Pharmaceuticals & Biotechnology

Source: Eikon Thomson Reuters

Market data

EPIC/TKR	VAL
Price (p)	3.00
12m High (p)	7.75
12m Low (p)	0.90
Shares (m)	531.63
Mkt Cap (£m)	7.92
EV (£m)	6.33
Free Float*	99%
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	0.5%

Diary

4Q'18	VAL201 readout
Mar'19	Results

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VALIRX

VAL401 Phase II trial completed

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 recent release of the interim results has been a good opportunity for VAL to update the market on its pipeline of clinical and pre-clinical products.

- **Strategy:** VAL operates as a virtual business, outsourcing 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 its products

- **Interims:** VAL highlighted that VAL401 Phase II had been completed and progress on VAL201 Phase II was going apace (interim or provisional data due by year-end). In the meantime, both pre-clinical assets are approaching key decision points. Cash at 30 June of £0.52m has been boosted by a post-period Placing of £1.15m gross.

- **VAL401:** The main event is the completion of the Phase II trial with VAL401 in patients with late-stage lung cancer. The data confirmed the palliative effect and improvement of quality of life in the patients treated. VAL is currently in discussions with potential partners for starting a Phase III trial, expected next 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.

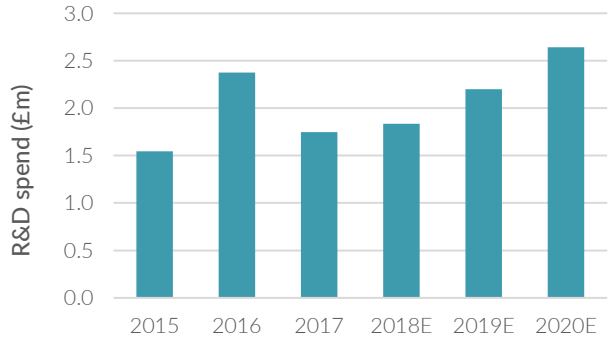
- **Investment summary:** VAL is undervalued relative to its peers at a similar stage of development. The reason for this is certainly its need for more capital to advance its clinical programmes – thereby building value. Given the clinical progress seen to date, the company should be attracting potential 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	-1,761	-1,849	-1,941
R&D	-1,543	-2,375	-1,747	-1,834	-2,201	-2,641
EBITDA	-2,877	-3,939	-2,938	-3,418	-3,873	-4,405
Underlying EBIT	-2,980	-4,042	-3,125	-3,595	-4,050	-4,582
Reported EBIT	-3,029	-3,987	-3,125	-3,595	-4,050	-4,582
Underlying PBT	-2,981	-4,380	-3,575	-3,592	-4,047	-4,598
Statutory PBT	-2,567	-5,569	-3,554	-3,592	-4,047	-4,598
Underlying EPS (p)	-8.0	-6.2	-2.0	-0.7	-0.7	-0.7
Statutory EPS (p)	-6.7	-8.2	-2.0	-0.7	-0.7	-0.7
Net (debt)/cash	232	-734	311	521	-3,092	-7,168
Capital increases	2,681	2,615	3,602	3,384	0	0

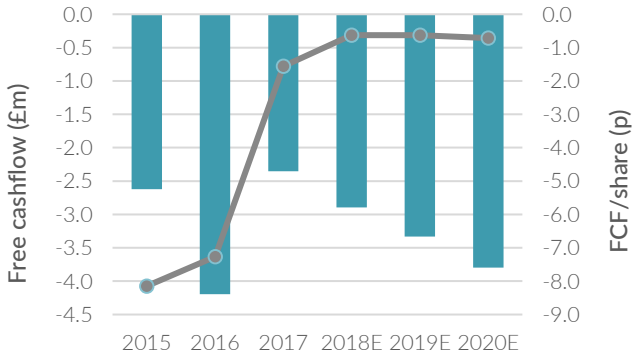
Source: Hardman & Co Life Sciences Research

