

4th May 2021

Stock Data

Ticker: VAL.L
Share Price: 20.0p
Market Cap: £13.3m

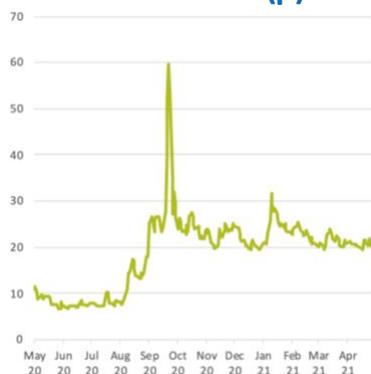
Source: Bloomberg (prior day's close)

* SP Angel provides Research Services to ValiRx and therefore this information should be viewed as a Marketing Communication.

Company Description

Clinical-stage life sciences company focused on the development of treatments in oncology and women's health

Share Price Chart (p)



Source: Bloomberg

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Flash Note

ValiRx plc (VAL.L)*

2020 results: Improved financial stability

Key points

- **2020 results demonstrate reduced losses:** ValiRx (VAL.L), a clinical stage drug developer and incubator, provided results for the year ended 31 December 2020 (FY20). FY20 operating losses narrowed to £1.65m (FY19: loss £2.70m) driven by a reduction in R&D costs and administrative expenses.
- **Improved cash position:** Cash at 31 March 2021 was £1.50m (Cash at FY20 period end: £1.85m) demonstrating a quarterly cash requirement of c.£0.35m and providing an expected runway for the next 12 months.
- **Reduced liabilities:** The Company has paid off its borrowings and has significantly reduced the balance of its trade and other payables.
- **New strategy coming on stream:** The evaluation agreement with Kalos Therapeutics marks the first step of the new strategy to identify and incubate promising early-stage assets.
- **Completion of VAL201 trials:** The completion of the VAL201 Phase 1/2 trial and subsequent clinical report was a significant milestone for the Group. Discussions are continuing with potential partners regarding future development of the asset.

Over the period, ValiRx has undergone a management change with Dr Suzanne Dilly, previously CEO of ValiSeek, taking up the role of CEO of ValiRx. Dr Kevin Cox also joined the Board as Non-Executive Chairman. The new management team has overseen a considerable improvement in ValiRx's financial position. The Group has reduced overheads and decreased its liabilities via the settlement of a debt facility and a substantial reduction in trade creditors.

With a new team in place, ValiRx has refocused its strategy to identify, develop and generate data for undervalued yet promising preclinical therapies. The new strategy could add additional value to the Group's current offering at a lower R&D cost compared to clinical development.

The Group is also focused on continuing discussions regarding its existing portfolio with a view to strike potential agreements. Discussions are continuing for VAL201 after the completion of the Phase 1/2 trial, whilst VAL301 is being evaluated by an unnamed Japanese pharma company. Should either of these discussions result in a deal, this would represent a significant milestone for the Group.

With cash raised from equity placings and warrant exercises as well as an improved cost base, the Group expects the current cash position to provide 12 months runway. This financial stability should support commercial discussions regarding existing clinical assets, such as VAL201, as well as the implementation of the Group's new strategy.

Year-end Dec	2016A	2017A	2018A	2019A	2020A
Income (£)	-	88,773	-	146,517	11,077
Pre-tax Profit (loss) (£)	(5,751,375)	(3,553,982)	(4,829,138)	(2,719,494)	(1,543,425)
EPS (p)	(8.22)	(2.00)	(0.94)	(33.08)	(3.81)
Net Cash/(Debt) (£)	(733,536)	311,290	372,872	(5,634)	1,841,387

Source: ValiRx

2020 Financial Highlights

ValiRx (VAL.L), a clinical stage drug developer and incubator, provided results for the year ended 31 December 2020 (FY20). Financial highlights included:

- FY20A Operating losses narrowed by 39% to £1.65m (FY19: loss £2.70m) with total overheads reduced by 41% (FY20A: £1.66m vs FY19A: £2.84m).
- Of the total overheads, administrative expenses, before loss on the disposal of intangible assets of £0.15m, were £1.28m (FY19A: £1.86m).
- R&D expenses fell by 77% to £0.23m (FY19: £0.98m) reflecting the completion of the VAL201 trial and the shift to preclinical stage R&D activities.
- Total comprehensive loss for FY20A was £1.44m (FY19: £2.39m) resulting in a loss per share of 3.81p.

