blood-based diagnostics tests for cancer.

Next events

Proof-of-concept data with product-grade assays	Q419/2020
Updates on the studies run with the National Taiwan University	2020
Update on the collaboration with the Texas A&M University in animal health	Q419/2020
Updates on the studies run with Fosun Long March	2020

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Fosun collaboration: Accessing the Chinese market

The collaboration with Fosun Long March, owned by the Chinese conglomerate Shanghai Fosun Pharmaceutical, is gaining pace. The Memorandum of Understanding (MoU) announced in March 2019 aims to explore VolitionRx's Nu.Q tests in the Chinese population. The first trial in lung cancer was initiated in July 2019 and, according to the Q319 update, the two companies have started working on the second trial in colorectal cancer. Neither financial details nor more concrete plans about Nu.Q positioning have been disclosed, presumably because the details are subject to Fosun's control. Fosun Long March is a large in vitro diagnostics company active in R&D, manufacturing and marketing of diagnostic and laboratory instruments and reagents. It therefore appears to be a suitable, well-funded partner, which could help access the Chinese market.

Taiwan University collaboration: The first large lung cancer trial

Progress with the R&D collaboration with the National Taiwan University was one of the highlights in Q319. The parties are running a large-scale, prospective study in lung cancer (blood samples from 1,200 subjects), the aim of which is to develop either a frontline screening test in lung cancer or a triage test before or after low-dose computed tomography (LDCT) (the current gold standard) to address low specificity associated with LDCT. The total cost for VolitionRx is estimated at $320k over the next two years (until 2021). The first data readout is expected in H120, which should include preliminary results from the first 600 patients enrolled in this study.

VolitionRx released the first proof-of-concept data from two smaller lung cancer studies with the product-grade assay in March 2019. In one lung cancer cohort (n=76), a single Nu.Q assay achieved an area under the curve (AUC) of 85% in differentiating cancer versus healthy subjects. The assay was also able to detect stage 1 cancer. In a second confirmatory lung cancer cohort (n=152), the same single Nu.Q assay also detected lung cancer with an AUC of 79%, in differentiating cancer versus healthy subjects. Although these studies were small, the assays started differentiating cancer as early as stage 1 and early detection is the ultimate goal in diagnostics. The ongoing trial in Taiwan is the first large-scale lung cancer trial following the proof-of-concept data.

Nu.Q Capture

In September 2019, VolitionRx announced a breakthrough in its work to enrich tumour nucleosomes using Nu.Q technology. This programme, called Nu.Q Capture, started in early 2018 as an internal R&D project, which explored Nu.Q technology's potential in enriching nucleosomes of tumour origin for use in ctDNA detection. The idea for Nu.Q Capture came from the collaboration with VolitionRx's scientific advisory board member Professor Axel Imhof seeking to identify how mass spectrometry could be helpful in advancing the Nu.Q ELISA platform. Mass spectrometry is a technique where a test object sample is bombarded with a beam of electrons so the atoms and molecules in it are ionized or become charged. Subsequently, detectors record a spectrum of these ionised particles. This information can then be used to identify the composition of the test sample.

The first challenge was that mass spectrometry would require larger blood sample volumes per run. The solution was to move away from traditional ELISA solid-surface plates and instead use magnetic beads to precipitate nucleosomes from plasma. According to the most recent update, VolitionRx was able to deplete nucleosomes by up to 100% and reach the required levels for mass

spectrometry. The next step is to determine the level of tumour-associated nucleosomes using mass spectrometry (and/or sequencing).

Specifically, for VolitionRx, this technique could significantly speed up the discovery process of new epigenetic modifications in nucleosomes. The ELISA method allows the targeting of one specific modification at a time. Although this is sufficient for a clinical test, in the discovery of biomarkers (nucleosome epigenetic modifications, in this case) mass spectrometry allows the analysis of multiple nucleosome modifications (known and undiscovered) at the same time.

