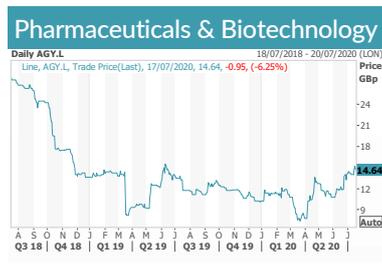




20 July 2020



Source: Refinitiv

**Market data**

EPIC/TKR	AGY
Price (p)	14.3
12m High (p)	15.0
12m Low (p)	7.3
Shares (m)	637.3
Mkt Cap (£m)	90.8
EV (£m)	66.6
Free Float*	23%
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
	<a href="http://www.allergytherapeutics.com">www.allergytherapeutics.com</a>

**Key shareholders**

Directors	0.7%
Abbott Labs	37.8%
Southern Fox	20.2%
SkyGem	19.5%
River & Mercantile	4.8%

**Diary**

23 Sep	Final results
Nov'20	AGM
2H'21	Ph. I peanut vaccine trial

**Analyst**

Martin Hall	020 7194 7622
	<a href="mailto:mh@hardmanandco.com">mh@hardmanandco.com</a>

# ALLERGY THERAPEUTICS

## Record sales and a COVID-19 wildcard

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 (SCIT) platform, which continues to make strong market share gains in a competitive environment. Several products using the PQ platform are in late-stage development in order to move them to full registration under new EU and US regulations. Another reassuring trading update states that the company has hit new records and has the resources in place to fund its pending R&D investment programme required to get its products approved by the regulators.

- **Strategy:** AGY is a fully integrated pharmaceutical company focused on the treatment of allergies. There are three parts to its strategy: i) continued development of its European business via investment or opportunistic acquisitions; ii) the US PQ opportunity; and iii) further development of its pipeline.
- **Trading update:** Sales in the past quarter were affected by the difficulty associated with patients attending hospitals during the COVID-19 lockdown. Despite this, June returned to "normal" and underlying sales in fiscal 2020 have grown 7% to £78.2m. AGY has strong gross cash of £37.0m to fund its future R&D investment.
- **COVID-19 test:** With financial support from government and official institutions in Spain, AGY has invested into expanding its microbiological diagnostic facilities (AT Immunolab) to run COVID-19 tests. At full capacity, its real-time SARS-COV-2 test is expected to be able to perform 200,000 tests a year.
- **Risks:** Over the next two years, AGY will be running several important clinical trials which, by their very nature, have binary outcomes. This is mitigated to some extent by the company's long-standing experience. Forecasts must be viewed as provisional in the event of a second wave of the COVID-19 pandemic.
- **Investment summary:** Despite COVID-19, AGY has reported another record year for sales in fiscal 2020, with June reassuringly returning to "normal" levels. Operating efficiencies and the timing of R&D investment have led to a strong EBIT performance. AGY is trading on an EV/sales of only 0.80x 2021E, which, in our view, is too low for a company with a long and profitable product history, and well below the multiples commanded by its direct competitors.

**Financial summary and valuation**

Year-end Jun (£m)	2017	2018E	2019E	2020E	2021E	2022E
Sales	64.1	68.3	73.7	78.2	83.0	88.0
R&D investment	-9.3	-16.0	-13.0	-7.0	-17.0	-22.0
Underlying EBIT	-3.6	-7.4	-2.2	4.1	-4.6	-7.9
Reported EBIT	-2.6	-7.4	3.8	7.3	-4.6	-7.9
Underlying PBT	-3.7	-7.5	-2.3	3.9	-5.0	-8.4
Statutory PBT	-2.7	-7.5	3.7	7.1	-5.0	-8.4
Underlying EPS (p)	-0.6	-1.3	-0.4	0.4	-1.1	-1.6
Statutory EPS (p)	-0.4	-1.3	0.5	0.9	-0.9	-1.4
Net cash/(debt)	18.8	12.5	25.0	24.2	16.3	4.6
Equity issues	0.0	0.0	10.6	0.3	0.3	0.3
P/E (x)	-24.2	-11.3	-35.1	38.0	-13.5	-8.9
EV/sales (x)	1.04	0.97	0.90	0.85	0.80	0.76

