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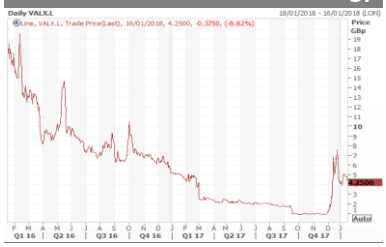
Pharmaceuticals & Biotechnology



Source: Eikon Thomson Reuters

Market data	
EPIC/TKR	VAL
Price (p)	3.96
12m High (p)	7.75
12m Low (p)	0.90
Shares (m)	407.46
Mkt Cap (£m)	16.14
EV (£m)	15.93
Free Float*	91%
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	Olivier de-Giorgio-Miller
	+44 20 3008 4416
	www.valirx.com

Key shareholders	
Directors	0.5%
Yorkville	6.8%
Nicholas Slater	1.7%

Diary	
1Q-18	Read-out VAL201
May-18	Final results

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ValiRx

VAL401 improves quality of life

ValiRx is a clinical-stage biopharmaceutical company focused on the development of therapeutics for the treatment of cancer, associated biomarkers and companion diagnostics. The company's two leading assets are in clinical trials: VAL201 (Phase I/II) – a peptide for advanced prostate cancer and potentially other hormone-induced indications; and VAL401 (Phase II) – a reformulation of risperidone for lung cancer. Following previous announcements on safety, tolerability and improvement in overall survival, VAL has disclosed further clinical analysis of its Phase II data with VAL 401, that demonstrate a positive impact on patients' quality of life.

- **Strategy:** ValiRx 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.
- **Quality of life:** VAL401 achieved an overall response rate of 60% and improved the quality of life in patients with late-stage lung cancer. There was some evidence to show that VAL401 improves the disease symptoms, suggesting a palliative effect, and could be a good candidate for a combination study.
- **Next steps:** Safety and tolerability of VAL401 has been confirmed in late stage patients affected by non-small cell lung cancer. With this new data showing an increase of the quality of life, management is currently preparing regulatory works for the next stage of clinical testing.
- **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 in the VAL201 trial mitigate these risks. More capital will be needed to further its proprietary assets along the value chain.
- **Investment summary:** The market has failed to recognise the potential of ValiRx, fretting more about the need for more capital to advance its clinical programmes than taking a rational view of the likely success of its clinical candidates. Given the clinical progress seen to date, the company is likely to be attracting the attention of potential commercial partners and/or institutional investors in order to achieve the true value of its assets.

Financial summary and valuation

Year end Dec (£000)	2014	2015	2016	2017E	2018E	2019E
Sales	88	83	0	0	0	0
SG&A	-1,514	-1,645	-1,666	-1,750	-1,837	-1,929
R&D	-1,772	-1,543	-2,375	-2,850	-3,421	-4,105
EBITDA	-2,958	-2,877	-3,939	-4,502	-5,155	-5,936
Underlying EBIT	-2,958	-2,888	-3,949	-4,508	-5,165	-5,941
Reported EBIT	-3,138	-3,029	-3,987	-4,734	-5,399	-6,182
Underlying PBT	-2,952	-2,889	-5,531	-4,581	-5,195	-5,995
Statutory PBT	-3,641	-2,567	-5,569	-4,807	-5,429	-6,235
Underlying EPS (p)	-10.5	-7.7	-8.2	-2.6	-1.3	-1.4
Statutory EPS (p)	-13.5	-6.7	-8.2	-2.8	-1.3	-1.5
Net (debt)/cash	453	232	-734	559	-4,194	-9,588
Capital increases	2,510	2,681	2,615	3,964	0	0

Source: Hardman & Co Life Sciences Research

VAL401 improves quality of life

In December 2017, ValiRx provided the market with the first set of clinical data from its Phase II trial demonstrating the benefit of VAL401, a smart and proprietary formulation of risperidone, on overall survival in patients with advanced non-small cell lung cancer (NSCLC) – see our report published on the 13th December 2017[1]: '*Clinical Efficacy of VAL401*'. These data demonstrated safety and tolerability of VAL401 added to a first evidence of efficacy with improved survival rate compared to untreated patients. In addition, pharmacokinetic data are in line with the traditional formulation of risperidone.

Key definitions

Taken from the National Cancer Institute Dictionary of Cancer Terms:

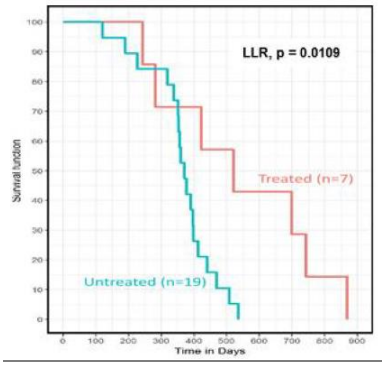
- **Overall survival (OS):** *The length of time from either the date of diagnosis or the start of treatment for a disease, such as cancer, that patients diagnosed with the disease are still alive. In a clinical trial, measuring the overall survival is one way to see how well a new treatment works.*
- **Progression-free survival (PFS):** *The length of time during and after the treatment of a disease, such as cancer, that a patient lives with the disease but it does not get worse. In a clinical trial, measuring the progression-free survival is one way to see how well a new treatment works.*

Additional clinical evidence

Background

Eligibility for the Phase II trial were patients with stage IV NSCLC that had failed on prior chemotherapy, with 3-6 months life expectancy and with no other therapeutic options for these patients other than palliative care. With VAL401, ValiRx does not intend to cure this very sick patient population, but to generally improve overall quality of life, with a palliative effect in addition to extending the life expectancy.