R&D investment



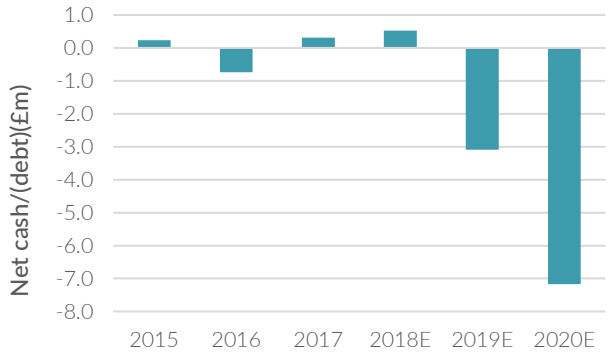
- VAL outsources all its research
- R&D expenditure is expected to increase with the new clinical programmes

Free cashflow and FCF/share



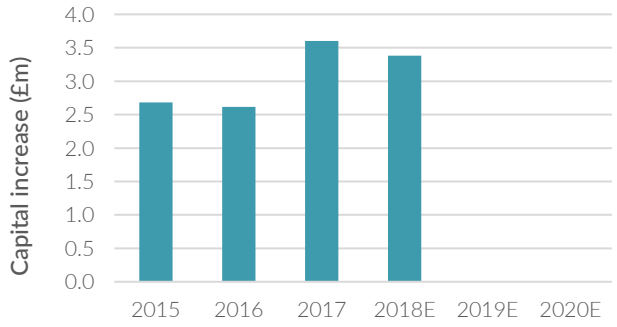
- Cashflow is driven by corporate overheads (SG&A) and R&D investment, offset by tax credits on R&D investment
- The monthly average cash burn is ca.£0.27m
- Manufacturing costs of clinical trial material were borne in fiscal 2016, which impacted cash flows
- VAL received an R&D tax credit of £0.42m in September 2018

Net cash



- Net cash at 30 June 2018 was £0.52m, with conversion into equity of all the convertible loan
- A Placing in September 2018 raised gross new funds of £1.15m (estimated £1.05m net)
- Our cash projections suggest that VAL will have sufficient funding until the end of the financial year

Capital increases



- During the first half of the year, VAL raised £2.07m gross of new capital by way of four Placings
- In 1H'18, £0.43m of bonds were converted into equity
- Post period-end the company undertook a Placing, raisin £1.15m gross

Source: Company data; Hardman & Co Life Sciences Research

2018 interim results

Development highlights

- VAL401: Completion of the Phase II trial in late-stage lung cancer, with data confirming the palliative effect and quality of life improvement in the small cohort of patients treated. VAL received confirmation of acceptance of the Clinical Study Report.
- VAL201: Safety and tolerability have been confirmed in the ongoing Phase I/II trial in patients with advanced or metastatic prostate cancer. Recruitment is continuing, with the MHRA decision to increase the dosing level, showing confidence in VAL201 and raising the probability of efficacy. Interim data or provisional VAL201 data are expected by year-end.
- VAL101: A second generation of VAL101 derived from its proprietary GeneICE platform has been generated, with an improved manufacturing process. Pre-clinical studies confirmed the inhibition of the Bcl-2 gene activity and apoptosis of cancer cells.
- 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, which are 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 2019.

Financial highlights

- R&D spend: Investment in R&D increased by 18% to -£0.85m (-£0.72m), below our forecast, and in line with the clinical effort and the completion of the Phase II trial with VAL401.
- Administration: SG&A costs increased by 21% to -£0.92m (-£0.76m).
- Net cash: VAL raised a total of £2.0m during the first half of the financial year and most of the outstanding bonds were either converted or repaid. At the period-end, the net cash was £0.59m, which was subsequently boosted by a Placing of £1.15m gross realised in September.

