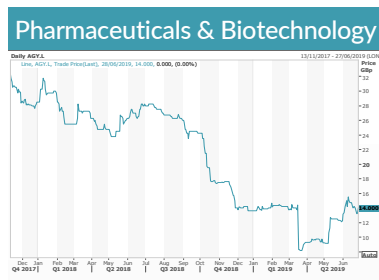




1 July 2019



Source: Refinitiv

Market data

EPIC/TKR	AGY
Price (p)	14.0
12m High (p)	29.0
12m Low (p)	7.3
Shares (m)	636.2
Mkt Cap (£m)	89.1
EV (£m)	69.1
Free Float*	39%
Market	AIM

*As defined by AIM Rule 26

Description

AGY provides information to professionals related to prevention, diagnosis and treatment of allergic conditions, with a 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

+44 1903 845 820

www.allergytherapeutics.com**Key shareholders**

Directors	0.7%
Abbott Labs	37.8%
Southern Fox	22.7%
SkyGem	15.6%
Invesco	4.5%

Diary

Sep'19	Final results
1H'20	Start Phase I Polyvac Peanut trial

Analysts

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ALLERGY THERAPEUTICS

Successful legal outcome removes uncertainty

AGY is a long-established specialist in the prevention, diagnosis and treatment of allergies. The Pollinex Quattro (PQ) platform, an ultra-short-course subcutaneous allergy immunotherapy (SCIT), continues to gain market share despite its availability in the EU on a 'named-patient' (NP) basis only. Several products are in clinical development, with the aim of moving the platform to full registration under the new regulatory framework. AGY has issued a positive trading update highlighting the strong operating performance of the group. Also, it has reached a successful settlement of an ongoing legal dispute with one of its third-party R&D contractors.

- **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:** Underlying sales growth appears close to expectations, rising 8.7% to £74.0m (£68.3m). Although further Brexit costs (-£0.5m est.) have dented any prospect of gross margin improvement, this has been more than offset by lower spend on marketing (+£1.0m), G&A (+£1.0m) and R&D (+2.0m).
- **Legal settlement:** AGY has settled a legal dispute with Inflamm Research Inc (Inflamm) regarding the inconclusive US Phase II Grass MATA MPL trial. Inflamm has paid AGY \$7.4m/£6.0m in full settlement of the dispute. In addition, Inflamm has agreed to pay a 'substantial portion' of AGY's legal costs.
- **Risks:** AGY's primary risk lies in the timings of the regulatory approval process, mostly outside of its control, related to the PQ Birch immunotherapy and the European TAV process for full approval. Ongoing trials do represent a risk, but this is limited by the products' use on a named-patient basis.
- **Investment summary:** The share price continues to recover from the overly pessimistic view of the PQ Birch trial primary endpoint failure in March and the positive trading update and news that the legal dispute has been settled will help. Despite the recovery to date, AGY is trading on an EV/sales of only 0.93x 2019E, down to 0.86x 2020E – well below the multiples commanded by its direct competitors.

Financial summary and valuation

Year-end June (£m)	2016	2017	2018	2019E	2020E	2021E
Sales	48.5	64.1	68.3	74.0	80.3	88.7
R&D investment	-16.2	-9.3	-16.0	-14.0	-17.0	-15.0
Underlying EBIT	-12.3	-2.9	-6.4	-3.6	-6.2	-2.0
Reported EBIT	-12.5	-2.6	-7.4	1.4	-7.2	-3.0
Underlying PBT	-12.5	-3.0	-6.5	-3.7	-6.5	-2.3
Statutory PBT	-12.2	-2.7	-7.5	1.3	-7.5	-3.3
Underlying EPS (p)	-2.4	-0.5	-1.1	-0.6	-1.1	-0.5
Statutory EPS (p)	-2.3	-0.4	-1.3	0.2	-1.2	-0.6
Net (debt)/cash	20.0	18.8	12.5	20.0	10.9	-19.6
Capital increase	11.0	0.0	0.0	10.4	0.3	0.3
P/E (x)	-5.9	-29.8	-12.7	-23.9	-12.3	-27.8
EV/sales (x)	1.4	1.1	1.0	0.9	0.9	0.8

Source: Hardman & Co Life Sciences Research

2019 trading update

Consistent with usual practice, AGY has provided the market with a trading update. Unlike previous years, though, it has come just ahead of it entering its close period at the end of June because of a strong operating performance. The operational performance of the group has been very good, with sales rising ahead of the market average and, coupled with careful control of operating costs and a lower-than-expected R&D spend, the underlying EBIT and cash position will be better than we had previously forecast. In addition, AGY has announced the successful settlement of a legal dispute with one of its R&D contractors which will also boost the cash position.