Source: Hardman &amp; Co Life Sciences Research

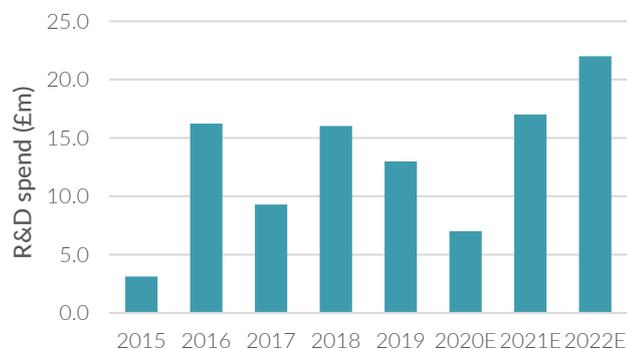
## Allergy Therapeutics

### Sales and product profit



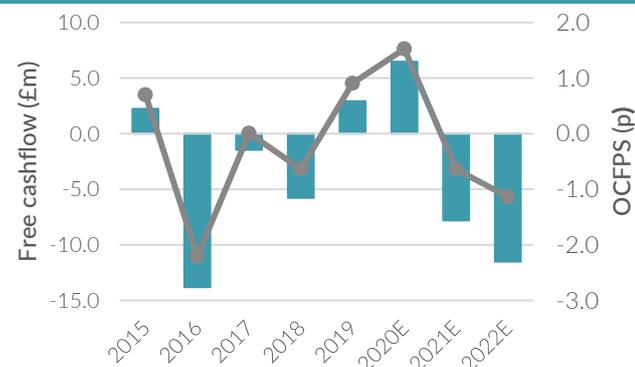
- ▶ Vast majority of sales are derived from a portfolio of AIT products sold in European markets.
- ▶ Even though availability of products is limited – named-patient basis only – AGY has a long track record of growth.
- ▶ After taking account of manufacturing, distribution and marketing costs, in-market products are profitable.
- ▶ Product margins have risen consistently over the past five years, reaching 39.8% in fiscal 2020.

### R&D investment



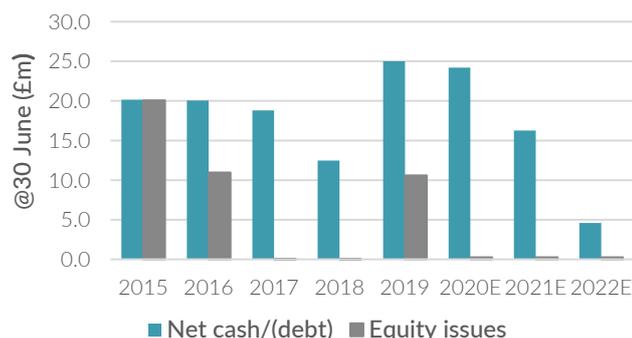
- ▶ Cumulative investment in R&D since 2000 has been >£141m.
- ▶ R&D investment is forecast to increase substantially to get PQ products onto the market in the US and formally approved in Europe.
- ▶ The US Gross MATA MPL trial will cost an estimated \$20m/£16m over the next two years, but will pave 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 past five years, AGY has generated free cashflow from its operating activities (before R&D).
- ▶ Considerable investment in R&D over the next three years will result in cash burn, which is resourced.
- ▶ 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



- ▶ Gross cash of £37.0m at 30 June 2020 will be used fund the planned US and EU trial programme.
- ▶ Based on current forecasts, AGY has a cash runway until fiscal 2023, dependent on exact timing of R&D spend.
- ▶ Should management decide to commercialise PQ in the US by itself, AGY will require working capital for investment in sales infrastructure.

Source: Company data; Hardman & Co Life Sciences Research

## Fiscal 2020 trading update

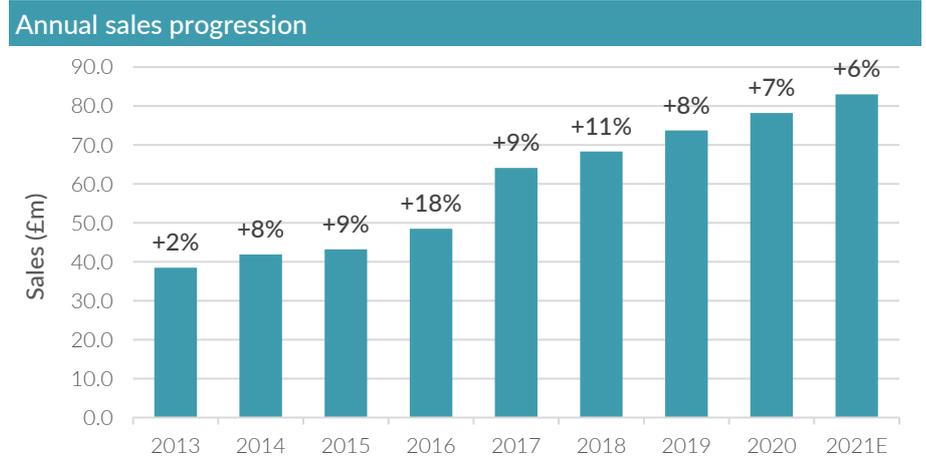
*Net profit in 2020 will be significantly ahead of market expectations*

