hardman&co

Pharmaceuticals & Biotechnology

Source: Eikon Thomson Reuters

Market data

EPIC/TKR	**AGY**
Price (p)	25.5
12m High (p)	39.5
12m Low (p)	23.0
Shares (m)	594.1
Mkt Cap (£m)	151.5
EV (£m)	128.9
Free Float*	37%
Market	AIM

**As defined by AIM Rule 26*

Description

AGY develops, manufactures and sells products related to prevention, diagnosis and treatment of allergic conditions, with a special focus on allergy vaccination for successful treatment of the underlying cause and not just of the symptoms.

Company information

CEO	Manuel Llobet
CFO	Nick Wykeman
Chairman	Peter Jensen
	+44 1903 845 820
	www.allergytherapeutics.com

Key shareholders

Directors	0.7%
Abbott Labs	40.5%
Southern Fox	21.4%
Odey	7.4%
Invesco	4.8%

Diary

16th Feb	Hardman PQ Grass report
2Q'18	Ph.II PQ Grass trial
2H'18	Ph.III PQBirch trial
Sept-18	Finals

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Allergy Therapeutics

Clinical development towards submission

AGY is a long-established specialist in the prevention, diagnosis and treatment of allergies. Pollinex Quattro (PQ) Grass, the subcutaneous allergy immunotherapy (AIT), continues to gain market share despite being available in the EU only on a 'Named Patient' basis. The Phase III trial, designed to obtain approval for PQ Birch as a biologic in Europe, is well advanced, and the Phase II PQ Grass trial will report data shortly. As explained in the February trading update, underlying 1H'18 sales growth, although weaker than expected due to a low pollen season in central Europe, suggests that AGY has continued to make market share gains.

- **Strategy:** AGY is a fully integrated pharmaceutical company focused on the treatment of allergies. There are three parts to its strategy: continued development of its European business via investment or opportunistic acquisitions; the US PQ opportunity; and further development of its pipeline.

- **Interims:** Underlying sales grew 1.3% to £42.2m (£40.4m) in 1H'18 despite an unexpectedly weak pollen season, which suggests further market share gains. Careful control of costs (marketing -2% at CER) and working capital, plus timing of the planned increase in R&D spend, generated a cash position of £25.8m.

- **Clinical update:** Of note, the PQ Birch Phase III trial completed recruitment in 1H fiscal 2018. The next step will be application to the European Commission for full approval of PQ Birch as a biological, expanding access in Europe. The Phase II PQ Grass trial will soon report data, advancing towards US market entry.

- **Forecasts:** Our forecasts for the full year have not changed; they were last altered following the February 2018 trading update. Total R&D investment is forecast to accelerate in 2H'18 and rise further, as larger US trials and further Phase II trials get under way.

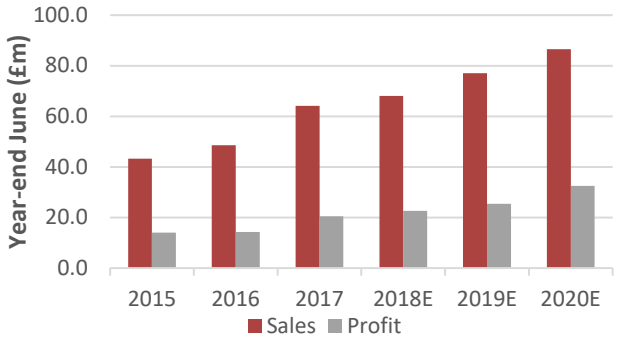
- **Investment summary:** AGY is in an exciting period, with a clear vision, gaining market share from competitors, and leading the race to have its products fully approved and regulated as biologicals – first in Europe, then in the US, where the regulators are demanding change. Read-out from the EU Phase III birch and US and EU Phase II grass trials will provide the next major value inflection points.

