Pharmaceuticals & Biotechnology

*Source: Eikon Thomson Reuters*

| Market data | |
|---|---|
| EPIC/TKR | **AGY** |
| Price (p) | 14.3 |
| 12m High (p) | 32.0 |
| 12m Low (p) | 13.5 |
| Shares (m) | 636.2 |
| Mkt Cap (£m) | 90.7 |
| EV (£m) | 78.2 |
| Free Float* | 39% |
| Market | AIM |

**As defined by AIM Rule 26*

## Description

Allergy Therapeutics (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% |
| Odey | 6.9% |
| Blackrock | 5.3% |
| Invesco | 4.5% |

## Diary

| | |
|---|---|
| 1Q'19 | Ph.III PQ Birch trial |
| Mar'19 | Interims |
| 1H'19 | Ph.I Acarovac trial |


## Analysts

Martin Hall 020 7194 7632
mh@hardmanandco.com
Dorothea Hill 020 7194 7626
dmh@hardmanandco.com
Grégoire Pavé 020 7194 7628
gp@hardmanandco.com


# ALLERGY THERAPEUTICS

## Trading update: gaining market share

**AGY is a long-established specialist in the prevention, diagnosis and treatment of allergies. The Pollinex Quattro (PQ) platform, the ultra-short course subcutaneous allergy immunotherapy (AIT), continues to gain market share, despite its availability in the EU only on a 'named-patient' basis. 2019 is expected to deliver progress in several areas, notably PQ Birch, for which top-line Phase III data are due in 1Q'19. A trading update has confirmed strong market share gains and cash generation in the traditionally strong 1H period. AGY also has important meetings scheduled with both the EU and US regulators during 1Q'19 regarding PQ grass trials.**

- **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 product sales were particularly strong in 1H'19, rising 10.6% to £46.7m (£42.2m) compared with our forecast of 7.0% growth, suggesting further market share gains. The cash position at the period-end was modestly below forecasts at £31.6m, representing £5.5m cash generation.

- **Clinical/regulatory update:** The statement also highlighted a wave of clinical and regulatory activity during 1H calendar 2019. Key will be the headline data from the European Phase III PQ Birch trial, expected in 1Q'19. In addition, meetings with both the FDA and the German regulators have been scheduled.

- **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:** AGY is approaching an exciting period. It has a clear vision, is gaining market share from competitors, and is leading the race to have its subcutaneous-administered products fully approved and regulated as biologicals – first in Europe and then in the US, where the regulators are demanding change. Read-out from the EU Phase III PQ Birch trial in 1Q'19 will provide the next major value inflection point.

## Financial summary and valuation

| Year-end Jun (£m) | 2016 | 2017 | 2018 | 2019E | 2020E | 2021E |
|---|---|---|---|---|---|---|
| Sales | 48.5 | 64.1 | 68.3 | 73.0 | 78.4 | 85.5 |
| R&D investment | -16.2 | -9.3 | -16.0 | -18.0 | -20.0 | -15.0 |
| Underlying EBIT | -12.3 | -2.9 | -6.4 | -7.8 | -8.9 | -2.0 |
| Reported EBIT | -12.5 | -2.6 | -7.4 | -8.8 | -9.9 | -3.0 |
| Underlying PBT | -12.5 | -3.0 | -6.5 | -8.1 | -9.2 | -2.4 |
| Statutory PBT | -12.2 | -2.7 | -7.5 | -9.1 | -10.2 | -3.3 |
| Underlying EPS (p) | -2.4 | -0.5 | -1.1 | -1.2 | -1.6 | -0.5 |
| Statutory EPS (p) | -2.3 | -0.4 | -1.3 | -1.4 | -1.6 | -0.5 |
| Net (debt)/cash | 20.0 | 18.8 | 12.5 | 13.8 | 1.7 | -29.0 |
| Capital increase | 11.0 | 0.0 | 0.0 | 10.4 | 0.3 | 0.3 |
| P/E (x) | -5.9 | -29.8 | -12.7 | -11.5 | -9.0 | -28.5 |
| EV/sales (x) | 1.6 | 1.2 | 1.1 | 1.0 | 1.0 | 0.9 |

*Source: Hardman & Co Life Sciences Research*

# 1H'19 trading update

Particularly strong 1H'19 performance…

AGY has issued a trading statement to update the market on its traditionally stronger first-half performance. The company focused on two aspects – operating performance and a clinical/regulatory update.

## *Operating performance*

- **Sales:** AGY reported that it had seen strong (10.6%) underlying growth of products in 1H'19 to £46.7m (£42.2m), which was well above our forecast 7.0% growth to £45.5m.
- **Cash:** The cash balance at 31 December 2018 was £31.6m, which was modestly (£0.5m) below our expectations based on the assumption that there has been no change in the debt/loan position (information not provided).

**Actual vs forecasts – summary**

| Interims £m | 1H'18 actual | 1H'19 actual | Change % | 1H'19 forecast | Difference Δ |
|---|---|---|---|---|---|
| Sales | 42.2 | 46.7 | +10.6% | 45.5 | +1.2 |
| Net cash/(debt) | 22.6 | - | - | 29.4 | - |
| Cash | 25.8 | 31.6 | - | 32.1 | -0.5 |

*Source: Hardman & Co Life Sciences Research*

…with significant market share gains from competitors

AGY has traded particularly well in 1H'19. Although some recovery in the rate of growth from a difficult European allergy market had been expected, underlying sales growth of 10.6% (vs. 1.3% in 1H'18) was well above our 7.0% forecast. At present, full-year sales data from AGY's competitors are unavailable, but based upon their reported first-half performances, AGY has made significant market share gains again.

