

**Market data**

EPIC/TKR	AGY
Price (p)	30.0
12m High (p)	39.5
12m Low (p)	23.0
Shares (m)	594.1
Mkt Cap (£m)	178.2
EV (£m)	159.4
Free Float*	37%
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. The emphasis is on treating the underlying cause and not just the symptoms.

Company information

CEO	Manuel Llobet
CFO	Nick Wykeman
Chairman	Peter Jensen

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www.allergytherapeutics.com**Key shareholders**

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

Diary

7 March	Interims
2Q'18	Ph.II PQ Grass trial
2H'18	Ph.III PQBirch trial

Analysts

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Allergy Therapeutics

Growth in a tough market

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. Trials designed to obtain regulatory approval for PQ approved as a biologic in both Europe and the US are well advanced. Meanwhile, although underlying sales growth was weaker than expected in 1H'18, this was on the back of an unusually shorter and lower pollen season in central Europe, suggesting that AGY has continued to make further market share gains.

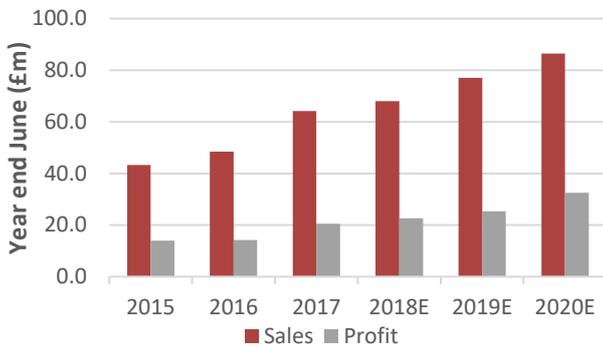
- **Strategy:** AGY is a fully integrated pharmaceutical company focused on the treatment of allergies. There are three parts to its strategy: continued development of its European business via investment or opportunistic acquisitions; the US PQ opportunity; and further development of its pipeline.
- **Trading update:** In 1H'18, underlying sales grew 1.3% to £42.2m (£40.4m), which was about 10% below expectations, largely because of an unexpectedly weak pollen season. Timing of R&D spend, coupled with careful control of costs and working capital, generated a cash position of £25.8m (£27.8m).
- **Pollen season:** Reports show that the pollen season was very weak in 2017, particularly in AGY's key markets of central Europe, Germany, Austria and Switzerland. Therefore, there is reason to believe that the low sales growth in 1H'18 was still sufficient for AGY to make further market share gains.
- **R&D spend:** Clinical trials designed to get full regulatory approval of Pollinex Quattro (PQ) as a biologic continue apace. The Phase III PQ Birch trial is fully recruited, with results due to be released in 2H calendar 2018. The Phase II PQ grass trial is still recruiting. Timing of R&D spend does affect the cash position.
- **Investment summary:** AGY is going through 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 PQ Birch trial in 2018 will provide the next major value inflection point.

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	-0.59	-1.6	-1.0	1.3
Statutory EPS (p)	0.02	-2.29	-0.42	-1.7	-1.1	1.2
Net (debt)/cash	20.14	20.04	18.80	8.5	4.1	15.7
Capital increase	20.08	10.97	0.03	0.3	0.3	0.3
P/E (x)	62.1	-12.7	-51.1	-18.6	-30.9	23.6
EV/sales (x)	3.7	3.3	2.5	2.3	2.1	1.8

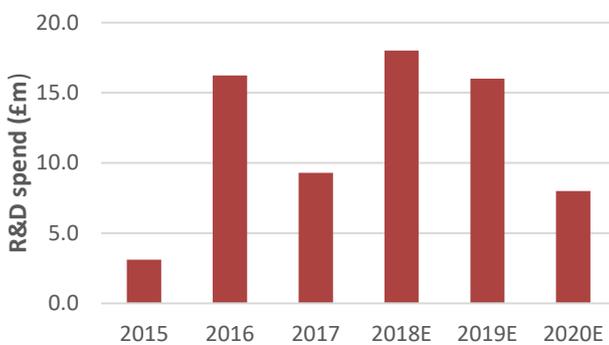
Source: Hardman & Co Life Sciences Research

