Pharmaceuticals & Biotechnology

Source: Refinitiv

Market data	
EPIC/TKR	**AGY**
Price (p)	13.0
12m High (p)	24.5
12m Low (p)	8.3
Shares (m)	636.2
Mkt Cap (£m)	82.7
EV (£m)	57.7
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

Nov'19	AGM
Jan'20	Trading update
Mch'20	Interim 2020 results

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

Continuing to gain market share

Allergy Therapeutics (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. Several products are in clinical development, with the aim of moving the platform to full registration under the new regulatory frameworks in both the EU and the US. Management has the plan and resources to achieve the ultimate goal: to be the first to launch a fully-regulated subcutaneous immunotherapy product in the US market.

- **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.

- **2019 results:** Underlying sales grew 8% to £73.7m (£68.3m) in a flat market, equating to a market share gain of ca.0.6ppts to 14.1%. The product profit margin (pre-R&D) increased 3.0ppts to 38.4% (35.4%). The net cash position was £25.0m, boosted subsequently by a $4.1m/£3.3m settlement of legal costs.

- **R&D update:** AGY is still analysing why the subjective primary endpoint in the Phase III Birch trial was not met, while there was a significant effect observed with the objective secondary endpoint. The findings will be used to tighten the US Phase III Grass MATA MPL trial protocol, due to start in 2H calendar 2020.

- **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 trial protocol.

- **Investment summary:** The strong trading updates, coupled with positive settlement of the outstanding litigation, have seen some share price recovery from the low caused by the PQ Birch trial outcome in March. Despite the recovery to date, AGY is trading on an EV/sales of only 0.72x 2020E, reducing to 0.67x 2021E. In our view, this is 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	-4.2
Equity issues	0.0	0.0	10.2	0.3	0.3	0.3
P/E (x)	-22.1	-10.3	-32.0	-14.9	-4.8	-20.8
EV/sales (x)	0.90	0.84	0.78	0.72	0.67	0.63

Source: Hardman & Co Life Sciences Research

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2019 results summary

Financials – key features

- **Sales:** Underlying sales grew 8% to £73.7m, as indicated in the June and July trading statements, and consistent with our forecast of £74.0m prior to those statements being issued.
- **Gross margin:** Given that AGY manufactures the majority of its products in the UK and sells most of them in Europe, any potential gains from the weakness of sterling were offset by inevitable additional Brexit-related costs (-£0.6m).
- **Marketing:** The lower investment in major marketing campaigns reported at the half-year stage has been maintained throughout the year, leaving overall spend unchanged, which was £2.1m better than we had forecast.
- **R&D:** AGY had already indicated that R&D spend would be coming in lower than expected due to the timing of, and payment for, clinical trials.

2019 results – actual vs. expectations

Year to Jun (£m)	2018 actual	2019 actual	Change	2019 *forecast	Delta Δ
Sales	68.4	73.7	8.0%	74.0	-0.3
COGS	-17.0	-18.4	8.0%	-18.0	-0.4
Marketing	-27.1	-27.0	-0.1%	-29.2	+2.2
Product profitability	**24.2**	**28.3**	**17.1%**	**26.8**	**+1.5**
Product margin	35.4%	38.4%		36.2%	+2.2pp
G&A	-14.6	-16.2	11.5%	-18.0	+1.8
Share-based costs	-1.0	-1.4		-1.0	-0.4
R&D	-16.0	-13.0	-18.0%	-14.0	+1.0
Underlying EBIT	-7.4	-2.2		-6.2	+4.0
Underlying EPS (p)	-1.3	-0.4		-0.7	+0.3
Net cash/(debt)	**12.5**	**25.0**		**14.8**	**+4.2**

**Our forecast prior to company trading statements made on 27 June 2019 and 11 July 2019*
Figures may not add up exactly due to rounding
Source: Hardman & Co Life Sciences Research

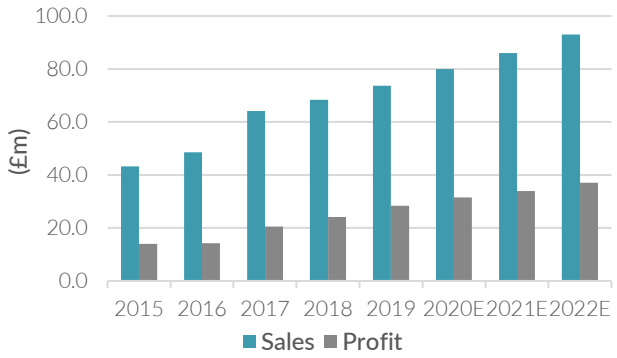
Operations – key features

- **Market share:** AGY estimates that it has gained 0.6ppts market share in Europe to 14.1%. This is consistent with our estimate of 14.5%, based on ex-factory sales data for 2018 compiled from the leading five players.
- **Birch trial:** Failure to show a treatment effect on the subjective primary endpoint in the Phase III Birch trial was inconsistent with the objective secondary endpoint measurement of immunoglobulin levels. Full analysis of the data and discussions with both the EU and US regulators are continuing.
- **R&D:** AGY reported a successful outcome in the Phase I trial with modified house dust mite (HDM), and has scaled up the manufacturing process of virus-like particles (VLP) for the peanut product.

