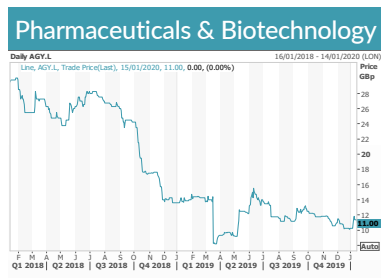




16 January 2020



Source: Refinitiv

Market data

EPIC/TKR	AGY
Price (p)	11.5
12m High (p)	17.8
12m Low (p)	7.3
Shares (m)	636.2
Mkt Cap (£m)	73.2
EV (£m)	48.2
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

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www.allergytherapeutics.com**Key shareholders**

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

Diary

Mar'20	Interim results
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ALLERGY THERAPEUTICS

Sales growth well above market average

Allergy Therapeutics (AGY) is a long-established specialist in the prevention, diagnosis and treatment of allergies. Pollinex Quattro (PQ) is an ultra-short course subcutaneous allergy immunotherapy (AIT) platform, which continues to make strong market share gains in a competitive environment. Several products using the PQ platform are in late-stage development, with the aim of moving them to full registration under new regulatory frameworks in both the EU and the US. AGY has just announced another solid operating performance and market share gains in its traditionally strong first half, with associated positive cashflow.

- **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.
- **1H'20 trading:** Underlying product sales were very solid again in 1H'20, rising 9% to £50.5m (£46.7m), suggesting further European market share gains. The gross cash position at the period-end was exactly in line with our forecast, at £39.7m, benefiting from the £3.2m settlement of legal costs with Inflammix.
- **Trial update:** The statement also highlighted progress made with two upcoming trials. First, AGY is taking a stepwise approach to the US Grass MATA MPL Phase III study, with the initial part starting in 2020. Secondly, peanut vaccine GMP material is being manufactured to support a Phase I trial.
- **Risks:** The risks inherent in subjective clinical trial outcomes were clear in the Phase III Birch trial. However, AGY prudently included an objective secondary endpoint of activity, which will be used in EU regulatory discussions about the way forward, and to adjust the pending US Phase III trial protocol.
- **Investment summary:** Over the last year, we have highlighted consistently that AGY is at an exciting juncture. While continuing to invest in its profitable European SCIT business, it is leading the race to have its SCIT products fully approved and regulated as biologicals in the US. Despite this, the current EV/sales appears too low for a company with a long and profitable product history, and well below the multiples commanded by direct competitors.

Financial summary and valuation

Year-end Jun (£m)	2017	2018	2019	2020E	2021E	2022E
Sales	64.1	68.3	73.7	80.0	86.0	92.0
R&D investment	-9.3	-16.0	-13.0	-16.0	-28.0	-15.0
Underlying EBIT	-3.6	-7.4	-2.2	-4.7	-16.2	-2.9
Reported EBIT	-2.6	-7.4	3.8	-1.4	-16.2	-2.9
Underlying PBT	-3.7	-7.5	-2.3	-4.8	-16.3	-3.1
Statutory PBT	-2.7	-7.5	3.7	-1.5	-16.3	-3.1
Underlying EPS (p)	-0.6	-1.3	-0.4	-0.9	-2.7	-0.6
Statutory EPS (p)	-0.4	-1.3	0.5	-0.2	-2.5	-0.5
Net (debt)/cash	18.8	12.5	25.0	20.6	1.7	-4.1
Equity issues	0.0	0.0	10.2	0.3	0.3	0.3
P/E (x)	-17.9	-8.3	-25.9	-12.0	-3.9	-16.8
EV/sales (x)	0.65	0.61	0.57	0.52	0.49	0.45

Source: Hardman & Co Life Sciences Research

1H'20 trading update

Another strong 1H'20 performance...

AGY has issued a trading statement to update the market on its positive operating performance during 1H'20, its traditionally stronger trading period. The company focused on two aspects – near double-digit sales growth across the portfolio and a clinical trial update.

Operating performance

- ▶ **Sales:** AGY reported that it had seen solid (9%) underlying sales growth of products in 1H'20 to £50.5m (£46.7m), which was marginally below our forecast 10% growth to £50.8m. Growth was seen across the portfolio, with particular progress seen with both Pollinex Quattro and Venomil.
- ▶ **Gross cash:** The cash balance at 31 December 2019 was £39.7m, which was exactly as we had forecast. This benefited from the strong trading contribution to cashflow (+£9m), coupled with the £3.2m receipt of legal fees from Inflamm Research Inc.

Actual vs. forecasts – summary					
Interims (£m)	1H'19 actual	1H'20 actual	Change	1H'20 forecast	Difference Δ
Sales	46.7	50.5	+9%	50.8	-0.3
Net cash/(debt)	*25.0	37.3	-	37.3	-
Gross cash	*27.4	39.7	+12.3	39.7	-

*at 30 June 2019

Source: Hardman & Co Life Sciences Research

...with further market share gains from competitors

AGY has again traded particularly well in 1H'20. The company consistently reports underlying sales growth in the range of 8%-10%, against a European allergy market growing at about half this level. The best performances in 1H'20 were seen in Germany, Spain, the Netherlands and Switzerland. At the time of writing, full-year sales data from AGY's competitors are unavailable, but, based upon their reported first-half performances, AGY has again made market share gains.

