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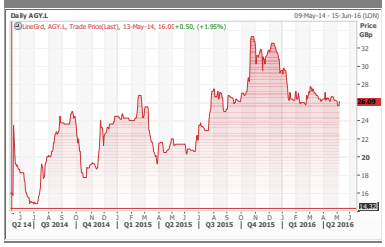
Pharmaceuticals & Biotech



Source: Fidessa

Market data

EPIC/TKR	AGY
Price (p)	26.5
12m High (p)	34.8
12m Low (p)	19.0
Shares (m)	589.2
Mkt Cap (£m)	156.1
EV (£m)	124.6
Free Float*	37%
Market	AIM

**As defined by AIM Rule 26*

Description

AGY provides information to professionals about prevention, diagnosis and treatment of allergic conditions with special focus on allergy vaccination, a successful treatment that deals with the underlying cause and not just the symptoms!

Company information

CEO	Manuel Llobet
CFO	Ian Postlethwaite
Chairman	Peter Jensen
	01483 685 670
	www.allergytherapeutics.com

Key shareholders

Directors	0.9%
Abbott Labs	40.8%
Southern Fox	21.2%
Odey	7.3%
Invesco	5.8%
Blackrock	3.2%

Next event

9 May	Latest Hardman Report
2Q 2016	G204 US dosing trial
Sept 2016	Finals
Nov 2016	AGM

Analysts

Martin Hall	020 7148 1433
	mh@hardmanandco.com
Gregoire Pave	020 7148 1434
	gp@hardmanandco.com

Allergy Therapeutics

Progress towards EU reg approval

AGY is a long-established specialist in the prevention, diagnosis and treatment of allergies. It's lead product, Pollinex Quattro is available in Europe only on a 'Named Patient' basis. However, protocols have been agreed with EU and US regulators for a programme of clinical trials to get full regulatory approval of Pollinex Quattro as a biological. AGY has reported positive outcomes from one of the trials required for EU approval. There remains a considerable valuation mis-match between AGY and its peers, which provides scope for considerable upside towards our risk-adjusted DCF valuation of 89p per share

- **Trial strategy**: AGY has an agreed three trial programme with the regulator by which Pollinex Quattro will receive full European approval as a short-course allergy vaccine. AGY has reported headline data from the second trial, PQ204, which will allow dose selection for the final Phase III trial starting early 2017.

- **PQ204:** This multi-dose, multi-centre, double-blind placebo-controlled Phase II trial was conducted in 371 patients sensitive to birch pollen. The aim of the study was to explore the safety and efficacy of Pollinex Quattro Birch (PQBirch) with the objective of identifying the optimal dose for the Phase III trial.

- **Results:** All doses (5,000-27,300 standardised units) of PQBirch produced a significant response compared to placebo, which was dose-dependent, thereby meeting the primary end-point. PQBirch was well tolerated and there were no safety concerns.

- **Valuation:** AGY has made considerable progress over the last 12 months towards de-risking its short course SCIT for target allergies in both Europe and the US. Despite this its valuation remains stubbornly below its peers, trading at an EV 4.0x to 9.7x lower, suggesting considerable upside potential ahead.

- **Investment summary:** Management is delivering on its goal to have its short-course allergy immunotherapy fully approved as a biologic in both Europe and the US. One-by-one the necessary trials are completing, keeping the regulatory filings on track for 2018. At some point the market will wake up to the growth prospects of the company and re-rate the shares more in-line with its peers.

Financial summary and valuation

Year end June (£m)	2013	2014	2015	2016E	2017E	2018E
Sales	39.28	41.96	43.23	46.06	49.26	53.25
R&D investment	-2.54	-2.96	-3.12	-13.00	-12.00	-10.00
Underlying EBIT	0.85	1.39	2.23	-9.36	-7.61	-4.72
Reported EBIT	0.67	1.21	0.72	-9.86	-7.61	-4.72
Underlying PTP	0.62	1.27	2.16	-9.45	-7.76	-4.91
Statutory PTP	0.43	1.08	0.65	-9.95	-7.76	-4.91
Underlying EPS (p)	0.17	0.20	0.34	-1.72	-1.40	-0.92
Statutory EPS (p)	0.13	0.16	0.02	-1.81	-1.40	-0.92
Net (debt)/cash	0.65	2.25	20.19	18.94	9.42	1.87
Capital increases	0.15	0.00	20.08	11.00	0.25	0.25
P/E (x)	154.4	126.9	76.5	-15.1	-18.6	-28.3
EV/sales (x)	3.1	2.9	2.8	2.6	2.5	2.3

Source: Hardman & Co Life Sciences Research

Progressing towards EU approval

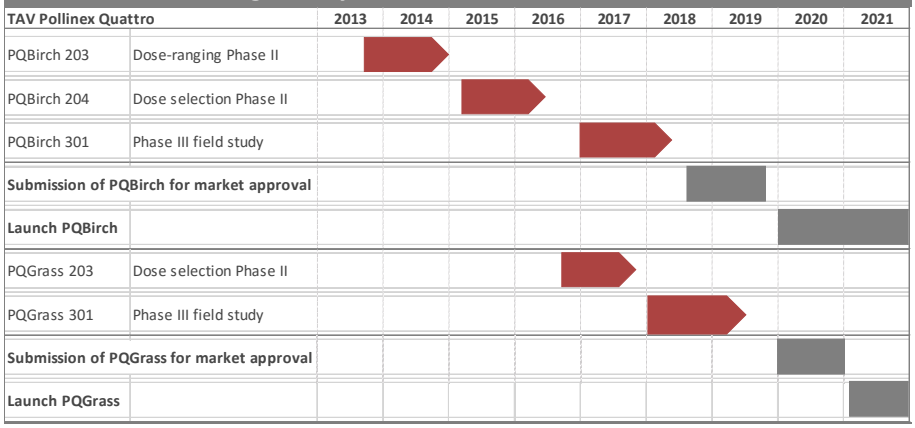
EU regulatory process

Pollinex Quattro has been available for some years in Europe...

