



Allergy Therapeutics

**Preliminary results
for the year ending
30 June 2017**

Delivering on our strategy – three areas for growth

September 2017



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Introduction to Allergy Therapeutics

Dedicated to allergy treatment and prevention



Leading allergy immunotherapy company with a portfolio of marketed products and strong development pipeline

Provide treatments that have potential to cure disease, not just symptoms. Focus on moderate to severe patients

Approximately 500 employees

Headquartered and manufacturing base in Worthing, West Sussex

Double digit compound annual growth achieved over the past 18 years

Robust revenue growth and successful M&A delivered. Three pillar strategy for growth: Europe, pipeline and US

Spun out of Smith Kline Beecham in 1999

Market capitalisation of approximately £200m, AIM ticker LSE:AGY



Financial highlights

~ Double digit compound annual growth achieved over the past 18 years ~

15*% ▲

increase in revenue
at constant currency to

£55.5m

(2016: £48.5m)**

32% ▲

increase in
revenue at

£64.1m

(2016: £48.5m)

Strong growth in operating profit pre R&D up

72% to £7.4m

as a result of leveraging broad investment in the business

(2016: £4.3m)

R&D expenditure of

£9.3m

(2016: £16.2m)

Cash balance of

£22.1m

(2016: £23.4m)

*Percentage based on numbers in thousands (2017: £55.545m, 2016: £48.509m)

** 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% 

(2016: 12%)