Financial summary and valuation

Year-end June (£m)	2015	2016	2017	2018E	2019E	2020E
Sales	43.23	48.51	64.14	68.0	77.0	86.5
R&D investment	-3.12	-16.22	-9.30	-18.0	-16.0	-8.0
Underlying EBIT	2.91	-12.34	-2.89	-9.7	-5.9	8.1
Reported EBIT	1.41	-12.53	-2.60	-10.4	-6.6	7.4
Underlying PBT	2.84	-12.45	-2.97	-9.8	-6.0	8.0
Statutory PBT	0.65	-12.21	-2.67	-10.5	-6.7	7.3
Underlying EPS (p)	0.48	-2.36	-0.47	-1.7	-1.0	1.2
Statutory EPS (p)	0.02	-2.29	-0.42	-1.8	-1.1	1.2
Net (debt)/cash	20.14	20.04	18.80	8.5	3.2	14.0
Capital increase	20.08	10.97	0.03	0.3	0.3	0.3
P/E (x)	52.8	-10.8	-54.4	-15.4	-26.3	21.1
EV/sales (x)	3.0	2.7	2.0	1.9	1.7	1.5

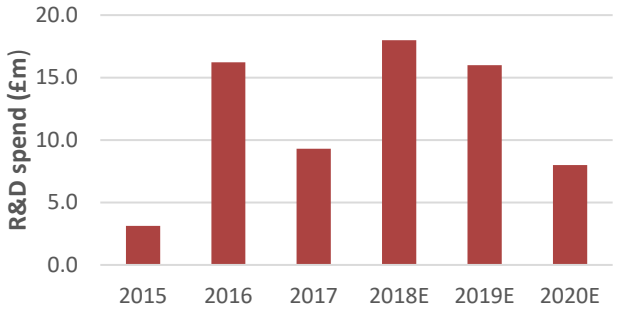
Source: Hardman & Co Life Sciences Research

Product analysis



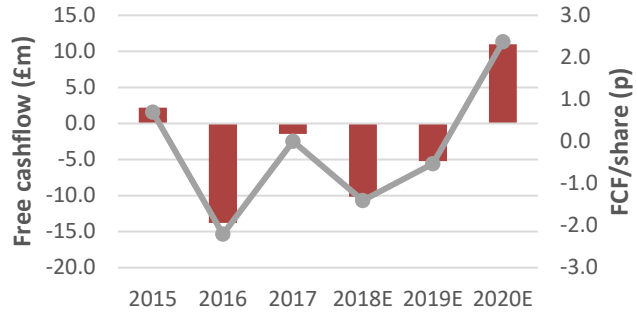
- AGY has a solid existing portfolio of products for AIT
- Products have shown consistent growth over the last five years, even though their availability is limited
- After taking account of manufacturing, distribution and marketing costs, in-market products are profitable
- Product margins have risen consistently over the last five years, reaching 31.9% in fiscal 2017

R&D investment



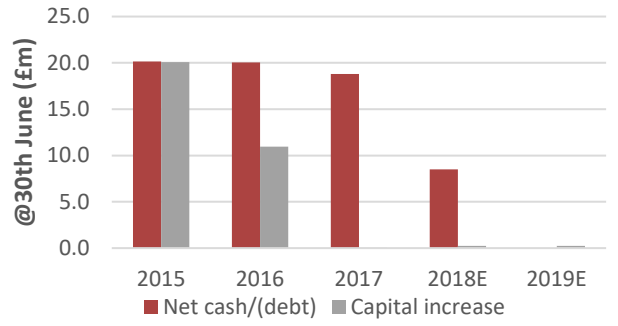
- Cumulative investment in R&D since 2000 has been >£105m
- R&D investment is forecast to rise substantially to get Pollinex Quattro products onto the market in the US and formally approved in Europe
- Three key trials for the US and Europe will cost ca.£40m over the next two years, but will pave the way to regulatory approvals in a changing marketplace