Litigation

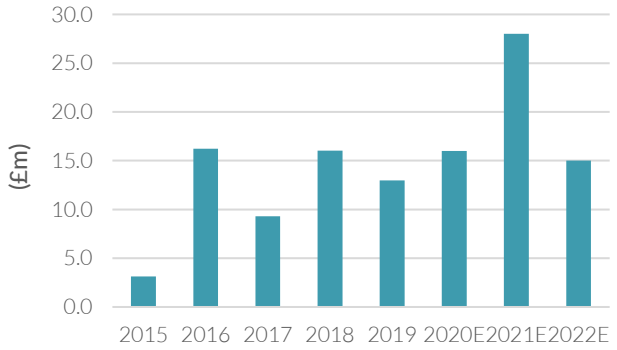
AGY reached a successful settlement with Inflamax for breach of contract and misrepresentation with respect to its Phase II US Grass trial run in 2015/16. AGY has received $7.6m/£6.0m from Inflamax, which has been recorded as an exceptional item in the 2019 accounts. In addition, post the period-end for inclusion in the fiscal 2020 accounts, AGY has agreed, and received, a $4.1m/£3.3m reimbursement of its legal expenses associated with the case.

Sales and product profit



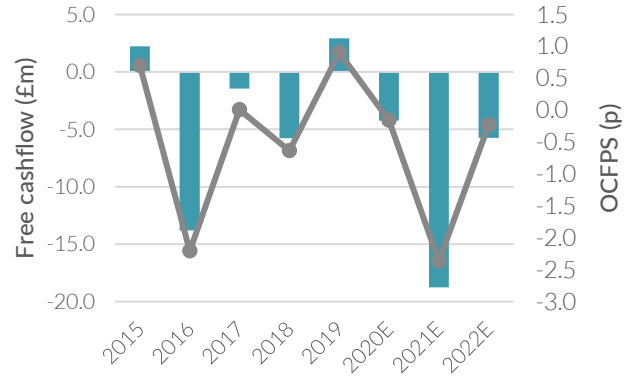
- Vast majority of sales are derived from a portfolio of AIT products sold in European markets
- Even though availability of products is limited – named-patient basis only – AGY has a long track record of growth
- After taking account of manufacturing, distribution and marketing costs, in-market products are profitable
- Product margins have risen consistently over the last five years, reaching 38.4% in fiscal 2019

R&D investment



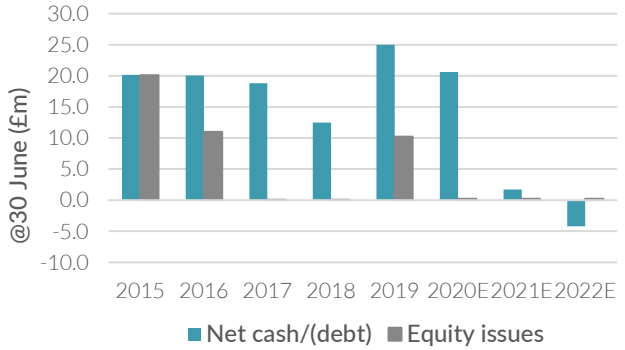
- Cumulative investment in R&D since 2000 has been >£125m
- R&D investment is forecast to rise substantially to get PQ products onto the market in the US and formally approved in Europe
- The US Grass MATA MPL trial will cost an estimated $20m/£16m over the next two years, but will pave the way to regulatory approvals in a changing marketplace
- AGY also has a number of smaller trials planned for the next two years

Free cashflow and OCFPS



- In each of the last five years, AGY has generated free cashflow from its operating activities (before R&D)
- Considerable investment in R&D and marketing will result in three years of cash burn
- The cash requirement towards the end of this decade will be dependent on the commercialisation strategy in the US
- In following the inorganic growth strategy, although acquisitions tend to be small, more cash might be required

Net cash/(debt) and equity issues



- £10m was raised in July 2018, largely to fund the key EU and US trials
- The net cash position was boosted in 2019 by the £6.0m legal settlement, with costs (£3.3m) benefiting 2020
- Based on current forecasts, AGY has a cash runway until fiscal 2021
- Should management decide to commercialise PQ in the US by itself, AGY will require working capital for investment in sales infrastructure

Source: Allergy Therapeutics, Hardman & Co Life Sciences Research

Three-pronged growth strategy

For a number of years, AGY has been focused on a growth strategy that is being driven by three approaches, all working concurrently:

- **Expansion in Europe:** Take advantage of the merits of its ultra-short course subcutaneous immunotherapy (SCIT) to grow market share of its profitable business in Europe.
- **New products and technologies:** Use the current revenue stream to invest in new products and technologies, further expanding growth opportunities.
- **Preparing for the US:** Invest in ultra-short course SCIT technology to submit for regulatory approval in the US, the largest allergy market in the world, which is undergoing significant regulatory change.

