



# Delivering on our strategy – three areas for growth

**Placing Roadshow - July 2018**

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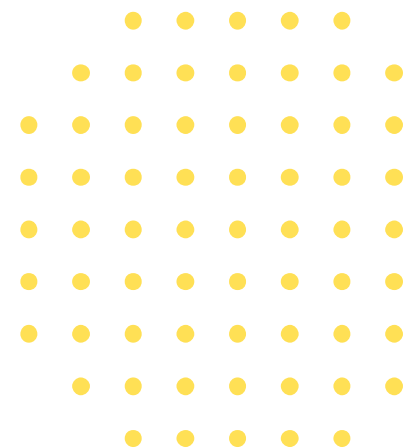
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# Our Business and the Strategy

# A Leading Allergy Immunotherapy Company: Three Pillars to Growth

## Three pillars to the business

01

### Expanding in Europe

Strongly performing profitable business

Growing market share and additional product registrations



02

### Preparing for US entry

Significant opportunity in largest allergy market

Changing environment to drive market share towards Allergy's products



03

### Strong pipeline

New technologies underpin pipeline breadth and depth

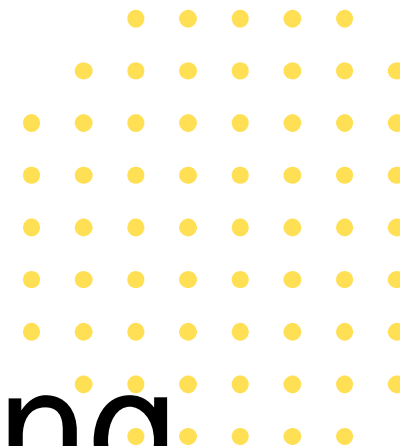
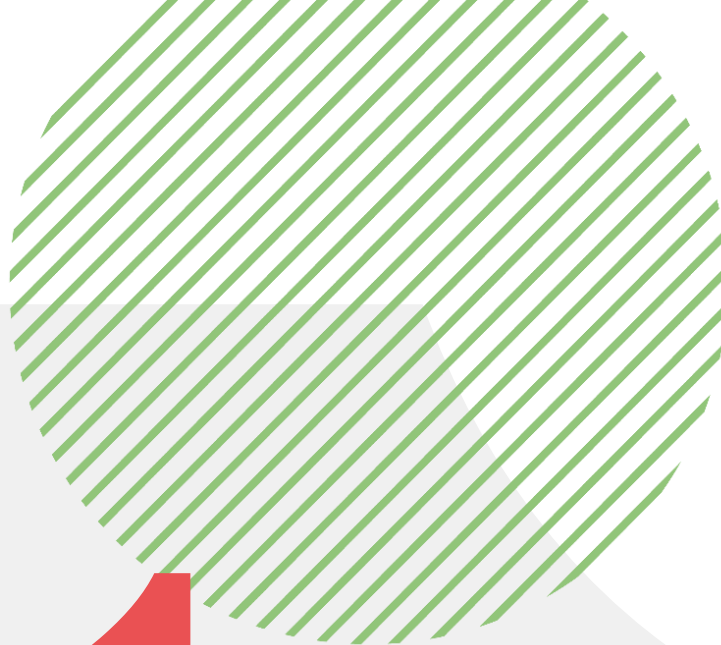
Investment strategy supported by growing revenue stream



# Innovative, Broad Pipeline and Marketed Products

	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					
Bee Venom SCIT		Short-course SCIT					
Wasp Venom SCIT		Short-course SCIT					
PQ Grass (lower dose)		Short-course Grass SCIT with MPL					
PQ Birch		Short-course Birch SCIT with MPL					
PQ Ragweed		Short-course Ragweed SCIT with MPL					
PQ Grass		Short-course Grass SCIT with MPL					
PQ Trees		Short-course Tree SCIT with MPL					
Oral Grass, Trees & House Dust Mite		Sublingual immunotherapy with flexible-dosing					
Modified Mite Platform		Short-course modified Allergen HDM SCIT + MPL					
Peanut SCIT		Short-course Peanut SCIT					

