

VolitionRx

New platform format; more proof-of-concept data

The last several months were eventful for VolitionRx. The publication of the first ever proof-of-concept data in haematological cancers was the R&D highlight in Q419. On the corporate front, the company has acquired Octamer, now an in-house manufacturer of a key assay component, and is rapidly developing its veterinary subsidiary in the US. From a platform perspective, VolitionRx is moving away from traditional ELISA plates to a new format immunoassay based on magnetic particles. This is expected to improve the analytical performance of VolitionRx's Nu.Q assays in the clinical studies. Our valuation stays at \$223m or \$5.42/share.

Year end	Revenue (\$m)	PBT* (\$m)	EPS* (\$)	DPS (\$)	P/E (x)	Yield (%)
12/18	0.0	(18.0)	(0.57)	0.0	N/A	N/A
12/19	0.0	(16.1)	(0.41)	0.0	N/A	N/A
12/20e	0.0	(17.4)	(0.43)	0.0	N/A	N/A
12/21e	0.1	(18.8)	(0.44)	0.0	N/A	N/A

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

Moving to magnetic particle-based assays

Historically, VolitionRx developed its Nu.Q assays using the classic ELISA plate-based technique. Although it had the advantage of being a very cost-effective method, VolitionRx recognised the need for a high-throughput solution. Therefore, the company has decided to move away from ELISA solid-surface plates and instead use magnetic particles to precipitate nucleosomes from blood plasma (magnetic immunoassay). When compared to ELISA, the new format provides a 10–20x improvement in sensitivity, a significant increase in the reproducibility of results and a test turnaround time improvement to around one hour 20 minutes from six hours before. VolitionRx plans to use the new format in its all clinical trials.

Financials: Well-controlled costs

VolitionRx reported an operating loss of \$16.1m in FY19, compared to \$17.9m a year ago, largely in line with our expectations. Its cash position at the end of 2019 was \$17.0m (\$2.8m in debt). VolitionRx has received in total \$16.5m in cash from warrant exercises by existing shareholders (\$3.3m were received in non-dilutive funding). Cash burn remained stable at around \$1.2m per month in 2019. Assuming a similar level of cash burn (approximately \$3.6m per quarter), our model suggests a runway to 2021.

Valuation: \$223m or \$5.42/share

Our valuation of VolitionRx is virtually unchanged at \$223m or \$5.42/share as rolling our model forward was offset by a lower net cash position. Our other R&D assumptions, detailed in our previous notes, remain unchanged, but we note that VolitionRx has multiple ongoing projects, which could result in new product ranges beyond those included in our model at this point, such as new cancer indications (blood cancer), Nu.Q Vet for animal health and Nu.Q Capture for liquid biopsy.

Q419 company results

Healthcare equipment & services

28 February 2020

Price **US\$3.33**

Market cap **US\$137m**

Net cash (\$m) at end Q419 14.1

Shares in issue 41.2m

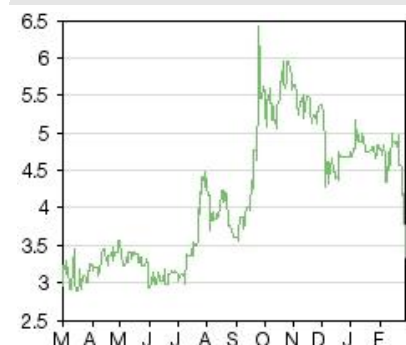
Free float 55%

Code VNRX

Primary exchange NYSE

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (28.4) (37.6) 15.2

Rel (local) (22.0) (34.0) 8.0

52-week high/low US\$6.42 US\$2.90

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 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 2020

Updates on the studies run with Fosun Long March 2020

Analyst

Jonas Peculis +44 (0)20 3077 5728

healthcare@edisongroup.com

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First ever proof-of-concept data in haematological malignancies

In December 2019, VolitionRx released results from a proof-of-concept study testing its Nu.Q assays in lymphoma and leukaemia. A single Nu.Q assay correctly detected 80% of newly diagnosed cases (at 95% of specificity) of non-Hodgkin's lymphoma (NHL), acute lymphocytic leukaemia (ALL) and acute myeloid leukaemia (AML). The area under the curve (AUC) was 91%. These results were achieved with only one assay. There is also potential for a multi assay panel in blood cancers as well, as VolitionRx reported that a number of its other Nu.Q assays reported individual performance results within the range of 79–91%.

