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Pharmaceuticals & Biotechnology

Source: Eikon Thomson Reuters

Market data	
EPIC/TKR	VAL
Price (p)	1.00
12m High (p)	11.50
12m Low (p)	0.96
Shares (m)	203.96
Mkt Cap (£m)	2.04
EV (£m)	2.33
Free Float*	97%
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

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Key shareholders

Directors	1.4%
Nicholas Slater	3.5%
Yorkville	1.8%

Diary

Nov-17	Interims
4Q-17	Read-out VAL201
4Q-17	Read-out VAL401

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ValiRx

Positive early data from VAL401

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 potential to treat other hormone-induced indications; and VAL401 (Phase II) – a novel reformulation of risperidone, in trials for lung cancer. ValiRx has released early analysis of its Phase II trial with VAL 401 in lung cancer patients. The pharmacokinetic data are positive and strengthen the commercial package for out-licensing. Final read-out is due by year-end.

- **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.

- **VAL401:** The Phase II product VAL401 is a proprietary complex formulation of the anti-psychotic drug risperidone, being developed for late stage and metastatic non-small cell lung cancer patients. This formulation allows cellular absorption of the active ingredient and inhibits cell growth and resistance.

- **Positive pharmacokinetic data:** Recruitment into the trial has been completed and data processing and analysing has commenced. Early pharmacokinetic results suggest significant and anticipated differences of the active ingredient risperidone and its metabolite compared to the conventional formulated drug.

- **Next steps:** Safety and tolerability of VAL401 has been confirmed in late stage patients affected by non-small cell lung cancer. The study has provided also the dosing level that will be used in subsequent trials. Full data analysis is underway and the final read-out of the study is expected by the year-end.

- **Investment summary:** ValiRx is undervalued. 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)	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	-4,622	-5,292	-6,092
Statutory PBT	-3,641	-2,567	-5,569	-4,848	-5,525	-6,332
Underlying EPS (p)	-10.5	-7.7	-8.2	-3.4	-3.3	-3.8
Statutory EPS (p)	-13.5	-6.7	-8.2	-3.6	-3.5	-3.9
Net (debt)/cash	453	232	-734	-3,224	-8,073	-13,564
Capital increases	2,510	2,681	2,615	1,090	0	0

Source: Hardman & Co Life Sciences Research

VAL 401 update

ValiSeek

VAL401 is being progress through ValiSeek, a joint venture between ValiRx and Tangent Reprofiling

ValiSeek Limited was formed in 2014 to progress the drug 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 ValiRx plc (with 60%) and Tangent Reprofiling Limited (40%). The CEO of ValiSeek is Dr Suzanne Dilly, who was instrumental in discovering the anti-cancer activity of VAL401 using technology developed at the University of Warwick.

VAL401 is a proprietary formulation of the antipsychotic drug risperidone

ValiRx, together with ValiSeek, is developing VAL401, which is a new formulation of risperidone (Risperdal, Johnson & Johnson), originally developed for the treatment of schizophrenia. In contrast to the conventional tablet formulation of risperidone, VAL401 is a liquid lipid-filled capsule containing risperidone plus rumenic acid (a conjugated naturally occurring linoleic acid). Interestingly, the anti-cancer activity is only present in the specific patent protected formulation of VAL401 – i.e. no anti-cancer activity is found when risperidone or rumenic acid are administered alone.

Phase II trial update

Successful outcomes are expected to lead to a licensing deal

VAL401 is currently in Phase II trials for the treatment of advanced non-small cell lung cancer. Longer-term, and supported by the following data, ValiRx will be seeking a partner to take VAL401 through expensive late-stage trials.