01



# Expanding in Europe

# European Business – 2018 Unaudited Full Year Results

**Solid sales growth of 3.5% in 2018 and increased market share of 0.7 points\* driven by:**

Innovative, convenient and patient-friendly (short-course) products

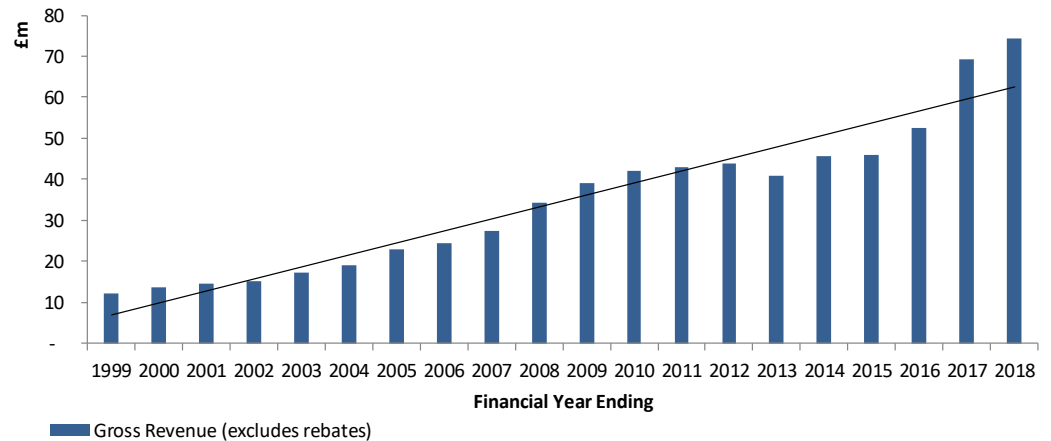
Increased regulatory requirements to ATL advantage (TAV)

Focused investment across business reflected in performance

Strength of broad portfolio with modified Mite and Venom SCIT

Scaling-up to drive technological and geographical expansion

**10% CAGR growth over last 19 years since formation**

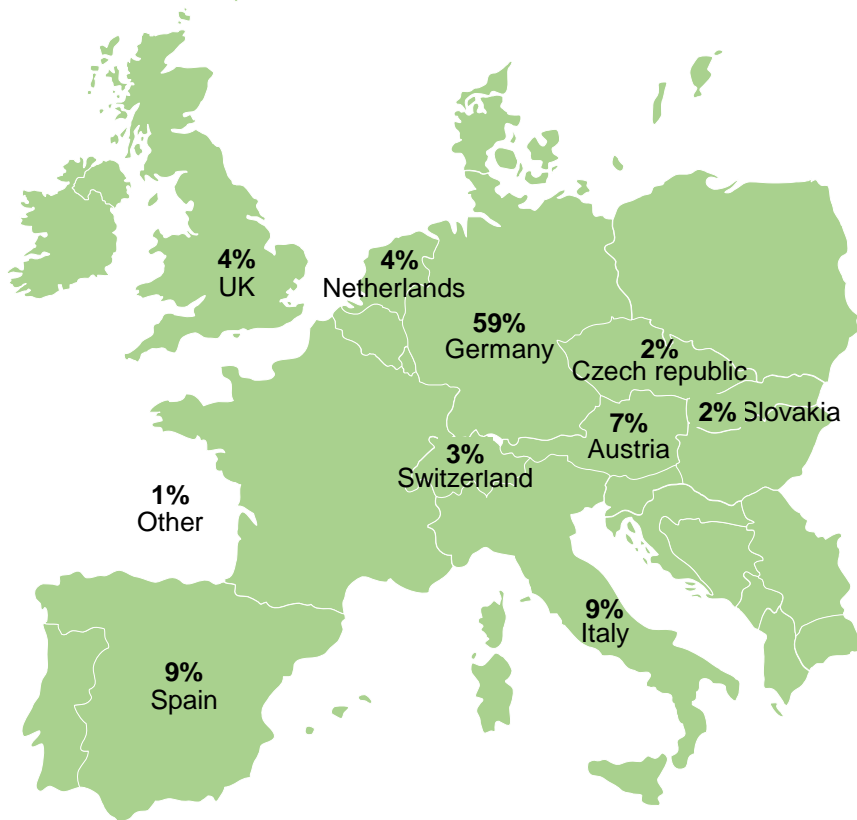


\*Market data and internal estimates for 9 months to 31 March 2018, for markets in which Allergy Therapeutics' operates excluding Switzerland (competitor data not available).