Free cashflow and FCF per share



- In each of the last four years, AGY has generated free cashflow from its operating activities (before R&D)
- Considerable investment in R&D and marketing will result in two years of cash burn
- Cash requirement towards the end of this decade will be dependent on the commercialisation strategy in the US
- In following the inorganic growth strategy, although acquisitions tend to be small, more cash could be required

Net cash/(debt)

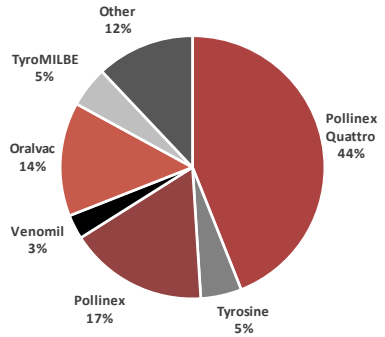


- £20m was raised in March 2015, largely to fund the key US trials
- Based on current forecasts, the net cash position will near a neutral position at the end of fiscal 2019
- Should management decide to commercialise Pollinex Quattro in the US by itself, AGY will require working capital for investment in sales infrastructure

Source: Company data; Hardman & Co Life Sciences Research

Interim results

Sales by product – fiscal 2017



Source: Allergy Therapeutics

Key features

- **Sales:** Sales were reported to the market in the January trading update, with underlying growth of 1.3% to £42.2m (£40.4m); the reported number includes a small currency benefit on translation of +£1.3m.
- **COGS:** Manufacturing costs were lower than expected, at -£8.7m, reflecting an acceleration in production in 1H to provide manufacturing capacity for clinical trial material in 2H. The excess stock is shown in the balance sheet. The gross margin increased 1.5 percentage points (pps) to 79.4% (77.9%).
- **Marketing:** Underlying marketing spend, undertaken mostly in Europe, fell 2% to a reported level of -£14.3m (-£13.8m), which was slightly greater than forecast. This spend provides a natural hedge against forex movement.
- **Product profitability:** One of our key measures of group performance – product profit – rose 9.1% to £19.3m (£17.7m), with margins rising 1.9pps to 45.6%.
- **R&D:** Although R&D increased significantly (55%) in 1H'18 to -£5.9m (-£3.8m), this was still less than forecast prior to the trading update. The increase was due to the running of the Grass MATA MPL Phase II and the PQ Birch Phase III trials. Overall expenditure in 2018 is expected to be around -£18.0m as the clinical programmes accelerate in the second half of the year.
- **G&A:** Tight control of administration costs resulted in a decrease to -£6.7m (-£7.2m) on an underlying basis, which excludes non-cash items such as share-based costs and retranslation of overseas assets at period-end rates.
- **Underlying EBIT:** Operating profit was flat at £6.7m, generating a margin of 15.7% (16.5%). This was due entirely to the lower sales growth in a weaker-than-expected market, as described in detail in our note on the trading statement.
- **Net cash/(debt):** £22.6m at the end of the reporting period represented a rise of £3.8m compared with the position at the end of June 2017.