- First dosing commenced in October 2016 at its trial site in Tbilisi, Georgia – three sites where involved in the trial
- Recruitment of 8 patients was completed in June 2017 and the trial closed to new patients
- Each patient initially received 2mg of VAL401 on the first day of treatment, which was escalated each day up to 10mg. Patients continued on 10mg or their MTD as evidenced by occurrence of side effects, such as tiredness.
- The data analysis is on the first 24h period after every patient received a single 2mg dose, orally, of VAL401, with 10 blood samples taken during the period
- For the pharmacokinetic aspects, the study measured blood levels of the active ingredient (risperidone) and its primary metabolite (9-hydroxy risperidone)
- Trial expected to be completed and results published by the year-end

Early pharmacokinetic data reveal a significant difference in absorption for VAL401 compared with risperidone, and provide an acceptable safety and tolerability profile

These early results indicate that VAL401 is readily absorbed, as evidenced by the presence of the active ingredient and its primary metabolite in the bloodstream. The pharmacokinetic analysis has revealed also a predicted significant difference in absorption and metabolism of VAL401 compared with the documented outcomes using conventionally formulated risperidone.

The blood levels of risperidone and its metabolite in patients taking VAL401 were consistent with those seen with comparable doses used in pre-clinical investigations. The safety and tolerability profile of 2mg of VAL401 in this patient population was also acceptable, which will be the dosing regimen used in subsequent trials.

These data represent an important step in ValiRx's development plan for VAL401. Being able to show that the drug is well absorbed and metabolised following a therapeutically active dose, consistent with those seen with the traditional tablet formulation. Further data analysis is being undertaken with headline results from the trial expected to be announced by the year end, paving the way to a licensing deal.

Financial summary

- No changes have been made to the company forecasts published in this report.

Financial forecast summary						
Year end Dec (£000)	**2014**	**2015**	**2016**	**2017E**	**2018E**	**2019E**
Profit & Loss						
SG&A	-1,362	-1,514	-1,645	-1,750	-1,837	-1,929
R&D	-1,622	-1,772	-1,543	-2,850	-3,421	-4,105
Other income	0	211	203	0	0	0
Underlying EBIT	**-2,856**	**-2,958**	**-2,888**	**-4,508**	**-5,165**	**-5,941**
Share based costs	0	-89	-49	-134	-141	-148
Statutory EBIT	-2,911	-3,138	-3,029	-4,734	-5,399	-6,182
Net financials	5	-503	462	-114	-126	-150
U/L pre-tax profit	**-2,850**	**-2,952**	**-2,889**	**-4,622**	**-5,292**	**-6,092**
Reported pre-tax	-2,906	-3,641	-2,567	-4,848	-5,525	-6,332
Tax liability/credit	308	397	391	744	893	1,072
Underlying net income	-2,647	-2,470	-2,440	-3,877	-4,399	-5,020
Underlying basic EPS (p)	**-19.1**	**-10.5**	**-7.7**	**-3.2**	**-3.1**	**-3.5**
Statutory Basic EPS (p)	-19.5	-13.5	-6.7	-3.4	-3.2	-3.7
Balance sheet						
Share capital	6,359	7,282	8,121	8,166	8,166	8,166
Reserves	-3,129	-4,520	-3,667	-9,920	-14,552	-19,812
Short-term loans	0	0	0	1,294	1,294	1,294
less: Cash	960	453	232	-1,930	-6,779	-12,270
Invested capital	**1,502**	**2,335**	**2,837**	**1,490**	**1,707**	**1,937**
Cashflow						
Underlying EBIT	-2,856	-2,958	-2,888	-4,508	-5,165	-5,941
Change in working capital	620	-366	-105	563	0	0
Company op cashflow	**-2,233**	**-3,317**	**-2,977**	**-3,939**	**-5,155**	**-5,936**
Capital expenditure	-134	-1	-32	0	0	0
Free cashflow	**-3,002**	**-2,622**	**-4,196**	**-4,196**	**-4,462**	**-5,104**
Capital increases	896	2,510	2,681	1,090	0	0
Change in net debt	**-1,301**	**-507**	**-220**	**-2,491**	**-4,849**	**-5,491**
Opening net cash	960	453	232	-734	-3,224	-8,073
Closing net cash	**453**	**232**	**-734**	**-3,224**	**-8,073**	**-13,564**

Source: Hardman & Co Life Sciences Research

MTD = Maximum Tolerated Dose

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