Product analysis



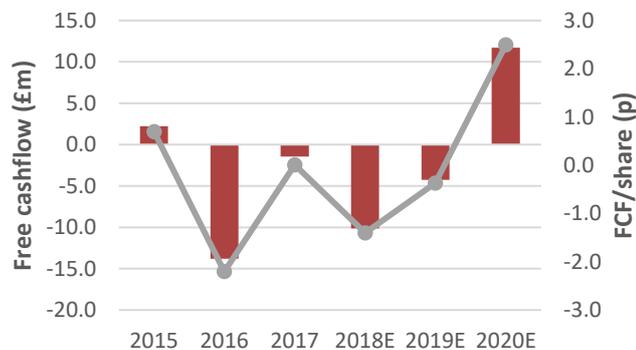
- ▶ AGY has a solid existing portfolio of products for allergy immunotherapy
- ▶ Products have shown consistent growth over the last five years, even though their availability is limited
- ▶ After taking account of manufacturing, distribution and marketing costs, in-market products are profitable
- ▶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

R&D investment



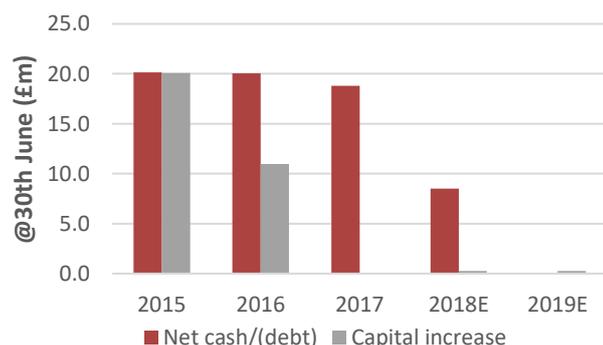
- ▶ Cumulative investment in R&D since 2000 has been £105m
- ▶ R&D investment is forecast to rise substantially to get Pollinex Quattro onto the market in the US and formally approved in Europe
- ▶ Three key trials for the US and Europe will cost ca.£35m over the next two years, but will pave the way to regulatory approvals in a changing market place

Free cashflow



- ▶ In each of the last four years, AGY has generated free cashflow from operations
- ▶ 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) and capital increases



- ▶ £20m was raised in March 2015 largely to fund the key US trials
- ▶ Based on current forecasts, the net cash position will reach 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

2018 trading update

Allergy Therapeutics has released a trading update to the market covering the first half of fiscal 2018, which includes headline sales information, the net cash position, and some up-to-date information regarding clinical trial progress. The complete interim statement will be published on 7th March 2018.

Key headlines

- ▶ Underlying sales growth was 1.3% to £42.2m (£40.4m)
- ▶ Cash balance was £25.8m at 31st December 2017 vs. £27.8m at 30th June 2017
- ▶ Progress with Pollinex Quattro trials in both Europe and the US
- ▶ The PQ Birch Phase III trial is fully recruited - results are due in 2H calendar 2018

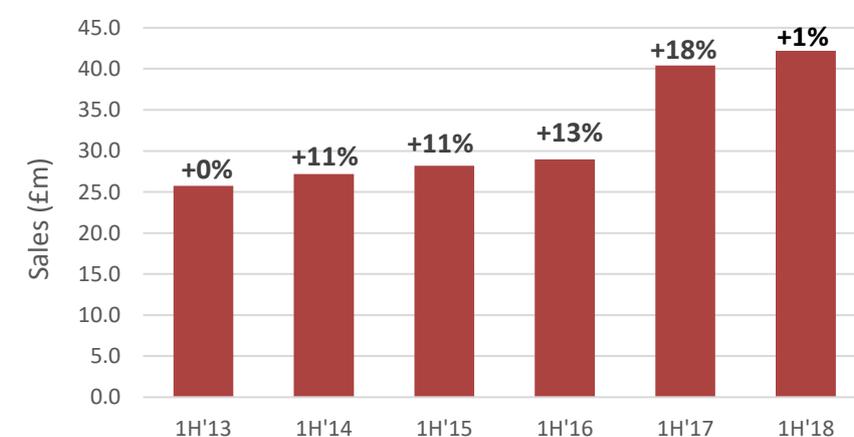
AGY 1H'18 – actual vs expectations					
Half-year (£m)	1H'17 actual	1H'18 actual	CER growth (%)	1H'18 forecast	Delta Δ
Group sales	40.4	42.2	+1.3%	46.4	-4.2
Cash balance	27.8	25.8	NM	26.2	-0.4
Net cash/(debt) est.	23.3	22.5	NM	23.0	-0.5

