

**Market data**

EPIC/TKR	AGY
Price (p)	24.0
12m High (p)	28.5
12m Low (p)	17.5
Shares (m)	593.4
Mkt Cap (£m)	142.4
EV (£m)	123.6
Free Float*	38%
Market	AIM

*As defined by AIM Rule 26

Description

AGY provides information to professionals related to prevention, diagnosis and treatment of allergic conditions with special focus on allergy vaccination and a successful treatment dealing with the underlying cause and not just 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	21.1%
Odey	7.4%
Invesco	5.7%
Blackrock	3.2%

Next event

29 March	Interims
Sept-17	Finals
Nov-17	AGM

Analysts

Martin Hall	020 7148 1433	mh@hardmanandco.com
Dorothea Hill	020 7148 1433	dnh@hardmanandco.com
Gregoire Pave	020 7148 1434	gp@hardmanandco.com

Allergy Therapeutics

Investment driving market share gains

AGY is a long-established specialist in the prevention, diagnosis and treatment of allergies. Pollinex Quattro continues to gain market share despite being available in Europe only on a 'Named Patient' basis. Trials to obtain full regulatory approval as a biological have progressed well in the EU, and are back on-track in the US with a planned new safety trial. AGY remains on course to have the first short-course allergy vaccine approved in both Europe and the US. Meanwhile, an excellent trading performance in 1H'17 shows that AGY is continuing to gain market share from its international peers.

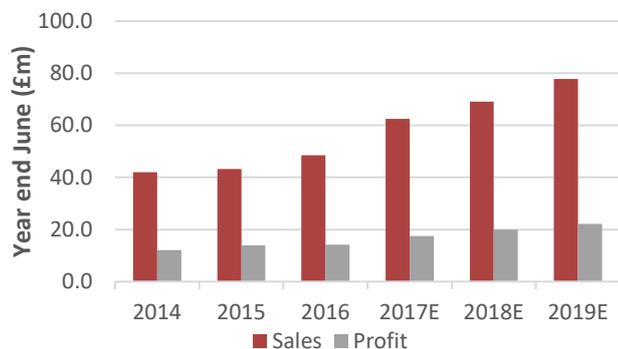
- ▶ **Trading update:** Sales in the six months to December 2016 were over £2m ahead of market expectations, with exceptional underlying growth of +18% to £40.4m (£29.0m). Weakness in sterling boosted the reported numbers by about £6.0m. This strong performance has continued into the second half.
- ▶ **Net cash:** At 31st December 2016, AGY had a cash balance of £27.8m, up from £23.4m at 30th June, and ca.£3.0m above forecasts. Assuming that debt has not changed significantly, net cash was £23.3m at the end of the period from £18.9m at 30th June, showing the cash generation from traditionally strong 1H trading.
- ▶ **Regulatory update:** Management has made important progress with the FDA and a revised programme of trials to get Grass MATA MPL approved in the US has been agreed in principle, with part of this being conducted in Europe. Meanwhile, the final trial for the EU submission is set to start in 3Q 2017.
- ▶ **Changes to forecasts:** Following the strong first half sales performance, we have increased our underlying sales growth expectation from +11.5% to +13%, which is still conservative and implies only +2% growth for 2H'17. Coupled to this we have corrected for forex, which adds £7.5m to reported sales numbers.
- ▶ **Investment summary:** AGY has reported another exceptional underlying sales performance in 1H'17 against a flat market, giving significant market share gains in some countries. It has also made considerable progress towards US regulatory approval with a revised trial programme. Despite this, the shares still trade stubbornly below those of international peers that are losing market share and do not have access to the new short-course immunotherapy (SCIT) technology.