Expansion in Europe

European allergy market grew 2.3% to €620m in 2018

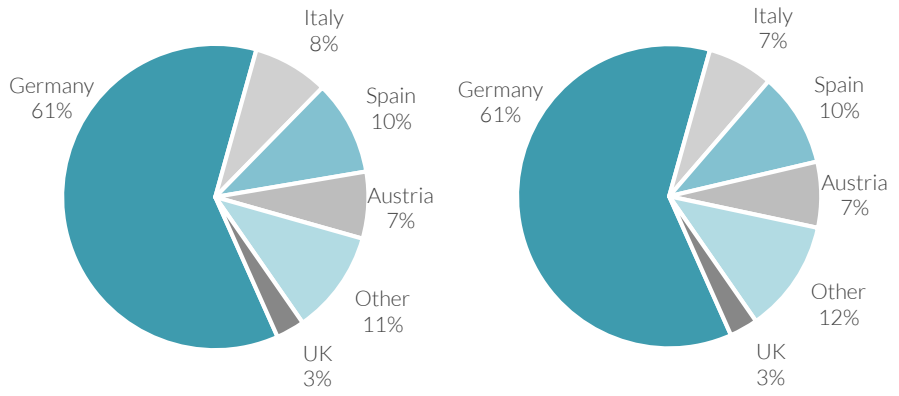
At present, AGY's products and sales are predominantly (97%) derived from Europe. Given that its fiscal year-end is June, results encompass the second half of the allergy market for 2018 and the first half for 2019. During calendar 2018, there were no notable changes to either pricing or reimbursement for AIT in Europe – except for France, a market where AGY does not operate – and overall market conditions were largely stable, despite the slightly lower incidence of grass pollen due to the hot weather. Based on ex-factory sales data compiled from the five leading players, the European market grew 2.3% to €620m in 2018, with this increase being accounted for entirely by the sales recovery of Stallergenes Greer in France.

Major markets

8% sales growth in generally flat markets

Against this backdrop, AGY's 8% sales growth in 2019 highlights its strong performance. This equates to a 0.7ppt gain in overall market share to 12.6%, and a 0.6ppt market share gain to 14.1% in the territories in which it operates. Particularly strong sales growth was reported in Austria, the Netherlands and Spain, while Germany saw 7.6% growth and remains AGY's strongest market, representing 61% of group sales. Once again, Italy was the weak spot; however, the rate of sales decline in 2019 (-2.5%) was markedly reduced compared with the 10.4% fall in fiscal 2018.

Geographical sales analysis



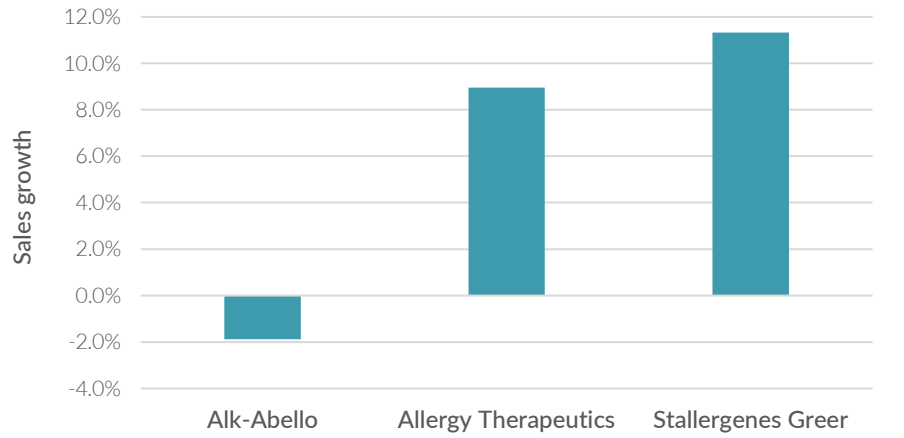
2018 sales: £68.3m | 2019 sales: £73.7m

Figures are based on consolidated reported sales figures
Source: Allergy Therapeutics, Hardman & Co Life Sciences Research

Performance relative to competition

A summary of the performance of the three main players in Europe in calendar 2018 is provided in the following chart.

Sales growth in Europe – 2018



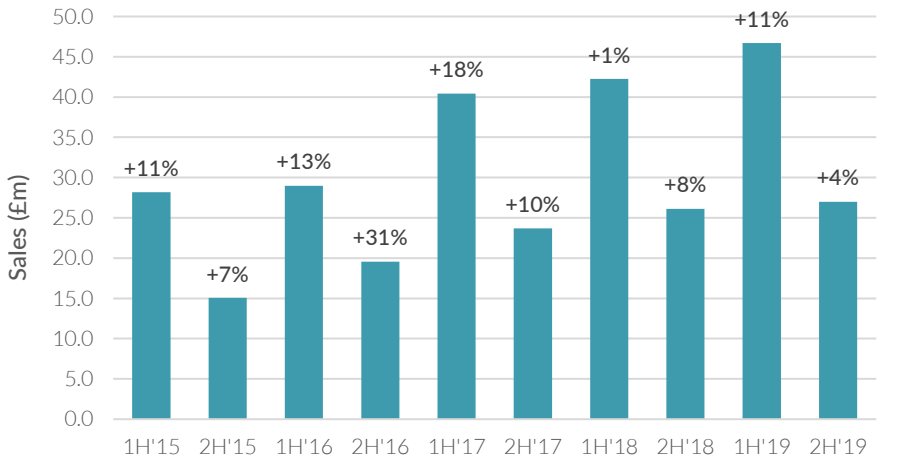
Source: Hardman & Co Life Sciences Research

Product performance

Consistent seasonal growth performance

AGY's trading performance remains very strong. Excluding R&D costs, underlying operating profit in fiscal 2019 improved by 24% to £10.8m (£8.7m). The company's AITs are currently sold on a named-patient basis in Europe, where they are highly competitive, being convenient short-course treatments. Underlying operating profit was aided in 2019 by an improving product margin, at 38.4% (35.4%), driven by containment of selling and marketing costs, despite the weakness of sterling against the Euro. At the group level, AGY incurred Brexit-related costs estimated to be ca.£0.6m.

