



# Allergy Therapeutics

**Interim results  
for the half year ending  
31 December 2016**

**March 2017**



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# Financial highlights

**18%** ▲  
increase in revenue  
at constant currency to  
**£34.2m**  
(H1 2016: £29.0m)\*

**39%** ▲  
increase in  
revenue at  
**£40.4m**  
(H1 2016: £29.0m)

R&D expenditure of

**£3.8m**

(H1 2016: £6.5m)

Cash balance of

**£27.8m**

(H1 2016: £33.2m)

Strong growth in operating profit pre R&D of

**40% to £11.1m**

as a result of broad investment in the business

(H1 2016: £7.9m)

\* 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



# Strategy

March 2017



# 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



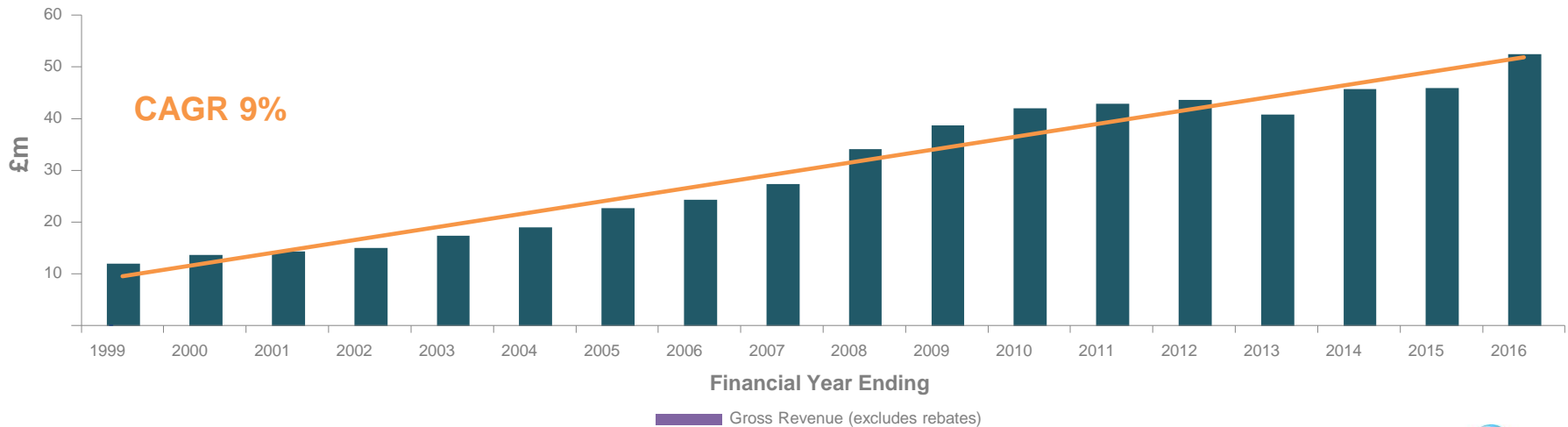
# European business



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

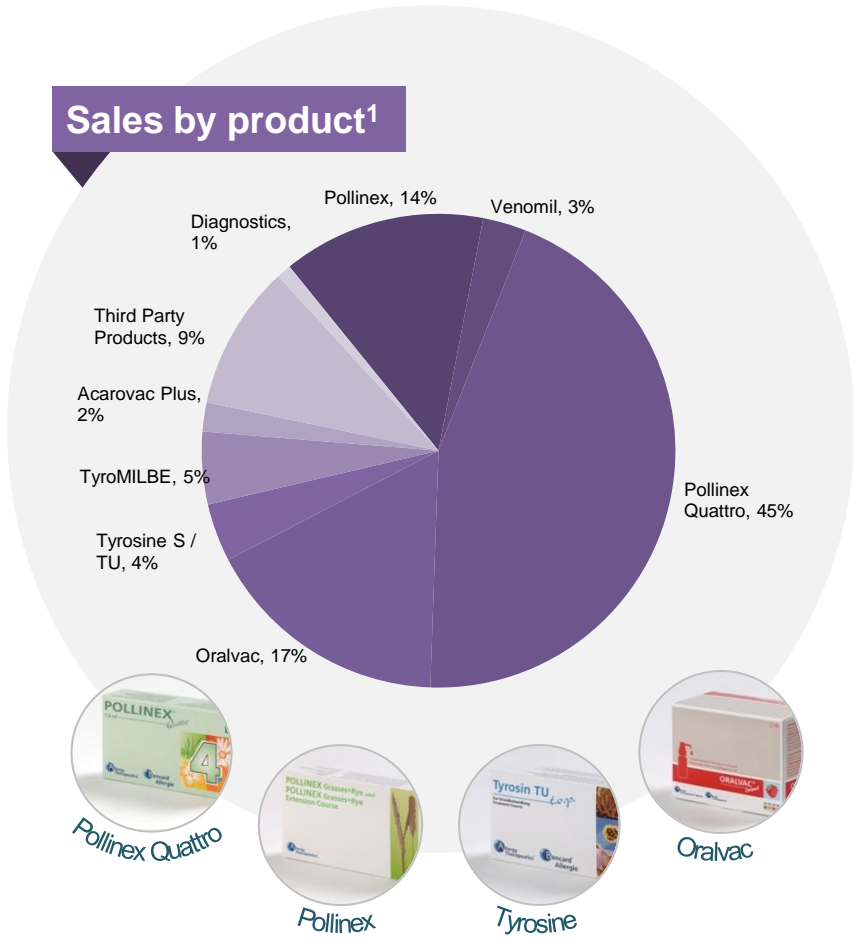