Sufficient cash runway for 12 months

Cash at period end was £1.8m (FY19: £nil) with a combined total of £4.2m raised through equity placings and warrant exercises over 2020. As of 31 March 2021, the Group's cash balance was £1.5m demonstrating a quarterly cash requirement of c.£0.35m. ValiRx expects that the cash position, combined with known receivables, will be sufficient to support the current level of activities for at least the next 12 months. This includes the R&D costs for evaluating four projects as part of the incubator strategy.

Settlement of Yorkville facility

In August 2020, ValiRx agreed with Yorkville to make a full and final settlement payment of £80,000 with the balance of the liability (£122,000) to be written off.

Financial liabilities – borrowings (£)

	2019A	2020A
Borrowings as at 1 January	313,699	193,781
Repayment	(138,000)	(80,000)
Deferral fee	18,082	8,219
Balance agreed to be written off	-	(122,000)
Borrowings as at 31 December	193,781	-

Source: ValiRx annual report

Reduction in trade and other payables

The Group has significantly reduced the balance of its Trade and other payables (FY20: £0.11m vs FY19: £1.18m), driven by a substantial reduction in trade creditors (FY20: £0.07m vs FY19: £0.95m).

Trade and other payables (£)

	2019A	2020A
Trade creditors	945,854	72,356
Social security and other taxes	119,169	6,107
Wages and salaries	6,310	-
Other payables	23,109	2,879
Accruals and deferred income	87,642	30,000
Total trade and other payables	1,182,084	111,342

Source: ValiRx annual report

Operational highlights

Alongside improving the financial position, the new management team is continuing with commercial activities for both the Group's existing asset portfolio as well as the new incubator strategy.

New incubator strategy on stream

In July 2020, ValiRx outlined a new strategy to identify, develop and generate data for undervalued yet promising preclinical therapies. ValiRx aims to use its own expertise in drug-development to progress the assets to the next stage of development and attract further investment. The Group aims to cover working capital costs by charging a service fee whilst retaining an equity stake in the holding vehicle of the asset to participate in any long-term value gain of the asset.

First evaluation agreement struck as part of the new incubator strategy

In November 2020, ValiRx struck an evaluation agreement with Kalos Therapeutics (Private) a US biotechnology company. As part of the agreement, ValiRx retains the option to license KTH222, a preclinical drug candidate for treating patients with ovarian cancer. In return, Kalos has been pledged 10,000 ValiRx shares, subject to shareholder approval at the 2021 AGM.

KTH222 is a peptide-based therapy which aims to regulate cell growth via inhibition of the mitogen-activated protein kinase (MAPK) pathway. ValiRx is performing a series of preclinical experiments to evaluate the use of KTH222 in combination with Paclitaxel, a standard of care chemotherapy. If the initial evaluation programme is a success, ValiRx may choose to in-license KTH222 and integrate the asset into a jointly owned subsidiary for further development.

Plan to evaluate up to four new projects in 2021

The agreement with Kalos Therapeutics marks the first agreement as part of the new incubator strategy. Over the course of 2021, ValiRx aims to perform evaluation work on up to four new projects and looks to progress at least two projects to a licensing agreement. Going forwards, the Group aims to evaluate between four to six innovative compounds with an intention to progress 50% to full adoption.