Half-year sales trend and underlying growth rates



Source: Hardman & Co Life Sciences Research

Pollinex franchise

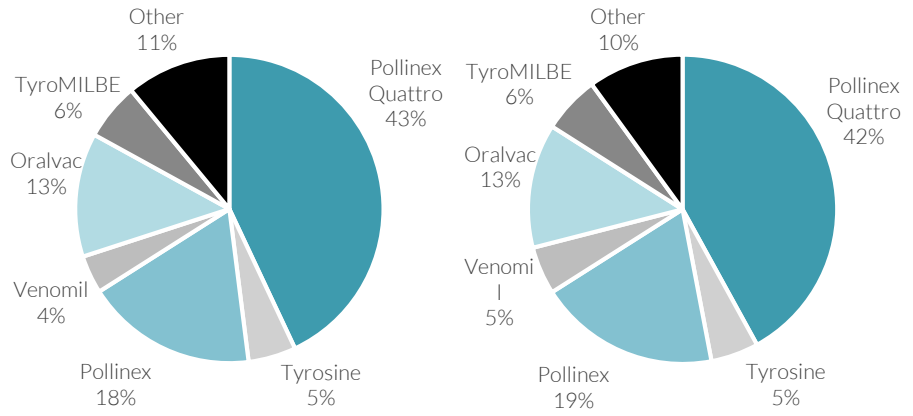
PQ and Pollinex dominate sales performance

The PQ immunotherapy brand in Europe (PQ Grass and Trees) remains the company's biggest seller, with ca.£31m in sales in the 12 months to June 2019. Although an earlier version of PQ, not being based on Monophosphoryl Lipid A (MPL), Pollinex also continues to sell well, bringing in sales of ca.£14m.

Venomil

The other mover in fiscal 2019 was Venomil, a specialist product used for bee and wasp allergies, which was used by a number of allergists for the first time.

Product sales analysis



2018 sales: £68.3m | 2019 sales: £73.7m

Source: Hardman & Co Life Sciences Research

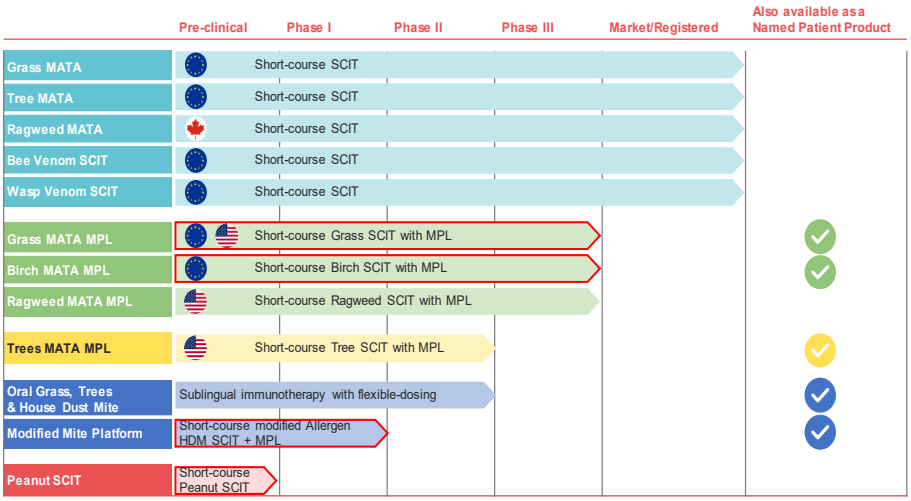
New products and technologies

Background

All of AGY's products remain in the TAV regulatory process

In 2008, under the direction of the Paul Ehrlich Institute (PEI) and based on European legislation, the Therapieallergene-Verordnung (TAV, Therapy Allergy Ordinance) in Germany commenced a process to have allergy vaccines fully regulated. At the beginning of the process, documentation for 123 vaccines was submitted to the TAV for consideration, including 10 from AGY. By September 2018 (as announced at the PEI seminar), the number of products remaining in the process had been reduced to 58 (ca.47%) through either withdrawal of applications or being turned down by the PEI. All of AGY's products remain in the process to become fully regulated.

Marketed and pipeline product portfolio



SCIT: Subcutaneous Immunotherapy
MATA: Modified Allergen Tyrosine Adsorbed
Source: Allergy Therapeutics

Clinical trial update

Phase III B301 PQ Birch trial

Phase III B301 Birch trial result was disappointing…

The key event in fiscal 2019 was the outcome from the Phase III B301 PQ Birch trial, which had been designed to support AGY's submission to the PEI to have PQ Birch moved from named-patient to full marketing approval. The B301 trial protocol was designed following positive outcomes in two Phase II trials and involved 582 patients recruited across 59 centres in four European countries.