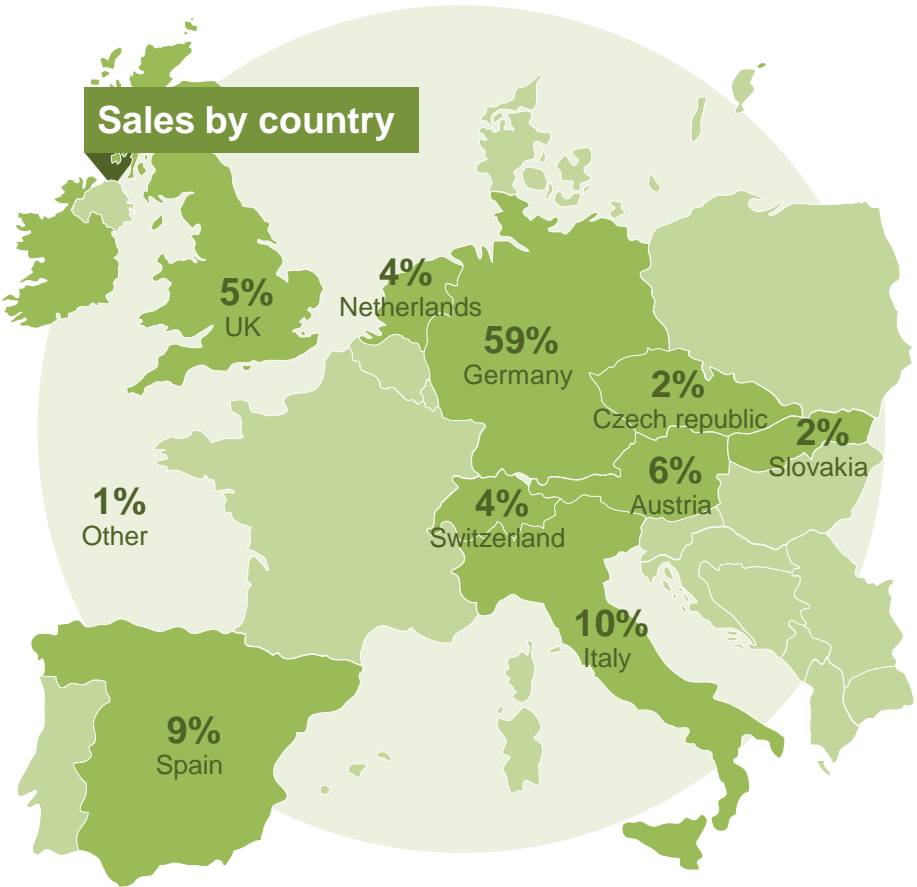
- Approved and named-patient basis sales
- Technically advanced, convenient (short-course) product
- Investment across business reflected in performance
- Increased portfolio of products – Acarovac Plus and Synbiotics
- Development and expansion of personnel in all areas

### Allergy Therapeutics Group Gross Revenue





# Recap on sales breakdown for FY 2016



<sup>1</sup>. 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

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**All 10 of Allergy's products submitted**  
in 2011 are still in process

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**Germany contributes**  
59% of AGY Group sales

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

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**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\*\*