Commencement of recruitment for pivotal Phase III Pollinex Quattro Birch trial



US Grass MATA programme proceeding well; safety study successfully completed



First patient recruited for Acarovac MPL Phase I trial in Spain



Positive pre-clinical proof of concept trial data announced for Polyvac Peanut



Strategy

September 2017



Delivering Our Strategy

Three Pillars to the Business

Expanding in Europe



Strongly performing
profitable business

Growing market share
and additional product
registrations

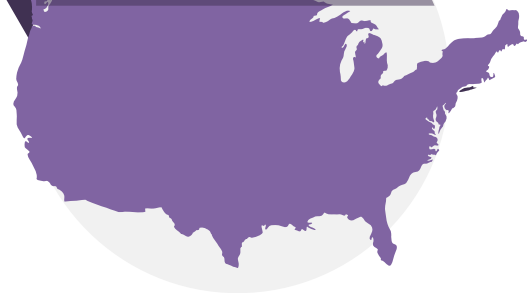
Strong Pipeline



New technologies
underpin pipeline breadth and depth

Investment strategy
supported by growing
revenue stream

Preparing for US entry



Significant opportunity
in largest allergy market

Changing environment
to drive market share
towards Allergy's products



Delivering Our Strategy

EXPANDING IN EUROPE





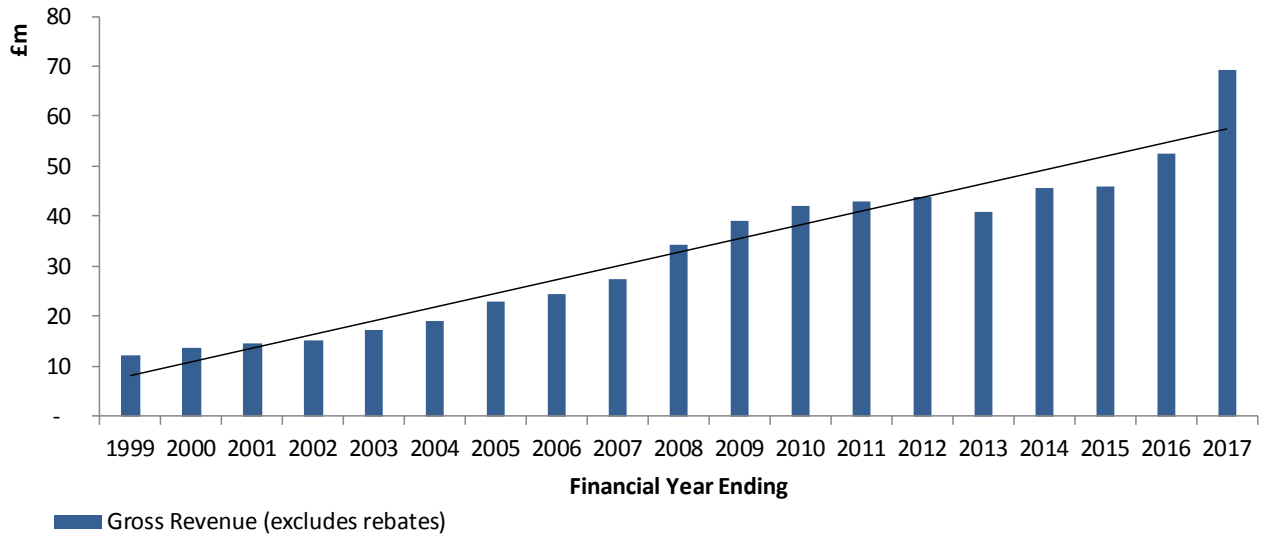
Delivery of European growth strategy



Sales Growth of 15%* in 2017 and increase of market share to 13% from 12% driven by:

- Growing approved and named-patient basis sales
- Innovative, convenient and patient-friendly (short-course) products
- Focused investment across business reflected in performance
- Increased portfolio of products – Acarovac Plus and Synbiotics
- Scaling-up to drive technological and geographical expansion

