Allergy Therapeutics

Interim results for the half year ending 31 December 2016

March 2017
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## Financial highlights

<table>
<thead>
<tr>
<th>Increase in revenue at constant currency to</th>
<th>R&amp;D expenditure of</th>
<th>Cash balance of</th>
</tr>
</thead>
<tbody>
<tr>
<td>18% (H1 2016: £29.0m)*</td>
<td>£3.8m (H1 2016: £6.5m)</td>
<td>£27.8m (H1 2016: £33.2m)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Increase in revenue at</th>
<th>Strong growth in operating profit pre R&amp;D of</th>
</tr>
</thead>
<tbody>
<tr>
<td>39% (H1 2016: £29.0m)</td>
<td>40% to £11.1m as a result of broad investment in the business (H1 2016: £7.9m)</td>
</tr>
</tbody>
</table>

* Constant currency uses prior year weighted average exchange rates to translate current year foreign currency denominated revenue to give a year on year comparison excluding the effects of foreign exchange movements. See table in financial review for an analysis of revenue.

N.B. All financial dates refer to the financial year. All clinical dates refer to the calendar year.
Operational highlights

Increased market share in main European markets to 13% (H1 2016: 12%)

- Pollinex franchise continues to expand and shape the market as a more convenient treatment
- First patient recruited in pivotal Pollinex Quattro Birch Phase III study in Europe
- US Grass MATA MPL programme proceeding as planned with safety trial advancing to dose-range finding study in H2 2017
- CTA approval in Spain for Phase I clinical study investigating safety and tolerability of Acarovac MPL
- Positive proof of concept preclinical trial results announced with Polyvac Peanut
Our Strategy

Three Pillars to the Business

**European Business**
- Strongly performing business.
- Growing market penetration and additional product registrations

**Development Pipeline**
- New technologies and markets.
- Strong investment in R&D aided by growing revenue stream

**US Market**
- Biotech type opportunity in largest market.
- Product regulatory steps on horizon
European business

Sales Growth of 18% in H1 2017 and increase of market share to 13% from 12% driven by:

- Approved and named-patient basis sales
- Technically advanced, convenient (short-course) product
- Investment across business reflected in performance
- Increased portfolio of products – Acarovac Plus and Synbiotics
- Development and expansion of personnel in all areas

Allergy Therapeutics Group Gross Revenue

CAGR 9%
Recap on sales breakdown for FY 2016

1. Sales breakdown based on gross sales at budget exchange rates (before freight, discounts, rebates and exchange) : £51.8 million. After deducting discounts, rebates, freight charges and foreign exchange adjustments, total sales for FY2016 is £48.5 million.
**TAV (Therapy Allergy Ordinance) process**

**TAV German process initiated in 2008**
and driven by the Paul Ehrlich Institute based on European legislation

- Includes all products without registration

- Germany contributes
  59% of AGY Group sales

- All 10 of Allergy’s products submitted in 2011 are still in process

- Future advantage of clinical evidence to support marketing as products become fully approved

- 30% of all submitted products have been removed from the process and are no longer on the market (Dr. Vieths, 2016)
The US opportunity

Allergy immunotherapy is expected to grow at a CAGR of 11% to 2020*

Estimated market:
cost to payer $2 billion**

Currently no registered injected products

Clinical Development Plan
for PQ Grass at dosage stage

Opportunity fully funded to end of Phase III trial based on current assumptions

Estimated peak grass sales
US$300 - US$400 million

US Sales in Allergic (US$bn)
Rhinitis Market 2013-2020

*Visiongain, AR forecast 2014
**Internal estimate
### Position of Pollinex Quattro vs US market

<table>
<thead>
<tr>
<th>Pollinex Quattro Grass in US offers:</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCIT product</td>
</tr>
<tr>
<td>GMP manufacture</td>
</tr>
<tr>
<td>Ultra short course</td>
</tr>
<tr>
<td>4-6 injections = convenience</td>
</tr>
<tr>
<td>Same sales channel</td>
</tr>
<tr>
<td>as currently used</td>
</tr>
</tbody>
</table>