Source: Allergy Therapeutics; Hardman & Co Life Sciences Research

Sales

Because of the seasonality of the pollen season, AGY sales are traditionally stronger in the first half of each financial year. Having seen consistent double-digit underlying growth at the interim stage for each of the last five years, the outcome in 1H'18 was quite a surprise, with underlying growth of just 1.3%. AGY being first to report financial information for this period, it is difficult to know how this compares with its immediate competitors. However, there are reports that the pollen season in Central Europe – notably key markets in Germany, Austria and Switzerland¹ – was very weak in 2017, which is corroborated by weak sales of OTC allergy products (down 10% in Germany, 2017 data from QuintilesIMS).

AGY – first-half sales trend and CER growth rates



Source: Hardman & Co Life Sciences Research

¹http://www.meteosuisse.admin.ch/content/dam/meteoswiss/fr/service-und-publikationen/publikationen/doc/bulletin_climato_saison_fruehling-2017_f.pdf

Clinical trial update

PQ Birch

PQ Birch is an ultra-short course convenient-to-use, aluminium-free subcutaneous immunotherapy (SCIT). Around 6% of the EU population is allergic to birch pollen, and European marketing authorisation via the Therapieallergene-Verordnung (TAV) for PQ Birch would represent the first MPL-adjuvant vaccine to be formally licensed, strengthening the position of AGY significantly.

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 to measure allergy rhinoconjunctivitis symptoms. Results are due to be released in the second half of calendar 2018.

PQ Grass

Recruitment into the Phase II PQ Grass trial is continuing. Again, data are expected to be released in 2H calendar 2018. Following these results, meetings will be held with both US and German regulators to generate an acceptable Phase III trial design.

OralVac Oral

Plans are on track with the German TAV for the clinical development programme for an oral version of AGY's OralVac vaccine, which a co-development programme recently announced with Ergomed (ERGO.L). A sub-lingual formulation offers an alternative option for patients who prefer not to have injections. Under the terms of the agreement, the clinical development of OralVac products for the treatment of grass pollen, tree pollen, and house dust mite allergies will be progressed by Ergomed. The collaboration includes a future revenue share and reduced service fee.

Changes to forecasts

At this stage, it is very difficult to predict the likely outcome for the pollen season in 2018. However, given the relative weakness observed in 1H'18, it seems prudent to adjust sales forecasts to a more conservative growth rate. Therefore, sales have been reduced by 6% for 2018, which has a knock-on effect on future years. Readers are reminded that, at this stage of the year, all forecasts are based on constant currency to provide a true picture of growth expectations.

In addition, timing of R&D spend is difficult to predict. Therefore, R&D investment has been maintained for the full-year at -£18.0m, suggesting an even more significant 2H bias than previously forecast. With tight cost control, the impact on pre-tax profit of these changes is only about £0.5m p.a.

Changes to forecasts				
Year-end June (£m)	2017	2018E	2019E	2020E
Group sales				
Old	64.1	72.0	81.5	92.0
New	-	68.0	77.0	86.5
Change		-6%	-6%	-6%
Pre-tax profit				
Old	-3.0	-9.3	-5.5	8.5
New	-	-9.8	-6.0	8.0
Change		-5%	-10%	-6%
EPS (p)	-0.6	-1.6	-1.0	1.3

Source: Hardman & Co Life Sciences Research

Financial forecasts

Profit & Loss

- ▶ **Sales:** Underlying sales growth for 2018 has been reduced from 13% to 6%, reflecting the weaker-than-expected pollen season in the first half.
- ▶ **R&D:** The investment is being maintained at -£18.0m for 2018, suggesting a much greater 2H bias than previously forecast.
- ▶ **Forex:** Even though there was a small currency benefit in 1H'18, it seems prudent to keep forecasts on a constant currency basis given recent signs of sterling strengthening. Readers are reminded that AGY has a natural currency hedge, with most of the marketing and R&D costs also being in EUR.