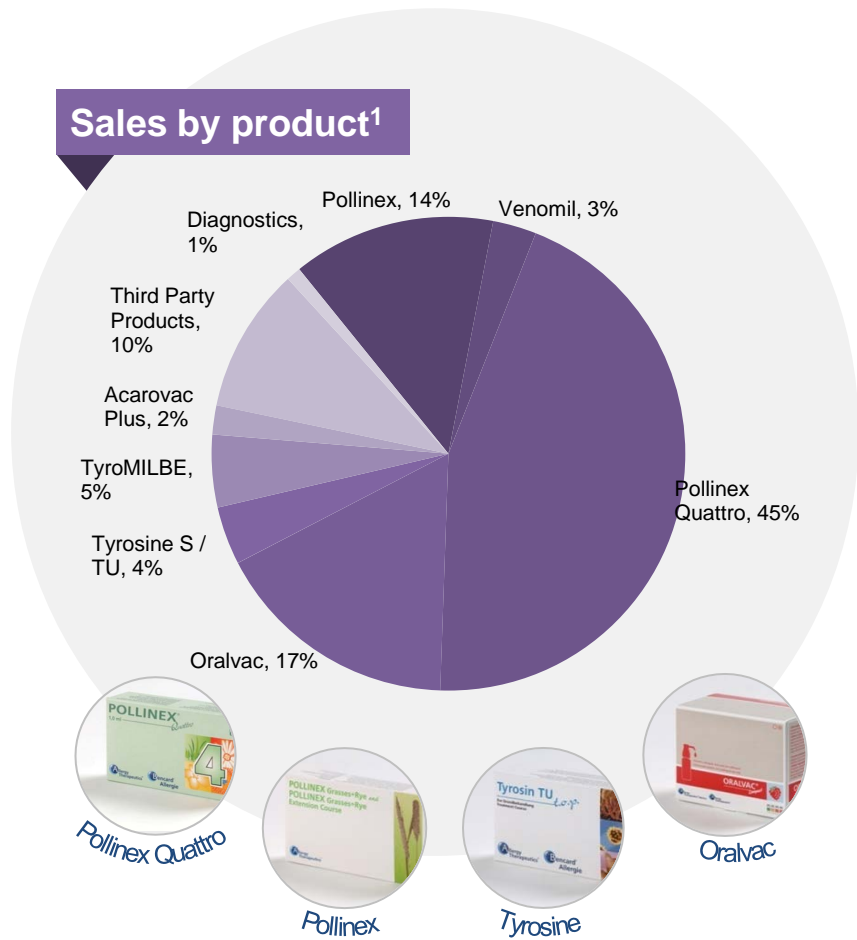
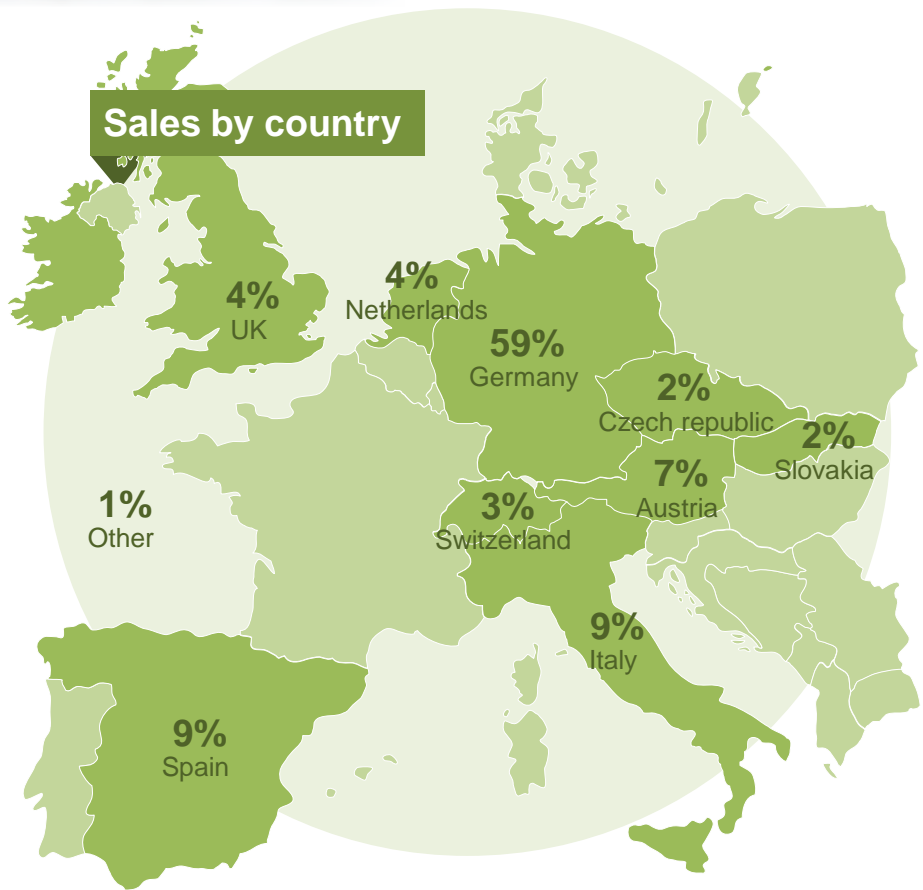
Double Digit CAGR growth over the last 18 years since formation



*Percentage based on figures in thousands (2017: £55.545m, 2016: £48.509m)



Sales breakdown for FY 2017



1. Sales breakdown based on gross sales at budget exchange rates (before freight, discounts, rebates and exchange) : £63.2 million. After deducting discounts, rebates, freight charges and foreign exchange adjustments, total sales for FY2017 is £64.1 million



Delivering Our Strategy

STRONG PIPELINE





Broad 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



Pipeline Trials

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

PQ Birch – Phase III (Germany)

first patient already treated
results expected H2 2018
if successful, regulatory submission 2019

PQ Grass – Phase II (US & Germany)

first patient treated in autumn 2017
results expected H2 2018
if successful, second Phase III study to follow in US/Europe

Acarovac MPL Phase I

trial with 32 patients in progress in Spain
results expected H2 2018
potential for US market with two Phase III trials



Polyvac Peanut Product

Positive results achieved from preclinical research of Polyvac Peanut

Single dose of Virus Like Particle (VLP) combined with recombinant peanut allergen successfully **protects against anaphylaxis** when challenged with peanut