Financial summary and valuation

Year end June (£m)	2014	2015	2016	2017E	2018E	2019E
Sales	41.96	43.23	48.51	62.5	69.1	77.8
R&D spend	-2.96	-3.12	-16.22	-10.5	-15.0	-16.0
Underlying EBIT	1.39	2.91	-12.06	-4.2	-7.3	-8.1
Reported EBIT	1.21	1.41	-12.38	-4.2	-7.3	-8.1
Underlying PTP	1.27	2.84	-12.17	-4.3	-7.5	-8.3
Statutory PTP	1.08	0.65	-12.06	-4.3	-7.5	-8.3
Underlying EPS (p)	0.20	0.48	-2.31	-0.9	-1.5	-1.6
Statutory EPS (p)	0.16	0.02	-2.29	-0.9	-1.5	-1.6
Net (debt)/cash	2.25	20.14	18.86	10.9	0.7	-12.4
Shares issued	0.00	20.08	10.97	0.3	0.3	0.3
P/E (x)	117.2	49.7	-10.4	-26.4	-16.3	-14.8
EV/sales (x)	2.9	2.9	2.5	2.0	1.8	1.6

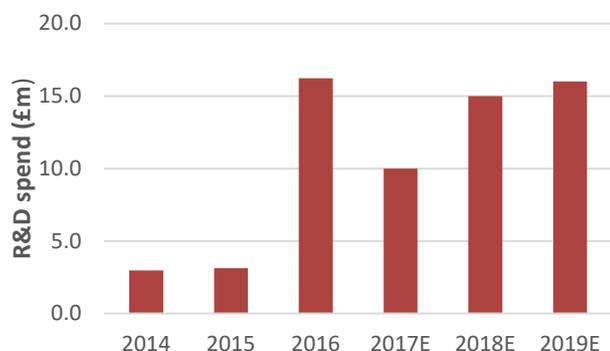
Source: Hardman & Co Life Sciences Research

Product analysis



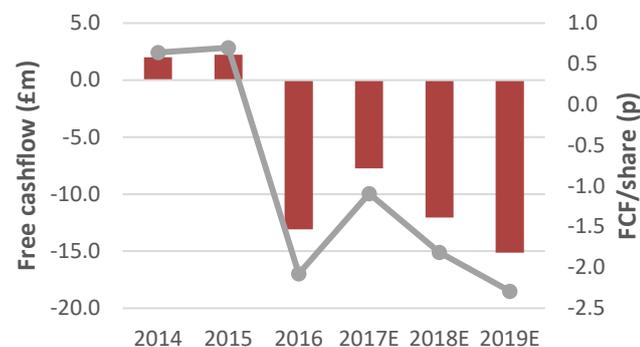
- ▶ AGY has a strong portfolio of products for allergy immunotherapy
- ▶ Products have shown consistent growth over the last five years even though their availability is limited by regulators
- ▶ After taking account of manufacturing, distribution and marketing costs, in-market products are profitable
- ▶ Investment in marketing ahead of formal approvals has resulted in a 2pp market share gain to 12%

R&D investment



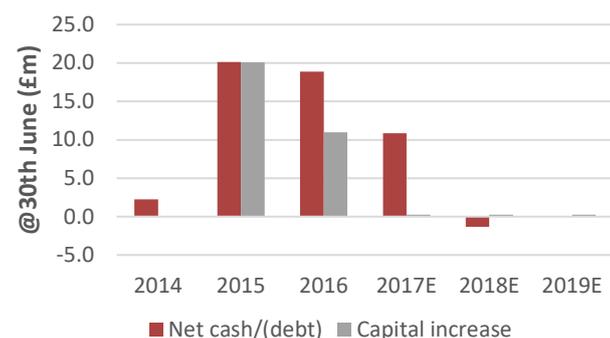
- ▶ Cumulative investment in R&D since 2000 has been £100m and looks set to be another £40m in next three years
- ▶ After peaking in 2016, R&D investment will ease off until 2018 in the absence of a significant US trial
- ▶ Three key trials for the US market will cost ca.£20m over the next three years, but will pave the way to FDA approval
- ▶ Trials for EU approval continue apace, with Germany being the lead country