...but only on a 'Named Patient' basis

Although Pollinex Quattro has been available in the EU for several years as the only short-course subcutaneous immunotherapy (SCIT), this has only been on a 'Named Patient' basis which limits the claims that can be made and marketing of the product. Towards the end of 2013, AGY agreed a programme of clinical trials whereby Pollinex Quattro could be approved as a biological with full marketing approval. The timetable that AGY has been working to is shown in the following graphic.

EU clinical trial & regulatory timetable



Source: Allergy Therapeutics; Hardman & Co Life Sciences Research

PQBirch 203

AGY has indicated previously that the Phase II PQBirch 203 study demonstrated a dose-response to Pollinex Quattro Birch (Birch Modified Allergen Tyrosine adsorbed and Monophosphoryl Lipid A (MPL)) in birch pollen induced seasonal allergic rhinitis for the dose range studied – 600 to 13,600 standardised units (SU).

Positive outcomes from PQBirch204 trial

PQBirch 204 is the second of three trials required for EU regulatory approval

AGY has now reported headline data from the second trial in the programme, PQBirch 204, a Phase II, multi-centre, double-blind placebo-controlled study exploring the safety and efficacy of different cumulative doses of PQ Birch.

371 patients were randomised into six cumulative dosing regimens plus placebo to evaluate the Total Symptom Score (TSS) following a conjunctival provocation test (CPT). The aim of the study was to identify the optimal dose of PQBirch to be used in the pivotal Phase III study due to start early in 2017.

PQBirch was both efficacious and safe

PQBirch showed a dose-dependent (5,000 to 27,300 SU) response compared to placebo, extending the dataset observed in the PQBirch 203 trial, and meeting the primary end-point. The product was well tolerated and there were no safety concerns reported in any treatment arm. Any adverse reactions that were observed did not appear to be related to the dose of the allergoid used.

A pivotal Phase III trial is scheduled to start early in 2017

Next steps

Full analysis of the data will allow the company to identify the optimal dose with which to perform the pivotal Phase III field study which will start early in 2017, coinciding with the birch pollen season. This trial is expected to take approximately 15-18 months to complete and read out. Following this, on the basis of a successful outcome – largely anticipated because Pollinex Quattro has been used successfully over a number of years in Named patients – PQBirch should be submitted to the European regulator around the middle of 2018, and approved in 2019.

Target market

Allergic rhinitis results from an IgE-mediated inflammation of the nasal mucosa and is thought to affect between 10% and 30% of the global population. Rates, if anything, are increasing and allergic rhinitis is a risk factor for development of asthma. In the 2013 'World Allergy Organisation White Book', the WHO estimated that there were 400 million people in the world suffering from allergic rhinitis and 300 million from asthma, which clearly identifies the scale of the problem.

Valuation

Considerable de-risking has had little impact on valuation...

...this must surely correct at some point

Despite the progress that Allergy therapeutics has made over the last 12 months, considerably de-risking the probability that Pollinex Quattro and GrassMATAMPL will be approved by the EMEA and the FDA respectively, the valuation of the company remains stubbornly below its four competitors/peers. AGY is the only player with a short-course immunotherapy in the market and good growth prospects once it receives full regulatory approval as a biologic.

Circassia and DBV Technologies have new technologies which will compete with Pollinex Quattro, if successful, in the longer-term. In contrast, ALK-Abelló and Stallergenes have stronger market positions with the established low-growth technologies, but without the potential to boost growth with new technologies. Yet all these companies command valuations that are 4.0x to 9.7x greater than that given Allergy Therapeutics by the market. Over time this will surely correct.

Comparative valuation

Company	ALK-Abello	Allergy Therap	Circassia	DBV Technologies	Stallergenes
Ticker	ALKB.CO	AGY.L	CIR.L	DBV.PA	STLEF.PK
	DKK	£	£	€	€
Share price	1,129.0	25.6	269.3	53.0	52.3
Shares in issue	9.7	589.2	284.9	24.2	14.1
Market cap	10,906.3	150.8	767.2	1,283.6	735.2
Mkt cap (£m)	1,158.5	150.8	767.2	1,014.7	581.2
Cash	608.0	33.2	203.8	326.1	150.2
Debt	-645.0	-1.8	0.0	-4.6	-17.7
EV (lc)	10,943.3	119.4	563.4	962.1	602.7
EV (£m)	**1,162.4**	**119.4**	**563.4**	**760.6**	**476.5**
2015 Sales	2,393.0	45.6	0.0	0.0	273.0
EV/sales	4.6	2.6	-	-	2.2
Relative EV	**9.7**		**4.7**	**6.4**	**4.0**

Prices taken at the close of business on 6th May 2016
Source: Hardman & Co Life Sciences Research

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Hardman & Co Research Limited (trading as Hardman & Co)
11/12 Tokenhouse Yard
London
EC2R 7AS
T +44 (0) 207 929 3399

Follow us on Twitter @HardmanandCo

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Hardman & Co

11/12 Tokenhouse Yard
London
EC2R 7AS
United Kingdom

Tel: +44(0)20 7929 3399
Fax: +44(0)20 7929 3377

www.hardmanandco.com