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

Safety profile of product evaluated and found **not to induce anaphylaxis**

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

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

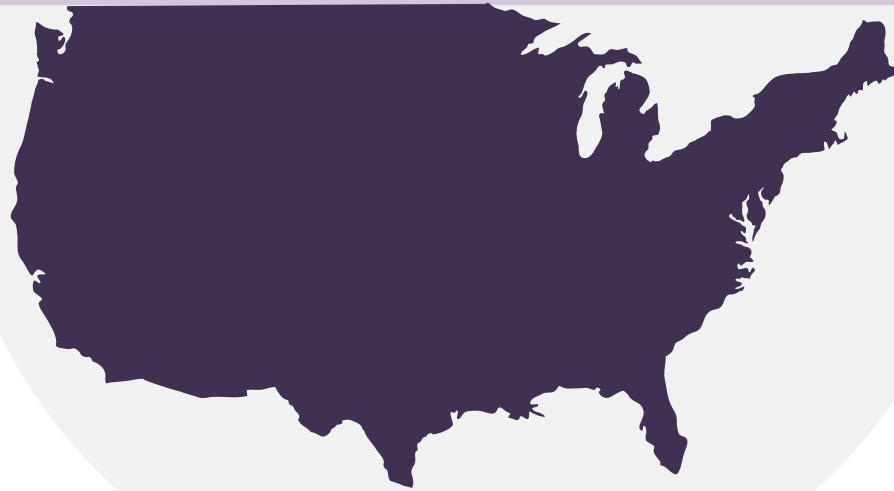
Pre-clinical development progressing according to plan with important product differentiation demonstrated – aim is long-term immunity

*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



Delivering Our Strategy

PREPARING FOR US ENTRY





The Evolving US Opportunity



* Hankin CS, Cox L, Lang D, et al 2007 JACI
**Internal estimate
***Professor Lawrence DuBuske MD



Financial Results

September 2017



P&L – year ended to 30 June 2017

	2017 £'m	2016 £'m	Variance £'m	%
Revenue	64.1	48.5	15.6	32%
Gross profit	47.4	34.4	13.0	38%
Overheads	(40.7)	(30.3)	(10.4)	(34%)
R&D	(9.3)	(16.2)	6.9	43%
Other Income	0.7	0.2	0.5	0%
Operating profit	(1.9)	(11.9)	10.0	(84%)
Financing costs	(0.1)	(0.1)	0.0	0%
Tax	(0.5)	(1.0)	0.5	50%
Profit after tax	(2.5)	(13.0)	10.5	(81%)

Strong sales performance
in most markets

Strong sales drives gross profit growth

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 £7.4m
(2016: £4.3m) due to investment,
leveraging strong sales



Sales – year ended 30 June 2017

	2017 £'m	2016 £'m	Variance £'m	%
Gross Revenue at Constant Exchange Rate	60.5	52.4	8.1	15%
Rebate at Constant Exchange Rate	(5.0)	(3.9)	(1.1)	(28%)
Net Revenue at Constant Exchange Rate	55.5	48.5	7.0	14%
Effect of Foreign Exchange	8.6		8.6	
Net Revenue	64.1	48.5	15.6	32%

* Constant exchange rate Euro/£ 1.36
 Current exchange rate Euro/£ 1.16

Significant increase in sales
 against flat markets

Most markets
 performing well

Strong growth in
 Pollinex Quattro, Venomil and Pollinex

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

FX impact due to weaker sterling
 for whole period



Balance sheet at 30 June 2017

	2017 £'m	2016 £'m	Var £'m
Non-current assets			
Property, plant and equipment	9.6	9.7	(0.1)
Intangible assets	5.5	5.4	0.1
Investments	4.6	4.0	0.6
	19.7	19.1	0.6
Current Assets			
Trade and other receivables	7.9	6.5	1.4
Inventories	7.5	7.7	(0.2)
Cash	22.1	23.4	(1.3)
Liabilities			
Financing liabilities	(3.3)	(3.4)	0.1
Other liabilities	(23.9)	(23.0)	(0.9)
Net assets	30.0	30.3	(0.3)
Equity			
Share capital and share premium	103.0	103.0	0.0
P&L account and other reserves	(73.0)	(72.7)	(0.3)
	30.0	30.3	(0.3)