Another opportunity that Nu.Q Capture could provide is in circulating tumour DNA (ctDNA) enrichment, which could be useful for players in liquid biopsy and DNA sequencing. The arrival of cheap next-generation sequencing technologies prompted a surge in R&D on so-called liquid biopsy tests. The main hurdle in ctDNA research is the very small amount of tumour DNA. Another layer of complexity is that there can be other types of DNA in the bloodstream, as seen in post-myocardial infarction patients or pregnant women, whose blood contains DNA from the baby (collectively, ctDNA and other types of circulating DNA are called cell-free DNA). For these reasons, the ctDNA-enriching technology could be interesting to other companies in the field.

Nu.Q Vet update

In October 2019, VolitionRx announced that it had signed a collaboration agreement with the Texas A&M College of Veterinary Medicine & Biomedical Sciences to develop a Nu.Q-based test for the veterinary market. This followed a previously announced MoU with the Texas A&M University. Furthermore, Texas A&M took a 12.5% stake in VolitionRx's subsidiary in the US, which was formed in August 2019 to lead veterinary product development. The university will provide expertise and R&D services. VolitionRx (via its subsidiary) will provide access to its intellectual property as well as an aggregate of $400k towards the collaboration.

VolitionRx introduced its plans to diversify beyond human health during its capital markets day in April 2019. Since then, it has worked with Texas A&M to conduct feasibility studies with Nu.Q tests in animals. Although a relatively new area, the feasibility studies showed that using the same assays as for humans, the researchers were able to detect nucleosomes in samples from dogs diagnosed with cancer. Animal health has the potential to be a commercially lucrative area due to the combination of a large market, high unmet need and a substantially lower regulatory hurdle compared with humans. VolitionRx indicated that the first product for dog cancer diagnostics could be ready for market as early as 2020.

Financials and valuation

VolitionRx booked its first sales of $17.1k from research use-only kits and the provision of contract research services. While there is potential for research use-only sales to grow, we see this as a way of increasing awareness of VolitionRx's technology among researchers and the wider community as an increasing amount of research using Nu.Q kits is published.

VolitionRx reported an operating loss of $4.2m in Q319, compared to $4.4m a year ago, largely in line with our expectations. The company had cash of $19.7m at end-Q319 after an existing investor exercised a further $4.8m in warrants in July (in total, $16.5m exercised in 2019). VolitionRx was also awarded $1.4m in non-dilutive grant funding from the Walloon Region in Q319. An additional $500k unsecured loan from the Texas A&M SOFINEX funding agency of the Walloon Region was provided to support VolitionRx's veterinary subsidiary Volition Veterinary Diagnostics Development. VolitionRx had $2.3m in gross debt at the end of Q319. Assuming a similar level of cash burn (approximately $3.6m per quarter), our model suggests a cash runway to 2021.

Our absolute valuation of VolitionRx is marginally lower at $223m or $5.42/share vs $226m or $5.50/share previously after updating the net cash position and rolling our model forward. Our other R&D assumptions, detailed in our previous notes, remain unchanged.

Exhibit 1: Valuation of VolitionRx

Product	Main indication	Status	Prob. of commercial success	Launch year	Peak sales ($m)	Patent protection	Economics	rNPV ($m)
Nu.Q	Colorectal	Development	30%	2021	$404	2034	56% peak margin	$159
	Colorectal triage	Development	40%	2021	$42	2034	50% peak margin	$10
	Lung	Development	20%	2022	$132	2034	61% peak margin	$30
	Pancreatic	Development	20%	2022	$42	2034	58% peak margin	$7
Total								$205
Net cash and cash equivalents (last reported, $m)								$17.4
Total firm value ($m)								$223
Total number of basic shares (m)								41.1
Value per basic share ($)								$5.42
Warrants and options (m)								6.0
Weighted average exercise price ($)								$3.70
Cash on exercise ($m)								$22.3
Total firm value (fully diluted) ($m)								$245
Total number of shares (fully diluted)								47.1
Value per share (fully diluted) ($)								$5.20