Consistent with its usual practice, AGY has provided the market with a trading update for the market following completion of its fiscal year end. This is in addition to, and more detailed than, the positive statement issued in the trading update on 24 June, which highlighted that the company “*expected to deliver a net profit for the year significantly above market expectations*”. Overall, the operational performance of the group has been very good again in fiscal 2020, with sales rising ahead of the market average (Hardman & Co estimate) and, coupled with a programme of cost efficiencies, together with lower-than-expected R&D spend, the underlying EBIT and cash position were better than we had previously forecast.

*7% underlying sales growth despite some COVID-19-related weakness in Southern Europe*

### Product sales

Underlying sales in fiscal 2020 have grown 7% to £78.2m, only modestly below our previous forecast of £80.0m. As indicated before, sales in the past quarter were affected by the increased difficulty for patients to attend hospitals during the coronavirus lockdown, although there was a marked improvement back to normal activity during June as restrictions were eased in some countries. Overall, Northern Europe was less affected than Southern Europe. Based on our analysis of ex-factory sales for calendar 2019, we believe that this growth rate is above average resulting in further market share gains. AGY has a strong track record of underlying product sales growth over the past seven years, with a CAGR of 9.7%, as can be seen in the following chart.



Source: Hardman & Co Life Sciences Research

*Re-phasing of R&D investment pushed ca.£9m spend into next two years*

### R&D investment

The pandemic and recent global lockdown has affected the phasing of AGY’s planned three-year R&D investment programme to get its allergy vaccines formally approved in both Europe and the US. Among other plans, the early stages of a US trial have been rescheduled, resulting in a movement in spend from 2H’20 into 2021. Overall, R&D spend in fiscal 2020 is expected to be about £9m lower than originally forecast, at £7m. This spend has been moved into 2021 and 2022.

*Strong gross cash position to fund R&D programme*

### Net cash/(debt)

The gross cash position at 30 June 2020 was ahead of our forecast at £37.0m. However, the group has also used some of its short-term banking facility, with debt rising from -£2.0m at 31 December to -£3.8m on 30 June. Consistent with our research on all companies, treating financial leases as debt, the net cash position at 30 June was £24.2m, £10m better than our forecast due to the lower R&D spend.

# COVID-19 response

## Operational

*Company maintained supply chain throughout lockdown*

From the early stages of the COVID-19 outbreak, AGY implemented social distancing measures at all of its sites and split vital functions into separate teams to minimise the risk of workers becoming infected. Overall, the group appears to have coped well with the challenges presented by the pandemic, maintaining production and distribution throughout the lockdown, with no disruption to the supply chain.

*Impact has come from patients' ability to attend clinic appointments*

As mentioned earlier, the greatest impact was on patients' ability and willingness to attend the specialist clinics and hospitals during the lockdown. Trading in Southern Europe was more affected than in Northern Europe, largely due to the greater number of allergy clinics being located within hospitals. Reassuringly, the company reported that sales returned to "normal" levels in June, albeit this is a traditionally quieter period for the group.

## Real-time PCR testing capability

*WHO advice is to "test, test, test"*

The world was taken by surprise by COVID-19. Some countries, particularly the UK, appear to have been slow to react to the crisis. However, one of the reasons was that diagnostic tests for COVID-19 were either insufficiently developed and validated or, where they were available, there was inadequate manufacturing capacity to meet the global demand, at a time when the advice from the WHO was to "test, test, test".

*Many companies, including AGY, have stepped up to provide testing capacity*

What was under-appreciated by the stock market was the tremendous world-leading technologies that exist in many of the UK's small life sciences companies, with many, including AGY, ready and able to step up to the mark with diagnostic tests to detect either active virus (molecular PCR tests), previous exposure (antibody-based tests) or potential vaccines.