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

Trade debtors higher
due to timing of significant receipt

Cash position
of £22.1m

Debt of £3.3m
Seasonal overdraft in place (undrawn)

Other liabilities increase
due to R&D creditors



Funds flow for the year ended June 2017

	2017 £'m	2017 £'m	2016 £'m	2016 £'m
Opening cash balance 1st July		23.4		21.2
Loss before tax	(2.0)		(12.1)	
Adjustments re operations	3.5		0.6	
Net cash generated by operations		1.5		(11.5)
Tax and interest paid		(1.3)		(0.3)
Investments and acquisitions	(0.5)		(0.3)	
Capital Expenditure	(1.5)		(1.2)	
Net cash used in investing activities		(2.0)		(1.5)
Proceeds from issue of shares			11.0	
Net movement in borrowings	(0.2)		1.5	
Net cash used in financing activities		(0.2)		12.5
Effects of exchange rates on cash		0.7		3.0
Closing Cash Balance 30 June		22.1		23.4

Net cash generated
driven by strong trading, and
currency effect and reduced study activity

Capital investment in factory
to improve efficiency and upgrade for FDA

Cash position
strong at year end but some expenditure in
R&D carried forward to 2018



Summary and Outlook

September 2017



Summary and Outlook

2018 set to be a pivotal year

Strong trading in 2017:

15*% 

sales growth at
constant currency

13%

market share



Delivering against our strategy: three pillars to growth



Strong financials set to continue



Clinical trials progressing as planned – broad pipeline underpinned by innovative technologies



Focused strategy to be first to market in the US SCIT segment



2018 set to be a pivotal year:

- Growth and expansion in European business
- Results of pivotal Birch Phase III trial and US Grass Phase II trial
- Robust future product development pipeline



Board remains confident about Group's future prospects

*Percentage based on figures in thousands (2017: £55.545m, 2016: £48.509m)



2018 expected key value driving newsflow



Half year results

Full year results

Q4 2017

Mar 18

H2 2018

First patient treated –
PQ Grass Phase II Trial
for US and Europe

**PQ Grass Phase II
for US and Europe –**
results of conjunctival
provocation test
dosing trial in Europe

**PQ Birch Phase III
for Europe**
- results of pivotal
field trial for PQ
technology and
part of the TAV
process

**Acarovac MPL
Phase I – results**
for the new dust
mite technology
which could be
developed for the
Global market



Appendix

September 2017



Analysis of regulated products

	Named patient basis	Approved ¹	German TAV process	US Process	Other Clinical trials
Vaccines					
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				
Oral					
Oralvac Grass	X		X		
Oralvac Trees	X		X		
Oralvac House Mite	X		X		