ValiRx – half-year results – actual vs expectations

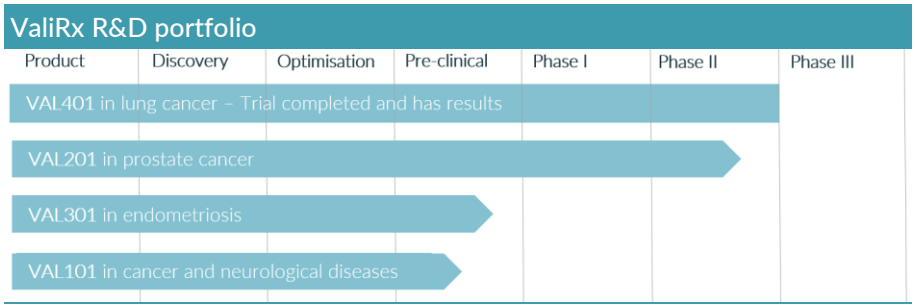
Dec Period-end (£m)	1H'17 actual	1H'18 actual	change %	1H'18 forecast	Delta Δ
R&D spend	-0.72	-0.85	+18%	-0.92	+0.07
Administration	-0.76	-0.92	+21%	-0.89	-0.03
Underlying EBIT loss	**-1.48**	**-1.77**	**+20%**	**-1.80**	**+0.03**
Tax credit	+0.19	+0.19	0%	-	-
Underlying net loss	**-1.51**	**-1.55**	**+3%**	**-1.58**	**+0.03**
Net cash/(debt)	-0.73	+0.59		+0.56	-0.04

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 (EU and US) and VAL301 (US).

Pipeline progress



Source: ValiRx, Hardman & Co Life Sciences Research

Clinical trial update

VAL401 in lung cancer – Phase II completed

The Phase II with VAL401 in late-stage lung cancer is now completed, with data fully accessible through the ClinicalTrials.gov website

VAL401 is the lead, asset and the Phase II trial has now been completed with excellent positive data on end-stage lung cancer patients. The programme has been progressed through a partnership between VAL and SEEK, which is called ValiSeek. VAL401 is a proprietary formulation of risperidone, an established CNS drug, and it is this specific formulation that confers the molecule anti-cancer activity.

The company has indicated that full data are now accessible through the ClinicalTrials.gov website (*www.ClinicalTrials.gov*), under the code name NCT02875340. This concludes all obligations on trials reporting. Also, VAL intends to publish the results and interpretation of the trial in peer-reviewed scientific journals.

Key definitions

These are 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 OS 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 the disease does not get worse. In a clinical trial, measuring PFS is one way to see how well a new treatment works.

Background

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

Eligibility for 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 OS 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.

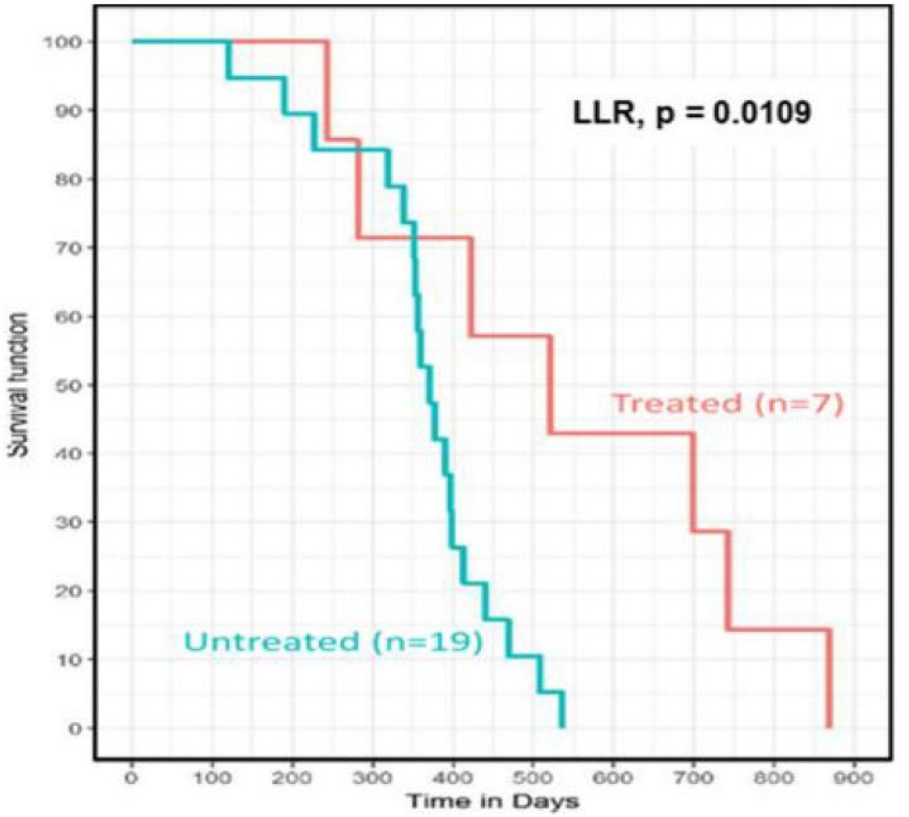
Clinical evidence

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

Statistical evidence shows a clear distinction between VAL401 and the control arms, highlighted by the Kaplan-Meier survival graph

The Kaplan-Meier graph 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 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.