…and inconsistent with the secondary objective endpoint

Although there was no difference between treated and placebo in the subjective primary endpoint, there was a strong and sustained immune response ($p<0.0001$) in the active arm of the study for the objective measurement of biomarkers of an immune response (immunoglobulins IgG and IgG4) as a secondary endpoint. AGY is using the information generated in this study to adjust the protocol for the equivalent trial in the US, which will be used to support the regulatory filing of Grass MATA MPL with the FDA.

Phase I Acarovac MPL trial

The AM101 Phase I HDM study was designed to support AGY's development of a fully-approved HDM allergy vaccine (Acarovac MPL) that builds on the success of the named-patient HDM allergy vaccine (Acarovac Plus) in Portugal and Austria.

AM101 evaluated the safety and tolerability of Acarovac MPL in 16 patients with allergic rhinoconjunctivitis in a 6- to 12-week course of treatment involving seven injections. The seven injections, spaced one to two weeks apart, were found to be well tolerated. The potential of this product is an eight-injection model compared with 12-15 for competitors, or once daily oral tablets for three years. The Phase II dosing trial is expected to start in the first half of calendar 2020.

Platform technologies

AGY has a range of cutting-edge platform technologies

AGY is at the forefront of technologies that aim to help allergy patients to manage their disease, which is a leading cause of lost work and school days. For most of the last century, salts of aluminium were the only approved adjuvants for use in humans, despite the fact that they affect the T-helper cells and, therefore, the type of antibodies produced. In addition, they are not biodegradable, and dangerous accumulation can occur if given in multiple doses. One of the key goals is the elimination of aluminium as an adjuvant from injectable allergy products, and AGY is a leader in this field, with a number of cutting-edge platform technologies.

Cutting-edge platform technologies

	Modified Allergen (Allergoid)	Native Allergen	Recombinant Allergen	Microcrystalline Tyrosine (MCT)	Monophosphoryl Lipid A (MPL)	Virus-Like Particles (VLP)
MATA	✓			✓		
MATA MPL (PQ)	✓			✓	✓	
Sublingual		✓				
Mite SCIT	✓			✓		
Mite SCIT + MPL	✓			✓	✓	
Venom SCIT		✓				
Peanut*			✓	✓		✓

**Product under pre-clinical investigation, with full product profile yet to be determined*
Source: Allergy Therapeutics

More recently, AGY has been investigating the use of VLP as a carrier. VLPs are derived from a bacteriophage (viruses that infect bacteria only), which does not include any viral genetic material, so they are unable to replicate. This sophisticated technology is being used to enhance, among others, the Polyvac peanut allergy product offering.

Preparing for the US

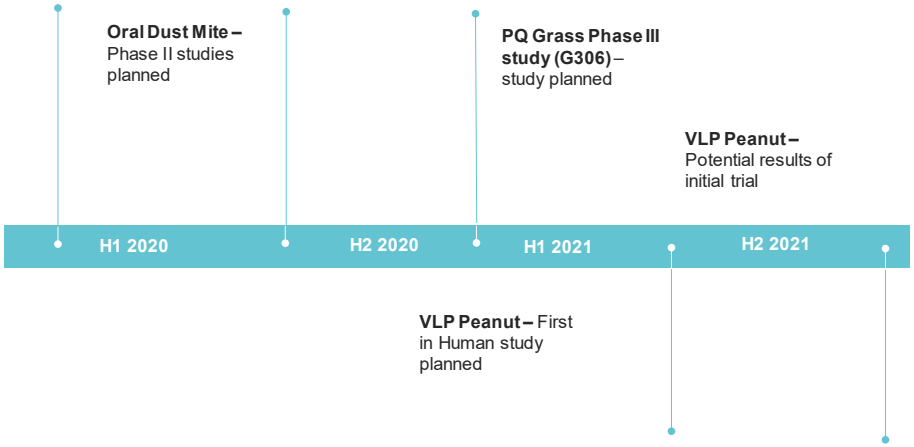
The US represents an enormous opportunity for AGY. At present, the US SCIT market is characterised by allergists creating home-made unlicensed vaccines for injection into patients. This is usually performed in non-registered, non-GMP facilities, and there is a drive by both the United States Pharmacopeia (USP), a legally recognised compendium of standards for drugs, and the FDA towards having the market regulated by pharmaceutical-grade, centrally-manufactured treatments.

AGY aiming to start Phase III Grass MATA MPL trial in the US in autumn 2020

Through its trial programme, AGY is aiming to be the first company to have a fully-regulated, standardised-dose vaccine commercially available on the US market. While the European Phase III B301 Birch trial was a setback, it has allowed the company to reconsider and tighten up the US protocol for its Phase III Grass MATA MPL trial, which is expected to start in autumn 2020.

News flow

Trial news flow in 2020/21



Source: Allergy Therapeutics

Financial forecasts

Profit & Loss

- **Sales:** Our forecasts are based on the assumption that AGY's differentiated products will continue to gain market share in Europe, which will equate to an annual growth rate in the range of 7%-8%.
- **Costs:** We believe that management will continue to keep tight control of costs, notwithstanding the need to invest to drive further market share gains.
- **R&D:** Timing of results and payment for clinical trials is extremely difficult to predict. However, given the expected commencement of the Phase III Grass trial in the US and progress with other trials, we expect £50m-£55m spend over a three-year period, subject to financing.
- **Litigation settlement:** The initial settlement (2019) and the costs settlement (2020) are shown as exceptional items, and not included in the underlying performance figures.