Larger market since 50% of patients do not start treatment and 50% drop out during treatment in current regimens
Research & Development

March 2017
## Pipeline

<table>
<thead>
<tr>
<th></th>
<th>Pre-clinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Market/Registered</th>
<th>Also available as a Named Patient Product</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pollinex Grass</strong></td>
<td></td>
<td>Short-course SCIT</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Pollinex Tree</strong></td>
<td></td>
<td>Short-course SCIT</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Pollinex Ragweed</strong></td>
<td></td>
<td>Short-course SCIT</td>
<td></td>
<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td><strong>Venomil Bee</strong></td>
<td></td>
<td></td>
<td>Bee venom SCIT</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Venomil Wasp</strong></td>
<td></td>
<td></td>
<td>Wasp venom SCIT</td>
<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td><strong>Pollinex Quattro Grass</strong></td>
<td>*</td>
<td>Short-course Grass SCIT with MPL</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Pollinex Quattro Birch</strong></td>
<td></td>
<td>Short-course Birch SCIT with MPL</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Pollinex Quattro Ragweed</strong></td>
<td></td>
<td>Short-course Ragweed SCIT with MPL</td>
<td></td>
<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td><strong>Pollinex Quattro Grass</strong></td>
<td>**</td>
<td>Short-course Grass SCIT with MPL</td>
<td></td>
<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td><strong>Pollinex Quattro Trees</strong></td>
<td></td>
<td>Short-course Tree SCIT with MPL</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Oralvac Grass, Trees &amp; house dust mite</strong></td>
<td></td>
<td>Sublingual immunotherapy with flexible-dosing</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Acarovac Platform</strong></td>
<td></td>
<td>Short-course modified Allergen HDM SCIT + MPL</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Polyvac Peanut</strong></td>
<td></td>
<td>Short-course Peanut SCIT</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* - 0.5mL formulation
** - 1.0 mL formulation
### Phase III Pollinex Quattro Birch in Europe (B301)

**Positive top-line results for Phase II**
Birch dosing study (B204) using Conjunctival Provocation Test

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**Phase III PQ Birch trial (B301) in TAV process:**

<table>
<thead>
<tr>
<th>Year</th>
<th>Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>First patient already recruited</td>
</tr>
<tr>
<td>H2 2017</td>
<td>Expected to start</td>
</tr>
<tr>
<td>2018</td>
<td>Results expected</td>
</tr>
<tr>
<td>2019</td>
<td>If successful, submission in 2019 and if approved, could be initially marketed in Germany</td>
</tr>
</tbody>
</table>
G104, G205 and G306 fully funded on current assumptions

Pollinex Quattro Grass MATA MPL

Safety study to evaluate additional dose (G104) in progress
- H1 2017
  - Results expected

Additional Phase II trial (G205)
- H2 2017
  - Expected to start
    - Using Conjunctival Provocation Test

Second Phase III trial (G306)
- Expected to start following completion of G205 and regulatory discussions
Acarovac MPL

Further development:
Planned progression to Phase II & Phase III
Potential for markets in EU as well as other regions

Phase I trial for Acarovac MPL (AM101)

- H1 2017: CTA approval received
- H1 2017: Trial expected to start shortly
- H2 2017: 32 patient multi-centre trial
- H2 2017: Results expected

H2 2017
Polyvac Peanut

Positive results achieved from preclinical research of Polyvac Peanut

Single dose of VLP combined with recombinant peanut allergen successfully protects against anaphylaxis when challenged with peanut

Commencing an R&D investment programme of c.£3m to progress programme through to start of Phase I trials over a 2-3 year period

Those vaccinated with candidate vaccine exhibited no symptoms compared to placebo, when challenged with peanut

Peanut represents a new opportunity into $8bn* worldwide food allergy market

Safety profile of product evaluated and found not to induce anaphylaxis

Pre-clinical development progressing according to plan

*The Journal of Allergy and Clinical Immunology 2016. 1% of US population. EACCI Food Allergy and Anaphylaxis Guidelines Group 2016 0.2% of Western European Population. Management assumption of annual treatment of $2k
Financial Results