Kaplan-Meier survival graph



Source: ValiRx,

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 an increase in mean PFS and in mean OS of 8.7 weeks and 12.9 weeks, respectively, compared with the non-responder population, at 4.3 weeks and 7.1 weeks, respectively. The difference and rationale between responders and non-responders to VAL401 is not clear yet, and will be investigated in future trials.

…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 expectation of the late-stage lung cancer patients and, also another important factor for this late-stage type of population, 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 general improvement in quality of life – for responders and non-responders, including:

- improvement in pain (4);
- improvement in insomnia (2);
- improvement in appetite (2);
- improvement in depression (2);
- improvement in irritability (1);
- improvement in fatigue (3) and ability to take part in leisure activities (2);

Next steps

A Phase III trial is expected to be run with or by a partner

A proposed Phase III trial in ca.200 NSCLC patients with and without standard-of-care will be run either with or by a partner. Management has indicated that discussions are under way, with several potential partners for the further development of VAL401.

VAL201 in prostate cancer – dose increased

Clinical update

VAL is currently undertaking a Phase I/II open-label dose escalation study with VAL201, registered on clinicaltrials.gov, under the code name NCT02280317, which is being run from University College London Hospital (UCLH). The trial is assessing the safety and tolerability of VAL201 in up to 50 invited patients with advanced or metastatic prostate cancer. It is also targeting patients with advanced solid tumours for whom no effective standard therapy is available.

The Phase I/II trial with VAL201 in advanced prostate cancer patients provides safety and tolerability data and the expected modulations of key proteins

VAL201 has proven to be safe and well tolerated, with some efficacy on patients' pharmacodynamic data where there is a dose-related modulation of the androgen, prostate-specific antigen (PSA), and various cell and protein turnover factors. These modifications in a patient's biology are essential when treating prostate cancer patients.

First data anticipated by year-end

There was a review of the protocol at the end of 2017, with VAL receiving the authorisation to escalate both the dose and frequency of administration from the MHRA and the research ethics committee. The decision represents a big step forward for VAL201, with the dose increased four times from 4mg to 16mg – thereby raising the potential for VAL201 to show anti-cancer efficacy. VAL has indicated that patients are now entering the final stage of the trial, and receiving the escalated dose of the therapeutic. Recruitment is still on going and interim data or provisional VAL201 data are anticipated by the year-end.

Background

In prostate cancer cells, steroid hormones and/or epidermal growth factors trigger the association of the androgen receptor (AR) and/or the oestrogen receptor (ER) complex with Src kinase. This interaction activates the Src protein, causing a cascade of activation, which ultimately stimulates DNA synthesis, cell cycle progression and proliferation.

VAL201 has a novel mechanism of action in preventing the association between AR and ER

VAL201 is a peptide, with a novel mechanism that inhibits the interaction between the AR/ER complex and the Src docking protein, without preventing the association between AR and ER, which is crucial in bone health, for example. By targeting a specific domain of the Src kinase, VAL201 aims to treat the cancer without causing side effects that include loss of libido, erectile dysfunction, infertility, hot flushes, extreme tiredness, weight gain, strength and muscle loss, breast-swelling, bone-thinning, risk of heart disease, stroke, diabetes and mood swings.

Pre-clinical developments

VAL301 – reduction of endometrial lesions

The Phase I study with VAL301 in endometriosis is expected to start in 2H'18-1H'19

The reformulated version of VAL201, targets the gynaecological disorder, endometriosis, and is hypothesised to have a lower side effect potential compared with the current standard-of-care. The dose increase of VAL201 authorised by the MHRA provides confidence in the safety of the product in the future Phase I study with VAL301. The product is currently undergoing late-stage pre-clinical studies, with the aim of having a complete pre-clinical package with the optimal formulation around year-end 2018.