Source: Edison Investment Research, VolitionRx reports

Exhibit 2: VolitionRx blood sample bank

Indication	Sponsor	Patients	Notes
Colorectal cancer	NCI Early Detection Research Network	9,000 prospective 4,600 retrospective	Frontline screening. Main programme in the US; collection ongoing to 2020.
Colorectal cancer	National Taiwan University	5,000 prospective	Frontline screening; collection ongoing to 2021.
Colorectal cancer	National Taiwan University	2,000 prospective	Diagnostic test in symptomatic patients; collection ongoing to 2021.
Colorectal cancer	Hvidovre Hospital (Denmark)	14,000+ prospective	Screening population. Collection complete and analysis ongoing.
Colorectal cancer	Hvidovre Hospital (Denmark)	30,000 prospective	Screening population. Collection complete and analysis ongoing.
Colorectal cancer	Hvidovre Hospital (Denmark)	4,800 retrospective	Diagnostic test in symptomatic patients. Collection complete and analysis ongoing.
Lung cancer	National Taiwan University	1,200 prospective	Collection expected to start in mid-2019 to 2021.
Pancreatic cancer	German Cancer Research Center (DKFZ)	750 retrospective	Collection complete and analysis ongoing.
27 most prevalent cancers	Bonn University Hospital (Germany)	4,500 prospective	Broad, prospective screen of 27 most prevalent cancers to identify differences in nucleosome modification. Collection complete and analysis ongoing.

Source: VolitionRx

Exhibit 3: Financial summary

$'000s	2017	2018	2019e	2020e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS				
Revenue	0	0	26	100
Cost of Sales	0	0	0	0
Gross Profit	0	0	26	100
Research & Development	(8,906)	(10,907)	(10,561)	(11,195)
Sales, General & Administrative	(6,140)	(6,991)	(7,690)	(8,459)
EBITDA	(15,046)	(17,898)	(18,226)	(19,554)
Operating profit (before amort. and except.)	(15,046)	(17,898)	(18,226)	(19,554)
Intangible Amortisation	0	0	0	0
Other	0	0	0	0
Exceptionals	0	0	0	0
Operating Profit	(15,046)	(17,898)	(18,226)	(19,554)
Net Interest	(73)	(111)	(125)	(118)
Other	414	0	0	0
Profit Before Tax (norm)	(15,119)	(18,009)	(18,351)	(19,671)
Profit Before Tax (FRS 3)	(14,705)	(18,009)	(18,351)	(19,671)
Tax	0	0	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(15,119)	(18,009)	(18,351)	(19,671)
Profit After Tax (FRS 3)	(14,705)	(18,009)	(18,351)	(19,671)
Average Number of Shares Outstanding (m)	26.4	37.0	40.3	41.9
EPS - normalised ($)	(0.57)	(0.49)	(0.46)	(0.47)
EPS - FRS 3 ($)	(0.56)	(0.49)	(0.46)	(0.47)
Dividend per share ($)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	4,057	3,587	2,838	2,269
Intangible Assets	576	467	467	467
Tangible Assets	3,481	3,120	2,371	1,802
Other	(0)	0	(0)	(0)
Current Assets	10,319	13,657	15,035	328
Stocks	0	0	0	0
Debtors	0	0	(95)	18
Cash	10,116	13,427	14,901	81
Other	202	230	230	230
Current Liabilities	(2,290)	(2,333)	(2,283)	(2,308)
Creditors	(1,847)	(1,917)	(1,867)	(1,892)
Short term borrowings	(444)	(417)	(417)	(417)
Long Term Liabilities	(2,376)	(3,015)	(3,015)	(4,815)
Long term borrowings	(1,313)	(1,984)	(1,984)	(3,784)
Other long-term liabilities	(1,063)	(1,031)	(1,031)	(1,031)
Net Assets	9,709	11,895	12,575	(4,527)
CASH FLOW				
Operating Cash Flow	(12,193)	(14,733)	(14,986)	(16,621)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(1,425)	(302)	0	0
Acquisitions/disposals	0	0	0	0
Financing	998	17,245	16,461	0
Dividends	0	0	0	0
Other	(136)	(138)	0	0
Net Cash Flow	(12,756)	2,073	1,474	(16,621)
Opening net debt/(cash)	(21,216)	(8,360)	(11,026)	(12,500)
HP finance leases initiated	0	0	0	0
Exchange rate movements	(89)	(379)	0	0
Other	(12)	973	0	0
Closing net debt/(cash)	(8,360)	(11,026)	(12,500)	4,120

Source: Company data, Edison Investment Research

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