Clinical/regulatory update (all timings on a calendar basis)

Preparing for some important trials in 2020...

- ▶ **US Grass MATA MPL trial:** AGY announced, in November 2019, that it had decided to take a stepwise approach to the US Grass MATA MPL Phase III study. The initial stage will coincide with the 2020/21 allergy season, and allow an interim analysis before moving to the second stage. The protocol has been adjusted based upon knowledge obtained from the Phase III Birch trial (B301).
- ▶ **Peanut vaccine:** AGY continues to make progress towards commencing a Phase I peanut vaccine trial in 2020. Having developed a manufacturing process that was successfully scaled up for pre-clinical studies, AGY has commenced the manufacturing of commercial material under GMP conditions. This will be used to support its clinical trial application to proceed with a Phase I trial.
- ▶ **PQ Birch:** AGY has finalised and submitted its report on the Phase III Birch trial to the Paul-Ehrlich-Institut (PEI, German regulator). The company remains in dialogue with the regulator about the next steps to be taken with this product.
- ▶ **Acarovac MPL trials:** Following successful evaluation of the safety and tolerability of Acarovac MPL in a Phase I trial (AM101), AGY is continuing to prepare for the Phase II dosing trial, which is expected to start in the first half of calendar 2020

...with results expected in calendar 2021

Most of the news flow with respect to clinical trials in calendar 2020 will be regarding the commencement of studies, with results likely to be reported during 2021.

Financial summary

- ▶ At this stage, no changes have been made to our forecasts.
- ▶ Operational performance is heavily weighted to the traditionally strong first half for allergy products.
- ▶ R&D investment in 2020 will be second-half-weighted (forecast 1H:2H split -£6.0m:-£10.0m), which will have a corresponding impact on cashflow.

Financial summary						
Year-end Jun (£m)	2017	2018	2019	2020E	2021E	2022E
GBP:EUR	1.171	1.130	1.135	1.135	1.135	1.135
Profit & Loss						
Sales	64.14	68.35	73.72	79.96	86.01	92.02
COGS	-16.77	-17.01	-18.38	-20.14	-21.84	-22.91
Gross profit	47.37	51.33	55.34	59.82	64.17	69.12
Gross margin	73.9%	75.1%	75.1%	74.8%	74.6%	75.1%
Marketing	-26.89	-27.13	-27.00	-28.34	-30.75	-33.83
Product profit	20.48	24.20	28.34	31.47	33.41	35.29
Product margin	31.9%	35.4%	38.4%	39.4%	38.9%	38.3%
G&A	-14.08	-14.56	-16.23	-18.80	-20.22	-21.82
R&D	-9.30	-16.02	-12.99	-16.00	-28.00	-15.00
EBITDA	-1.66	-5.34	0.30	-2.16	-13.64	-0.36
Depreciation	-1.51	-1.57	-2.09	-2.09	-2.09	-2.09
Underlying EBIT	-3.60	-7.36	-2.24	-4.70	-16.18	-2.90
EBIT margin	-5.6%	-10.8%	-3.0%	-5.9%	-18.8%	-3.2%
Net interest	-0.07	-0.17	-0.10	-0.07	-0.13	-0.19
Underlying PBT	-3.67	-7.53	-2.34	-4.77	-16.31	-3.10
Tax payable/credit	0.19	-0.01	-0.23	-0.07	0.42	-0.21
Underlying net income	-3.48	-7.53	-2.57	-5.56	-17.14	-3.98
Weighted avg. shares (m)	592.2	595.1	632.8	636.2	636.2	636.2
Underlying EPS (p)	-0.59	-1.27	-0.41	-0.87	-2.70	-0.63
Fully-diluted EPS (p)	-0.57	-1.21	-0.39	-0.82	-2.49	-0.58
Balance sheet @30 Jun:						
Share capital	0.60	0.61	0.65	0.65	0.65	0.65
Reserves	29.36	22.43	36.91	35.62	19.99	16.93
Liabilities	10.67	11.03	12.77	12.77	12.77	12.77
Debt	3.33	3.06	2.44	2.44	2.44	2.44
less: Cash	22.12	15.53	27.44	23.08	4.18	-1.71
Invested capital	42.66	51.24	59.30	68.47	86.66	120.54
Net cash/debt	18.80	12.48	25.00	20.65	1.74	-4.15
Cashflow:						
Underlying EBIT	-3.60	-7.36	-2.24	-4.70	-16.18	-2.90
Working capital	2.16	0.21	-2.25	-0.77	-0.75	-0.88
Tax & interest	-1.28	0.10	0.17	-0.90	-0.20	0.23
Operational cashflow	0.04	-3.78	5.72	-0.98	-15.03	-1.47
Capital expenditure	-1.50	-2.01	-2.81	-3.23	-3.72	-4.27
Free cashflow	-1.46	-5.79	2.91	-4.21	-18.75	-5.74
Acquisitions	-0.23	-0.18	-0.29	-0.10	-0.10	-0.10
Share issues	0.03	0.00	10.20	0.25	0.25	0.25
Change in net debt	-1.25	-6.32	12.53	-4.36	-18.90	-5.89
OCFPS (p)	0.01	-0.64	0.90	-0.15	-2.36	-0.23

Source: Hardman & Co Life Sciences Research

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