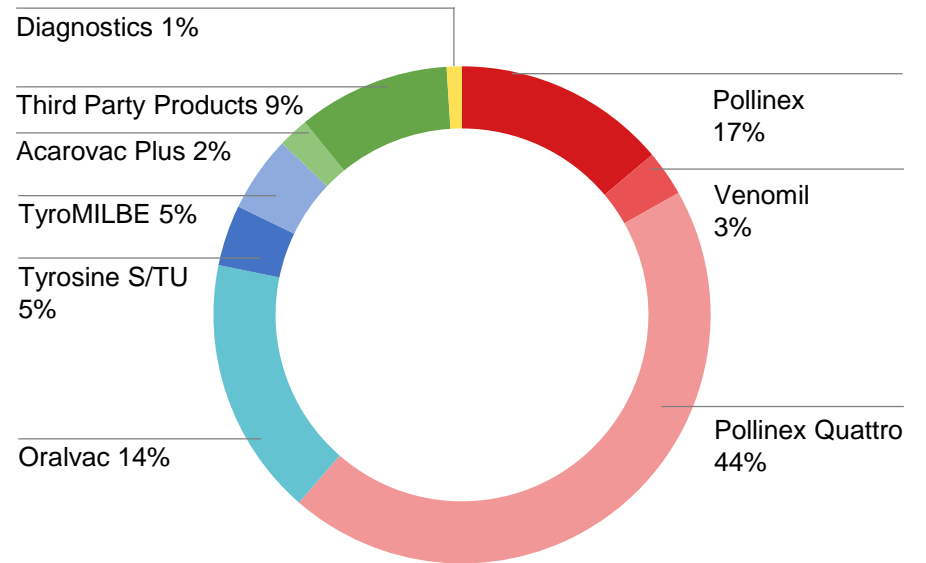
# Sales breakdown for FY 2017

## - injectable focus fits well with US market

### Sales by country



### Sales by product<sup>1\*</sup>



Pollinex Quattro

Pollinex

Tyrosine

Oralvac

<sup>1</sup> 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

\*Allergy Therapeutics currently has no products licensed for sale in the USA





02

# Preparing for US entry

# US allergy immunotherapy market represents a significant and attractive commercial opportunity

**\$2bn\*\***

estimated allergy immunotherapy market

**2-3m\*\*\***

Americans receive allergy immunotherapy

**>100 injections**

Current treatment: up to 100 injections over 3-5 years\*\*\*

**15%\***

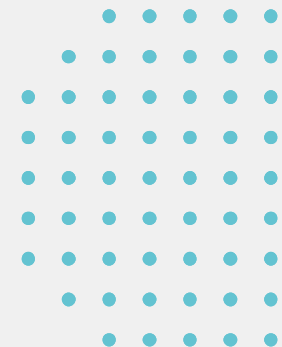
Some adherence levels as low as 15%\*

**None**

Currently no registered injected products

**\$300-400m\*\***

Estimated peak gross sales



\* Hankin CS, Cox L, Lang D, et al 2007 JACI

\*\*Internal estimate

\*\*\*Professor Lawrence DuBuske MD

# The changing US regulatory landscape offers potential for significant commercial growth

## 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

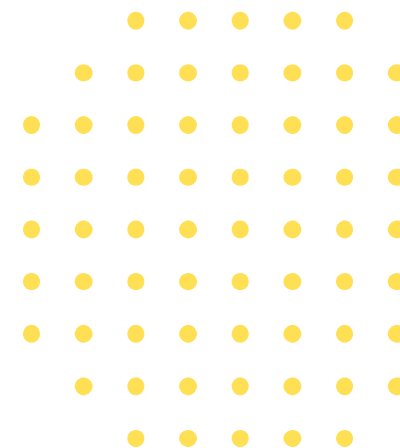


- **Standardised** dose vaccine
- **GMP** manufactured
- **FDA submission**
- **Multiple** clinical studies
- **Ultra- short course** treatment: **4 to 6** injections
- **Efficacy** in 3 weeks for 4 shot treatment
- **High** compliance