Free cashflow



- ▶ Products sold into the market are profitable and cash generative
- ▶ Considerable investment in R&D and marketing will result in a planned period of cash burn
- ▶ Cash requirement towards the end of this decade will be dependent on commercialisation strategy in the US
- ▶ In following an inorganic growth strategy, although acquisitions tend to be small, more cash might be required

Net cash/(debt)



- ▶ Net cash at 31st December 2016 was estimated at £23.3m
- ▶ Re-balancing of the R&D spend leaves AGY adequately funded for the next 18 months
- ▶ AGY usually takes on seasonal overdrafts and this could be extended if required ahead of the regulatory approvals
- ▶ 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

2017 trading update

Allergy Therapeutics has released a trading update to the market covering the first half sales for fiscal 2017. The full interim statement will be published on 29th March 2017. Underlying sales growth was ca.£2m ahead of market expectations, boosted at the reported level by the weakness of sterling.

Key headlines

- ▶ Underlying sales growth +18% to £40.4m (£29.0m)
- ▶ Cash balance of £27.8m at 31st December 2016 vs £23.4m at 30th June
- ▶ Progress with Pollinex Quattro trials in both EU and the US

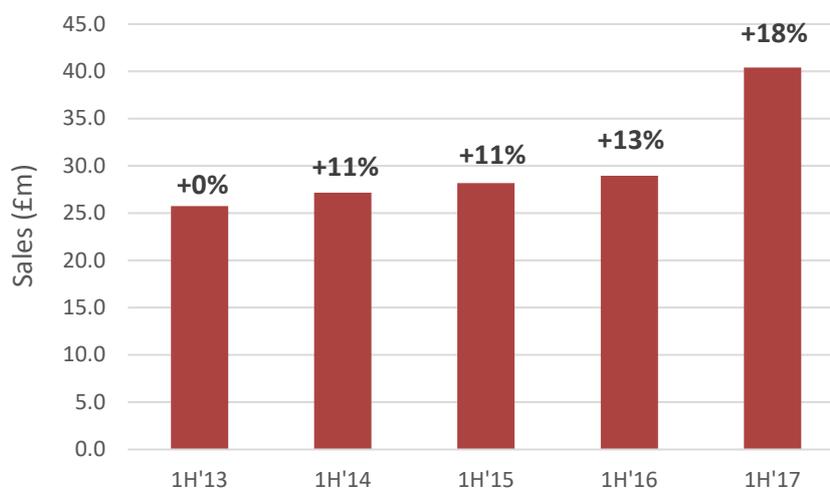
AGY 1H'17 – actual vs expectations					
Half-year (£m)	1H'16 actual	1H'17 actual	CER growth %	1H'17 forecast	Delta
Group sales	29.0	40.4	+18%	38.2	+2.2
Cash balance	33.2	27.8	nm	24.6	+3.2
Net cash/(debt)	31.6	23.3	nm	20.0	+3.3

Source: Allergy Therapeutics; Hardman & Co Life Sciences Research

Sales

AGY has seen a strong underlying sales performance in most of its European territories, notably Germany, Austria, Spain and The Netherlands. This strong positive momentum is the result of a good product offering supported by an investment in marketing against a background of a flat market. This is the sixth half year in succession of solid market share gains. In terms of products, it is the ultra-short course aluminium-free allergy vaccines that are driving the growth.

Allergy Therapeutics – First half sales trend & CER growth rates



Source: Hardman & Co Life Sciences Research

There is a seasonality to the business with about two-thirds of annual sales generated in the first half. Moreover, the rate of growth also tends to be higher in 1H versus 2H. This is expected to recur again in fiscal 2017 but overall, growth is expected to continue in 2H'17 driving solid double digit sales growth for the full year.

Regulatory update

The announcement also contained an update on the clinical trial and regulatory progress that has been made with Pollinex Quattro (PQ), known as Grass MATA MPL in the US. Following the inconclusive trial results in the G204 dose ranging study in the US announced in 2016, AGY has held talks with the FDA and is working to a revised Grass MATA MPL trial programme.