Profit & Loss account						
Year-end June (£m)	2015	2016	2017	2018E	2019E	2020E
GBP:EUR	1.270	1.338	1.171	1.171	1.171	1.171
GBP:USD	1.576	1.484	1.281	1.281	1.281	1.281
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
Marketing	-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
Other income	0.07	0.00	0.00	0.00	0.00	0.00
Underlying EBIT	2.91	-12.34	-2.89	-9.68	-5.88	8.11
Share-based costs	-0.41	-0.33	-0.70	-0.70	-0.70	-0.70
Exceptional items	-1.10	0.14	1.00	0.00	0.00	0.00
Statutory EBIT	1.41	-12.53	-2.60	-10.38	-6.58	7.41
Net financials	-0.07	-0.11	-0.07	-0.13	-0.13	-0.11
Pre-tax profit	2.84	-12.45	-2.97	-9.80	-6.00	8.00
Extraordinary items	-0.68	0.43	0.00	0.00	0.00	0.00
Reported pre-tax	0.65	-12.21	-2.67	-10.51	-6.71	7.30
Tax payable/credit	-0.55	-0.86	0.19	0.21	0.23	-0.44
Minorities	0.00	0.00	0.00	0.00	0.00	0.00
Underlying net income	2.29	-13.46	-3.48	-9.60	-5.78	7.56
Statutory net income	0.11	-13.07	-2.48	-10.30	-6.48	6.86
Ordinary 0.1p shares:						
Period-end (m)	545.8	589.2	594.1	594.1	594.1	594.1
Weighted average (m)	475.2	570.3	592.2	594.1	594.1	594.1
Fully diluted (m)	498.2	589.2	615.1	622.0	627.0	635.0
Underlying basic EPS (p)	0.48	-2.36	-0.59	-1.62	-0.97	1.27
Statutory basic EPS (p)	0.02	-2.29	-0.42	-1.73	-1.09	1.15
U/I fully-diluted EPS (p)	0.46	-2.28	-0.57	-1.54	-0.92	1.19
Stat. fully-diluted EPS (p)	0.02	-2.22	-0.40	-1.66	-1.03	1.08
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 2017, AGY had a cash balance of £25.8m, which we estimate to equate to a net cash of £22.5m, a rise of £3.5m compared with the position at the end of June 2017. Cash will outflow in 2H'18, leaving net cash at ca.£8.5m at the end of June 2018.

Balance sheet						
@30th June (£m)	2015	2016	2017	2018E	2019E	2020E
Shareholders' funds	34.47	30.32	29.97	19.67	13.19	20.04
Cumulated goodwill	0.00	0.00	0.00	0.00	0.00	0.00
Total equity	34.47	30.32	29.97	19.67	13.19	20.04
Share capital	0.56	0.60	0.60	0.60	0.60	0.60
Reserves	33.91	29.73	29.36	19.06	12.58	19.44
Capitalised R&D	9.43	21.13	25.42	36.43	43.65	42.13
Minorities	0.00	0.00	0.00	0.00	0.00	0.00
Provisions/liabilities	0.21	1.44	0.70	0.70	0.70	0.70
Deferred tax	0.30	0.33	0.35	0.35	0.35	0.35
Long-term loans	1.55	3.07	2.94	2.94	2.94	2.94
Short-term loans	0.30	0.30	0.39	5.39	15.39	3.83
less: Cash	21.20	23.41	22.12	16.84	22.42	22.42
less: Deposits	0.78	0.00	0.00	0.00	0.00	0.00
less: Non-core invests.	3.16	4.05	4.59	4.59	4.59	4.59
Invested capital	27.86	39.32	42.66	53.66	58.82	52.59
Fixed assets	8.75	9.67	9.67	9.82	10.23	11.68
Intangible assets	2.02	2.08	2.07	1.79	1.51	1.23
Capitalised R&D	9.43	21.13	25.42	36.43	43.65	42.13
Goodwill	2.98	3.27	3.39	3.39	3.39	3.39
Inventories	6.75	7.69	7.48	7.44	8.42	9.46
Trade debtors	2.84	4.68	4.19	4.44	6.57	8.95
Other debtors	2.22	1.84	3.67	3.67	3.67	3.67
Tax liability/credit	-0.59	-1.43	-1.43	-1.43	-1.43	-1.43
Trade creditors	-3.05	-3.11	-4.11	-4.36	-9.22	-17.29
Other creditors	-3.53	-6.51	-7.68	-7.52	-7.97	-9.19
Debtors less creditors	-2.11	-4.53	-5.37	-5.20	-8.39	-15.30
Invested capital	27.81	39.32	42.66	53.66	58.82	52.59
Net cash/(debt)	20.14	20.04	18.80	8.5	4.1	15.7
Net debt/equity (%)	58%	66%	63%	43%	31%	78%
After-tax ROIC	9%	-33%	-8%	-17%	-9%	15%
NAV/share (p)	7.25	5.32	5.06	3.31	2.22	3.37
Stock days	198	182	165	148	151	181
Debtor days	24	28	25	23	26	33
Creditor days	83	80	79	88	127	283