This was the first time VolitionRx released Nu.Q performance results in haematological malignancies. Furthermore, the results demonstrated in these indications was the best single Nu.Q assay performance in any cancer tested by VolitionRx. Therefore, we believe that the company will explore this direction further even though the primary indications of interest remain colorectal, lung and prostate cancer. VolitionRx mentioned that the next step in haematological malignancies is to conduct a larger clinical trial using patient blood samples.

It is too early to consider how Nu.Q could fit in the current diagnostic protocols in these cancers, but definitive tools to diagnose blood malignancies are tissue sample analysis obtained by lymph node biopsy or bone marrow aspiration, so highly invasive. An accurate, non-invasive, blood-based test would have an advantage in this setting, but more Nu.Q performance data are needed.

In our last [outlook report](#) we described the proof-of-concept data with product grade assays in lung and colorectal cancers released last year.

Octamer acquisition ensures supply of key component

From a corporate development perspective, the acquisition of Octamer was the highlight of Q419. In December 2019, VolitionRx announced that its Belgian subsidiary had reached an agreement to acquire epigenetics company Octamer for approximately €650k (\$725k) in cash and restricted common stock of VolitionRx (€350k cash plus 73,000 shares). In addition, the parties entered into a five-year royalty agreement, based on which previous owners of Octamer would receive single-digit royalties from sales of recombinant nucleosomes to pharma companies. This was a strategic acquisition, which ensured that VolitionRx now has a full control of the supply of the key component for its product grade assays, the recombinant nucleosome used as the calibrant. In our last outlook report we described in detail how transformative the development of the recombinant nucleosome was for VolitionRx's Nu.Q technology.

In addition to recombinant nucleosomes, Octamer also manufactures and sells histones, octamers and DNA templates, which are used in epigenetic research and drug discovery. VolitionRx indicated that it will explore the opportunity to commercialise Octamer's remaining product portfolio as well, although no specific details have been given yet.

Financials and valuation

VolitionRx reported an operating loss of \$16.1m in FY19, compared to \$17.9m a year ago, largely in line with our expectations. The company had cash of \$17.0m at end-Q419 (\$2.8m in debt) vs \$13.4m a year ago. Throughout 2019 VolitionRx received in total \$16.5m in cash from warrant exercises by existing shareholders, demonstrating strong support. An additional \$3.3m was

received in non-dilutive funding. Cash burn remained stable at around \$1.2m per month in 2019. Assuming a similar level of cash burn (approximately \$3.6m per quarter), our model suggests a runway to 2021. We include \$10m in the form of long-term debt (as per our principles) to fund the operations until the end of 2021.

Our valuation of VolitionRx is unchanged at \$223m or \$5.42/share, as rolling our model forward was offset by a lower net cash position (vs our last [update](#) issued in November 2019). Our other R&D assumptions, detailed in our [previous notes](#), remain unchanged. VolitionRx, however, has multiple ongoing projects, which could result in product ranges beyond those included in our model at this point, such as new cancer indications (blood cancer), Nu.Q Vet and Nu.Q Capture. These projects are still relatively early, and we therefore do not include them in our valuation.

Newsflow that VolitionRx expects to report in 2020 includes:

- more clinical data with the upgraded magnetic particle-based assays in a range of cancers;
- updates on the large-scale trials in Asia, Europe and the US (more details in [our last report](#));
- progress within its Nu.Q Vet program; the company expects to complete pre-analytical and clinical studies and launch the first product potentially even this year;
- 2019 was a breakthrough year for VolitionRx's so called [Nu.Q Capture](#) project, which is exploring the use of Nu.Q technology to enrich cancer nucleosomes for liquid biopsy; in coming months VolitionRx expects to report more updates; and
- publications of abstracts and peer-reviewed articles with clinical results.