- ▶ **G104** – AGY will perform a small safety study with Grass MATA MPL in the US ahead of a new dose escalation study. This will be similar to the G102 safety study performed at the end of 2015, but using a higher dosing regimen
- ▶ **G205** – A new dose-ranging conjunctival provocation study starting in 2017, which, as agreed with the FDA, will be performed in Europe. This is a replacement for the old G204 dose ranging study that was undertaken in a controlled environment chamber that produced the unusual results. Given that it is being undertaken in Europe, the costs are likely to be lower
- ▶ **G306** – Once the optimal dose has been ascertained in G205, it will be used in a Phase III field study. This replaces the original G304 efficacy chamber study

AGY has clearly made progress with the FDA and has a clear plan of action to get Grass MATA MPL approved for the US market. Meanwhile, clinical trials with Pollinex Quattro, in order to obtain full regulatory approval in Europe, are continuing as planned with the Phase III field study (PQB301) due to start in 3Q 2017.

Changes to forecasts

Until now our full year forecasts have been based on constant currency to provide a true picture of growth expectations. Given the large movement in sterling over the last six months we are correcting our forecasts to account for this change. With most of AGY's sales generated in Europe, translation of EUR denominated sales has a large positive effect on reported numbers. On an underlying basis, following the 1H'17 trading update, we have revised upwards our underlying sales growth forecast from 11.5% to 13%, which remains conservative and implies only 2% growth in 2H'17. This change runs through subsequent years which are all on a constant currency basis.

With most of its marketing spend in EUR and R&D investment in both EUR and USD, AGY has a natural hedge against forex movements, the cost base rising about the same amount as sales. However, manufacturing costs are mostly UK based and will not change, therefore there is a positive effect on the gross margin.

Changes to forecasts			
Year end Dec (£m)	2017E	2018E	2019E
Group sales			
Old	54.0	59.7	67.2
New	62.5	69.1	77.8
Underlying change	+2%	n/c	n/c
Pre-tax profit			
Old	-5.7	-9.7	-10.6
New	-4.3	-7.5	-8.3
EPS (p)			
Old	-1.15	-1.84	-2.03
New	-0.91	-1.47	-1.62
Change	+11%	+20%	+20%

n/c = no change

Source: Hardman & Co Life Sciences Research

Financials

Profit & Loss

- ▶ **Sales:** Underlying growth of +13% in fiscal 2017, which has ca.£7.5m currency benefit on translation
- ▶ **R&D:** The investment split for 2017 is likely to be 2H'17 biased, with most of these costs being in EUR
- ▶ **Forex:** There is a large currency benefit at the sales level due to the weakness of GBP against the EUR. However, there is a natural hedge with most of the marketing and R&D costs also being in EUR