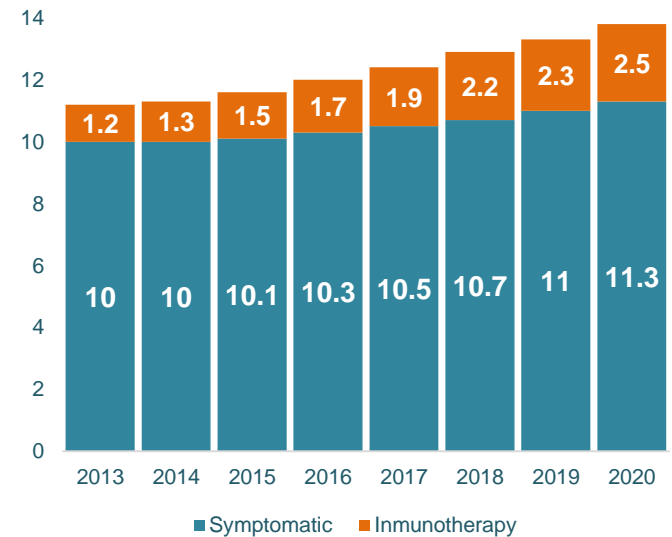
**Currently no registered**  
injected products

**Clinical Development Plan**  
for PQ Grass at dosage stage

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

**Estimated peak gross 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

Regulatory pressure  
of FDA



Pollinex Quattro Grass in US offers:

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**SCIT product**

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**GMP manufacture**

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**Ultra short course**

4-6 injections = convenience

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**Same sales channel**

as currently used

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



# Research & Development

**March 2017**



# Pipeline

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

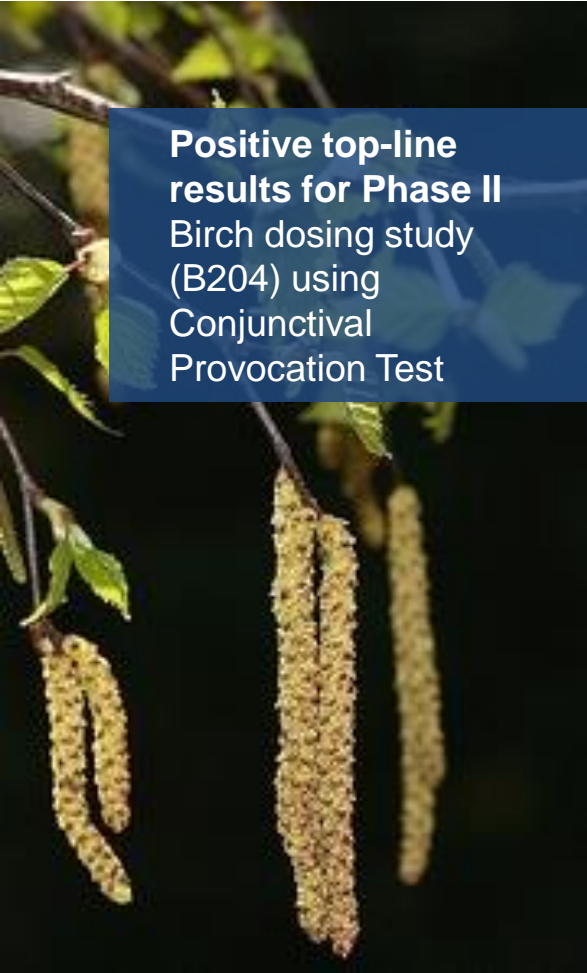
\* - 0.5mL formulation  
 \*\* - 1.0 mL formulation





# Phase III Pollinex Quattro Birch in Europe (B301)

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



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





# Pollinex Quattro Grass MATA MPL

G104, G205 and G306 fully funded on current assumptions

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)

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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

Trial expected  
to start shortly

32 patient multi-  
centre trial

H2 2017

Results  
expected



# 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

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

**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

|   | 2017<br>£'m | 2016<br>£'m | Variance<br>£'m | %     |
|---|-------------|-------------|-----------------|-------|
| Gross Revenue at Constant Exchange Rate | 37.4        | 31.4        | 6.0             | 19%   |
| Rebate at Constant Exchange Rate        | (3.2)       | (2.4)       | (0.8)           | (33%) |
| Net Revenue at Constant Exchange Rate   | 34.2        | 29.0        | 5.2             | 18%   |
| Effect of Foreign Exchange              | 6.2         | 0.0         | 6.2             |       |
| Net Revenue                             | 40.4        | 29.0        | 11.4            | 39%   |

