hardman&co

Pharmaceuticals & Biotechnology

*Source: Eikon Thomson Reuters*

| Market data | |
|---|---|
| EPIC/TKR | **AGY** |
| Price (p) | 27.3 |
| 12m High (p) | 39.5 |
| 12m Low (p) | 23.0 |
| Shares (m) | 594.1 |
| Mkt Cap (£m) | 161.9 |
| EV (£m) | 143.1 |
| 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 |
| 1H FY19 | Ph.II PQGrass trial results |
| 1H FY19 | Ph.III PQBirch trial results |


## Analysts

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# Allergy Therapeutics

## Grass allergy vaccine data imminent

**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 as a biologic for PQ Birch in Europe, and for PQ Grass in both Europe and the US, are well advanced. Recruitment to the Phase II PQ Grass trial is complete: more than 440 patients have undergone conjunctival provocation testing in a placebo-controlled, dose-response and safety study. Data are now expected in early 2H calendar 2018.**

- **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.

- **Allergy immunotherapy:** AIT is an option for severe allergies where symptoms are not adequately controlled by traditional products for symptomatic relief. It involves a course of prophylactic immunisations in order to reduce allergy severity. PQ Grass is a short-course, subcutaneous AIT (SCIT) for allergic rhinitis.

- **PQ Grass trial:** As part of the new clinical strategy, redesigned with the FDA following unexpected results from a US dose-finding study, recruitment has been successfully completed for the Phase II G205 PQ Grass study. This is evaluating dose-response and safety towards licensing applications in the US and Europe.

- **US market:** AGY anticipates that the US will be the main market for PQ Grass, with potential peak sales of $300m-$400m from grass AITs. The overall US AIT market is estimated at $2bn. Preference for route of administration differs among territories, e.g. subcutaneous injection in the US vs. sublingual in France.

- **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, and 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) | 56.4 | -11.5 | -46.4 | -16.9 | -28.0 | 21.4 |
| EV/sales (x) | 3.3 | 3.0 | 2.2 | 2.1 | 1.9 | 1.7 |

*Source: Hardman & Co Life Sciences Research*

# Grass allergy immunotherapy

**POLLINEX Quattro packaging**


*Source: Allergy Therapeutics*

## Pollinex Quattro (PQ)

Pollinex represents a technology platform that can be targeted to different allergies by altering the attached allergen/allergoid. In the form of PQ, it is administered as a short course of four injections over a three-week period, showing efficacy after three weeks that lasts for several years. The launch of PQ in 1999 was the first short-course allergy vaccine for the treatment of severe allergies. AGY sells PQ in Europe on a 'Named-Patient' basis only; it has been used in more than 200,000 patients to date. There are essentially three parts to PQ, which work synergistically to produce its beneficial effects:

- **Allergoid**: an allergen that is chemically modified by glutaraldehyde.
- **Adjuvant**: MPL, in-licensed from GSK, helps promote the immune response and is biodegradable.
- **Depot:** Micro Crystalline Tyrosine (MCT) keeps the allergoid and adjuvant near the injection site, and also helps to promote the immune response.

## PQ Grass development progress

### *Background*

'Named-Patient' approval allows AGY to make sales and garner experience with the product; however, this limited approval prevents universal marketing. With the backing of more clinical trials, the company is seeking full product approval as a biological in Europe and the US – since 2005, AGY has completed 14 clinical trials investigating PQ's safety and efficacy in ca.2,800 patients across Europe and North America. Unfortunately, this has been a tortuous process for reasons that were mostly out of AGY's hands – the introduction of Therapeutic Allergen Regulation in Europe in 2010 and a historical FDA-imposed 'clinical hold' in the US, which affected multiple companies in the allergy vaccine space. In Europe, AGY has submitted 10 therapeutic products, including PQ Grass, to the Paul Ehrlich Institut regulatory process – Therapieallergene-Verordnung (TAV) – for approval initially in Germany, to then facilitate access to other European countries.