Profit & Loss account						
Year end June (£m)	2014	2015	2016	2017E	2018E	2019E
GBP:EUR	1.198	1.270	1.338	1.170	1.170	1.170
GBP:USD	1.626	1.576	1.484	1.260	1.260	1.260
Sales	41.96	43.23	48.51	62.49	69.09	77.83
COGS	-11.95	-12.18	-14.07	-15.62	-17.00	-18.99
Gross profit	30.00	31.05	34.44	46.86	52.09	58.83
Marketing	-17.92	-17.06	-20.22	-27.24	-29.77	-34.08
Product profit	12.08	13.99	14.22	19.62	22.32	24.75
Product margin	28.8%	32.4%	29.3%	31.4%	32.3%	31.8%
G&A	-7.80	-8.03	-10.20	-13.32	-14.66	-16.83
R&D	-2.96	-3.12	-16.22	-10.50	-15.00	-16.00
EBITDA	2.68	4.20	-10.39	-2.53	-5.68	-6.41
Depreciation & Amortis.	-1.29	-1.29	-1.67	-1.67	-1.67	-1.67
Other income	0.08	0.07	0.15	0.00	0.00	0.00
Underlying EBIT	1.39	2.91	-12.06	-4.20	-7.34	-8.07
Share based costs	-0.18	-0.41	-0.33	0.00	0.00	0.00
Exceptional items	0.00	-1.10	0.00	0.00	0.00	0.00
Statutory EBIT	1.21	1.41	-12.38	-4.20	-7.34	-8.07
Net financials	-0.13	-0.07	-0.11	-0.09	-0.15	-0.19
Pre-tax profit	1.27	2.84	-12.17	-4.29	-7.49	-8.27
Exceptional items	0.00	-0.68	0.43	0.00	0.00	0.00
Reported pre-tax	1.08	0.65	-12.06	-4.29	-7.49	-8.27
Tax payable/credit	-0.34	-0.55	-1.01	-1.11	-1.22	-1.34
Minorities	0.00	0.00	0.00	0.00	0.00	0.00
Underlying net income	0.92	2.29	-13.18	-5.40	-8.71	-9.61
Statutory net income	0.74	0.11	-13.07	-5.40	-8.71	-9.61
Ordinary shares:						
Period-end (m)	451.5	545.8	589.2	593.4	593.4	593.4
Weighted average (m)	451.5	475.2	570.3	593.2	593.4	593.4
Fully diluted (m)	471.5	498.2	589.2	615.0	620.3	625.3
Underlying Basic EPS (p)	0.20	0.48	-2.31	-0.91	-1.47	-1.62
Statutory Basic EPS (p)	0.16	0.02	-2.29	-0.91	-1.47	-1.62
U/I Fully-diluted EPS (p)	0.20	0.46	-2.24	-0.88	-1.40	-1.54
Stat. Fully-diluted EPS (p)	0.16	0.02	-2.22	-0.88	-1.40	-1.54
DPS (p)	0.00	0.00	0.00	0.00	0.00	0.00

Source: Hardman & Co Life Sciences Research

Balance sheet

- **Net cash/(debt):** At 31st December 2016, AGY had a cash balance of £27.8m, which we believe equates to net cash of £23.3m, a rise of £4.6m compared to the position at the end of June 2016. Cash will outflow in 2H'17 leaving net cash at ca.£11m in June 2017

Balance sheet						
@30th June (£m)	2014	2015	2016	2017E	2018E	2019E
Shareholders' funds	15.08	34.47	30.32	24.92	16.21	6.60
Cumulated goodwill	0.00	0.00	0.00	0.00	0.00	0.00
Total equity	15.08	34.47	30.32	24.92	16.21	6.60
Share capital	0.42	0.56	0.60	0.60	0.60	0.60
Reserves	14.66	33.91	29.73	24.33	15.61	6.01
Capitalised R&D	10.83	9.43	21.13	26.47	34.71	42.15
Minorities	0.00	0.00	0.00	0.00	0.00	0.00
Provisions/liabilities	0.22	0.21	0.26	0.26	0.26	0.26
Deferred tax	-0.04	0.30	0.33	0.33	0.33	0.33
Long-term loans	0.07	1.55	3.07	3.07	3.07	3.07
Short-term loans	0.05	0.30	1.48	2.98	7.98	17.98
less: Cash	2.03	21.20	23.41	16.92	11.72	8.60
less: Deposits	0.35	0.78	0.00	0.00	0.00	0.00
less: Non-core invests.	3.21	3.16	4.05	4.05	4.05	4.05
Invested capital	27.04	27.86	39.32	47.24	56.97	67.92
Fixed assets	7.03	8.75	9.67	9.58	9.55	9.79
Intangible assets	1.29	2.02	2.08	1.80	1.52	1.24
Capitalised R&D	10.83	9.43	21.13	26.47	34.71	42.15
Goodwill	2.48	2.98	3.27	3.27	3.27	3.27
Inventories	6.47	6.75	7.69	9.41	9.90	11.16
Trade debtors	2.76	2.84	4.68	6.03	6.66	8.79
Other debtors	2.61	2.22	1.84	1.84	1.84	1.84
Tax liability/credit	-0.59	-0.59	-1.43	-1.43	-1.43	-1.22
Trade creditors	-2.46	-3.05	-3.11	-4.01	-4.43	-9.38
Other creditors	-3.37	-3.53	-6.51	-5.71	-4.62	0.28
Debtors less creditors	-1.06	-2.11	-4.53	-3.29	-1.98	0.31
Invested capital	27.04	27.81	39.32	47.24	56.97	67.92
Net cash/(debt)	2.25	20.14	18.86	10.87	0.67	-12.45