\* 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

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

**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:

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**18%**

sales growth at constant  
currency with gain in market  
share of competitive markets  
from

**12% to 13%**

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Operating profit before R&D  
continues to grow

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Clinical trials progressing  
as planned

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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

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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



# Appendix

March 2017



# Analysis of regulated products

|                                  | Named patient basis | Approved <sup>1</sup> | German TAV process | US Process | Other Clinical trials |
|----------------------------------|---------------------|-----------------------|--------------------|------------|-----------------------|
| <b>Vaccines</b>                  |                     |                       |                    |            |                       |
| Pollinex                         | X                   | X                     |                    |            |                       |
| Pollinex Quattro Grass           | X                   |                       | X                  | X          |                       |
| Pollinex Quattro Birch           | X                   |                       | X                  |            |                       |
| Pollinex Quattro Ragweed         | X                   |                       |                    | X          |                       |
| Pollinex Quattro Trees           | X                   |                       | X                  | X          |                       |
| Pollinex Quattro Grass & Birch   | X                   |                       | X                  |            |                       |
| Pollinex Quattro Grass & Tree    | X                   |                       | X                  |            |                       |
| Pollinex Quattro Grass & Mugwort | X                   |                       | X                  |            |                       |
| <hr/>                            |                     |                       |                    |            |                       |
| Acarovac Plus                    | X                   | X                     |                    |            |                       |
| Acarovac MPL                     |                     |                       |                    |            | X                     |
| <hr/>                            |                     |                       |                    |            |                       |
| TyroMILBE                        | X                   |                       | X                  |            |                       |
| Venomil                          | X                   | X                     |                    |            |                       |
| TA Top                           | X                   |                       |                    |            |                       |
| <b>Oral</b>                      |                     |                       |                    |            |                       |
| Oralvac Grass                    | X                   | X                     | X                  |            |                       |
| Oralvac Trees                    | X                   | X                     | X                  |            |                       |
| Oralvac House Mite               | X                   | X                     | X                  |            |                       |