Operating performance

Key features

- ▶ **Sales:** Underlying sales growth is expected to be ca.8.7% to £74.0m (£68.3m), continuing the positive trend seen in the traditionally stronger first-half of each fiscal year, due to the seasonality of pollen symptoms.
- ▶ **COGS:** Given that AGY manufactures the majority of its products in the UK and sells most of them in Europe, there have been inevitable additional costs (est - £0.5m) associated with the delay to Brexit. We now expect the gross margin to be broadly similar to the 75% reported for fiscal 2018.
- ▶ **Marketing spend:** Some recovery in the allergy market through a stronger pollen season, coupled with lower investment in major marketing campaigns reported in 1H'19, have led to a more modest rate of growth in marketing expenditure for the full year, reducing overall spend by ca.£1.0m to -£28.0m.
- ▶ **G&A:** Similarly, although administration costs have increased in 2H'19 compared with 1H'19, the rate of increase has been carefully controlled such that it looks set to be ca.£1.0m lower than previously forecast at -£17.0m.
- ▶ **R&D:** We often highlight how difficult it is to predict the timing of, and payment for, clinical trials. 2019 has been no exception for AGY. The statement indicates that R&D spend will be no higher than -£14.0m, which is approximately £2.0m lower than forecast. Influencing this has been the timing of the PQ grass project. In addition, the legal costs incurred in the dispute with Inflamax have been included in the R&D figure.
- ▶ **EBIT:** Taking all these points together, the underlying EBIT looks set to be about -£3.5m in fiscal 2019, compared with our previous forecast of -£7.2m.
- ▶ **Gross cash:** This improved operating performance, coupled with the legal settlement (see below) suggests that the gross cash position at 30 June will be ca.£23.0m, which reduces to a net cash position of £20.0m after allowing for debt.

Legal settlement

Included in its interim 2019 report, AGY stated that it was in a legal dispute with one of its third party R&D suppliers over potential cost overruns on one of its clinical trials, which had the potential to lead to additional expenses for the group. At that point in time, while no information was disclosed, we suspected that this related to the inconclusive 2016 US Phase II Grass MATA MPL trial.

At the interim stage, AGY had issued a claim of \$22m against the contractor in damages, and additionally, interest and legal fees. The third party was counter claiming \$4.3m in what it claims are unpaid invoices, plus interest and legal fees.

Based on legal advice, management was of the opinion that AGY had a strong claim against the contractor and a full defence to the counterclaim. This dispute has now been resolved, removing considerable uncertainty.

In a separate statement to the market, AGY has reached a successful settlement with Inflammax. AGY has received \$7.6m/£6.0m from Inflammax, which will be recorded as an exceptional item in the 2019 accounts. Although this settlement figure appears to be lower than the original claim for \$22m, a large element of the claim was for 'loss of future earnings'. Excluding this element, the original claim was for £10.2m (source: 2018 annual report).

Inflammax has also agreed to pay a substantial part of AGY's legal costs, although the precise amount and timing of payment are still to be agreed. At the time of writing, our forecasts have allowed for all the legal costs that have been incurred by AGY as part of R&D expenditure in fiscal years 2018 and 2019. This will be offset by the settlement, which has been included as an exceptional item in 2019. Forecasts do not allow for the potential recovery of part of these costs, which are likely to be resolved with Inflammax after the period-end and will be included, once disclosed, in fiscal 2020.

AGY also stated that the dispute did, as suspected, relate to the inconclusive Phase II Grass MATA MPL trial which took place in the US in 2015-16. The company had taken the decision to perform the trial in mobile challenge chambers provided by Inflammax because it provided greater flexibility regarding the timing of the trial – it could be run outside the pollen season – potentially speeding up the overall Grass MATA MPL trial programme. The rest is now history and AGY is back on a revised track with the US regulatory programme.