March 2017
### P&L – 6 months to 31 December 2016

<table>
<thead>
<tr>
<th></th>
<th>2017 £'m</th>
<th>2016 £'m</th>
<th>Variance £'m</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>40.4</td>
<td>29.0</td>
<td>11.4</td>
<td>39%</td>
</tr>
<tr>
<td>Gross profit</td>
<td>31.5</td>
<td>21.6</td>
<td>9.9</td>
<td>46%</td>
</tr>
<tr>
<td>Overheads</td>
<td>(20.5)</td>
<td>(13.7)</td>
<td>(6.8)</td>
<td>(50%)</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>(3.8)</td>
<td>(6.5)</td>
<td>2.7</td>
<td>42%</td>
</tr>
<tr>
<td>Operating profit</td>
<td>7.2</td>
<td>1.4</td>
<td>5.8</td>
<td>414%</td>
</tr>
<tr>
<td>Financing costs</td>
<td>0.0</td>
<td>(0.1)</td>
<td>0.1</td>
<td>100%</td>
</tr>
<tr>
<td>Tax</td>
<td>(0.4)</td>
<td>(0.2)</td>
<td>(0.2)</td>
<td>(100%)</td>
</tr>
<tr>
<td>Profit after tax</td>
<td>6.8</td>
<td>1.1</td>
<td>5.7</td>
<td>518%</td>
</tr>
</tbody>
</table>

**Strong sales performance in all markets**

**Strong sales drives gross profit growth and gross profit % up on constant basis**

**Overheads up due to FX and investment**

**Significant R&D investment last year in US Grass Study and PQ Birch in Europe**

**Operating profit pre R&D of £11.1m (H1 2016: £7.9m) due to investment**
## Sales – 6 months ended 31 December 2016

<table>
<thead>
<tr>
<th></th>
<th>2017 £'m</th>
<th>2016 £'m</th>
<th>Variance £'m</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross Revenue at Constant Exchange Rate</td>
<td>37.4</td>
<td>31.4</td>
<td>6.0</td>
<td>19%</td>
</tr>
<tr>
<td>Rebate at Constant Exchange Rate</td>
<td>(3.2)</td>
<td>(2.4)</td>
<td>(0.8)</td>
<td>(33%)</td>
</tr>
<tr>
<td>Net Revenue at Constant Exchange Rate</td>
<td>34.2</td>
<td>29.0</td>
<td>5.2</td>
<td>18%</td>
</tr>
<tr>
<td>Effect of Foreign Exchange</td>
<td>6.2</td>
<td>0.0</td>
<td>6.2</td>
<td></td>
</tr>
<tr>
<td>Net Revenue</td>
<td>40.4</td>
<td>29.0</td>
<td>11.4</td>
<td>39%</td>
</tr>
</tbody>
</table>