Source: Hardman & Co Life Sciences Research

Cashflow

- ▶ **1H'17 inflow:** From the trading side there is a natural bias to the first half of the year because of the seasonality of business. Product sales are profitable and cash generative. In the absence of large R&D investment in the first half of the year, this drops all the way through the accounts
- ▶ **R&D investment:** Coupled to this, R&D investment in fiscal 2017 will be biased to the second half of the year
- ▶ **Net debt:** Consequently, there was an estimated cash generation of £4.6m in the first half. The lower level of trading seen in the second half, coupled to increased R&D spend will lead to significant cash outflow, with net cash estimated at ca.£11m on 30th June 2017

Cashflow						
Year end June (£m)	2014	2015	2016	2017E	2018E	2019E
Trading profit	1.39	2.91	-12.06	-4.20	-7.34	-8.07
Depreciation	1.01	1.01	1.39	1.39	1.39	1.39
Amortisation	0.28	0.28	0.28	0.28	0.28	0.28
Inventories	-0.63	-0.42	-0.59	-1.72	-0.49	-1.25
Working capital	0.78	0.63	-0.87	-1.07	-1.27	-2.27
Exceptionals/provisions	0.00	0.29	0.30	0.00	0.00	0.00
Disposals	0.00	0.00	0.00	0.00	0.00	0.00
Other	0.14	-0.97	0.00	0.00	0.00	0.00
Company op cashflow	2.97	3.73	-11.54	-5.31	-7.44	-9.93
Net interest	-0.03	-0.24	-0.39	-0.09	-0.15	-0.19
Tax payable/credit	-0.05	-0.17	0.09	-1.01	-1.11	-1.22
Operational cashflow	2.89	3.32	-11.84	-6.41	-8.69	-11.34
Capital Expenditure	-0.90	-1.09	-1.23	-1.29	-1.36	-1.63
Capitalised R&D	0.00	0.00	0.00	0.00	0.00	0.00
Sale of fixed assets	0.00	0.00	0.00	0.00	0.00	0.00
Free cashflow	2.00	2.23	-13.07	-7.71	-10.05	-12.97
Dividends	0.00	0.00	0.00	0.00	0.00	0.00
Acquisitions	-0.02	-2.67	0.00	-0.23	-0.10	-0.10
Disposals	0.00	0.00	0.00	0.00	0.00	0.00
Other investments	-0.28	-0.28	-0.26	-0.30	-0.30	-0.30
CF after investments	1.69	-0.71	-13.33	-8.24	-10.45	-13.37
Share repurchases	0.00	0.00	0.00	0.00	0.00	0.00
Share issues	0.00	20.08	10.97	0.25	0.25	0.25
Currency effect	-0.08	-1.10	1.08	0.00	0.00	0.00
Borrowings acquired	0.00	-0.37	0.00	0.00	0.00	0.00
Change in net debt	1.61	17.89	-1.28	-7.99	-10.20	-13.12
Opening net cash	0.64	2.26	20.15	18.86	10.88	0.67
Closing net cash	2.26	20.15	18.86	10.88	0.67	-12.44
Hardman FCF/share (p)	0.64	0.70	-2.08	-1.08	-1.47	-1.91

Source: Hardman & Co Life Sciences Research

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*Hardman & Co Research Limited (trading as Hardman & Co)
11/12 Tokenhouse Yard
London
EC2R 7AS
T +44 (0) 207 929 3399*

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Hardman & Co

11/12 Tokenhouse Yard
London
EC2R 7AS
United Kingdom

Tel: +44(0)20 7929 3399
Fax: +44(0)20 7929 3377

www.hardmanandco.com