Changes to forecasts

All of our previous forecasts were based on constant currency to give a clearer picture of underlying performance. Current forecasts have been corrected for the impact of exchange. In fiscal 2019, there was a very small weakening of GBP against EUR. This has the effect of modestly improving reported sales, but reducing reported Spanish manufacturing costs and EU marketing costs. In addition, the figures in the table below take account of the reduced underlying operating costs highlighted on the previous page.

The litigation settlement is shown as an exceptional item. AGY is likely to include this within its overall administration line in the P&L account, but shown as a separate item for transparency.

Changes to forecasts						
Year-end Dec (£m)	2019E			2020E		
	*old	**new	***Δ	*old	**new	Δ
Sales	74.0	74.0	-	80.0	80.4	+0.4
COGS	-18.0	-18.5	-0.5	-18.7	-20.3	-1.6
Marketing	-29.2	-28.0	+1.0	-31.0	-29.8	+1.2
G&A	-18.0	-17.0	+1.0	-19.3	-19.5	-0.2
R&D	-16.0	-14.0	+2.0	-20.0	-17.0	+3.0
Underlying EBIT	-7.2	-3.5	+3.7	-9.0	-6.3	+2.7
Exceptionals	0.0	6.0	-	0.0	0.0	-
Underlying EPS (p)	-1.13	-0.59	-	-1.58	-0.64	-
Gross cash	15.8	23.0	+7.2	3.5	14.0	+9.5
Net cash/(debt)	12.8	20.0	-	0.4	10.9	-

*Based on constant currency; **corrected for actual exchange rates; ***underlying change
Numbers may not add up precisely due to rounding
Source: Hardman & Co Life Sciences Research

Summary financials

The following table is a summary of our detailed spreadsheet and reflects the changes stated on the previous pages.

- **Legal settlement:** Forecasts, under exceptional items, include the received legal settlement from Inflammix and the legal costs incurred to date by AGY. Agreement and receipt of the legal costs being recovered are likely to occur in fiscal 2020.

Summary financials						
Year-end Jun (£m)	2016	2017	2018	2019E	2020E	2021E
GBP:EUR	1.338	1.171	1.130	1.130	1.130	1.130
Profit & Loss:						
Sales	48.51	64.14	68.35	74.00	80.35	88.72
COGS	-14.07	-16.77	-17.01	-18.50	-20.30	-22.06
Gross profit	34.44	47.37	51.33	55.50	60.05	66.66
Gross margin	71.0%	73.9%	75.1%	75.0%	74.7%	75.1%
Marketing	-20.22	-26.89	-27.13	-28.04	-29.80	-32.33
Product profit	14.22	20.48	24.20	27.46	30.25	34.33
Product margin	29.3%	31.9%	35.4%	37.1%	37.7%	38.7%
G&A	-10.33	-14.08	-14.56	-17.02	-19.50	-21.35
R&D investment	-16.22	-9.30	-16.02	-14.00	-17.00	-15.00
EBITDA	-10.68	-0.96	-4.36	-1.09	-3.78	0.45
Depreciation	-1.43	-1.51	-1.57	-2.02	-2.02	-2.02
Underlying EBIT	-12.34	-2.89	-6.38	-3.56	-6.25	-2.02
EBIT margin	-25.4%	-4.5%	-9.3%	-4.8%	-7.8%	-2.3%
Net interest	-0.11	-0.07	-0.17	-0.13	-0.23	-0.33
Underlying pre-tax profit	-12.45	-2.97	-6.54	-3.69	-6.47	-2.35
Exceptional items	0.14	1.00	0.00	6.00	0.00	0.00
Tax payable/credit	-0.86	0.19	-0.01	-0.03	0.01	-0.18
Underlying net income	-13.46	-2.78	-6.55	-3.72	-7.23	-3.21
Weighted average (m)	570.3	592.2	595.1	633.4	636.2	636.2
Underlying basic EPS (p)	-2.36	-0.47	-1.10	-0.59	-1.14	-0.50
Underlying fully-dil. EPS (p)	-2.28	-0.45	-1.05	-0.56	-1.07	-0.47
Balance sheet (at 30 Jun):						
Share capital	0.60	0.60	0.61	0.64	0.64	0.64
Reserves	29.73	29.36	22.43	34.11	26.90	23.62
Liabilities	11.95	10.67	11.03	11.03	11.03	11.03
Debt	3.37	3.33	3.06	3.06	3.06	3.06
less: Cash	23.41	22.12	15.53	23.09	14.00	-16.54
Invested capital	39.32	42.66	51.24	61.11	69.85	100.42
Net cash/(debt)	20.04	18.80	12.48	20.04	10.94	-19.60
Cashflow:						
Underlying EBIT	-12.34	-2.89	-6.38	-3.56	-6.25	-2.02
Working capital	-1.45	2.16	0.21	-3.85	-0.35	-20.35
Exceptionals/provisions	0.00	0.00	0.00	6.00	0.00	0.00
Tax & interest	-0.30	-1.28	0.10	-0.76	-0.91	-0.32
Operational cashflow	-12.57	0.03	-3.78	-0.16	-5.49	-21.75
Capital expenditure	-1.23	-1.50	-2.01	-2.31	-3.46	-8.65
Free cashflow	-13.80	-1.47	-5.79	-2.46	-8.95	-30.39
Acquisitions	0.00	-0.23	-0.18	-0.10	-0.10	-0.10
Share issues	10.97	0.03	0.00	10.43	0.25	0.25
Change in net debt	-0.10	-1.25	-6.32	7.56	-9.10	-30.54
OCFPS (p)	-2.20	0.01	-0.64	-0.03	-0.86	-3.42