* Constant exchange rate Euro/£  
  1.39

* Current exchange rate Euro/£  
  1.16 1.39

**Significant improvement in sales against flat markets**

**All markets performing well**

**Strong growth in**
Pollinex Quattro and Oralvac

** Rebates up due to increase in prices and volume wins in Germany**

**FX impact due to stronger euro for whole period**
## Balance sheet at 31 December 2016

<table>
<thead>
<tr>
<th></th>
<th>2017 £'m</th>
<th>2016 £'m</th>
<th>Variance £'m</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-current assets</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Property, plant and equipment</td>
<td>9.7</td>
<td>8.8</td>
<td>0.9</td>
</tr>
<tr>
<td>Intangible assets</td>
<td>5.4</td>
<td>5.0</td>
<td>0.4</td>
</tr>
<tr>
<td>Investments</td>
<td>4.3</td>
<td>3.5</td>
<td>0.8</td>
</tr>
<tr>
<td></td>
<td>19.4</td>
<td>17.3</td>
<td>2.1</td>
</tr>
<tr>
<td><strong>Current Assets</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade and other receivables</td>
<td>10.7</td>
<td>7.1</td>
<td>3.6</td>
</tr>
<tr>
<td>Inventories</td>
<td>7.0</td>
<td>6.8</td>
<td>0.2</td>
</tr>
<tr>
<td>Cash</td>
<td>27.8</td>
<td>33.2</td>
<td>(5.4)</td>
</tr>
<tr>
<td><strong>Liabilities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Financing liabilities</td>
<td>(3.4)</td>
<td>(1.6)</td>
<td>(1.8)</td>
</tr>
<tr>
<td>Other liabilities</td>
<td>(23.0)</td>
<td>(16.1)</td>
<td>(6.9)</td>
</tr>
<tr>
<td><strong>Net assets</strong></td>
<td>38.5</td>
<td>46.7</td>
<td>(8.2)</td>
</tr>
<tr>
<td><strong>Equity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Share capital and share premium</td>
<td>103.0</td>
<td>103.0</td>
<td>0.0</td>
</tr>
<tr>
<td>P&amp;L account and other reserves</td>
<td>(64.5)</td>
<td>(56.3)</td>
<td>(8.2)</td>
</tr>
<tr>
<td></td>
<td>38.5</td>
<td>46.7</td>
<td>(8.2)</td>
</tr>
</tbody>
</table>

**Increase in non-current assets**
driven by currency movements and investment in infrastructure

**Trade debtors higher**
due to FX and timing of significant receipt

**Cash position**
of £27.8m

**Debt of £3.4m**
Seasonal overdraft in place (undrawn)

**Other liabilities increase**
due to FX, R&D creditors and hedging liability
Summary and Outlook

March 2017
Summary and outlook

Strong trading in H1 2017:

18% sales growth at constant currency with gain in market share of competitive markets from 12% to 13%

Operating profit before R&D continues to grow

Clinical trials progressing as planned

Strategy to be first to market in the US SCIT segment with a registered product and market leaders in the SCIT allergy segment by 2020

Continued growth in line with market expectations for FY 2017
  • Continued growth and expansion in European business
  • Future product development pipeline
  • Geographic expansion opportunities
2017 expected newsflow

**July 2017**
- Trading Update

**September 2017**
- Full Year 2017 Results

**H2 2017**
- First Patient Treated – Pollinex Quattro Birch Phase III
- CTA approval of Pollinex Quattro Grass Phase II
- First Patient Pollinex Quattro Grass Phase II
## Analysis of regulated products

<table>
<thead>
<tr>
<th>Vaccines</th>
<th>Named patient basis</th>
<th>Approved¹</th>
<th>German TAV process</th>
<th>US Process</th>
<th>Other Clinical trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pollinex</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pollinex Quatto Grass</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pollinex Quatto Birch</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pollinex Quatto Ragweed</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pollinex Quatto Trees</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pollinex Quattro Grass &amp; Birch</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pollinex Quattro Grass &amp; Tree</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pollinex Quattro Grass &amp; Mugwort</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acarovac Plus</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acarovac MPL</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>TyroMILBE</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Venomil</td>
<td>X</td>
<td></td>
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<tr>
<td>TA Top</td>
<td>X</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oralvac Grass</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oralvac Trees</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oralvac House Mite</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹ Approved in Germany or other major market

<table>
<thead>
<tr>
<th>Analysis</th>
<th>Name</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMC</td>
<td>Acarovac MPL</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>TyroMILBE</td>
<td>X</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Trials in process</th>
<th>CMC process</th>
<th>Trials undertaken</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

[Allergy Therapeutics®](https://www.allergytherapeutics.com)
Global presence

Sales and marketing network comprising c.160 European sales force

Subsidiaries in 7 countries and distribution agreements in additional 8 countries
Notes:
1. While in the TAV process all products can continue to be sold. Once rejected they must be removed from the market
2. All products must either have been approved or must go through the TAV process
3. The trials needed are tolerability, dose ranging and efficacy
Microcrystalline tyrosine (MCT)

Patent protection for MCT

Processing patent covers MCT

MCT particles are formulated as sterile in state of the art processes enabling defined particle morphology and size optimised for binding to wide variety of antigens.