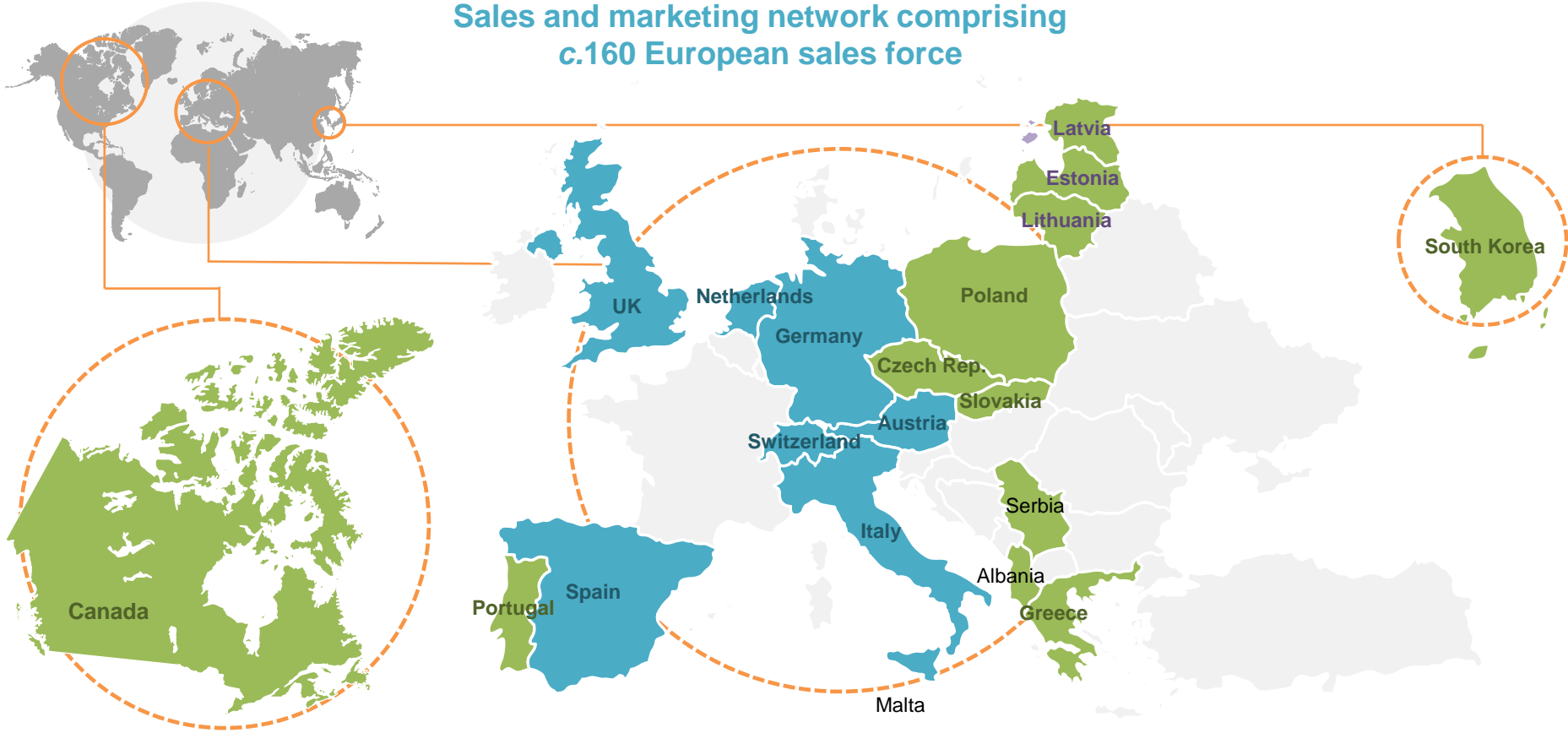
Trials in process
 CMC process
 Trials undertaken

¹ 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 13 countries



Portfolio of products to capture US opportunity



**Pollinex
Quattro
Grass**



**Pollinex
Quattro
Ragweed**



**Pollinex
Quattro
Trees**



Acarovac



**Polyvac
Peanut**

- ✓ **Proprietary, IP protected 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

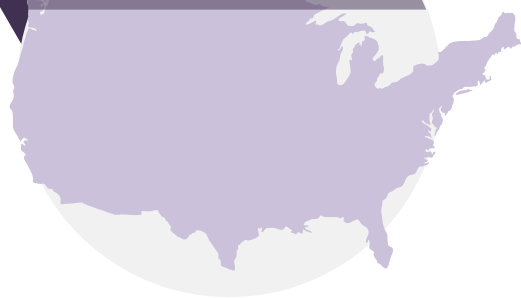
- ✓ **Strategic fit for US market**

- ✓ **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



Changing US landscape to drive market share

Current US SCIT market



Home made, unlicensed 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

New USP and FDA
regulations drive
towards
pharmaceutical
grade, centrally
manufactured, **single**
allergen treatments