Completion of VAL201 trial

At the end of September 2020, ValiRx provided headline results from its Phase 1/2 clinical trial of VAL201, the Group's treatment candidate for advanced prostate cancer (ClinicalTrials.gov ID: NCT02280317). Data from the trial demonstrated the drug's safety and tolerability as well as an early efficacy signal (54% of relevant patients demonstrated a positive response to the treatment). Although this was an early stage study, the data indicated that further clinical investigation of the drug is warranted. In November 2020, ValiRx, received the full dataset to be used for the Clinical Study Report regarding the VAL201 trial.

Potential partnering discussions continue

Identifying a commercial partner for VAL201 remains a high priority for ValiRx. The Group is sharing the dataset with potential industry partners who have expressed an interest after the headline results were released. An appropriate partner could fund a larger clinical trial, such as a Phase 2b, to build on the results from the Phase 1/2 trial.

Collaboration agreement with Physiomics

In February, ValiRx entered into an agreement with Physiomics plc (PYC.L), an oncology drug development consultancy. Physiomics is evaluating the clinical data generated regarding VAL201 as well as modelling the use of the VAL201 peptide in endometriosis (VAL301) and COVID-19 (BC201) indications. Physiomics is eligible for a fee (capped at £6m) of 6% of any future net revenues relating to the commercialisation of VAL201 and its derivatives in any indication. This agreement enables ValiRx to leverage Physiomics' expertise in oncology to guide the future development of the VAL201 peptide, such as the design of future clinical trials.

Ongoing evaluation of VAL301 by a Japanese pharma company

VAL301 is a preclinical stage treatment candidate for endometriosis, a common gynaecological condition. In May 2020, ValiRx struck a material transfer agreement (MTA) with an unnamed global Japanese pharmaceutical company. Preclinical evaluation as part of the MTA is ongoing. Should the Japanese company decide to adopt VAL301 into their pipeline, there is potential for a global or regional licence. Alongside the MTA, ValiRx is maintaining discussions with other interested parties and is carrying out additional preclinical studies to support the next clinical development plan for VAL301.

VAL401

VAL401 is an anticancer treatment candidate based on a reformulation of risperidone, an existing antipsychotic therapy. Whilst VAL401 previously completed a small trial in lung cancer patients, ValiRx is looking to progress further development in Pancreatic Ductal Adenocarcinoma, a cancer indication underserved by current treatments.

To demonstrate the utility of VAL401 in pancreatic cancer, additional clinical trials are required. ValiRx has stated that it is looking for external partners to fund further development of the asset.

In January 2020, ValiSeek signed a letter of intent with Black Cat Bio for the funding and future clinical development of VAL401. As part of the agreement, the VAL401 IP license will be transferred from ValiSeek to Black Cat Bio if Black Cat Bio raises a certain amount (undisclosed). In return, all shareholders of ValiSeek will become shareholders of Black Cat Bio. Black Cat Bio are currently fundraising, and confirmation of funding is yet to be announced.

Consortium progressing preclinical work on BC201

In June 2020, ValiRx entered a two-year collaboration agreement with Oncolytika Limited and Black Cat Bio to explore the use of VAL201 as part of a combination treatment, known as BC201, for patients suffering a hyperimmune response to SARS-CoV2 infection.

Black Cat Bio is coordinating the project, with ValiRx and Oncolytika managing certain project elements. ValiRx is not responsible for financial support but, in return for the use of VAL201 in BC201, the Group retains a 40% stake in the programme.

Progress so far

A patent covering the use of BC201 in COVID-19 has been submitted by Oncolytika and Black Cat Bio. The partners have commenced initial preclinical studies on BC201 to demonstrate proof of principle for the proposed mechanism of action. Successful completion of these studies would warrant further investigation of the treatment candidate, such as *in vivo* preclinical studies. The consortium is seeking additional development partners and funding to further progress the product.