Trials in process

CMC process

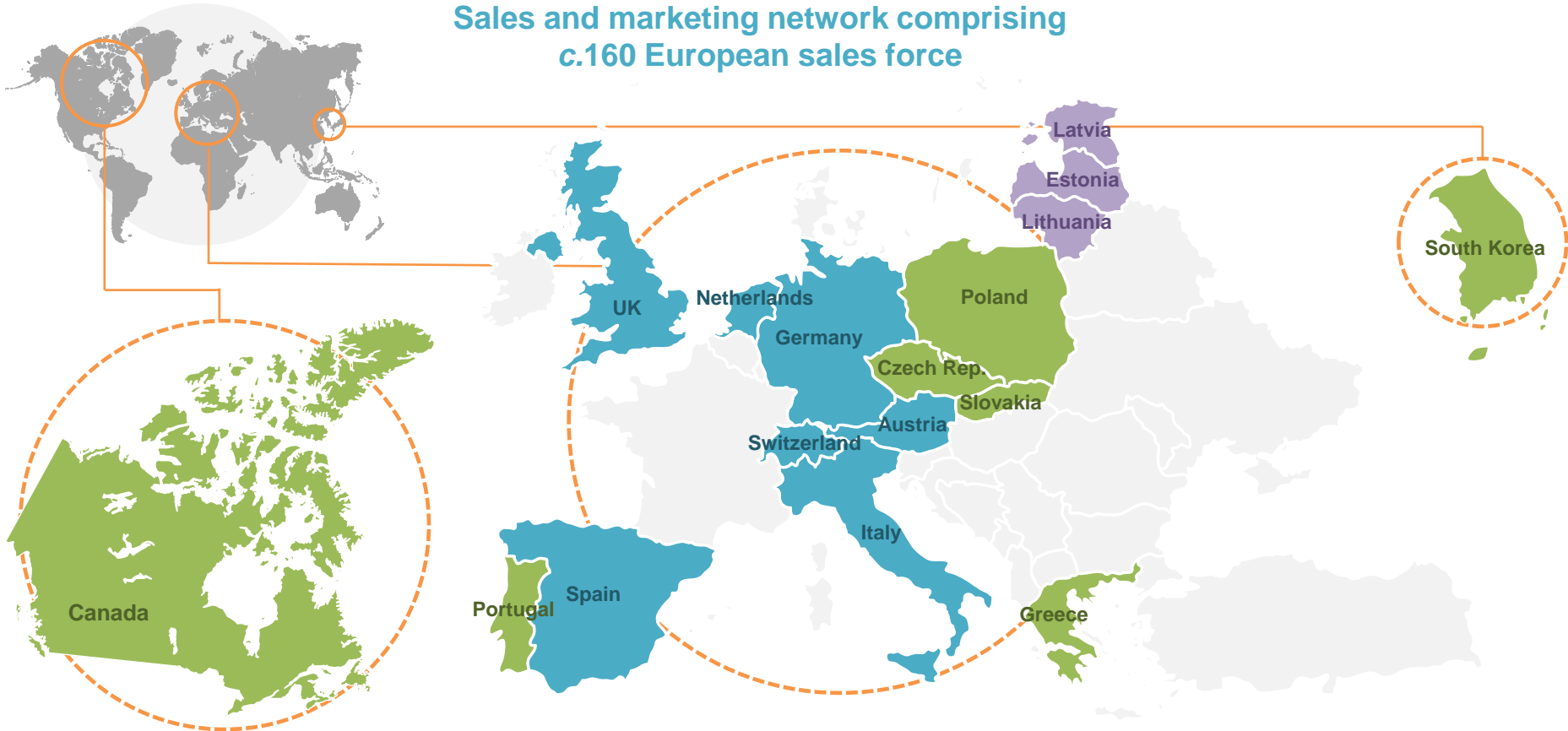
Trials undertaken

<sup>1</sup> Approved in Germany or other major market



# Global presence

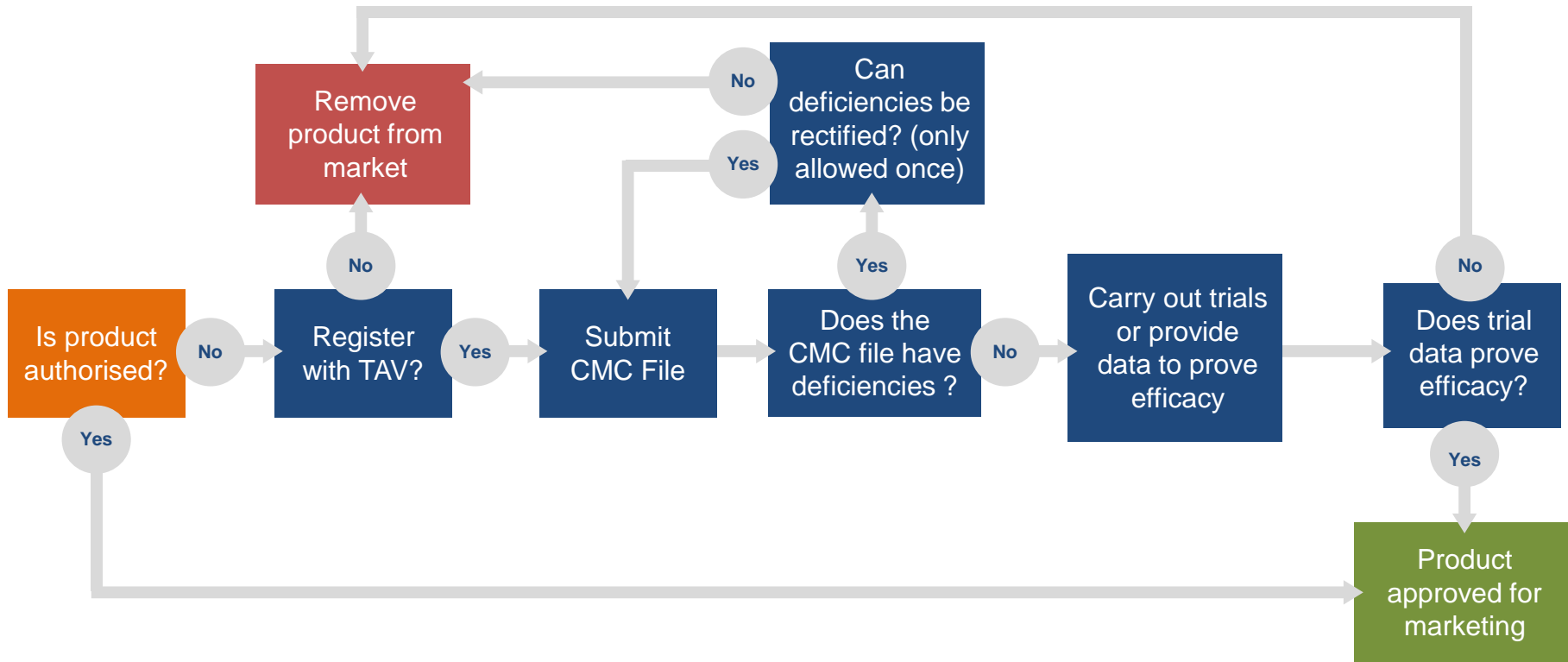
Sales and marketing network comprising c.160 European sales force