03

Strong  
Pipeline



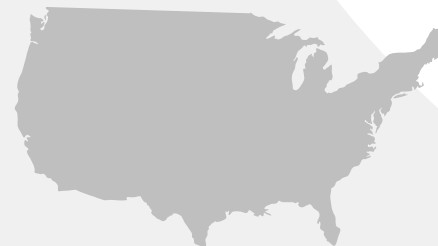
# Overview of Clinical Trials

## PQ Birch



- Phase III field trial in Europe
- 582 patients from 59 centres in Germany, Austria, Poland and Sweden
- Double blind placebo controlled trial
- Pivotal trial for approval in Germany
- Combined Symptom Medication Score – based on patient daily symptom score and level of medication taken
- Co-seasonal trial
- Readout Calendar Q3 2018

## PQ Grass



- Phase II dosing trial to move towards second Phase III trial + safety database
- Conjunctival Provocation Test to determine optimal efficacious cumulative dose
- 447 patients in 50 sites in Germany, Austria and Poland
- Total Symptom Score – measures four aspects of eye symptoms
- Pre seasonal trial
- Highly positive Phase II results announced calendar Q2 2018



## G205: Key Study Results

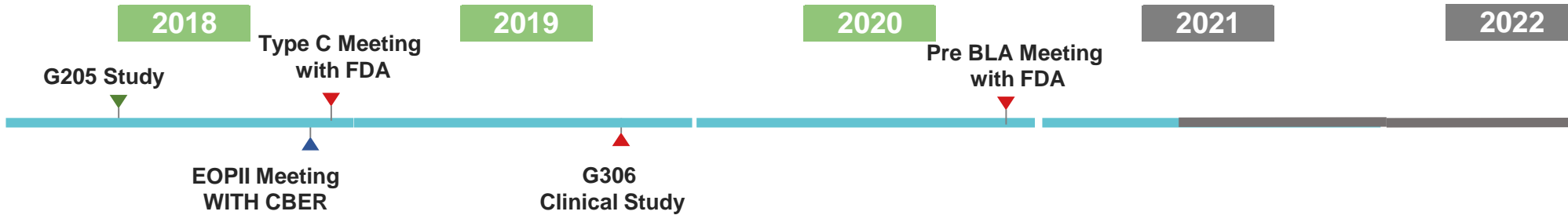
- Primary endpoint of trial met with highly statistically significant dose-response relationship
- All dosing regimes safe and well tolerated
- Current marketed product showed significant improvement compared to placebo
- Significant increase in immunoglobulin results, highly consistent with dose response observed for primary endpoint
- Adherence to short course treatment excellent (>95%)



## G306 Phase III trial

- Field study in both US and Europe
- Pivotal for both US and Europe
- Dosing planned to commence in calendar H2 2019 with results in H2 2020
- Funding for trial based on current resources plus proposed placement funding

# PQ Grass MATA MPL Timelines



## Key Considerations for Grass MATA MPL

### Market

- Allergies are the 6th leading cause of chronic illness in the U.S.<sup>1</sup> Market worth \$2Bn/yr
- More than 50 million Americans suffer from allergies each year.

### Competition

- 2<sup>nd</sup> Generation antihistamines (Claritin) started to become OTC in ~2003<sup>2</sup>
- Allegra (Fexofenadine) and Xyzal (Levocetirizine) followed suit (OTC not covered by insurance)
- Grass tablet (Grastek) launched by ALK in 2014 (1 Grass spp. EpiPen co-prescribed)
- Grass tablet (Oralair) launched by Stallergenes in 2014 (5 Grass spp. EpiPen co-prescribed)

### Perception of Grass MATA MPL

- Modified allergen injected product (positive perception on enhanced safety profile)
- Inclusion of adjuvant MPL leads to shorter therapy duration & thus increased compliance
- A registered injected AIT with proven efficacy would be beneficial (better than compounding)

### Pricing

- Grastek<sup>®</sup> costs \$300<sup>3</sup> and Oralair costs \$500<sup>4</sup> per 30 days
- Perception amongst HCPs in USA is that Grass MATA MPL should be ~\$2000<sup>5</sup>