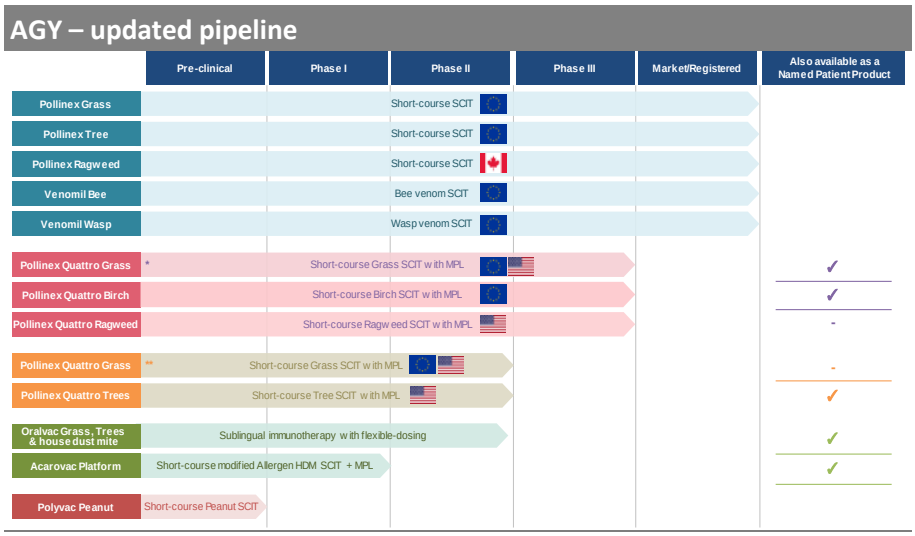
Interim analysis

Half-year analysis £m	1H'17 actual	1H'18 actual	1H'18 forecast	Delta Δ
Sales	40.4	42.2	*42.2	0.0
COGS	-8.9	-8.7	-9.2	+0.5
Gross profit	31.5	33.5	33.0	+0.5
Gross margin	77.9%	79.4%	78.2%	+1.2pp
Marketing	-13.8	-14.3	-13.6	-0.7
Product profit	**17.7**	**19.3**	**19.4**	**-0.2**
Product margin	43.7%	45.6%	45.9%	-0.3pp
G&A	-7.2	-6.7	-6.5	-0.2
R&D	-3.8	-5.9	-6.0	+0.1
EBITDA	**7.6**	**7.6**	**7.6**	**0**
Depreciation	-0.8	-1.0	-0.8	-0.2
Other income	0.0	0.0	**0.0**	-
Underlying EBIT	**6.7**	**6.7**	**6.8**	**-0.1**
EBIT margin	16.5%	15.7%	16.1%	-0.4pp
Underlying PBT	6.7	6.6	6.8	-0.2
Net cash/(debt)	**24.4**	**22.6**	**22.5**	**+0.1**

**As reported in February trading update*
Figures may not add up exactly due to rounding
Source: Hardman & Co Life Sciences Research

Operational update

Although PQ has been available in the EU for several years as the only short-course subcutaneous immunotherapy (SCIT), this has only been on a 'Named Patient' basis which limits the claims that can be made and the marketing of the product. Over the last six months, good progress has been made in the two clinical programmes for PQ pollen allergy vaccines that are underway as part of the process of achieving full regulatory approval as a biological in both Europe and the US, in order to expand their market potential. A further allergy vaccine, Polyvac Peanut, which is part of the food allergy pipeline, is progressing towards clinical development, with a focus on the US market. AGY's current pipeline is shown in the following graphic.



**0.5mn formulation, **1.0m formulation*
Source: Allergy Therapeutics

Driven by the Paul Ehrlich Institute based on European legislation, the Therapieallergene-Verordnung (TAV, Therapy Allergy Ordinance) process commenced in 2008, with the goal of having a number of fully regulated allergy vaccines. At the beginning of the process, documentation for 123 vaccines was submitted to the TAV for consideration, which included 10 from AGY. At the Paul Ehrlich Institute (PEI) seminar in 2017, a number of competitor products (estimated at ca.40%) have had applications withdrawn or turned down, although none of these are related to AGY's products, improving the company's position in the wider competitive landscape.

Ongoing clinical development

Birch

Recruitment into the pivotal PQB301 Phase III study, which is designed to evaluate the safety and efficacy of PQ Birch, is now fully recruited. 560 patients from 59 centres in four European countries have been immunised and will be assessed during the 2018 birch pollen season (May through July) to measure any allergy rhinoconjunctivitis symptoms. Results are due in the second half of calendar 2018, representing the next major value inflection point. Following this, the next step will be to submit its application to the PEI for market authorisation in Europe.

Grass

As part of the new clinical strategy, redesigned with the FDA following unexpected results from a US dose-finding study, recruitment of more than 440 patients in over 50 centres was completed successfully, ahead of schedule, for the Phase II G205 PQ Grass study. This trial is evaluating dose-response and safety towards licensing applications in both Europe and the US. Headline results are now expected to be released early in the second half of 2018 (first half of AGY's fiscal 2019).