Allergy Therapeutics' entry in the US



Standardised dose vaccine

GMP manufactured
FDA submission
Multiple clinical studies

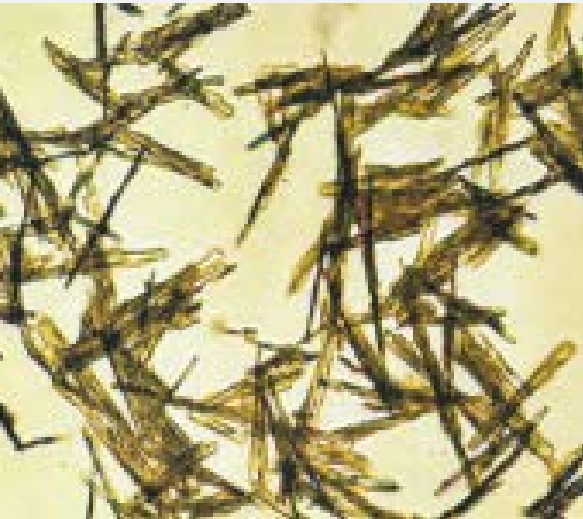
Ultra- short course treatment:
4 to 6 injections

Efficacy in 3 weeks

High compliance



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

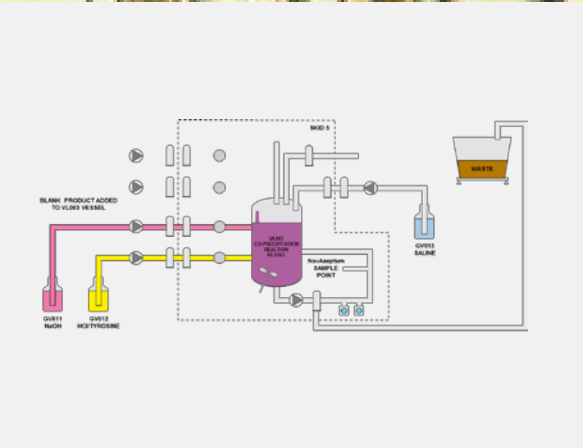
Within the last 12 months, studies have been completed supporting MCT use as a depot immunomodulator in each application:

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





PQ: a unique platform technology

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

MPL Adjuvant

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

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

Micro Crystalline Tyrosine (MCT)

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



Acarovac MPL House Dust Mite Product

Short-course product with global potential



Phase I first patient treated in June 2017 as part of 32 patient trial (AM101)

Acarovac product without MPL growing well in Spain and Austria

Potential of 8 injection model compared to 12-15 average of competitors and once a day for 3 years oral treatment

Results of Phase I Trial expected autumn of 2018

Market opportunity of \$3-4bn* worldwide with only Europe partly tapped already

Potential additional product in US portfolio following two Phase III trials

*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



Bencard Adjuvant Systems Division

Strategy

MCT, MPL & VLP
Researching on MCT
mechanism of action

Potential for licencing or
use in development of
products to boost efficiency

Studies

Pre-clinical study using MCT in a
seasonal influenza model – elicited
immune response indicative of protection

Pre-clinical model using MCT and
VLP in malaria – offered best
protection compared with antigens
formulated with aluminium

Studies show MCT both alone and in
adjuvant system elicit high, sustained
antibody titres demonstrating enhanced
protective efficacy compared to
conventional adjuvants including aluminium