**When to use which SARS-CoV-2 diagnostic test?**

Is my sickness COVID-19?	How is my body's immune system reacting to the virus?
 <p><b>Tests that detect the virus</b></p> <ul style="list-style-type: none"> <li>Reverse transcription polymerase chain reaction (RT-PCR)</li> <li>Antigen tests</li> </ul>	 <p><b>Tests that detect immune response and potential immunity*</b></p> <ul style="list-style-type: none"> <li>Antibody tests</li> </ul>
 <p><b>Time &amp; disease progress</b></p>	

*\*Whether immunity is gained by individuals who have been infected with SARS-CoV-2 is yet to be confirmed due to the novelty of the virus  
Source: European Commission guidelines, Roche*

## Allergy Therapeutics

*Supported by Spanish government and institutions, AGY has invested in response to the need...*

*...that will reach 200,000 test p.a. at full capacity*

*Regular testing has become the “new normal” in trying to prevent a second wave*

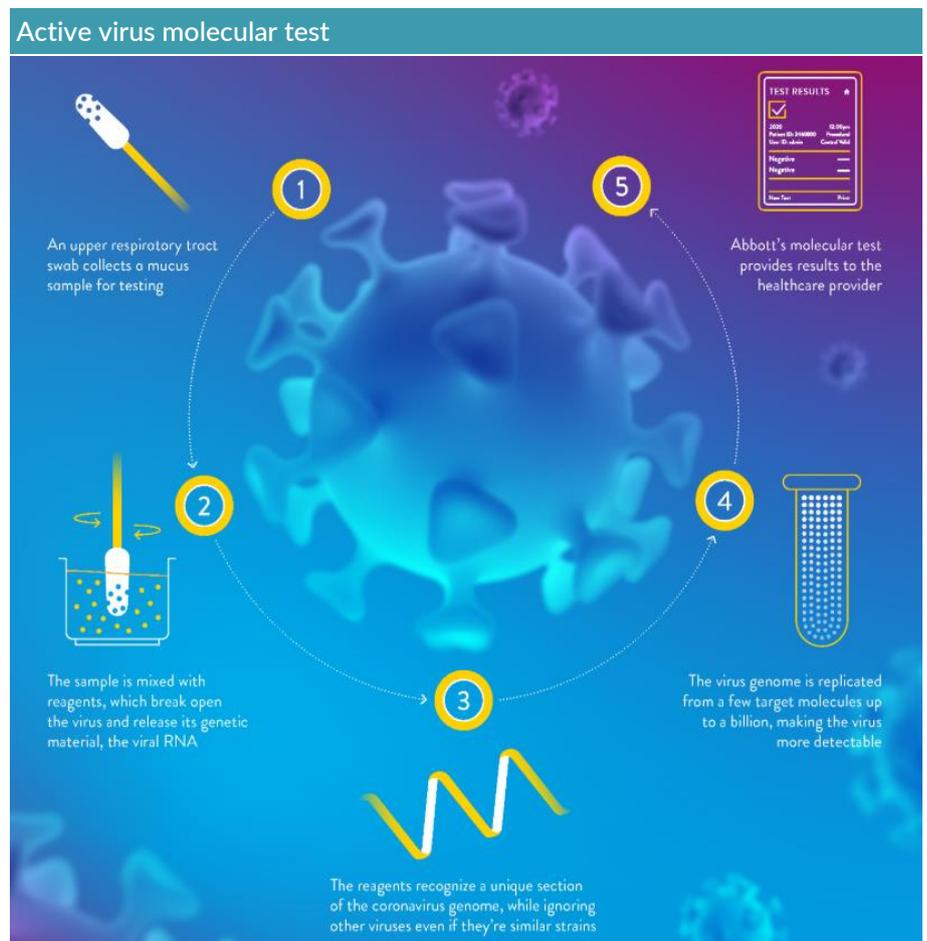
*PCR tests are used to identify active virus*

AGY has invested capital into expanding its microbiological diagnostic facilities (AT Immunolab) in Alcalá, Spain, in response to the urgent need to increase the global capacity to diagnose infected COVID-19 patients. This facility has been authorised by the Spanish Health Authority in a significantly accelerated timeframe and has received financial support from the Centre for the Development of Industrial Technology and the Technology Fund, the Ministry of Science and Innovation and Universities of Spain. AT Immunolab began commercial analysis of patient samples with its real-time SARS-COV-2 test using ThermoFisher (TMO) technology in the first week of July and, at full capacity, is expected to be able to perform 200,000 tests a year.

