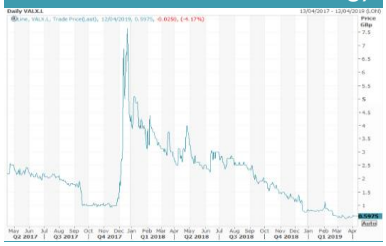
Pharmaceuticals & Biotechnology



Source: Eikon Thomson Reuters

Market data	
EPIC/TKR	VAL
Price (p)	0.6
12m High (p)	4.24
12m Low (p)	0.50
Shares (m)	681.63
Mkt Cap (£m)	4.09
EV (£m)	3.09
Free Float*	100%
Market	AIM

**As defined by AIM Rule 26*

Description

ValiRx (VAL) 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	0.3%
N. Slater	3.3%

Diary

May'19	2018 final results
2H'19	Read-out VAL201

Analysts

Martin Hall	020 7194 7632
	mh@hardmanandco.com
Dorothea Hill	020 7194 7626
	dmh@hardmanandco.com
Grégoire Pavé	020 7194 7628
	gp@hardmanandco.com

VALIRX

VAL401 is going forward

VAL is a clinical-stage biopharmaceutical company focused on the development of therapeutics for the treatment of cancer. The company has two leading assets: VAL201 (Phase I/II) – a peptide for advanced prostate cancer and potential to treat other hormone-induced indications; and VAL401 (completed Phase II) – a novel reformulation of risperidone, for advanced lung cancer. Both drugs are targeted at multi-billion-dollar markets that are inadequately served by current drugs. VAL is in a joint venture with the SEEK group for the VAL401 programme, with ValiSeek having agreed Letters of Intent with two partners to progress VAL401 further into the clinic.

- **Strategy:** VAL operates as a virtual business, outsourcing most of its activities. The core strategy is to develop its therapeutic assets through the early clinical pathway, and then seek a partner/licensing deal to complete the development programme and regulatory submissions to commercialise the products.

- **VAL401:** VAL401 is a proprietary formulation of risperidone for use in late-stage lung cancer patients. The completed open-label Phase II trial with VAL401 confirmed the palliative effect of the drug, showing improved survival times, together with an improvement in the quality of life of the patients treated.

- **Partnership deals:** On the back of the Phase II trial results, ValiSeek, the VAL joint venture company for the VAL401 programme, has been seeking partners to progress the drug into late-stage development and has agreed Letters of Intent with two international partners (from the US and from Europe) to co-finance it.

- **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 mitigates these risks. ValiSeek is looking for external financing with its new partners to fund a late-stage trial.

- **Investment summary:** VAL appears to be under-appreciated by the market. Reasons for this include the lack of institutional shareholders and a continuing need for more capital to advance its clinical programmes, thereby building value. On the back of clinical progress, the company is attracting potential commercial partners to help pay for the costs of late-stage development. This should be the catalyst needed to attract institutional investors into the company.

Financial summary and valuation

Year-end Dec (£m)	2015	2016	2017	2018E	2019E	2020E
Sales	0.08	0.00	0.00	0.00	0.00	0.00
SG&A	-1.64	-1.67	-1.47	-1.76	-1.85	-1.94
R&D	-1.54	-2.38	-1.75	-1.83	-2.20	-2.64
EBITDA	-2.88	-3.94	-2.94	-3.42	-3.87	-4.41
Underlying EBIT	-2.98	-4.04	-3.13	-3.59	-4.05	-4.58
Reported EBIT	-3.03	-3.99	-3.13	-3.59	-4.05	-4.58
Underlying PBT	-2.98	-4.38	-3.57	-3.59	-4.05	-4.60
Statutory PBT	-2.57	-5.57	-3.55	-3.59	-4.05	-4.60
Underlying EPS (p)	-7.96	-6.16	-2.01	-0.57	-0.52	-0.58
Statutory EPS (p)	-6.66	-8.22	-2.00	-0.57	-0.52	-0.58
Net cash/(debt)	0.23	-0.73	0.31	0.52	-3.09	-7.17
Capital increase	2.68	2.61	3.60	3.38	0.00	0.00

Source: Hardman & Co Life Sciences Research

Partners identified for VAL401

VAL401 to be progressed into late-stage development

Following the successful outcome from the Phase II trial with VAL401, highlighting both the improvement of quality of life and improved survival time of late-stage lung cancer patients, ValiSeek has been in discussions with potential partners in order to fund and conduct the next late-stage trial. VAL has a 55.5% shareholding in ValiSeek.

Co-funding partners identified

ValiSeek has agreed Letters of Intent with two international partners to progress VAL401 further into the clinic

ValiSeek has announced that Letters of Intent have been agreed with two undisclosed partners to progress VAL401 further into the clinic: one from Europe and one from the US. As part of the agreement, the next clinical trial will be on a co-financing basis between ValiSeek and its two partners. ValiSeek is now looking for external funding towards its share of the next trial costs.