Profit & Loss account						
Year-end Jun (£m)	**2017**	**2018**	**2019**	**2020E**	**2021E**	**2022E**
GBP:EUR	1.171	1.130	1.135	1.135	1.135	1.135
GBP:USD	1.281	1.341	1.297	1.297	1.297	1.297
Sales	64.14	68.35	73.70	80.00	86.00	92.00
COGS	-16.77	-17.01	-18.38	-20.14	-21.84	-22.91
Gross profit	47.37	51.33	55.32	59.86	64.16	69.09
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
Share-based costs	-0.70	-0.99	-1.37	-1.37	-1.37	-1.37
R&D investment	-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
Other income	0.00	0.00	0.00	0.00	0.00	0.00
Underlying EBIT	**-3.60**	**-7.36**	**-2.24**	**-4.70**	**-16.18**	**-2.90**
Exceptional items	1.00	0.00	6.04	3.30	0.00	0.00
Statutory EBIT	-2.60	-7.36	3.80	-1.40	-16.18	-2.90
Net financials	-0.07	-0.17	-0.10	-0.07	-0.13	-0.20
Underlying PBT	**-3.67**	**-7.53**	**-2.34**	**-4.77**	**-16.31**	**-3.10**
Extraordinary items	0.00	0.00	0.00	0.00	0.00	0.00
Statutory PBT	-2.67	-7.53	3.70	-1.47	-16.31	-3.10
Tax payable/credit	0.19	-0.01	-0.23	-0.07	0.42	-0.21
Minorities	0.00	0.00	0.00	0.00	0.00	0.00
Underlying net income	**-3.48**	**-7.53**	**-2.57**	**-5.56**	**-17.14**	**-3.98**
Statutory net income	-2.48	-7.53	3.47	-1.54	-15.88	-3.31
Ordinary 0.1p shares:						
Period-end (m)	594.1	596.2	636.2	636.2	636.2	636.2
Weighted average (m)	592.2	595.1	633.4	636.2	636.2	636.2
Fully-diluted (m)	613.4	621.1	664.4	675.1	687.1	689.1
Underlying basic EPS (p)	**-0.59**	**-1.27**	**-0.41**	**-0.87**	**-2.70**	**-0.63**
Statutory basic EPS (p)	-0.42	-1.27	0.55	-0.24	-2.50	-0.52
Underlying fully-dil. EPS (p)	-0.57	-1.21	-0.39	-0.82	-2.50	-0.58
Statutory fully-dil. EPS (p)	-0.40	-1.21	0.52	-0.23	-2.31	-0.48
DPS (p)	0.00	0.00	0.00	0.00	0.00	0.00

Source: Hardman & Co Life Sciences Research

Balance sheet

- **Net cash/(debt):** At 30 June 2019, AGY had net cash of £25.0m, comprised of a cash balance of £27.4m less debt, mostly long-term, of -£2.4m. The debt is largely within AGY's Alerpharma subsidiary in Spain, providing a natural currency hedge. Based on cashflow forecasts, AGY has sufficient cash through to the end of fiscal 2021.
- **Seasonality:** There is a natural first-half bias to performance due to the seasonality of allergy treatment, with more cash being generated in the first half of the year from operations (ex-R&D).
- **R&D:** AGY's accounting policy is to write off R&D investment in the year in which the expense is incurred. Solely for the calculation of invested capital and NOPLAT, we add back R&D and amortise it over eight years to enable a direct comparison of ROIC among all the companies under coverage.
- **Inventories:** Building up stock for either the seasonality of the business or in preparation for upcoming clinical trials means that AGY tends to carry an average of about six months' supply of inventory.