Regular testing is likely to become the “new normal”; therefore, demand is expected to be maintained for some time. Testing for COVID-19, along with contact tracing, are fundamental cogs within governments’ exit strategies from the severe lockdowns being implemented in many countries. However, there is a risk of moving too early and, at the time of writing, there is increasing evidence of a second wave, notably in the US. This highlights that demand for testing capacity will remain strong for the foreseeable future.

### Molecular (PCR) tests

Molecular tests are used to diagnose the presence of an infection. They are designed to target small quantities of the virus, which can then be amplified many millions of times until there is a sufficient amount to be detected and analysed. The process by which this works is shown in the following diagram.



Source: Abbott Labs

There are five key steps:

- ▶ A swab is used to collect a mucous sample from the upper respiratory tract or oral cavity.
- ▶ The sample is mixed with specific reagents to break open the virus and release its genetic material – viral DNA.
- ▶ The PCR reagents recognise a unique code within the viral genome, while ignoring other viruses with similar codes.
- ▶ The fragment is replicated from a few molecules up to a billion, making them more detectable.
- ▶ Data is analysed and the result is produced.

## Other news

### Grass MATA MPL

*Phased approach to Grass MATA MPL trials in the US...*

As part of the strategy to gain regulatory approval as biologicals for its allergy vaccines in the US, AGY is expected to start the Grass MATA MPL clinical programme in August. The pilot field study will recruit about 150 adults in the US and Europe. The timing to completion of this initial phase will be dependent on the ability to recruit patients in a timely manner in an environment where COVID-19-related procedures are being implemented.

*...with the protocol benefiting from the European experience*

In addition, this study will include all of the lessons learned from the Phase III Birch trial in Europe, for which the primary endpoint measurements were recently deemed invalid by the Paul Ehrlich Institute (PEI), the German regulator. This pilot study is expected to clarify some concepts that have never been used previously in allergy immunotherapy (AIT) studies. Any learnings will then be used to help design an improved protocol for the pivotal Phase III study (G306), which is expected to begin recruiting during calendar 2021.

### Knowledge-sharing agreement

*Expanding VLP relationship with Saiba*

In November 2015, AGY acquired a licence from Saiba AG to develop novel virus-like particle (VLP) technology for use as an adjuvant for its peanut vaccine. The trading update indicated that the company has now signed a knowledge-sharing agreement to assist with the development of Saiba's COVID-19 vaccine candidates. The agreement has the potential to benefit the company in the future, by supplying both pre-clinical and clinical data using the same novel VLP platform that AGY is developing as part of its peanut vaccine candidate programme.

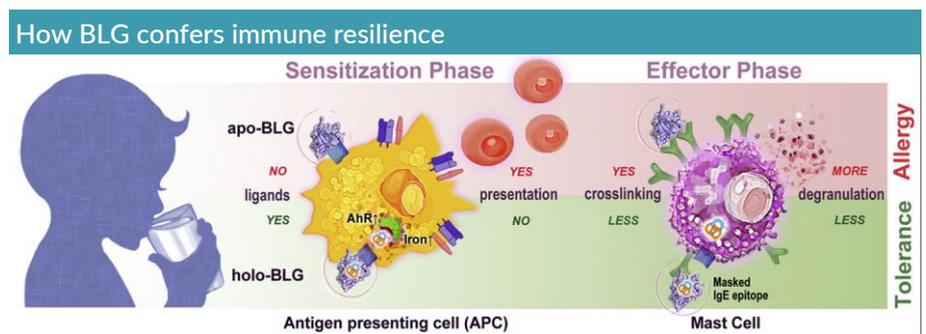
### Commercial agreement – ImmunoBON

*Commercial rights to an oral allergy therapy...*

AGY has also signed a commercial agreement with Biomedical International R+D GmbH for exclusive rights to ImmunoBON. No financial terms were disclosed. ImmunoBON is a patented, protein-based, oral treatment that has been developed to replicate the reduction in incidence of allergy as seen by those who live on a farm with livestock, the so-called "farm effect".

