

**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 |
| | +44 20 3008 4416 |
| | www.valirx.com |

Key shareholders

| | |
|-----------------|------|
| Directors | 1.4% |
| Nicholas Slater | 3.5% |
| Yorkville | 1.8% |

Next event

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

Analysts

| | | |
|---------------|---------------|--|
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ValiRx**Progressing all the pipeline**

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. Interim results highlighted the fact that ValiRx is advancing well both its clinical and pre-clinical products, and crucially, read-outs of clinical results are expected at the end of the year for VAL201 and VAL401.

- **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.
- **Interims:** Results provided the occasion for ValiRx to update the market about the on-going clinical trials with VAL201 and VAL401, and pre-clinical works. Proceeds from £0.5m Placing will be used to progress the dose escalation study with VAL201 and continued development of GeneICE/VAL101 and VAL301.
- **Clinical pipeline:** The end of calendar year will be crucial for ValiRx with read-outs from both its clinical trials with VAL201 and VAL401. Early data released on both trials have been positive, with good safety and tolerability recorded, and are expected to pave the way to a potential licensing deal.
- **Pre-clinical pipeline:** Results from late pre-clinical studies on VAL301 suggest superiority compared to the standard of care. ValiRx aims to bring VAL101 into the clinic in 2018, since improvements to the manufacturing process of VAL101 compound have accelerated its future entry into the clinic.
- **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

2017 interim results

Development highlights

- ▶ **VAL201:** Recruitment is still on-going for the final arm of the Phase I/II trial in patients with advanced or metastatic prostate cancer. In addition to safety and tolerability, some early signs of efficacy have been recorded. Read-out is expected by year-end
- ▶ **VAL401:** Recruitment from three sites is now complete for the Phase II trial in locally advanced or metastatic non-small cell lung cancer. The trial is expected to report by the end of 2017
- ▶ **VAL101:** Pre-clinical studies and drug optimisation still on going for the Bcl2 gene silencing product. Post-period announcement reported that optimisation in the manufacturing process – production, purification –will speed-up the development of VAL101 towards the clinic
- ▶ **VAL301:** The reformulated version of VAL201 underwent 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. Final optimisation and the regulatory package are underway with the aim to enter the clinic in 2018

Corporate highlights

- ▶ **Advisory Board:** ValiRx has recently created and recruited an advisory board to provide and support the main Board with expertise in venture capital, life sciences, finance and contacts. The Board is comprised of three members: Seppo Mäkinen (ex-NED), Ajay Agrawal (current CSO), Andrew King (ex-CFO NeuTec).
- ▶ **Licensing agreement:** Post-period, ValiRx has signed a licensing agreement with Mystic Pharmaceuticals in Bangladesh to access ValiRx's pre-clinical asset for a period of five year

Financial highlights

- ▶ **R&D spend:** Investment in R&D increased by 13% to -£0.72m (-£0.64m) and was in line with our forecast
- ▶ **Administration:** SG&A cost increased by 11% to £0.96m
- ▶ **Net cash:** The company raised £1.16m in March 2017 which left net cash of nearly £0.4m at the period end; this has been boosted subsequently by the £0.5m Placing in in September

| ValiRx interims 2017 – actual vs expectations | | | | | |
|---|---------------|---------------|-------------|----------------|--------------|
| Half-year to end June (£m) | 1H'16 actual | 1H'17 actual | change % | 1H'17 forecast | Delta Δ |
| R&D spend | -0.638 | -0.723 | +13% | -0.75 | -0.03 |
| Administration | -0.866 | -0.903 | +4% | -1.05 | -0.09 |
| Underlying EBIT loss | -1.306 | -1.579 | -21% | -1.80 | -0.11 |
| Tax credit | +0.215 | +0.195 | -10% | +0.10 | +0.09 |
| Underlying net loss | -1.039 | -1.609 | -55% | -1.70 | +0.10 |
| Net cash/(debt) | 0.561 | -0.742 | | -0.76 | +0.05 |

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

Post-period highlights

- ▶ **R&D Tax Credits:** ValiRx received c.£650,000 in August from the HMRC in relation to its R&D investment
- ▶ **VAL401:** Positive pharmacokinetic data in late stage patients with non-small cell lung cancer were highlighted in our recent report entitled "*Positive early data from VAL401*" published on 28th September. Safety and tolerability were also confirmed in this Phase II trial. Full data analysis is underway

Anticipated newsflow

| Date | News |
|---------|---|
| 4Q 2017 | VAL 201 Phase II Read out |
| 4Q 2017 | VAL401 Phase II Read out |
| 2018 | VAL301 regulatory approval for first-in-man trial |

Source: Hardman & Co Life Sciences Research

Financial summary

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

Profit & Loss account

| 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 | -124 | -148 |
| U/L pre-tax profit | -2,850 | -2,952 | -2,889 | -4,622 | -5,289 | -6,089 |
| Reported pre-tax | -2,906 | -3,641 | -2,567 | -4,848 | -5,522 | -6,330 |
| Tax liability/credit | 308 | 397 | 391 | 744 | 893 | 1,072 |
| Underlying net income | -2,647 | -2,470 | -2,440 | -3,877 | -4,396 | -5,018 |
| Underlying basic EPS (p) | -19.1 | -10.5 | -7.7 | -2.7 | -2.2 | -2.5 |
| Statutory Basic EPS (p) | -19.5 | -13.5 | -6.7 | -2.9 | -2.3 | -2.6 |
| 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 | -14,549 | -19,807 |
| Short-term loans | 0 | 0 | 0 | 1,294 | 1,294 | 1,294 |
| less: Cash | 960 | 453 | 232 | -1,430 | -6,276 | -11,765 |
| Invested capital | 1,502 | 2,335 | 2,837 | 990 | 1,207 | 1,437 |
| 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 | -4,460 | -5,102 |
| Capital increases | 896 | 2,510 | 2,681 | 1,590 | 0 | 0 |
| Change in net debt | -1,301 | -507 | -220 | -1,991 | -4,847 | -5,488 |
| Opening net cash | 960 | 453 | 232 | -734 | -2,724 | -7,571 |
| Closing net cash | 453 | 232 | -734 | -2,724 | -7,571 | -13,059 |

Source: Hardman & Co Life Sciences Research

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