Balance sheet						
@30 Jun (£m)	**2017**	**2018**	**2019**	**2020E**	**2021E**	**2022E**
Shareholders' funds	29.97	23.03	37.56	36.27	20.63	17.58
Cumulated goodwill	0.00	0.00	0.00	0.00	0.00	0.00
Total equity	29.97	23.03	37.56	36.27	20.63	17.58
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
Capitalised R&D	25.42	34.69	39.53	45.63	60.56	91.60
Minorities	0.00	0.00	0.00	0.00	0.00	0.00
Provisions/liabilities	0.70	0.38	0.70	0.70	0.70	0.70
Deferred tax	0.35	0.31	0.32	0.32	0.32	0.32
Long-term loans	2.94	2.41	1.74	1.74	1.74	1.74
Short-term debt	0.39	0.64	0.69	0.69	0.69	0.69
less: Cash	22.12	15.53	27.44	23.06	4.14	-1.75
less: Deposits	0.00	0.00	0.00	0.00	0.00	0.00
less: Non-core investments	4.59	5.04	5.55	5.55	5.55	5.55
Invested capital	**42.66**	**51.24**	**59.30**	**68.49**	**86.70**	**120.58**
Fixed assets	9.67	10.10	11.48	13.07	15.15	17.78
Intangible assets	2.07	1.54	1.41	0.96	0.51	0.06
Capitalised R&D	25.42	34.69	39.53	45.63	60.56	91.60
Goodwill	3.39	3.41	3.43	3.43	3.43	3.43
Inventories	7.48	8.81	9.41	10.21	10.98	11.75
Trade debtors	*4.34*	*3.78*	*3.83*	*4.15*	*4.47*	*4.78*
Other debtors	*3.52*	*2.80*	*5.95*	*6.95*	*7.95*	*7.95*
Tax liability/credit	*-1.54*	*-2.22*	*-2.22*	*-0.23*	*-0.07*	*0.42*
Trade creditors	*-2.88*	*-3.19*	*-3.45*	*-3.78*	*-4.10*	*-4.30*
Other creditors	*-8.81*	*-8.48*	*-10.07*	*-11.89*	*-12.17*	*-12.89*
Debtors less creditors	-5.37	-7.30	-5.96	-4.81	-3.92	-4.04
Invested capital	**42.66**	**51.24**	**59.30**	**68.49**	**86.70**	**120.58**
Net cash/(debt)	**18.80**	**12.48**	**25.00**	**20.63**	**1.70**	**-4.18**
Net debt/equity	63%	54%	67%	57%	8%	-24%
After-tax ROIC	-9%	-15%	-5%	-8%	-20%	-3%
NAV/share (p)	5.06	3.87	5.93	5.70	3.24	2.76
Stock days	165	167	170	160	165	169
Debtor days	26	22	19	18	18	17
Creditor days	65	65	66	66	66	67

Source: Hardman & Co Life Sciences Research

Cashflow

- **Cash outflow:** Increased R&D expenditure in the next three years offsets cash generated from product sales, resulting in overall cash burn over the forecast period.
- **R&D investment:** Important clinical trials are due to begin, for which stage payments will be made in fiscal 2020 and 2021. Forecasts are based solely on the planned clinical trial programmes; however, in all likelihood, further clinical trials for the pipeline (including for house dust mites and peanuts) will be performed in fiscal 2020, which may alter the spend profile.
- **Litigation settlement:** As noted earlier, receipts from Inflamax in relation to the settlement itself (2019) and the legal costs (2020) are shown as exceptionals in the cashflow statement.
- **Cash position:** The capital increase in July 2018 has provided sufficient funds to undertake the Phase III PQ Grass trials in the US and Europe. Both the timing and size of the US Grass trial will dictate the need for more cash. In the event that more capital is required, this could come from one of, or a combination of, equity, debt and licensing/distribution deals.

Cashflow						
Year-end Jun (£m)	**2017**	**2018**	**2019**	**2020E**	**2021E**	**2022E**
Underlying EBIT	-3.60	-7.36	-2.24	-4.70	-16.18	-2.90
Depreciation	1.51	1.57	1.64	1.64	1.64	1.64
Amortisation	0.43	0.45	0.45	0.45	0.45	0.45
Share-based costs	0.70	0.99	1.37	1.37	1.37	1.37
Inventories	*0.33*	*-1.33*	*-0.54*	*-0.80*	*-0.77*	*-0.77*
Receivables	*1.00*	*3.30*	*-1.86*	*-0.32*	*-0.31*	*-0.31*
Payables	*0.82*	*-1.76*	*0.16*	*0.33*	*0.32*	*0.20*
Change in working capital	2.16	0.21	-2.25	-0.79	-0.77	-0.88
Exceptionals/provisions	0.00	0.00	6.04	3.30	0.00	0.00
Disposals	0.00	0.01	0.00	0.00	0.00	0.00
Other	0.11	0.26	0.54	0.00	0.00	0.00
Company operating cashflow	1.32	-3.88	5.55	-0.10	-14.85	-1.69
Net interest	-0.18	-0.27	-0.05	-0.07	-0.13	-0.20
Tax paid/received	-1.10	0.37	0.23	-0.83	-0.07	0.42
Operational cashflow	**0.04**	**-3.78**	**5.72**	**-1.00**	**-15.05**	**-1.46**
Capital expenditure	-1.50	-2.01	-2.81	-3.23	-3.72	-4.27
Capitalised R&D	0.00	0.00	0.00	0.00	0.00	0.00
Sale of fixed assets	0.00	0.00	0.00	0.00	0.00	0.00
Free cashflow	**-1.46**	**-5.79**	**2.91**	**-4.23**	**-18.77**	**-5.74**
Dividends	0.00	0.00	0.00	0.00	0.00	0.00
Acquisitions	-0.23	-0.18	-0.29	-0.10	-0.10	-0.10
Disposals	0.00	0.00	0.00	0.00	0.00	0.00
Other investments	-0.26	-0.37	-0.41	-0.30	-0.30	-0.30
Cashflow after investments	**-1.95**	**-6.33**	**2.22**	**-4.63**	**-19.17**	**-6.14**
Share repurchases	0.00	0.00	0.00	0.00	0.00	0.00
Share issues	0.03	0.00	10.20	0.25	0.25	0.25
Currency effect	0.67	0.01	0.12	0.00	0.00	0.00
Borrowings acquired	0.00	0.00	0.00	0.00	0.00	0.00
Change in net debt	**-1.25**	**-6.32**	**12.53**	**-4.38**	**-18.92**	**-5.89**
Opening net cash	20.04	18.80	12.48	25.00	20.63	1.70
Closing net cash	**18.80**	**12.48**	**25.00**	**20.63**	**1.70**	**-4.18**
OCFPS (p)	0.01	-0.64	0.90	-0.16	-2.37	-0.23