Kaplan-Meier Survival Graph



Source: ValiRx

Eight patients were recruited into the trial and seven have been used for the Overall Survival analysis. Each patient was acclimatised onto the drug regimen on escalating doses, starting at 2mg per day, until they reached either 10mg per day or their maximum tolerated dose if lower. Benchmark patients (19 untreated): patients that would have been eligible for the trial but for various reasons did not participate.

The Kaplan-Meier graph represents the impact of VAL401 on these late stage and very sick patients and show a clear distinction between patients treated with VAL401 (red, 7 patients) and those that received only palliative care (green, 19 patients), despite the trial being on a very small patient population. The statistical outcome had not been expected in such a small patient population.

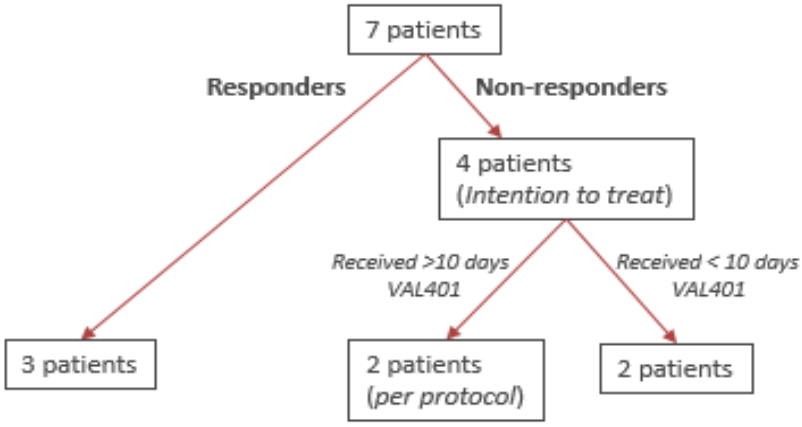
Additional clinical results

Data were collected and analysed by Ariana's KEM (Knowledge Extraction and Management), advanced Artificial Intelligence technology, an independent clinical research organisation. Overall, seven patients took part in the trial and were eligible for this extended analysis.

[1] http://www.hardmanandco.com/docs/default-source/company-docs/valirx-plc-documents/13.12.17-clinical-efficacy-of-val401.pdf

- Three patients responded to VAL401 treatment and saw an improvement in mean PFS and OS, compared to non-responders.
- Four patients were considered to be non-responders of which, only two received VAL401 for more than 10 days (per protocol population), the other two receiving less and were *de facto* removed from the response rate.

Split in the patient population



Source: Hardman & Co Life Sciences Research

The overall response rate was evaluated at 60% of the patients that followed the study protocol. From this small patient population, data suggest that responder patients obtain an increase in mean PFS and in mean OS of 8.7 weeks and 12.9 weeks, respectively, compared to the non-responder population with 4.3 weeks and 7.1 weeks, respectively. The difference and rationale between responders and non-responders to VAL401 is not clear yet, and it is being investigated by Ariana.

PFS and OS data

Time		PFS		OS	
(Weeks)	n	mean	range	mean	range
Responders	3	8.7	7.1 - 11.6	12.9	11.6 - 15.3
Non-responders total	4	2.5	0.4 - 4.7	3.9	0.4 - 7.4
Non-responders, >10 days dosing	2	4.3	4.0 - 4.7	7.1	6.8 - 7.4

Source: ValiRx

In addition, biochemical analyses on two responders suggest that VAL401 did not reduce the number of white blood cells and, therefore, does not cause the immune suppression usually seen with traditional therapies. Hence, there is potential for VAL401 to be taken in combination with other chemotherapy or immunotherapy drugs.

Quality of Life data

With VAL401, the initial aim ValiRx is targeting is not to cure these very sick patient population, but to extend the life expectation and to improve their quality of life. A questionnaire encompassing 19 factors was completed by several patients:

- General improvement of quality of life seen in patients – responders and non-responders – with improved appetite (1), improved depression (1) and irritability (1) and ability to take part in leisure activities (2).
- Improvement in pain associated with high exposure to VAL401.
- Improvement in fatigue associated with low exposure to VAL401.

Next step

A proposed Phase III trial in ca.200 late-stage NSCLC patients with and without standard of care to be run either with or by a partner.

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Some professional investors, who are subject to the new MiFID II rules from 3rd January, may be unclear about the status of Hardman research and, specifically, whether it can be accepted without a commercial arrangement. Hardman's company research is paid for by the companies about which we write and, as such, falls within the scope of 'minor non-monetary benefits', as defined in the Markets in Financial Instruments Directive II.

In particular, Article 12(3) of the Directive states: 'The following benefits shall qualify as acceptable minor non-monetary benefits only if they are' (b) 'written material from a third party that is commissioned and paid for by an[sic] corporate issuer or potential issuer to promote a new issuance by the company, or where the third party firm is contractually engaged and paid by the issuer to produce such material on an ongoing basis, provided that the relationship is clearly disclosed in the material and that the material is made available at the same time to any investment firms wishing to receive it or to the general public;'

The fact that we are commissioned to write the research is disclosed in the disclaimer, and the research is widely available.

The full detail is on page 26 of the full directive, which can be accessed here: http://ec.europa.eu/finance/docs/level-2-measures/mifid-delegated-regulation-2016-2031.pdf

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