Preparation for clinical trials

Polyvac Peanut

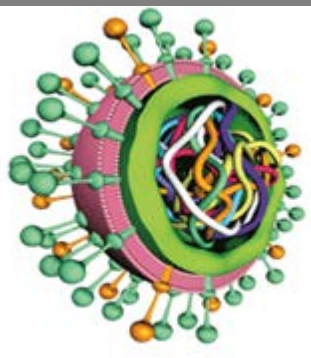
In November 2015, AGY purchased a licence for access to virus-like particle (VLP) technology for use in its programmes, including for a vaccine against peanut allergy. An estimated 2-3 million children in the US alone are allergic to peanuts, and Polyvac Peanut is being developed to counter the huge unmet need in this population. The market is estimated at $8bn per year globally. VLPs are recombinant constructs consisting of a viral envelope studded with antigen specific to the allergen, meaning that the VLP is readily recognised by the immune system. This primes immunity against the allergen itself should it be encountered in the future.

CMC agreement

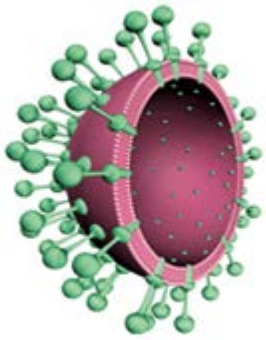
Having shown strong early safety and efficacy in pre-clinical models, Polyvac Peanut is now ready to enter clinical development. Immunisation with the candidate vaccine protected against anaphylaxis during challenge with peanut allergen and moreover, induced protective (long-term) immunity. The vaccine itself did not induce anaphylaxis.

Chemistry, manufacturing, and controls (CMC) processes are now under way, with AGY announcing an agreement with the Contract Manufacturing Organisation (CMO), AGC Biologics, in February 2018. AGC Biologics will develop scaled-up manufacturing of Polyvac Peanut in preparation for clinical trials; it has experience with clinical GMP production of VLP constructs and specialises in manufacture of recombinant biological products.

Virus-like particles



Virus containing DNA



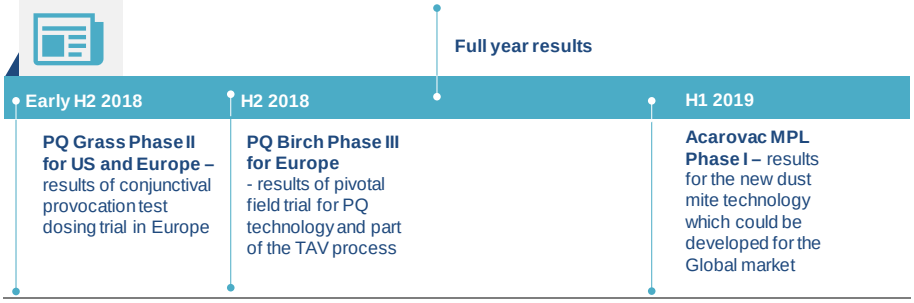
Virus-like particle

Source: Medicargo

Expected pipeline news flow

Given that recruitment for the two trials has been completed and, in the case of PQ Grass, is ahead of expectations, the revised timetable of expected trial news flow is shown in the following graphic.