Source: Hardman & Co Life Sciences Research

Valuation

Shares trading on EV/sales of only 0.72x 2020E, reducing to 0.67x 2021E

When considering the valuation of AGY, the market tends to ignore that the company has a long history of sales and profits in the specialist field of AITs. This has been achieved without any significant marketing, with its key products, the ultra-short course SCITs, being available only on a named-patient basis in Europe. The company then uses these profits to reinvest in R&D, with the aim of obtaining full regulatory approval as a biological in both the EU and the US. While there is still some way to go to achieve this goal, the market appears to be taking an overly pessimistic view, with the shares trading on a prospective EV/sales of just 0.72x.

Comparative valuation

- **Quoted peers:** There are now only two quoted peers in the AIT field: Alk-Abello, the world #1, and DBV Technologies, a relatively new player, which has just submitted its BLA to the FDA for peanut allergy.
- **Stallergenes Greer:** In May 2019, Stallergenes Greer was taken private through its acquisition by Ares Life Sciences, a specialist life sciences investor, for an EV of €677m/£604m, equating to an exit multiple of 2.3x sales.

Peer comparisons

Company	Alk-Abello	Allergy Therapeutics	DBV Technologies
Ticker	ALKb.CO	AGY.L	DBV.PA
Local currency (l.c.)	DKK	GB£	EUR
Share price*	1,313	12.5	27.7
Shares in issue (m)	11.1	636.2	36.2
Market cap (l.c. m)	14,521	79.5	1,002
Market cap (£m)	**1,713**	**79.5**	**894.3**
Cash	207	27.4	107.3
Debt	-951	-2.4	-4.6
EV (l.c. m)	15,265	54.5	898.9
EV (£m)	**1,801**	**54.5**	**802.6**
Relative EV	33.0x	-	14.7x
EV/sales	4.6x	**0.65x	∞

**At close of business on 23 September 2019, **corrected for a December year-end*
Source: Hardman & Co Life Sciences Research

Discounted cashflow

Valuing biopharmaceutical companies on a DCF basis

The best approach to valuing biopharmaceutical companies is to prepare detailed discounted cashflow (DCF) analyses of key products through to patent expiry and then to risk-adjust the NPV based upon industry standards for the probability of the product reaching the market. In the case of AGY, given that PQ has the potential to dominate sales and profits of the company, we have undertaken such an analysis just on this one technology. This methodology is totally dependent on the input assumptions for the US market and implies a risk-adjusted NPV of 48p per share.

DCF analysis

DCF for forecast period (£m)	744	100%
Terminal value (£m)	0	0%
Total enterprise value (£m)	**744**	**100%**
Net cash/(debt) in year 1 (£m)	25	
Implied market value (£m)	769	
Fully diluted shares (m)	636	
Implied value per share (p)	121	
Risk adjustment/probability (completed Phase IIb)	40%	
Risk-adjusted NPV (p)	**48**	

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

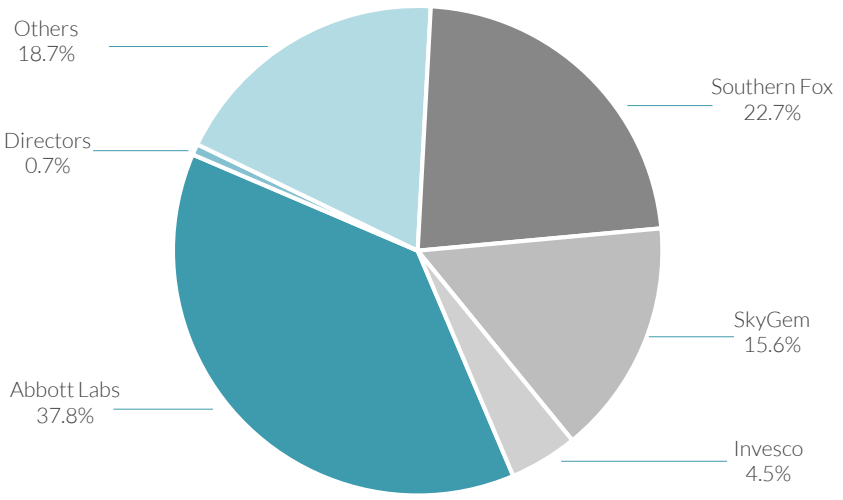
Position	Name	Nominations	Remuneration	Audit
Chairman	Peter Jensen	C		M
Chief Executive Officer	Manuel Llobet			
Chief Financial Officer	Nick Wykeman			
Non-executive director	Scott Leinenweber			
Non-executive director	Tunde Otulana	M	M	
Non-executive director	Stephen Smith	M	C	M
Non-executive director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

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.

Shareholders



Source: Hardman & Co Life Sciences Research

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The full detail is on page 26 of the full directive, which can be accessed here: http://ec.europa.eu/finance/docs/level-2-measures/mifid-delegated-regulation-2016-2031.pdf

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research@hardmanandco.com

35 New Broad Street
London
EC2M 1NH

+44(0)20 7194 7622

www.hardmanandco.com