Pre-clinical studies have demonstrated the efficacy of VAL301 with a reduction of 50% in the endometrial lesions in animal models. VAL is continuing with the late pre-clinical works, aiming to submit an IND to start clinical trials in 2H'18-1H'19, depending on the funding requirement and regulatory clearance.

VAL101 – triggers cancer cell death

VAL101 is a product derived from the GeneICE platform, targeting the Bcl-2 gene

VAL101 targets and silences the gene that expresses Bcl-2, an oncogenic protein that plays a crucial role in cell death regulation. The product is derived from the proprietary GeneICE (Gene Inactivation by Chromatin Engineering) platform, which is designed to efficiently silence targeted genes. This technology is based on natural mechanisms and has the potential to halt and reverse tumour growth.

Having finalised and improved the manufacturing process of VAL101, pre-clinical works are still ongoing through a consortium of partners Deutsche Krebsforschungzentrum (DKFZ), the Institute of Oncology in Heidelberg, and Pharmatest Services Limited, a specialist clinical research organisation in Finland. VAL has demonstrated the generation of cancer cell death (apoptosis) through the inhibition of the Bcl-2 gene expression with VAL101. Pre-clinical works are still ongoing in animal models, and VAL aims to submit VAL101 in the clinic in due course.

Financial summary

- VAL 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.
- **R&D:** investment in R&D is expected to increase in line with new assets going into the clinic.
- **Net cash:** following the post-period Placing of £1.15m gross, our forecasts suggest VAL to have sufficient cash until the year-end.
- **Convertible loan:** all of the outstanding convertible loan was converted into equity during the period, with the elimination £0.43m from long-term debt.

Financial summary

Year-end-Dec (£000)	2015	2016	2017	2018E	2019E	2020E
Profit & Loss						
SG&A	-1,514	-1,645	-1,467	-1,761	-1,849	-1,941
R&D	-1,772	-1,543	-1,747	-1,834	-2,201	-2,641
Other income	211	203	89	0	0	0
Underlying EBIT	**-3,049**	**-2,980**	**-3,125**	**-3,595**	**-4,050**	**-4,582**
Share-based costs	-89	-49	0	0	0	0
Statutory EBIT	-3,138	-3,029	-3,125	-3,595	-4,050	-4,582
Net financials	-503	462	-429	3	3	-15
Underlying pre-tax profit	**-3,042**	**-2,981**	**-3,575**	**-3,592**	**-4,047**	**-4,598**
Reported pre-tax	-3,641	-2,567	-3,554	-3,592	-4,047	-4,598
Tax liability/credit	397	391	416	437	525	630
Underlying net income	-2,567	-2,532	-3,040	-3,154	-3,523	-3,968
Underlying basic EPS (p)	**-11.0**	**-8.0**	**-2.0**	**-0.7**	**-0.7**	**-0.7**
Statutory basic EPS (p)	-13.5	-6.7	-2.0	-0.7	-0.7	-0.7
Balance sheet (@31 Dec)						
Share capital	7,282	8,121	8,433	8,537	8,537	8,537
Reserves	-4,520	-3,667	-5,255	-8,514	-12,037	-16,005
Short-term loans	0	0	390	0	0	0
less: Cash	453	232	701	521	-3,092	-7,168
Invested capital	**2,335**	**2,837**	**2,724**	**-640**	**-433**	**-324**
Cashflow						
Underlying EBIT	-3,049	-2,980	-3,125	-3,595	-4,050	-4,582
Change in working capital	-366	-105	69	100	100	100
Company op. cashflow	**-3,317**	**-2,977**	**-2,952**	**-3,318**	**-3,773**	**-4,305**
Capital expenditure	-1	-32	0	0	0	0
Free cashflow	**-2,622**	**-4,196**	**-2,351**	**-2,894**	**-3,333**	**-3,796**
Capital increases	2,510	2,681	3,602	3,384	0	0
Change in net debt	**-507**	**-220**	**1,045**	**210**	**-3,613**	**-4,076**
Opening net cash	453	232	-734	311	521	-3,092
Closing net cash	**232**	**-734**	**311**	**521**	**-3,092**	**-7,168**

Source: Hardman & Co Life Sciences Research

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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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