Disposal of non-core assets

A business review completed in May 2020 identified several assets as non-core. This resulted in the disposal of assets acquired from FitBiotech Oy (acquired in 2019) and the portfolio surrounding the TRAC technology (acquired in 2015). Additionally, the licenses for the GeneICE technology have been discontinued. The business review highlights the streamlining of the Group's activities to its core focus on women's health and oncology.

Peer Group review

We have updated our peer group of London-listed drug developers with oncology assets at a clinical or preclinical stage. ValiRx's current market capitalisation is nearly fourfold less than that of the peer-group median (£52.1m). Given that ValiRx has two clinical stage assets as well as a preclinical programme, we maintain that this price discrepancy is unjustified.

Peer-group comparison of London-listed drug developers with oncology assets at a clinical or preclinical stage

Name	Ticker	Mkt Cap
Median	-	52.14
Valirx	VAL LN	13.34
Hemogenyx Pharmaceuticals	HEMO LN	12.85
Sareum Holdings	SAR LN	74.87
Okyo Pharma	OKYO LN	52.14
Tiziana Life Sciences	TILS LN	166.39
Redx Pharma	REDX LN	182.13
Scancell Holdings	SCLP LN	169.16
Evgen Pharma	EVG LN	21.72
Midatech Pharma	MTPH LN	17.43

Source: Bloomberg; SP Angel act as Broker to Hemogenyx

Financials

Income Statement

Year-end December (GBP)	2016A	2017A	2018A	2019A	2020A
Other income	-	88,773	-	146,517	11,077
Research and developments	(2,375,354)	(1,746,808)	(1,698,791)	(984,457)	(230,115)
Administrative expenses	(1,794,284)	(1,467,268)	(2,166,798)	(1,860,379)	(1,431,587)
Overheads	(4,169,638)	(3,214,076)	(3,865,589)	(2,844,836)	(1,661,702)
Operating loss	(4,169,638)	(3,125,303)	(3,865,589)	(2,698,319)	(1,650,625)
Fair value loss on derivative financial assets	(1,619,187)	(23,446)	(442,229)	-	
Finance income	17	489	-	-	(14,800)
Fair value gain on derivative liability	375,621	44,146	-	-	
Finance costs	(338,188)	(449,868)	(14,565)	(21,175)	
Provision for bad debt	-	-	(506,755)	-	
Discount on settlement of financial liability	-	-	-	-	122,000
Loss before income tax	(5,751,375)	(3,553,982)	(4,829,138)	(2,719,494)	(1,543,425)
Income tax credit	620,104	416,336	461,296	293,738	75,182
Loss after income tax	(5,131,271)	(3,137,646)	(4,367,842)	(2,425,756)	(1,468,243)
<i>Profit from the year from discontinued operations</i>	<i>182,750</i>	-	-	-	-
Non-controlling interest	200,518	117,962	69,020	37,049	25,075
Total comprehensive loss for the year	(4,748,003)	(3,019,684)	(4,298,822)	(2,388,707)	(1,443,168)
Loss per share – basic and diluted from continuing operations (p)	(8.22)	(2.00)	(0.94)	(33.08)	(3.81)
Weighted average number of shares	57,743,223	151,071,019	458,715,753	7,221,102	37,898,019

Source: ValiRx, SP Angel forecasts

Cash Flow

Year-end December (GBP)	2016A	2017A	2018A	2019A	2020A
<i>Cash flows from operating activities</i>					
Cash outflow from operations	(4,233,412)	(2,952,275)	(3,776,840)	(1,801,714)	(2,200,088)
Interest paid	(338,188)	(35,897)	(866)	(3,093)	(6,252)
Tax credit received	375,926	636,739	424,197	463,144	295,623
Net cash outflow from operating activities	(4,195,674)	(2,351,433)	(3,353,509)	(1,341,663)	(1,910,717)
<i>Cash flows from investing activities</i>					
Purchase of goodwill	(141,066)	(73,599)	-	-	
Purchase of intangible fixed assets	(245,559)	(206,727)	(324,028)	(396,776)	(93,287)
Sale of subsidiary undertaking	857,136	-	-	146,517	
Sale of tangible fixed assets	3,470	-	-	-	2,000
Non-controlling interests	141,068	73,599	-	-	
Interest received	17	489	-	-	
Net cash from investing activities	615,066	(206,238)	(324,028)	(250,259)	(91,287)
<i>Cash flows from financing activities</i>					
New convertible loan notes	2,993,113	263,704	-	-	
Repayment of convertible loan notes	-	(347,481)	(25,000)	(138,000)	(80,000)
Costs of convertible loan notes	(190,846)	-	-	-	50,000
Share issue	1,695,906	3,068,406	3,720,000	1,576,000	4,132,714
Costs of shares issued	(589,267)	(286,311)	(346,001)	(224,584)	(245,675)
Repayment of lease liabilities	-	-	-	-	(2,500)
Net cash from financing activities	3,908,906	2,698,318	3,348,999	1,213,416	3,854,539
Increase in cash and cash equivalents	328,298	140,647	(328,538)	(378,506)	1,852,535
Cash and cash equivalents at beginning of year	232,465	560,763	701,410	372,872	(5,634)
Cash and cash equivalents at end of year	560,763	701,410	372,872	(5,634)	1,846,901

Source: ValiRx, SP Angel forecasts

Balance sheet

Year-end December (GBP)	2016A	2017A	2018A	2019A	2020A
Goodwill	1,528,923	1,602,522	1,602,522	1,602,522	1,602,522
Intangible assets	1,295,690	1,325,283	1,623,950	1,620,207	1,329,188
Property, plant and equipment	10,553	-	-	-	-
Right-of-use asset	-	-	-	-	20,995
Non-current assets	2,835,166	2,927,805	3,226,472	3,222,729	2,952,705
Trade and other receivables	780,942	766,475	174,089	90,083	66,735
Tax receivable	644,497	424,094	461,193	291,787	71,346
Derivative financial assets	140,675	117,229	-	-	-
Cash and cash equivalents	560,763	701,410	372,872	-	1,846,901
Current assets	2,126,877	2,009,208	1,008,154	381,870	1,984,982
Total assets	4,962,043	4,937,013	4,234,626	3,604,599	4,937,687
Called up share capital	8,165,650	8,432,708	8,680,694	9,417,225	9,669,828
Share premium	12,998,102	16,419,494	19,779,905	20,596,143	24,380,356
Merger reserve	637,500	637,500	637,500	637,500	637,500
Reverse acquisition reserve	602,413	602,413	602,413	602,413	602,413
Share option reserve	331,453	464,000	885,963	830,449	540,803
Retained earnings	(20,385,278)	(23,378,744)	(27,461,771)	(29,729,817)	(30,919,728)
Non-controlling interest	19,619	(24,744)	(93,764)	(130,813)	(155,888)
Total equity	2,369,459	3,152,627	3,030,940	2,223,100	4,755,284
Trade and other payables	1,254,139	1,394,266	889,987	1,182,084	111,342
Borrowings	1,294,299	390,120	-	5,634	5,514
Derivative liabilities	44,146	-	313,699	193,781	-
Lease liabilities	-	-	-	-	7,622
Current liabilities	2,592,584	1,784,386	1,203,686	1,381,499	124,478
Borrowings	-	-	-	-	44,486
Lease liabilities	-	-	-	-	13,439
Non-Current liabilities	-	-	-	-	57,925
Total liabilities	2,592,584	1,784,386	1,203,686	1,381,499	182,403
Total equity and liabilities	4,962,043	4,937,013	4,234,626	3,604,599	4,937,687

Source: ValiRx, SP Angel forecasts

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Buy - Expected return >15%

Hold - Expected return range -15% to +15%

Sell - Expected return < 15%