Expected news flow – updated



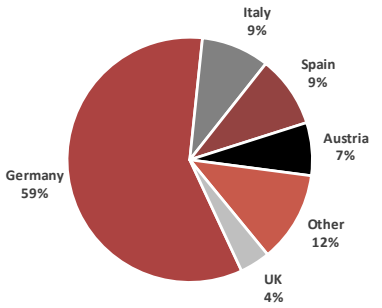
Source: Allergy Therapeutics

Sales performance

Growth in flat market

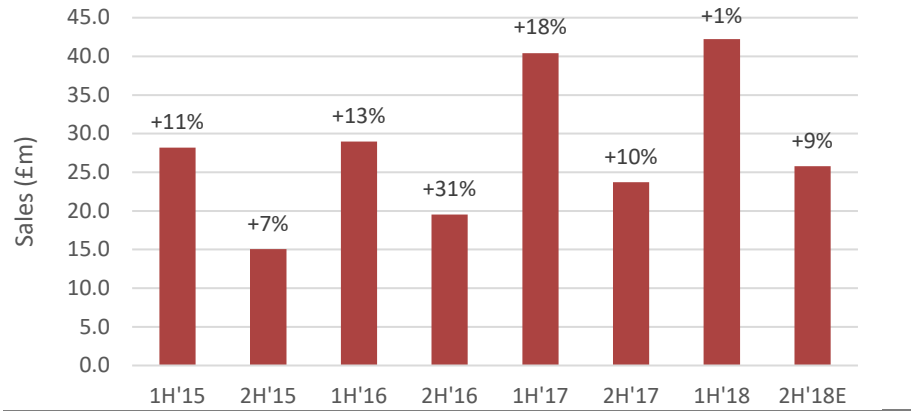
Our sales forecasts for fiscal 2018 were updated at the time of the trading statement, to reflect the lower-than-expected rate of growth seen during 1H'18, resulting from a weak pollen season (May to July): 'Growth in a tough market'[1]. Sales are seasonal, with a heavy bias to the first half of the financial year.

Sales by territory – fiscal 2017



Source: Allergy Therapeutics

AGY – first-half sales trends and CER growth rates



Source: Hardman & Co Life Sciences Research

The majority of AGY's activities are in Europe, with Germany being the biggest single market. During 1H'18, sales grew 1.3% to £42.2m. Although this was less than had been expected, there were reports[2] and data from IMS Quintiles that the overall market was flat, suggesting that AGY outperformed the market and increased market share.

Competitor performance

ALK's sales fell by 2% over the same reporting period…

…and it is anticipating a further decline in 2018

Recent results from ALK-Abello (ALK), the market leader in AIT both globally and in Europe, indicated that it had seen a 2.2% decline in sales over the same reporting period (2H calendar 2017). Moreover, although it reported that the overall market for AIT in Europe had grown by about 10% in 2017, much of this was due to a recovery in the supply chains encountered by Stallergenes Greer (STAGR) in 2016. In addition, despite this improvement in the overall European market, ALK expects that its sales will decline further in 2018, caused by price and reimbursement pressure, as well as capacity constraints.

Stallergenes is recovering form manufacturing issues in 2016…

…but does not appear to have solved all of these completely

STAGR has not yet reported its 2017 results (due 22nd March). Given its manufacturing and supply issues in 2016, it re-entered the market last year, which resulted in a strong sales performance in 1H'17. Current market forecasts suggest that its European sales will only just approach the levels seen in 2015 before its problems arose. Interestingly, STAGR also reported (25th January) that it had received an injunction following an inspection of its SCIT manufacturing facility by the French National Agency for Medicines and Health Products Safety, although it claims that this will not affect current business.

[1] http://www.hardmanandco.com/docs/default-source/company-docs/allergy-therapeutics-documents/02.02.18-growth-in-a-tough-market.pdf
[2] http://www.meteosuisse.admin.ch/content/dam/meteoswiss/fr/service-und-publikationen/publikationen/doc/bulletin_climato_saison_fruehling-2017_f.pdf

Summary financials

- **Forecasts:** Our forecasts for 2018 have not changed; they were last altered following the February 2018 trading update (http://www.hardmanandco.com/docs/default-source/company-docs/allergy-therapeutics-documents/02.02.18-growth-in-a-tough-market.pdf)**.** All forecasts are based on constant currency.
- **Sales:** Underlying sales growth of 6% is forecast for fiscal 2018. With R&D spend heavily biased to 2H'18, this gives an expected cash balance of £16.8m and net cash of ca.£8.5m at the end of June 2018.