Source: Hardman & Co Life Sciences Research

Cashflow

- ▶ **1H'18 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 during the period, this drops all the way through the accounts.
- ▶ **R&D investment:** Coupled to this, R&D investment in fiscal 2018 is expected to be biased to the second half of the year.
- ▶ **Net debt:** Consequently, there was an estimated cash generation of £3.7m in the first half. The lower level of trading seen in the second half, coupled with increased R&D spend, will lead to a significant cash outflow, with net cash estimated at ca.£8.5m on 30th June 2018.

Cashflow						
Year-end June (£m)	2015	2016	2017	2018E	2019E	2020E
Underlying EBIT	2.91	-12.34	-2.89	-9.68	-5.88	8.11
Depreciation	1.01	1.39	1.66	1.66	1.66	1.66
Amortisation	0.28	0.28	0.28	0.28	0.28	0.28
<i>Inventories</i>	-0.42	-0.59	0.33	0.05	-0.99	-1.03
<i>Receivables</i>	-0.45	-0.37	1.00	-0.25	-6.57	-2.38
<i>Payables</i>	1.08	-0.50	0.82	0.25	9.22	8.07
Change in working capital	0.21	-1.45	2.16	0.04	1.67	4.66
Exceptionals/provisions	0.29	0.00	0.00	0.00	0.00	0.00
Disposals	0.00	0.00	0.00	0.00	0.00	0.00
Other	-0.98	-0.15	0.11	0.00	0.00	0.00
Company op. cashflow	3.72	-12.28	1.32	-7.70	-2.28	14.70
Net interest	-0.24	-0.39	-0.18	-0.13	-0.13	-0.11
Tax paid/received	-0.17	0.09	-1.10	-0.51	0.21	0.23
Operational cashflow	3.31	-12.57	0.03	-8.33	-2.20	14.82
Capital expenditure	-1.09	-1.23	-1.50	-1.80	-2.07	-3.11
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	2.22	-13.80	-1.47	-10.13	-4.27	11.71
Dividends	0.00	0.00	0.00	0.00	0.00	0.00
Acquisitions	-2.67	0.00	-0.23	-0.10	-0.10	-0.10
Disposals	0.00	0.00	0.00	0.00	0.00	0.00
Other investments	-0.28	-0.26	-0.26	-0.30	-0.30	-0.30
CF after investments	-0.72	-14.06	-1.95	-10.53	-4.67	11.31
Share repurchases	0.00	0.00	0.00	0.00	0.00	0.00
Share issues	20.08	10.97	0.03	0.25	0.25	0.25
Currency effect	-1.10	3.00	0.67	0.00	0.00	0.00
Borrowings acquired	-0.37	0.00	0.00	0.00	0.00	0.00
Change in net debt	17.88	-0.10	-1.25	-10.28	-4.42	11.56
Opening net cash	2.26	20.14	20.04	18.79	8.51	4.09
Closing net cash	20.14	20.04	18.79	8.51	4.09	15.66
Hardman FCF/share (p)	0.70	-2.20	0.01	-1.40	-0.37	2.49

Source: Hardman & Co Life Sciences Research

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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>

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