Platform Technologies

	Modified Allergen (Allergoid)	Native Allergen	Recombinant Allergen	Microcrystalline Tyrosine (MCT)	Monophosphoryl Lipid A (MPL)	Virus-Like Particles (VLP)
Pollinex	✓	-	-	✓	-	-
Pollinex Quattro	✓	-	-	✓	✓	-
Oralvac	-	✓	-	-	-	-
Acarovac Plus	✓	-	-	✓	-	-
Acarovac MPL	✓	-	-	✓	✓	-
Venomil	-	✓	-	-	-	-
Peanut*	-	-	✓	✓	-	✓

* - Product under pre-clinical investigation, full product profile yet to be determined



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

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

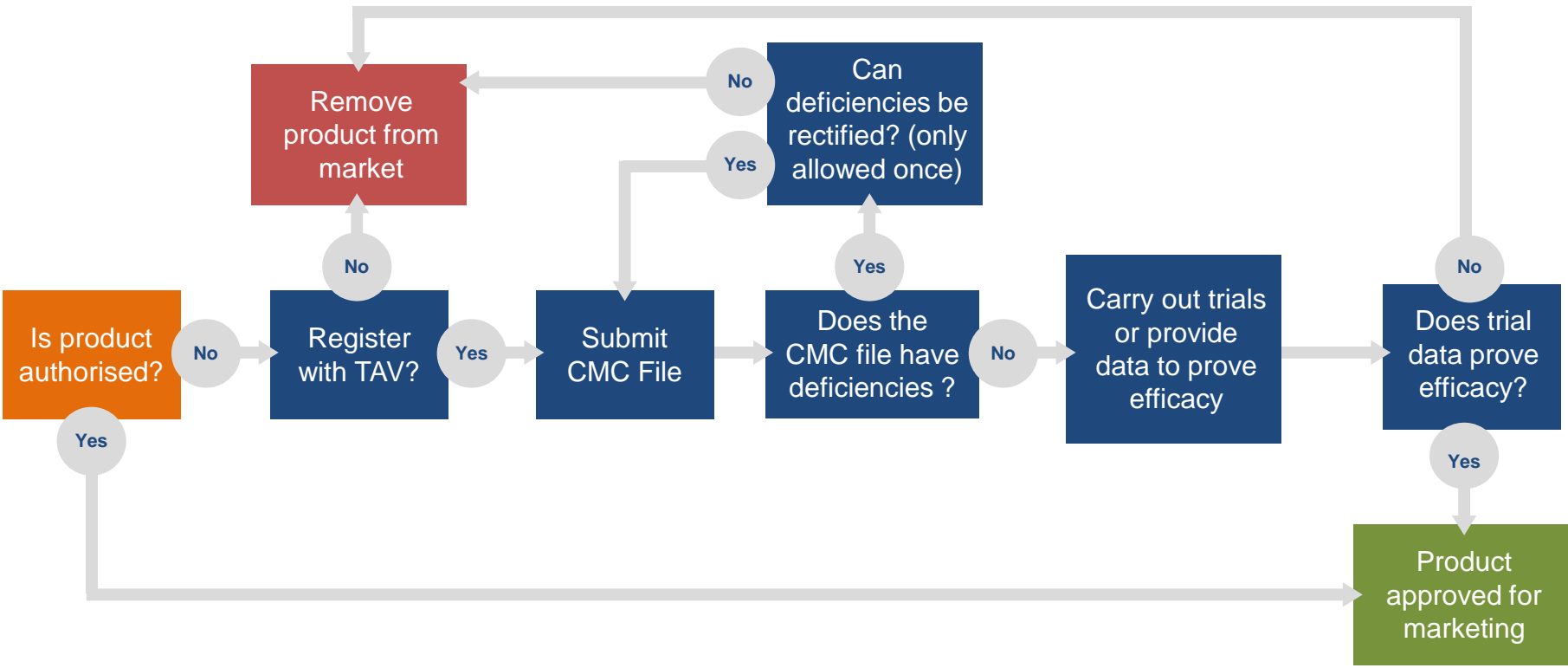
Germany contributes
59% of AGY Group sales

Future advantage of clinical evidence
to support marketing plus potential reduction in competition

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



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