Subsidiaries in 7 countries and distribution agreements in additional 8 countries



# TAV process



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

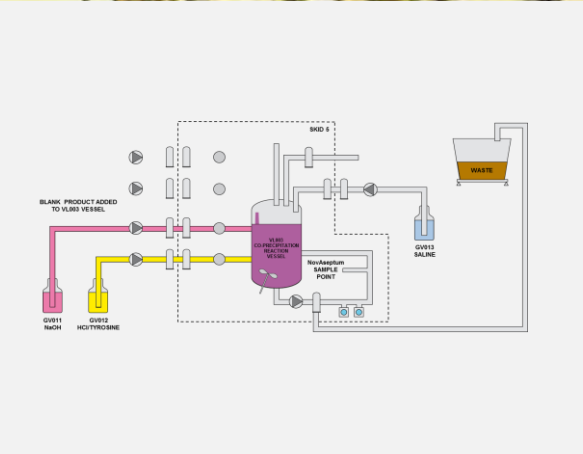
**Within the last 12 months, studies have been completed supporting MCT use as a depot immunomodulator in each application:**

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

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

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

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

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**Regulators clamping down on** manufacturing standards in extracts

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**Enforcement of 28 day shelf life** of mixed extracts

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**Insurer pressure to reduce number** of physician visits

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**Drive towards single allergen treatment due to shelf life requirement**



# PQ: a unique platform technology in the US

**Pollinex Quattro:**  
4 injections in 3 weeks, efficacy in 3 weeks



### MPL Adjuvant

MPL (Monophosphoryl Lipid A) is a non-toxic derivative of lipopolysaccharide (LPS))

MPL allows the SIT treatment course to be shortened (big impact on adherence)

Regulates expression of co-stimulatory molecules on antigen-presenting cells

Acts locally as a TLR4 agonist and increases IgG production

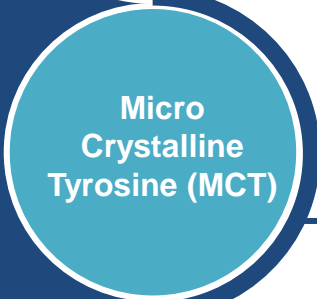


### Allergoid

Allergen chemically modified with glutaraldehyde

Retains IgG-allergen stimulating properties patient adherence

Reduces IgE reactivity vs. that induced by native allergens used in SIT



### MPL Adjuvant

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

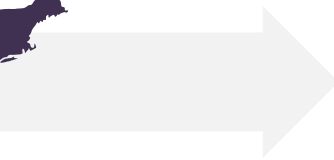
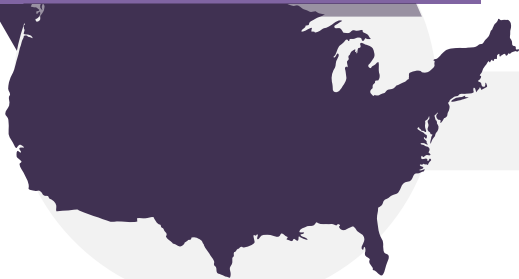
30-year history of safe use in vaccines

Rebalances TH1 response



# US PQ product opportunity

Current US SCIT market



Allergy Therapeutics' entry in the US



- Home made preparation

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- Non GMP manufacturing
- Non registered
- No clinical evidence

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- Long courses of treatment:  
50 to 100 injections

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- Slow to act: 6 to 12 months

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- Low compliance

- Standardised dose vaccine

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

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- Ultra- short course treatment:  
4 to 6 injections

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- Efficacy in 3 weeks

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- 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

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## 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

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**Integrated, efficient**  
and scalable platform technology

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**Strong late stage pipeline**  
of aluminium-free allergy products



Well established European commercial presence through direct sales force & distributors

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MHRA-approved manufacturing facility with significant headroom

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

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