*...on which there has been considerable research by the University of Vienna*

Beta-lactoglobulin (BLG) is a bovine lipocalin in milk with an innate defence function. However, the circumstances under which BLG is associated with tolerance of, or allergy to, milk are not fully understood. Consequently, this has been investigated by a research group at the University of Vienna, which demonstrated that "loaded" BLG (holo-BLG) was important in preventing allergy *in vivo*, compared with BLG without cargo (apo-BLG), which acted as an allergen, priming human mast cells for degranulation in an antigen-independent fashion<sup>1</sup>.



Source: Roth-Walter et al, 2020<sup>1</sup>

<sup>1</sup> Roth-Walter et al., 2020, <https://www.sciencedirect.com/science/article/pii/S0091674920307429#!>

The group provided a mechanistic explanation, shown above, as to why the same proteins can act either as tolerogens or as allergens. This has led to the hypothesis that allergy protection can be traced back to a specific whey protein found in untreated raw milk.

*Recent conference presentations support the hypothesis*

In June 2020, at the European Academy of Allergy and Clinical Immunology conference, two poster presentations demonstrated that the product significantly reduced allergic symptoms in both a mouse model and also among patients in a double-blind placebo-controlled pilot study. Additionally, a recently completed study in an allergen exposure chamber (European Centre for Allergy Research Foundation, Berlin, Germany) revealed a significant improvement in allergy symptoms in house dust mite allergic patients (source: AGY).

*Initial launch will be in Germany*

The product will be launched OTC and be made available in the same way as healthy food supplements (probiotics) and, therefore, other than CE marking, do not need regulatory approval. AGY will be undertaking a modest amount of further work on human trials in order to expand the packaging claims and further the IP protection. ImmunoBON will be made available initially in Germany, with rollout across the rest of Europe to follow.

## Forecast summary

Although we have taken a conservative approach to forecasting, in the event of a second COVID-19 outbreak and a further major global lockdown, forecasts for 2021 and 2022 are potentially subject to revision.

- ▶ **Sales:** Underlying sales growth in 2020 was 7%.
- ▶ **Product profitability:** Reduced marketing and conference costs related to the global lockdown are expected to see the product EVBIT rise 10% to £31.1m.
- ▶ **R&D:** About £9m has been re-phased from 2020 into the next two years.