Source: Hardman & Co Life Sciences Research

Company matters

Registration

Incorporated in the UK with company registration number: 5141592

Registered address:

Dominion Way
Worthing
West Sussex
BN14 8SA

+44 1903 844 700

www.allergy.therapeutics.com

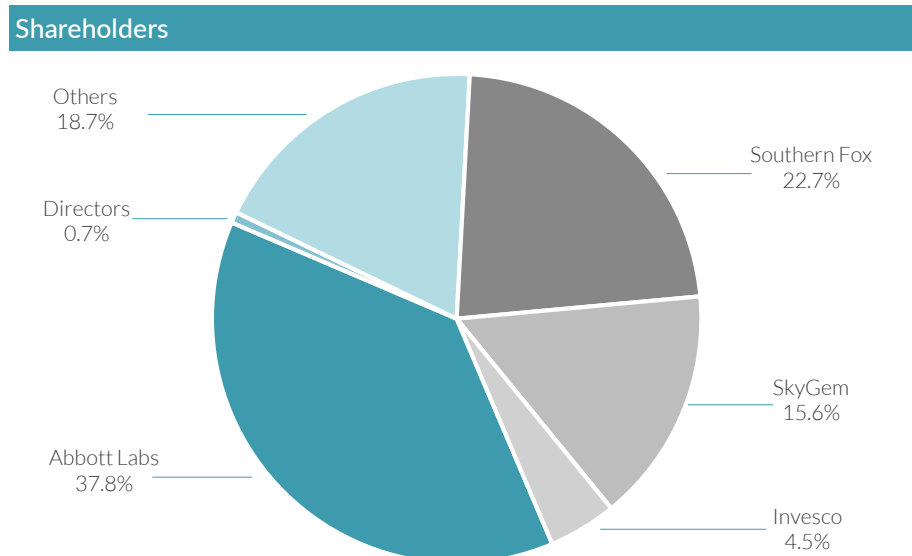
Board of Directors

Board of Directors				
Position	Name	Nominations	Remuneration	Audit
Chairman	Peter Jensen	C		M
Chief Executive Officer	Manuel Llobet			
Chief Financial Officer	Nick Wykeman			
Non-executive director	Scott Leinenweber			
Non-executive director	Tunde Otulana	M	M	
Non-executive director	Stephen Smith	M	C	C
Non-executive director	Mary Tavener			M

M = member; C = chair
Source: Company reports

Share capital

The total number of Ordinary shares of 0.1p in issue is 636,168,616. In addition, there are 25,968,750 share options outstanding with a low-cost exercise price.



Source: Hardman & Co Life Sciences Research

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