### *US regulatory process*

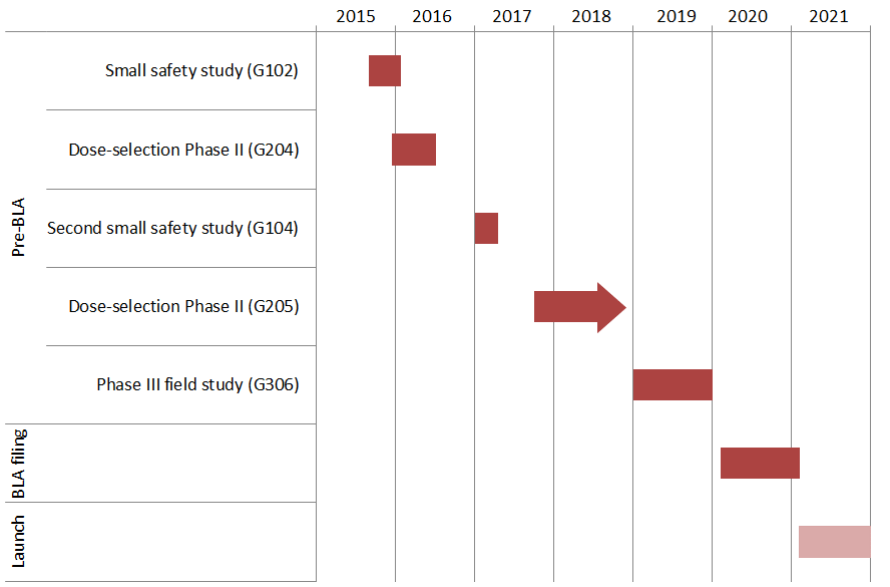
In late 2015, Grass MATA MPL (as PQ Grass is known in the US) demonstrated inconclusive results in the US dose-ranging study, G204. It is understood that this was due to issues surrounding subjective patient-reported rhinoconjunctivitis symptoms. The programme was revised with the FDA in 2016 (outlined in the chart below), whereby AGY undertook a successful second safety study (G104) to evaluate an additional dosing strength. This was completed in 1H calendar 2017, and PQ Grass/MATA MPL is currently in the Phase II G205 trial.

### *Phase II study*

The G205 dose-ranging conjunctival provocation study is being performed at 50 sites in Germany, Austria, and Poland and replaces the original US-based G204 study. More than 440 patients have been immunised subcutaneously with PQ Grass or with a placebo prior to conjunctival challenge with grass pollen allergen. Efficacy is being measured using total symptom score. This should provide the optimal dose of PQ Grass for the Phase III G306 field study, to be performed in both Europe and the US, to evaluate efficacy towards both a biologics license application (BLA) in the US and a marketing authorisation application (MAA) in Europe.

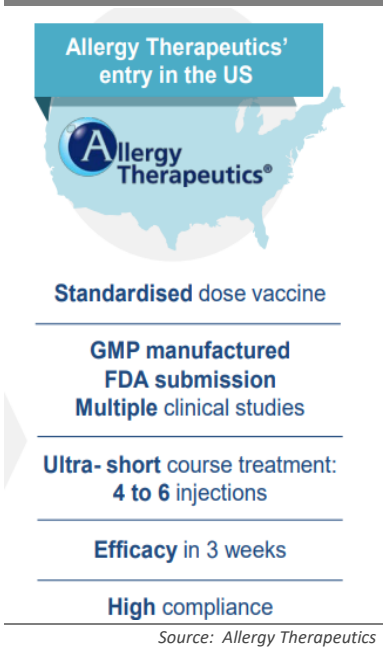
Data are expected to be released early in 2H calendar 2018 (1H fiscal 2019). While this is two years behind the original plans outlined in 2017, for the reasons outlined above, completion of recruitment is ahead of the revised expectations.

**MATA MPL: revised US clinical development plan**




*Arrow: stage currently ongoing; calendar year shown*
*Source: Hardman & Co Life Sciences Research*

**Changing US landscape**




*Source: Allergy Therapeutics*

## *Outlook*

The grass pollen season in central Europe and North America is from April to August, peaking in June. We would expect patient recruitment and immunisation to take place from 1H calendar 2019 in readiness for the start of the 2019 season – in April 2019. Phase III efficacy data could, therefore, be reported in the first half of calendar 2020, with BLA submission in the same year.

## US market

The AIT segment currently comprises only 10%[1] of the global allergy drug market; therefore, it is worth around $200m in the US. Once short-course SCIT products are approved, the AIT share of the allergy market is expected to grow rapidly. AGY estimates that sales of grass AIT products alone could reach $400m p.a.

If MATA MPL is approved as a biologic by the FDA, it will be the first registered SCIT in the US. This is a key market for the product, which, although already sold globally, will appeal particularly to US allergists, who have a preference for injectable allergy immunotherapies (SCITs) over the sublingual AITs. Sublingual formulations have sometimes struggled in the USA and Canada, as demonstrated by Merck & Co's return of GRASTEK® rights to ALK in 2016 following lower-than-expected sales. AGY has an advantage here: in the US, its competitors Stallergenes Greer and ALK have fully licensed sublingual grass AITs, and ASIT biotech has a grass SCIT that is currently still in clinical trials.

[1] ASIT Biotech Investor presentation 2017

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