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	\$161
	Colorectal triage	Development	40%	2021	\$42	2034	50% peak margin	\$11
	Lung	Development	20%	2022	\$132	2034	61% peak margin	\$30
	Pancreatic	Development	20%	2022	\$42	2034	58% peak margin	\$7
Total								\$209
Net cash and cash equivalents (last reported, \$m)								\$14.1
Total firm value (\$m)								\$223
Total number of basic shares (m)								41.2
Value per basic share (\$)								\$5.42
Warrants and options (m)								4.4
Weighted average exercise price (\$)								\$3.84
Cash on exercise (\$m)								\$16.7
Total firm value (fully diluted) (\$m)								\$239
Total number of shares (fully diluted) (m)								45.4
Value per share (fully diluted) (\$)								\$5.27
Source: Edison Investment Research, VolitionRx reports								

Exhibit 2: Financial summary

	\$000s	2017	2018	2019	2020e	2021e
Year end 31 December		US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS						
Revenue		0	0	17	30	100
Cost of Sales		0	0	0	0	(183)
Gross Profit		0	0	17	30	(83)
Research & Development		(8,906)	(10,907)	(10,363)	(10,985)	(11,644)
Sales, General & Administrative		(6,140)	(6,991)	(5,697)	(6,266)	(6,893)
EBITDA		(15,046)	(17,898)	(16,085)	(17,221)	(18,620)
Operating profit (before amort. and except.)		(15,046)	(17,898)	(16,085)	(17,221)	(18,620)
Intangible Amortisation		0	0	0	0	0
Other		0	0	(42)	0	0
Exceptionals		0	0	0	0	0
Operating Profit		(15,046)	(17,898)	(16,085)	(17,221)	(18,620)
Net Interest		(73)	(111)	(14)	(143)	(221)
Other		414	0	0	0	0
Profit Before Tax (norm)		(15,119)	(18,009)	(16,099)	(17,364)	(18,842)
Profit Before Tax (FRS 3)		(14,705)	(18,009)	(16,099)	(17,364)	(18,842)
Tax		0	0	0	0	0
Deferred tax		(0)	(0)	(0)	(0)	(0)
Profit After Tax (norm)		(15,119)	(18,009)	(16,099)	(17,364)	(18,842)
Profit After Tax (FRS 3)		(14,705)	(18,009)	(16,099)	(17,364)	(18,842)
Average Number of Shares Outstanding (m)		26.4	31.4	39.2	40.7	42.4
EPS - normalised (\$)		(0.57)	(0.57)	(0.41)	(0.43)	(0.44)
EPS - FRS 3 (\$)		(0.56)	(0.57)	(0.41)	(0.43)	(0.44)
Dividend per share (\$)		0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets		4,057	3,587	3,735	3,020	2,477
Intangible Assets		576	467	372	372	372
Tangible Assets		3,481	3,120	2,981	2,266	1,723
Other		(0)	0	381	381	381
Current Assets		10,319	13,657	17,289	1,566	644
Stocks		0	0	0	0	9
Debtors		0	0	0	5	18
Cash		10,116	13,427	16,966	1,238	295
Other		202	230	323	323	323
Current Liabilities		(2,290)	(2,333)	(3,860)	(3,327)	(3,593)
Creditors		(1,847)	(1,917)	(3,212)	(2,679)	(2,946)
Short term borrowings		(444)	(417)	(648)	(648)	(648)
Long Term Liabilities		(2,376)	(3,015)	(3,233)	(3,233)	(13,233)
Long term borrowings		(1,313)	(1,984)	(2,195)	(2,195)	(12,195)
Other long term liabilities		(1,063)	(1,031)	(1,038)	(1,038)	(1,038)
Net Assets		9,709	11,895	13,931	(1,975)	(13,705)
CASH FLOW						
Operating Cash Flow		(12,193)	(14,733)	(12,739)	(15,728)	(10,942)
Net Interest		0	0	0	0	0
Tax		0	0	0	0	0
Capex		(1,425)	(302)	(511)	0	(1)
Acquisitions/disposals		0	0	0	0	0
Financing		998	17,245	16,591	0	0
Dividends		0	0	0	0	0
Other		(136)	(138)	(142)	0	0
Net Cash Flow		(12,756)	2,073	3,198	(15,728)	(10,943)
Opening net debt/(cash)		(21,216)	(8,360)	(11,026)	(14,123)	1,605
HP finance leases initiated		0	0	0	0	0
Exchange rate movements		(89)	(379)	140	0	0
Other		(12)	973	(241)	0	0
Closing net debt/(cash)		(8,360)	(11,026)	(14,123)	1,605	12,548

Source: Company data, Edison Investment Research

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Frankfurt +49 (0)69 78 806 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1,185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia