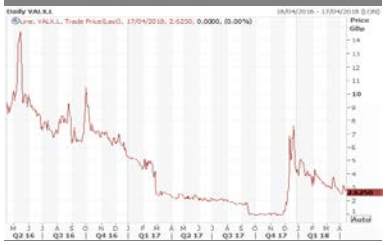
hardman&co

Pharmaceuticals & Biotechnology



Source: Eikon Thomson Reuters

Market data	
EPIC/TKR	**VAL**
Price (p)	3.00
12m High (p)	7.30
12m Low (p)	0.96
Shares (m)	133.36
Mkt Cap (£m)	12.22
EV (£m)	11.80
Free Float*	99%
Market	AIM

**As defined by AIM Rule 26*

Description

ValiRx is a clinical-stage biopharmaceutical company focused on novel treatments for cancer and associated biomarkers. It currently has two products in Phase I/II and Phase II clinical trials. Its business model focuses on out-licensing or partnering drug candidates after clinical trials.

Company information

CEO	Dr Satu Vainikka
CFO	Gerry Desler
Chairman	Oliver de Giorgio-Miller
	+44 20 3008 4416
	www.valirx.com

Key shareholders

Directors	0.5%

Diary

8 May	AGM
Sep'18	Interims

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ValiRx

2017: a pivotal year

ValiRx (VAL) is a clinical-stage biopharmaceutical company focused on the development of therapeutics for the treatment of cancer. The company's two leading assets are in clinical trials: VAL201 (Phase I/II) – a peptide for advanced prostate cancer and potential to treat other hormone- induced indications; and VAL401 (Phase II) – a novel reformulation of risperidone, in trials for lung cancer. Both drugs are targeted at multi-billion dollar markets that are inadequately served by current drugs. The aim is to progress the clinical data and exit via a collaboration or commercial out-licensing to a larger partner.

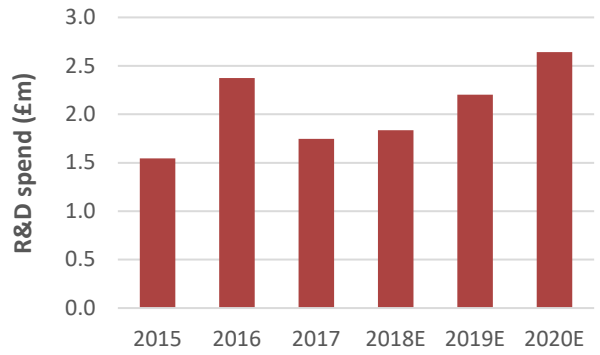
- **Strategy:** VAL operates as a virtual business, out-sourcing most of its activities. The core strategy is to develop its therapeutic assets through the clinical pathway and seek a partner/licensing deal to complete the development programme and regulatory submissions to commercialise the products.
- **2017 results:** Lower than expected R&D spend and corporate overhead meant that full-year results were better that expectations, with the net loss reducing 34% to -£3.02m (-£4.75m). This fed through to the net cash position, which was also better than forecast at £0.31m (-£0.73m).
- **Trial progress:** VAL has made substantial progress with all of its clinical candidates during 2017, with further trial results due for release during 2018. Most progress has been made with VAL401 in non-small cell lung cancer, with a view to out-licensing it for further development this year.
- **Risks:** New and/or first-in-class drugs carry the risk that they might fail in clinical trials. However, the substantial safety history of the active ingredient in VAL401 and the consistent safety record to date in the VAL201 trial mitigate these risks. More capital is needed to further its proprietary assets along the value chain.
- **Investment summary:** VAL is undervalued relative to its peers at a similar stage of development. The reason for this is certainly its need for more capital to advance its clinical programmes, thereby building value. Given the clinical progress seen to date, the company should be attracting potential commercial partners and/or institutional investors in order to achieve the real value of its assets.

Financial summary and valuation

Year-end Dec (£000)	2015	2016	2017	2018E	2019E	2020E
Sales	83	0	0	0	0	0
SG&A	-1,645	-1,666	-1,467	-1,511	-1,587	-1,587
R&D	-1,543	-2,375	-1,747	-1,834	-2,201	-2,641
EBITDA	-2,877	-3,939	-2,938	-3,158	-3,600	-4,040
Underlying EBIT	-2,888	-3,949	-2,948	-3,168	-3,611	-4,051
Reported EBIT	-3,029	-3,987	-3,125	-3,345	-3,788	-4,228
Underlying PBT	-2,889	-4,288	-3,398	-3,200	-3,656	-4,114
Statutory PBT	-2,567	-5,569	-3,554	-3,377	-3,834	-4,291
Underlying EPS (p)	-7.7	-6.0	-1.9	-0.7	-0.8	-0.9
Statutory EPS (p)	-6.7	-8.2	-2.0	-0.7	-0.8	-0.9
Net (debt)/cash	232	-734	311	-2,514	-5,903	-9,662
Capital increases	2,681	2,615	3,602	120	0	0

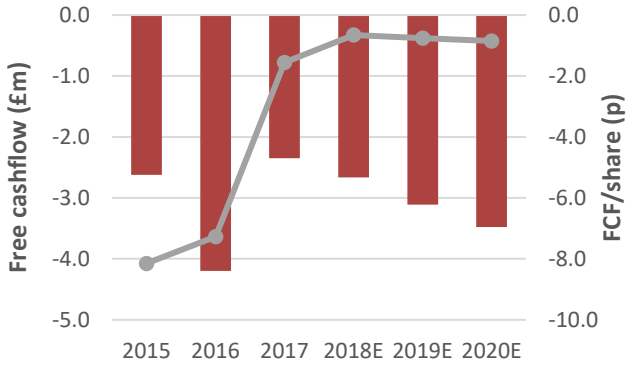
Source: Hardman & Co Life Sciences Research

R&D Investment



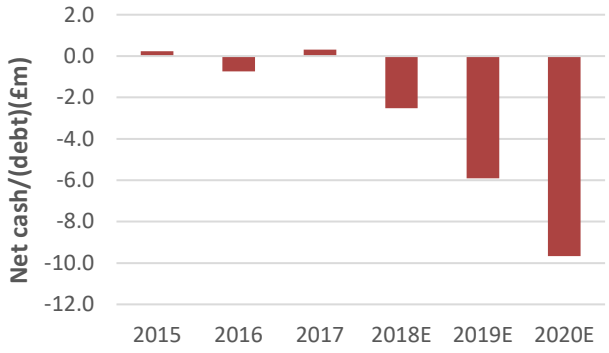
- ValiRx outsources all its research
- The cost of the current clinical trial for VAL201 and VAL401 where borne during 2016
- R&D expenditure is expected to increase with the new clinical programmes

Free cashflow



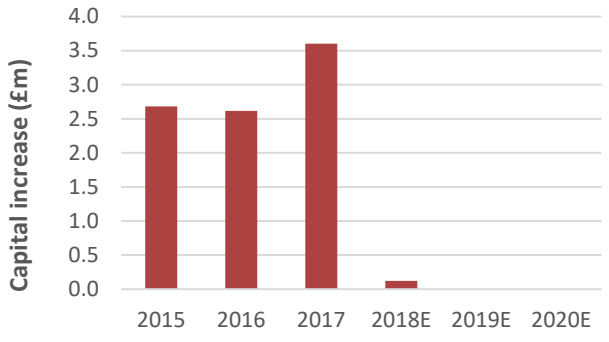
- Cashflow is driven by the corporate overhead (SG&A) and R&D investment, offset by tax credit on R&D investment
- The monthly average cash burn is ca.£0.25m
- Manufacturing costs of clinical trial material was borne in fiscal 2016, which impacted cash flows
- The R&D tax credit in the balance sheet is £0.42m which will be received in fiscal 2018, and is expected to rise as greater investment is made in clinical programmes

Net cash



- Net cash at 31st December 2017 was £0.31m, comprising cash of £0.70m and convertible loans of -£0.39m, which, in all likelihood, will be converted into equity
- Our cash projections suggest that VAL will need cash injection during 2018 in the absence of a licensing deal

Capital increase



- During 2017, VAL raised £3.07m gross (£2.78m net) new capital by way of four Placings
- In 2017, £0.56m of bonds were converted into equity and a further £0.35m were re-paid. At the period end £0.39m bonds were outstanding which are expected to convert into equity.
- Further resources will be needed in the near future

Source: Company data; Hardman & Co Life Sciences Research

Full-year 2017 results

Development highlights

- **VAL201:** Safety and tolerability have been confirmed in the ongoing Phase I/II trial in patients with advanced or metastatic prostate cancer. In addition, the MHRA decision to increase the dosing level, shows confidence in VAL201 and raises the probability of efficacy. Data read-out is expected during 2018.
- **VAL401:** Completion of the Phase II trial in lung cancer, with data suggesting some palliative effect added to an improvement in symptoms and the survival prospect in the small cohort of patients treated.
- **VAL101:** A second generation of VAL101 derived from its proprietary GeneICE platform has been generated, with an improved manufacturing process – production and purification – that will speed-up the progression of VAL101 towards the clinic.
- **VAL301:** The reformulated version of VAL201 has undergone late pre-clinical studies for the treatment of endometriosis. Evidence shows no effect on bone density or fertility, side effects usually seen in current treatments. The product is undergoing additional late pre-clinical toxicology work with the aim of entering the clinic during 2018.

Financial highlights

- **R&D spend:** Investment in R&D decreased by 27% to -£1.74m (-£2.37m), largely because of the absence of manufacturing costs for clinical trial materials which were incurred in 2016.
- **Administration:** SG&A costs reduced by 12% to £1.47m (-£1.67m).
- **Net cash:** VAL raised a total of £3.07m during the financial year and most of the outstanding bonds were either converted or repaid. At the period end, it had net cash was £0.31m, made up of £0.70m cash offset by £0.39m of convertible bonds, which in all likelihood are expected to be converted into equity.

ValiRx full-year results – actual vs expectations

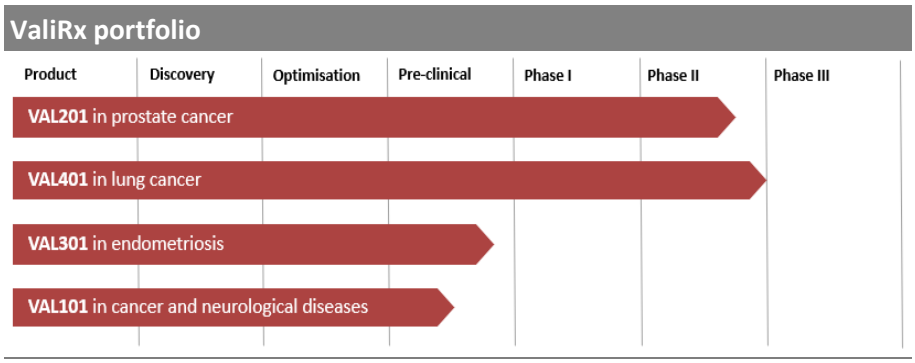
Year-end December (£m)	2016 actual	2017 actual	change %	2017 forecast	Delta Δ
R&D spend	-2.37	-1.74	-27%	-2.85	+1.11
Administration	-1.67	-1.47	-12%	-1.75	+0.28
Underlying EBIT loss	**-3.95**	**-2.95**	**-25%**	**-4.51**	**+1.56**
Tax credit	+0.62	+0.42	-32%	+0.74	-0.32
Underlying net loss	**-3.47**	**-2.86**	**-18%**	**-3.84**	**+0.98**
Net cash/(debt)	-0.73	+0.31		+0.56	-0.25

Figures may not add up exactly due to rounding
Source: Hardman & Co Life Sciences Research

Corporate highlights

- **Strengthened IP**: The company has been granted additional patent protection for both VAL201 and VAL401, with a US patent for VAL201 being issued post the period-end, in 1Q'18.
- **Advisory Board:** VAL has created an advisory board to support the main Board and provide additional expertise. It is comprised currently of two members: Ajay Agrawal (CSO), Andrew King (ex-CFO NeuTec).

Pipeline progress



Source: ValiRx; Hardman & Co Life Sciences Research

Clinical trial update

VAL201

High safety and tolerability, plus some early evidence of efficacy, has been observed in the Phase I/II trial in advanced/metastatic prostate cancer for the peptide inhibitor that possesses a distinctive mode of action on the androgen receptor. Consequently, the research ethic committee, in consultation with the MHRA, decided to escalate both the dose and frequency of administration, thereby raising the potential for VAL201 to show anti-cancer efficacy. Headline data are expected during 2018.

VAL401

The reformulated oral version of risperidone allows specific targeting of cancer cells has completed a pilot Phase II trial in late-stage lung cancer patients. Results were very favourable, with VAL401 achieving an overall response rate of 60% and improved the quality of life in patients with late-stage disease. In addition, there was some evidence to show that VAL401 improves disease symptoms (pain and fatigue), suggesting that it has a palliative effect, and making it a good candidate for a combination study. A proposed Phase III trial in ca.200 late-stage NSCLC patients with and without standard-of-care will be run either with or by a partner. Management indicated that discussions are underway with several potential partners for the further development of VAL401.

Pre-clinical developments

VAL301

The reformulated version of VAL201, targeting the gynaecological disorder endometriosis, which is hypothesised to have a lower side effect potential compared to current standard-of-care. VAL301 is currently undergoing late-stage pre-clinical studies with the aim of having a complete pre-clinical package with the optimal formulation during 2018. VAL is expected to submit an IND to start clinical trials in 2018.

VAL101

Through a consortium of partners, led by ValiRx, the manufacturing process for the GeneICE platform has been optimised. This has paved the way for accelerated pre-clinical development of a new version of VAL101 that targets the gene expressing Bcl2. Having shown that VAL101 produced programmed cell death (apoptosis) in cancer cell models, the product is now being prepared for testing in clinical trials.

Financial forecasts

Profit & Loss

- ValiRx is a virtual company with most of its activity being outsourced.
- In the medium term, the P&L account is driven by two numbers, the corporate overhead/administration costs and the investment in R&D/clinical trials.
- **SG&A:** Overall administrative costs in 2017 decreased to -£1.47m (-£1.67m), with tight control of corporate overhead.
- **R&D:** Despite the progress made in clinical trials, R&D costs decreased unexpectedly. This was largely the consequence of the cost of manufacturing the batches of drugs for use in clinical trials being borne in fiscal 2016. With more trials being planned, R&D costs are expected to rise over the forecast period.

Profit & Loss account

Year-end Dec (£000)	2015	2016	2017	2018E	2019E	2020E
Sales	83	0	0	0	0	0
COGS	-78	0	0	0	0	0
SG&A	-1,645	-1,666	-1,467	-1,511	-1,587	-1,587
R&D	-1,543	-2,375	-1,747	-1,834	-2,201	-2,641
Other income	203	0	89	0	0	0
EBITDA	-2,877	-3,939	-2,938	-3,158	-3,600	-4,040
Depreciation	-11	-11	-11	-11	-11	-11
Amortisation	-92	-92	-177	-177	-177	-177
Underlying EBIT	**-2,980**	**-4,042**	**-3,125**	**-3,345**	**-3,788**	**-4,228**
Share-based costs	-49	-128	0	0	0	0
Exceptional items	0	183	0	0	0	0
Statutory EBIT	-3,029	-3,987	-3,125	-3,345	-3,788	-4,228
Net financials	462	-1,582	-429	-32	-47	-64
Underlying pre-tax profit	**-2,981**	**-4,380**	**-3,575**	**-3,377**	**-3,834**	**-4,292**
Reported pre-tax	-2,567	-5,569	-3,554	-3,377	-3,834	-4,292
Tax liability/credit	391	620	416	437	525	630
Tax rate	-15%	-11%	-12%	-13%	-14%	-15%
Underlying net income	**-2,532**	**-3,559**	**-3,040**	**-2,940**	**-3,310**	**-3,663**
Statutory net income	-2,118	-4,748	-3,020	-2,940	-3,310	-3,663
Ordinary 0.1p shares:						
Period-end (m)	38.34	83.25	399.06	407.46	407.46	407.46
Weighted average (m)	31.79	57.74	151.07	406.54	407.46	407.46
Fully-diluted (m)	35.58	98.51	259.52	520.84	521.76	521.76
Underlying basic EPS (p)	**-8.0**	**-6.2**	**-2.0**	**-0.7**	**-0.8**	**-0.9**
Statutory basic EPS (p)	-6.7	-8.2	-2.0	-0.7	-0.8	-0.9
U/l fully-diluted EPS (p)	**-7.1**	**-3.6**	**-1.2**	**-0.6**	**-0.6**	**-0.7**
Stat. fully-diluted EPS (p)	-6.0	-4.8	-1.2	-0.6	-0.6	-0.7
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0