The statement indicates that the sales growth was across a number of territories, including Germany, Austria, Switzerland and the Netherlands. In addition, growth was seen in Spain, despite a significant regulatory change in the marketplace. One manufacturer of bacterial products flouted the 'named-patient' rules, such that the regulator demanded that all bacterial products were withdrawn from the market. While AGY was also affected by this withdrawal, physicians were able to change to 'individual' treatments created by AGY, based on patient samples. Margins on these individual treatments were also relatively good.

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

Important flow of clinical and regulatory information during 2019

- Headline results from the European Phase III PQ Birch trial will be announced during 1Q'19.
- Headline data from the Phase I Acarovac (dust mite allergy) trial are expected to be announced during 1H'19.
- Meetings with the Paul-Ehrlich-Institut (PEI, German regulator) and the FDA, in relation to the PQ Grass trials, have been scheduled for 1Q'19.

AGY is going to have an important flow of clinical and regulatory information during 2019. First will be the headline data from its European Phase III PQ Birch trial. A positive outcome will provide the basis of a regulatory filing with the PEI, enabling AGY to become the first company to achieve full approval for a subcutaneous immunotherapy under the new regulations (note: regulatory approval has been achieved for some allergy therapies administered sub-lingually). Meetings with both EU and US regulators during 1Q'19 will also be very important.

# Financial summary

- 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 2019 will be second-half weighted.

| Financial summary | | | | | | |
|---|---|---|---|---|---|---|
| Year-end June (£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** | **73.04** | **78.39** | **85.54** |
| COGS | -14.07 | -16.77 | -17.01 | -17.89 | -18.42 | -19.75 |
| Gross profit | 34.44 | 47.37 | 51.33 | 55.15 | 59.97 | 65.79 |
| Gross margin | 71.0% | 73.9% | 75.1% | 75.5% | 76.5% | 76.9% |
| Marketing | -20.22 | -26.89 | -27.13 | -29.73 | -32.69 | -35.24 |
| Product profit | 14.22 | 20.48 | 24.20 | 25.42 | 27.29 | 30.54 |
| Product margin | 29.3% | 31.9% | 35.4% | 34.8% | 34.8% | 35.7% |
| G&A | -10.33 | -14.08 | -14.56 | -15.27 | -16.23 | -17.54 |
| R&D | -16.22 | -9.30 | -16.02 | -18.00 | -20.00 | -15.00 |
| EBITDA | -10.68 | -1.42 | -4.82 | -5.82 | -6.92 | 0.03 |
| Depreciation | -1.43 | -1.48 | -1.56 | -2.02 | -2.02 | -2.02 |
| **Underlying EBIT** | **-12.34** | **-2.89** | **-6.38** | **-7.84** | **-8.94** | **-1.99** |
| EBIT margin | -25.4% | -4.5% | -9.3% | -10.7% | -11.4% | -2.3% |
| Net interest | -0.11 | -0.07 | -0.17 | -0.24 | -0.27 | -0.37 |
| **Underlying pre-tax profit** | **-12.45** | **-2.97** | **-6.54** | **-8.08** | **-9.21** | **-2.36** |
| Tax | -0.86 | 0.19 | -0.01 | 0.34 | 0.22 | -0.09 |
| **Underlying net income** | **-13.46** | **-2.78** | **-6.55** | **-7.74** | **-9.89** | **-3.13** |
| | | | | | | |
| Weighted avg. shares (m) | 570.3 | 592.2 | 595.1 | 633.4 | 636.2 | 636.2 |
| **Underlying EPS (p)** | **-2.36** | **-0.47** | **-1.10** | **-1.22** | **-1.55** | **-0.49** |
| Fully-diluted EPS (p) | -2.28 | -0.45 | -1.05 | -1.16 | -1.46 | -0.45 |
| | | | | | | |
| Balance sheet @30 Jun: | | | | | | |
| Share capital | 0.60 | 0.60 | 0.61 | 0.64 | 0.64 | 0.64 |
| Reserves | 29.73 | 29.36 | 22.43 | 13.67 | 3.69 | 0.26 |
| 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 | 16.84 | 4.71 | -25.96 |
| **Invested capital** | **39.32** | **42.66** | **51.24** | **50.43** | **61.56** | **91.21** |
| Net cash/debt | 20.04 | 18.80 | 12.48 | 13.78 | 1.65 | -29.01 |
| | | | | | | |
| Cashflow: | | | | | | |
| Underlying EBIT | -12.34 | -2.89 | -6.38 | -7.84 | -8.94 | -1.99 |
| Working capital | -1.45 | 2.16 | 0.21 | 0.29 | -0.82 | -20.82 |
| Tax & interest | -0.30 | -1.28 | 0.10 | -0.88 | -0.77 | -0.16 |
| Operational cashflow | -12.57 | 0.03 | -3.78 | -6.41 | -8.52 | -21.87 |
| Capital expenditure | -1.23 | -1.50 | -2.01 | -2.31 | -3.46 | -8.65 |
| **Free cashflow** | **-13.80** | **-1.47** | **-5.79** | **-8.72** | **-11.98** | **-30.52** |
| 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** | **1.31** | **-12.13** | **-30.67** |
| Hardman FCF/sh. (p) | -2.20 | 0.01 | -0.64 | -1.01 | -1.34 | -3.44 |

*Source: Hardman & Co Life Sciences Research*

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research@hardmanandco.com

35 New Broad Street
London
EC2M 1NH

+44(0)20 7194 7622

www.hardmanandco.com