VAL's commitment

With respect to VAL's existing agreement with ValiSeek, the company does not have any requirement to finance and progress the programme further, in line with VAL's strategy for the VAL401 programme. ValiSeek will continue all the commercial negotiations, and VAL will benefit from potential development milestones and royalties on future sales.

The Phase II results

VAL401 aims to improve the quality of life of late-stage lung cancer patients

The Phase II trial targeted patients with stage IV NSCLC who had failed on prior chemotherapy, had a minimum of three months' life expectancy and had no other therapeutic options other than palliative care. With VAL401, ValiSeek does not expect to cure this very sick patient population, but, rather, to generally improve overall quality of life, with a palliative effect, in addition to extending life expectancy.

Eight patients were recruited into the trial and seven have been used for the Overall Survival (OS)[1] 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) were patients who would have been eligible for the trial but who, for various reasons, did not participate.

Clinical evidence

The Kaplan-Meier graph (see below) represents the impact of VAL401 on these late-stage and very sick patients and shows a clear distinction between patients treated with VAL401 (red, seven patients) and those benchmark patients who 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.

The study shows a distinction between responders and non-responders, and a 60% overall response rate…

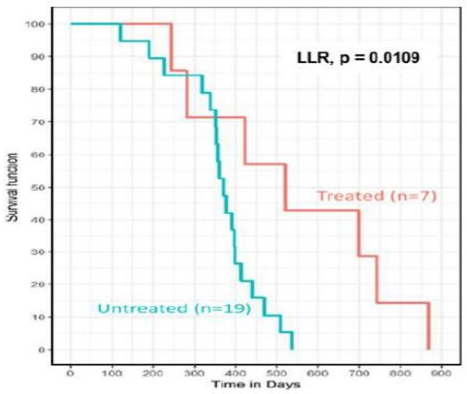
Patients were classified into responders and non-responders as a result of obvious visual clustering in survival times. Of those patients who had more than 10 days of VAL401 treatment, 60% fell into the responders' group, providing an overall response rate of 60%. From this small patient population, data suggest that responder patients obtain in mean progression-free survival (PFS)[2] and in mean OS of 8.7 weeks and 12.9 weeks, respectively, compared with the non-responder population, at 4.3 weeks and

[1] **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 OS is one way to see how well a new treatment works.

[2] **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 the disease does not get worse. In a clinical trial, measuring PFS is one way to see how well a new treatment works.

7.1 weeks, respectively. The difference and rationale between responders and non-responders to VAL401 are not clear yet and will be investigated in subsequent trials.

Kaplan-Meier survival graph from Phase II VAL401 trial



Kaplan-Meier Survival Graph showing length of time in days of patient Overall Survival from time of first lung cancer chemotherapy treatment as a proxy for date of diagnosis

Source: ValiSeek/ValiRx

...with physiological evidence suggesting that VAL401 could be taken in a combination therapy

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. The side effects recorded were expected, as they included effects attributed to the underlying disease of the patients and were also expected for risperidone use.

Quality of life data

VAL401 improves the quality of life of lung cancer patients in 19 specific factors

With VAL401, the initial aim of ValiSeek is to extend the life expectancy of the late-stage lung cancer patients and to improve their quality of life. A questionnaire consisting of over 30 questions was completed by the patients and revealed various aspects of their quality of life. Nineteen specific factors were seen to have improved after treatment, with a general improvement in quality of life – for responders and non-responders, including factors shown in the table below.

Phase II trial outcomes/quality of life (number of patients)	
Improvement in pain (4)	Improvement in depression (2)
Improvement in insomnia (2)	Improvement in irritability (1)
Improvement in appetite (2)	Improvement in fatigue (3) and ability to take part in leisure activities (2)

Source: ValiSeek/ValiRx

Next steps

The next trial will be co-funded with its partners

A proposed late-stage trial in ca.200 NSCLC patients with and without standard-of-care will be run by ValiSeek and its new partners. The CTA is expected to be submitted to the regulators before the end of the year, with a possible start in 2020.

ValiSeek

ValiSeek is a joint venture between VAL (55.5%) and Tangent Reprofiling (37%)

ValiSeek Ltd was formed in 2014 to progress VAL401 through pre-clinical development and Phase II trials for the treatment of lung cancer and other oncology indications. ValiSeek is a joint venture between VAL (with 55.5%) and Tangent Reprofiling Limited (with 37%). The CEO of ValiSeek is Dr Suzanne Dilly (holding a share of 7.5%), who was instrumental in discovering the anti-cancer activity of VAL401 using technology developed at the University of Warwick and successfully progressed the compound through the clinical trial. VAL401 is a proprietary formulation of risperidone, an established CNS drug developed originally for the treatment of schizophrenia, and it is this specific formulation that confers the molecule anti-cancer activity.

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research@hardmanandco.com

35 New Broad Street
London
EC2M 1NH

+44(0)20 7194 7622

www.hardmanandco.com