Summary financials

Year-end June (£m)	2015	2016	2017	2018E	2019E	2020E
GBP:EUR	1.270	1.338	1.171	1.171	1.171	1.171
Profit & Loss:						
Sales	43.23	48.51	64.14	68.01	77.04	86.49
COGS	-12.18	-14.07	-16.77	-17.51	-19.53	-17.08
Gross profit	31.05	34.44	47.37	50.50	57.51	69.41
Gross margin (%)	71.8%	71.0%	73.9%	74.3%	74.7%	80.3%
SG&A	-17.06	-20.22	-26.89	-27.90	-32.14	-36.95
Product profit	**13.99**	**14.22**	**20.48**	**22.60**	**25.37**	**32.46**
Product margin (%)	**32.4%**	**29.3%**	**31.9%**	**33.2%**	**32.9%**	**37.5%**
G&A	-8.03	-10.33	-14.08	-14.28	-15.25	-16.35
R&D	-3.12	-16.22	-9.30	-18.00	-16.00	-8.00
EBITDA	**4.20**	**-10.68**	**-1.24**	**-8.02**	**-3.94**	**10.05**
Depreciation	-1.01	-1.39	-1.66	-1.66	-1.94	-1.94
Underlying EBIT	2.91	-12.34	-2.89	-9.68	-5.88	8.11
EBIT margin (%)	6.7%	-25.4%	-4.5%	-14.2%	-7.6%	9.4%
Net interest	-0.07	-0.11	-0.07	-0.13	-0.13	-0.12
Pre-tax profit	**2.84**	**-12.45**	**-2.97**	**-9.80**	**-6.01**	**7.99**
Tax	-0.55	-0.86	0.19	-0.04	0.24	-0.45
Net income	2.29	-13.46	-2.78	-9.84	-5.76	7.18
Weighted av. shares (m)	475.2	570.3	592.2	594.1	594.1	594.1
Underlying EPS (p)	**0.48**	**-2.36**	**-0.47**	**-1.66**	**-0.97**	**1.21**
Balance sheet:						
Share capital	0.56	0.60	0.60	0.60	0.60	0.60
Reserves	33.91	29.73	29.36	18.82	12.35	19.19
Liabilities	7.26	11.95	10.67	10.67	10.67	10.67
Debt	1.84	3.37	3.33	8.33	18.33	7.50
less: Cash	21.98	23.41	22.12	16.84	21.49	21.49
Invested capital	**27.86**	**39.32**	**42.66**	**53.41**	**59.52**	**54.01**
Net cash/debt	20.14	20.04	18.80	8.51	3.16	13.99
Cashflow:						
Underlying EBIT	2.91	-12.34	-2.89	-9.68	-5.88	8.11
Working capital	0.21	-1.45	2.16	0.04	1.67	4.66
Tax & interest	-0.41	-0.30	-1.28	-0.64	-0.85	-0.62
Operational cashflow	**3.31**	**-12.57**	**0.03**	**-8.33**	**-3.13**	**14.08**
Capital expenditure	-1.09	-1.23	-1.50	-1.80	-2.07	-3.11
Free cashflow	**2.22**	**-13.80**	**-1.47**	**-10.13**	**-5.20**	**10.98**
Acquisitions	-2.67	0.00	-0.23	-0.10	-0.10	-0.10
Share issues	20.08	10.97	0.03	0.25	0.25	0.25
Change in net debt	**17.88**	**-0.10**	**-1.25**	**-10.28**	**-5.35**	**10.83**
Hardman FCF/sh. (p)	0.70	-2.20	0.01	-1.40	-0.53	2.37

Source: Hardman & Co Life Sciences Research

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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

In addition, it should be noted that MiFID II's main aim is to ensure transparency in the relationship between fund managers and brokers/suppliers, and eliminate what is termed 'inducement', whereby free research is provided to fund managers to encourage them to deal with the broker. Hardman is not inducing the reader of our research to trade through us, since we do not deal in any security.

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