Source: Hardman & Co Life Sciences Research

Balance sheet

- **Net cash/(debt)** – at 31st December 2017, VAL had net cash of £311k on its balance sheet, comprising cash of £701k and outstanding convertible loan notes of £390k, which are treated as debt, although in all likelihood these will be converted into shares. Therefore, the company effectively has £700k of working capital.
- To continue funding R&D investment at current levels, further capital will be required during 2018. This could come either from licensing agreements, collaborative deals with equity components and/or an equity placing by the company

Balance sheet

at 31st Dec (£000)	2015	2016	2017	2018E	2019E	2020E
Shareholders' funds	4,533	2,369	3,153	213	-3,096	-6,757
Cumulated goodwill	0	0	0	0	0	0
Total equity	4,533	2,369	3,153	213	-3,096	-6,757
Share capital	8,121	8,166	8,433	8,433	8,433	8,433
Reserves	-3,667	-5,816	-5,255	-8,195	-11,504	-15,165
Minorities	79	20	-25	-25	-25	-25
Provisions/liabilities	0	0	0	0	0	0
Deferred tax	0	0	0	0	0	0
Long-term debt	0	0	0	0	0	0
Short-term loans	0	1,294	390	390	390	390
less: Cash	232	561	701	-2,124	-5,513	-9,272
less: Deposits	0	0	0	0	0	0
less: Non-core invests.	1,463	97	117	117	0	0
Invested capital	**2,837**	**3,006**	**2,724**	**2,610**	**2,807**	**2,905**
Fixed assets	22	11	0	-11	-21	-32
Intangible assets	2,673	2,825	2,928	3,074	3,074	3,074
Inventories	44	0	0	0	0	0
Trade debtors	*33*	*0*	*0*	*0*	*0*	*0*
Other debtors	*253*	*781*	*766*	*613*	*583*	*553*
Tax credit/liability	*400*	*644*	*424*	*437*	*525*	*630*
Trade creditors	*-448*	*-1,127*	*-1,200*	*-1,100*	*-1,000*	*-900*
Other creditors	*-141*	*-127*	*-194*	*-404*	*-353*	*-421*
Debtors less creditors	98	171	-204	-454	-246	-138
Invested capital	**2,837**	**3,006**	**2,724**	**2,610**	**2,807**	**2,905**
Net cash/(debt)	**232**	**-734**	**311**	**-2,514**	**-5,903**	**-9,662**

Source: Hardman & Co Life Sciences Research

Cashflow

- **Capital increases:** During the year, VAL raised a total of £3.67m gross new capital by the way of four small Placings.
- **Convertible Loan Notes:** Most of the convertible loans notes were converted, or repaid, in 2017. In December 2017, VAL decided to close down the loan facility. In addition, Yorkville exercised 106m of warrants into ordinary shares, generating £1.5m.
- **Warrants:** In January 2018, 8.4m warrants were exercised, raising £0.12m of new capital for the company. There are a further 92.1m warrants outstanding at exercise prices between 4p and 9p.
- **Cash requirement:** To fund the business over the next two years, we forecast a minimum cash requirement of ca.£7m. This could come in the form of up-front payments as part of licensing deal(s), equity participation in a collaborative deal, an equity fund raise or a combination of these options.