MCT Process patent extended-UK (2032)/EU filing 2032

R&D update Allergy / Non – Allergy indications

Within the last 12 months, studies have been completed supporting MCT use as a depot immunomodulator in each application:

Key publication in The Journal of Inorganic Biochemistry provides insight to the role of the (MCT) for use in existing and future therapeutic development incl. synergies with MCT and MPL in our Pollinex Quattro brand

MCT improves efficacy in non-allergy models (Influenza, Malaria) – Public Health England, University of Oxford (Jenner Institute), respectively. (publication in preparation)

Immunomodulation of MCT in allergy (publication pending 2016) – University of Zurich

MCT to enhance immunogenicity of different vaccines – for malaria study
**Recent developments in US**

- **Allergists coming under regulations of compounding pharmacies (USP797)**
- **Demand for product that improves patient adherence**
- **Regulators clamping down on manufacturing standards in extracts**
- **Enforcement of 28 day shelf life of mixed extracts**
- **Insurer pressure to reduce number of physician visits**
- **Drive towards single allergen treatment due to shelf life requirement**
**PQ: a unique platform technology in the US**

<table>
<thead>
<tr>
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<th><strong>Allergoid</strong></th>
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**Pollinex Quattro:**
4 injections in 3 weeks, efficacy in 3 weeks

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Allergoid

- Allergen chemically modified with glutaraldehyde.
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Micro Crystalline Tyrosine (MCT)

- A natural amino acid which is readily metabolised.
- L-tyrosine retains the Allergoid and MPL at the site of injection (half life = 48 hours) as depot.
- 30-year history of safe use in vaccines.
- Rebalances TH1 response.
US PQ product opportunity

**Current US SCIT market**

*Home made* preparation

*Non* GMP manufacturing  
*Non* registered  
*No* clinical evidence

*Long* courses of treatment:  
50 to 100 injections

*Slow to act*: 6 to 12 months  
*Low* compliance

**Allergy Therapeutics’ entry in the US**

*Standardised* dose vaccine

*GMP manufactured*  
*FDA submission* planned in 2020  
*Multiple* clinical studies

*Ultra-short* course treatment:  
4 to 6 injections

*Efficacy* in 3 weeks  
*High* compliance
Keys to success for PQ in the US

Proprietary Technology

De-risked opportunity
Treated more than 250,000 patients and marketed in 7 countries

First mover advantage
First to market in the seasonal injected segment
High entry barriers: regulatory requirements for extensive trials on efficacy and safety

IP Protected

Strategic fit for US market*
Pollinex Quattro is an injected product for an injected market

Building on Progress to date in the US:
US$ 100 million invested in clinical studies to date
15 clinical trials completed to date, including Phase I, II & III successful studies
Investigated in over 3,000 patients worldwide, mainly in the US

Source:
*The Current States of Therapy for Allergic Rhinitis in the United States. Lawrence Du Buske, MD
Acarovac Plus / Acarovac Quattro

Acarovac Plus – Next Generation Products for Short-Course Dust Mite Immunotherapy

Acarovac Plus has undergone further clinical development, building on success of 2014 publication and is the top selling mite product in Spain this year

A 1-year follow up study reveals a >50% reduction in symptom scores and significant improvement in clinical endpoints accepted for publication in 2015

Product approved for sale in Austria and Spain

Developing Acarovac Quattro, an ultra-short course therapy utilising the adjuvant monophosphoryl lipid A (MPL), as used in successful Pollinex Quattro product range
Other developments

**Adjuvant Systems**

MCT, MPL & VLP  
Researching on MCT mechanism of action  
Testing adjuvant systems in several vaccines  
Results and publication expected soon

**Synbiotics**

Synbiotics = prebiotics + probiotics  
Synbiotics as modulators of the allergic response  
Innovative products focused on allergy  
Sales progressing well
Key investment highlights

Lead product Pollinex Quattro, a proven, unique and highly differentiated allergy vaccination

Integrated, efficient and scalable platform technology

Strong late stage pipeline of aluminium-free allergy products

Well established European commercial presence through direct sales force & distributors

MHRA-approved manufacturing facility with significant headroom

Strong financial performance with trend over 17 years of gross sales growth

Focused on the US opportunity & strengthening position in European allergy rhinitis market