Forecast summary						
Year-end Jun (£m)	2017	2018	2019	2020E	2021E	2022E
GBP:EUR	1.171	1.130	1.135	1.144	1.144	1.144
<b>Profit &amp; Loss:</b>						
<b>Sales</b>	<b>64.14</b>	<b>68.35</b>	<b>73.72</b>	<b>78.21</b>	<b>83.00</b>	<b>87.99</b>
COGS	-16.77	-17.01	-18.38	-21.60	-22.97	-23.91
Gross profit	47.37	51.33	55.34	56.60	60.03	64.08
Gross margin	73.9%	75.1%	75.1%	72.4%	72.3%	72.8%
Marketing	-26.89	-27.13	-27.00	-25.44	-26.46	-27.78
Product profit	20.48	24.20	28.34	31.16	33.57	36.30
Product margin	31.9%	35.4%	38.4%	39.8%	40.4%	41.3%
G&A	-14.08	-14.56	-16.23	-18.69	-19.83	-20.85
R&D	-9.30	-16.02	-12.99	-7.00	-17.00	-22.00
EBITDA	-1.66	-5.34	0.30	8.40	-0.34	-3.62
Depreciation	-1.51	-1.57	-2.09	-3.84	-3.84	-3.84
<b>Underlying EBIT</b>	<b>-3.60</b>	<b>-7.36</b>	<b>-2.24</b>	<b>4.11</b>	<b>-4.63</b>	<b>-7.92</b>
EBIT margin	-5.6%	-10.8%	-3.0%	5.3%	-5.6%	-9.0%
Net interest	-0.07	-0.17	-0.10	-0.16	-0.42	-0.47
<b>Underlying pre-tax profit</b>	<b>-3.67</b>	<b>-7.53</b>	<b>-2.34</b>	<b>3.94</b>	<b>-5.05</b>	<b>-8.39</b>
Exceptional items	1.00	0.00	6.04	3.20	0.00	0.00
Tax payable/credit	0.19	-0.01	-0.23	-1.24	-0.91	-0.82
<b>Underlying net income</b>	<b>-3.48</b>	<b>-7.53</b>	<b>-2.57</b>	<b>2.39</b>	<b>-6.73</b>	<b>-10.21</b>
Weighted avg. shares (m)	592.2	595.1	632.8	636.2	636.2	636.2
<b>Underlying basic EPS (p)</b>	<b>-0.59</b>	<b>-1.27</b>	<b>-0.41</b>	<b>0.38</b>	<b>-1.06</b>	<b>-1.60</b>
Fully-diluted EPS (p)	-0.57	-1.21	-0.39	0.35	-0.98	-1.48
<b>Balance sheet (@30 Jun):</b>						
Share capital	0.60	0.61	0.65	0.65	0.65	0.65
Reserves	29.36	22.43	36.91	43.06	37.35	28.39
Liabilities	10.67	11.03	12.77	13.52	13.52	13.52
Debt	3.33	3.06	2.44	3.80	3.80	3.80
less: Cash	22.12	15.53	27.44	37.00	28.02	15.33
<b>Invested capital</b>	<b>42.66</b>	<b>51.24</b>	<b>59.30</b>	<b>64.98</b>	<b>73.64</b>	<b>85.38</b>
Net cash/debt	18.80	12.48	25.00	24.21	16.25	4.60
<b>Cashflow:</b>						
Underlying EBIT	-3.60	-7.36	-2.24	4.11	-4.63	-7.92
Working capital	2.16	0.21	-2.25	-0.47	-0.61	-0.74
Exceptionals/provisions	0.00	0.00	6.04	3.20	0.00	0.00
Tax & interest	-1.28	0.10	0.17	-0.99	-1.66	-1.39
Operational cashflow	0.04	-3.78	5.72	9.69	-4.09	-7.23
Capital expenditure	-1.50	-2.01	-2.81	-3.23	-3.72	-4.27
<b>Free cashflow</b>	<b>-1.46</b>	<b>-5.79</b>	<b>2.91</b>	<b>6.46</b>	<b>-7.80</b>	<b>-11.51</b>
Acquisitions	-0.23	-0.18	-0.29	-0.10	-0.10	-0.10
Equity issues	0.03	0.00	10.60	0.25	0.25	0.25
<b>Change in net debt</b>	<b>-1.25</b>	<b>-6.32</b>	<b>12.53</b>	<b>-0.79</b>	<b>-7.95</b>	<b>-11.66</b>
OCFPS (p)	0.01	-0.64	0.90	1.52	-0.64	-1.14

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.allergytherapeutics.com](http://www.allergytherapeutics.com)

### Board of Directors

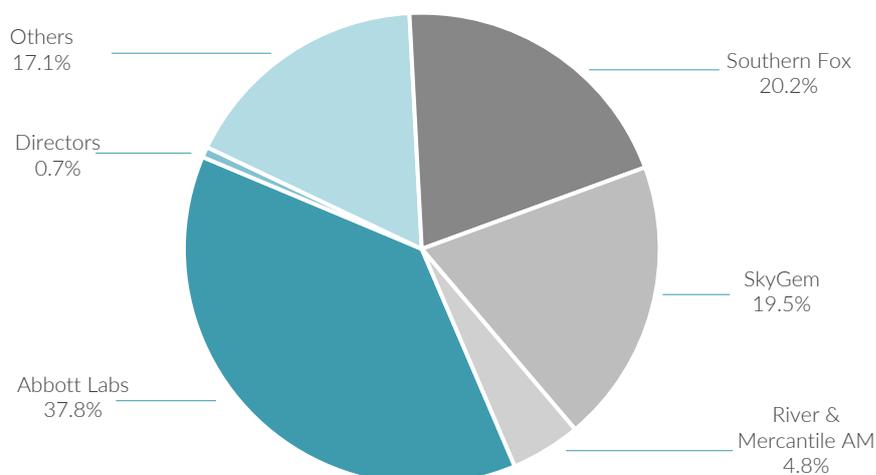
Board of Directors				
Position	Name	Nominations	Remuneration	Audit
Chairman	Peter Jensen	C		M
Chief Executive Officer	Manuel Llobet			
Chief Financial Officer	Nick Wykeman			
Non-executive director	Scott Leinenweber			
Non-executive director	Tunde Otulana	M	M	
Non-executive director	Stephen Smith	M	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 637,285,804. In addition, there are 25,968,750 share options outstanding.

#### Shareholders



*Source: Hardman & Co Life Sciences Research*

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