Cashflow

Year-end Dec (£000)	2015	2016	2017	2018E	2019E	2020E
Underlying EBIT	-2,980	-4,042	-3,125	-3,345	-3,788	-4,228
Depreciation	11	11	11	11	11	11
Inventories	*-33*	*12*	*0*	*0*	*0*	*0*
Receivables	*95*	*-1,072*	*14*	*0*	*0*	*0*
Payables	*-167*	*788*	*54*	*100*	*100*	*100*
Change in working capital	-105	-272	69	100	100	100
Exceptionals/provisions	0	0	0	0	0	0
Other	5	-22	-83	0	0	0
Company op cashflow	**-2,977**	**-4,233**	**-2,952**	**-3,058**	**-3,500**	**-3,940**
Net interest	-1	-338	-35	-32	-46	-63
Tax paid/received	388	376	637	424	437	525
Operational cashflow	**-2,590**	**-4,196**	**-2,351**	**-2,665**	**-3,109**	**-3,478**
Capital expenditure	-32	0	0	0	0	0
Sale of fixed assets	0	0	0	0	0	0
Free cashflow	**-2,622**	**-4,196**	**-2,351**	**-2,665**	**-3,109**	**-3,478**
Dividends	0	0	0	0	0	0
Acquisitions	-390	-387	-280	-280	-280	-280
Disposals	0	861	0	0	0	0
Other investments	110	141	74	0	0	0
Cashflow after invests.	**-2,901**	**-3,581**	**-2,558**	**-2,946**	**-3,389**	**-3,759**
Share repurchases	0	0	0	0	0	0
Capital increases	2,681	2,615	3,602	120	0	0
Currency effect	0	0	0	0	0	0
Cash/(debt) acquired	0	0	0	0	0	0
Change in net debt	**-220**	**-966**	**1,045**	**-2,826**	**-3,389**	**-3,759**
Hardman FCF/share (p)	-8.1	-7.3	-1.6	-0.7	-0.8	-0.9
Opening net cash	453	232	-734	311	-2,514	-5,903
Closing net cash	**232**	**-734**	**311**	**-2,514**	**-5,903**	**-9,662**

Source: Hardman & Co Life Sciences Research

Company matters

Registration

Incorporated in the UK with company registration number: 3916791

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UK

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Board of Directors

Board of Directors

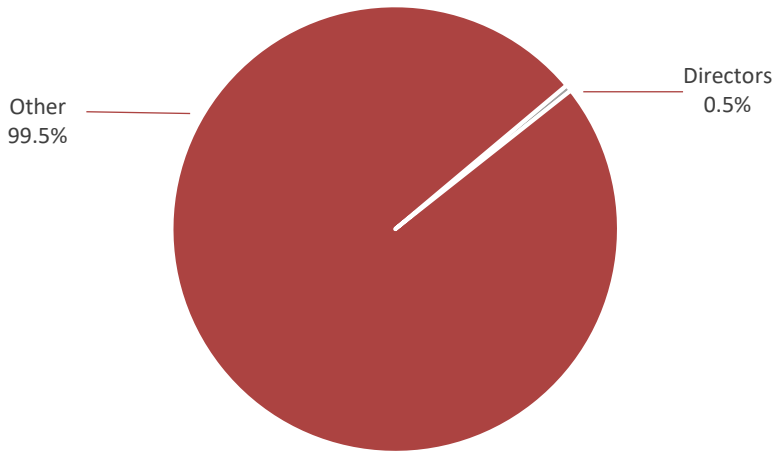
Position	Name	Remuneration	Audit
Chairman	Oliver de Giorgio-Miller	M	
Chief Executive Officer	Dr Satu Vainikka		
Chief Financial Officer	Gerry Desler		M
Chief Operations Officer	Dr George Morris		M
Non-executive director	Kevin Alexander	M	

M = member; C = chair
Source: Company reports

Share capital

At the time of going to press, there were 407,426,717 Ordinary shares of 0.1p in issue and 20,712,960 outstanding share options (all out of the money). In addition, there are currently 93.59m warrants outstanding with an exercise price between 4p and 9p, which could generate up to £7.4m of additional capital for the company in the future, although it should be noted that ca.68% of these are exercisable at 9.0p.

ValiRx shareholders



Source: Company reports/announcements

Notes

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