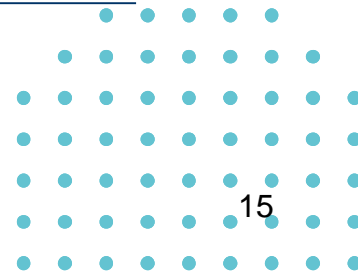
1 – <https://www.cdc.gov/>

2 – <https://www.medicinenet.com/script/main/art.asp?articlekey=21882> (accessed Mar 2018)

3 – <http://www.rxiconsult.com/healthcare-articles/Grastek-Timothy-Grass-Pollen-Allergen-Extract-Cost-Dosage-Side-Effects-632/>

4 – <https://www.goodrx.com/oralair>

5 – Personal communication at AAAAI 2018



# Mite MPL house dust mite product

**Phase I first patient treated**  
Study ongoing

**Results of Phase I Trial**  
expected calendar H1 2019

**Acarovac product without  
MPL growing well in Spain  
and Austria**

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

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

**Potential additional product**  
in **US** portfolio following two  
Phase III trials

**Short-course  
product  
with global  
potential**

\*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



# Preclinical Pipeline: Polyvac peanut product

**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**

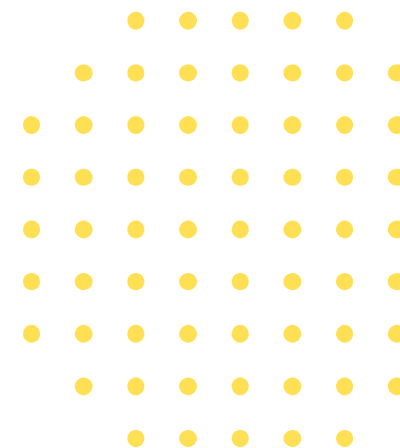
**Manufacturing contract for scale-up of Polyvac product signed with AGC Biologics** with aim of having first trial in humans in 2019

**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

**Positive results achieved from preclinical research of Polyvac Peanut**

\*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



# Placing

# Purpose of Placing

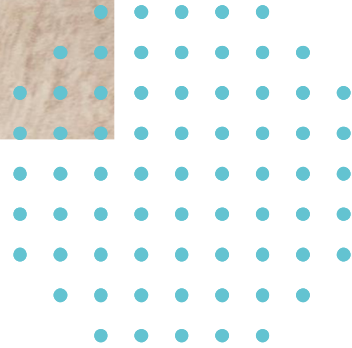
Raising of £10m primarily for:

- 1) Expansion of planned Phase III PQ Grass Trial (start H2 2019):
  - increase number of patients to power up study
  - vaccinate placebo arm (following completion of trial) to:
    - reduce overall cost of potential safety database<sup>1</sup>
  - additional project to analyse pollen trends in US to maximise exposure of patients to grass pollen
- 2) Part funding of Acarovac Phase II Trial (balance of funding for trial from CDTI, subject to contract, start 2019)
- 3) Continued progress on diversified pipeline (including peanut)



**PQ Grass  
Potential in US:  
Sales of U\$300-  
400m per year**

<sup>1</sup>Safety database subject to discussions with regulatory authorities in the autumn



# Summary and outlook



# 2018 Financial highlights

10% compound annual growth achieved over the past 19 years

**3.5%\*** 

increase in revenue  
at constant currency\* to

**£66.4m**

(H1 2017: £64.1m)

**6.6%** 

increase in  
reported revenue at

**£68.3m**

(H1 2017 £64.1m)

Increase in market share over 9 months to March 2018

**Up 0.7 of a market share point**

as a result of quality of technology and organisation

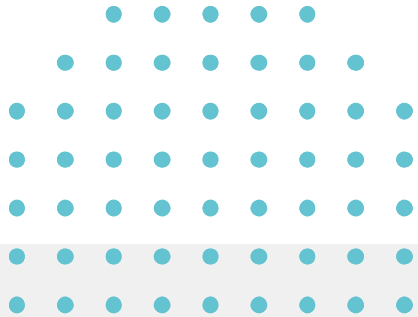
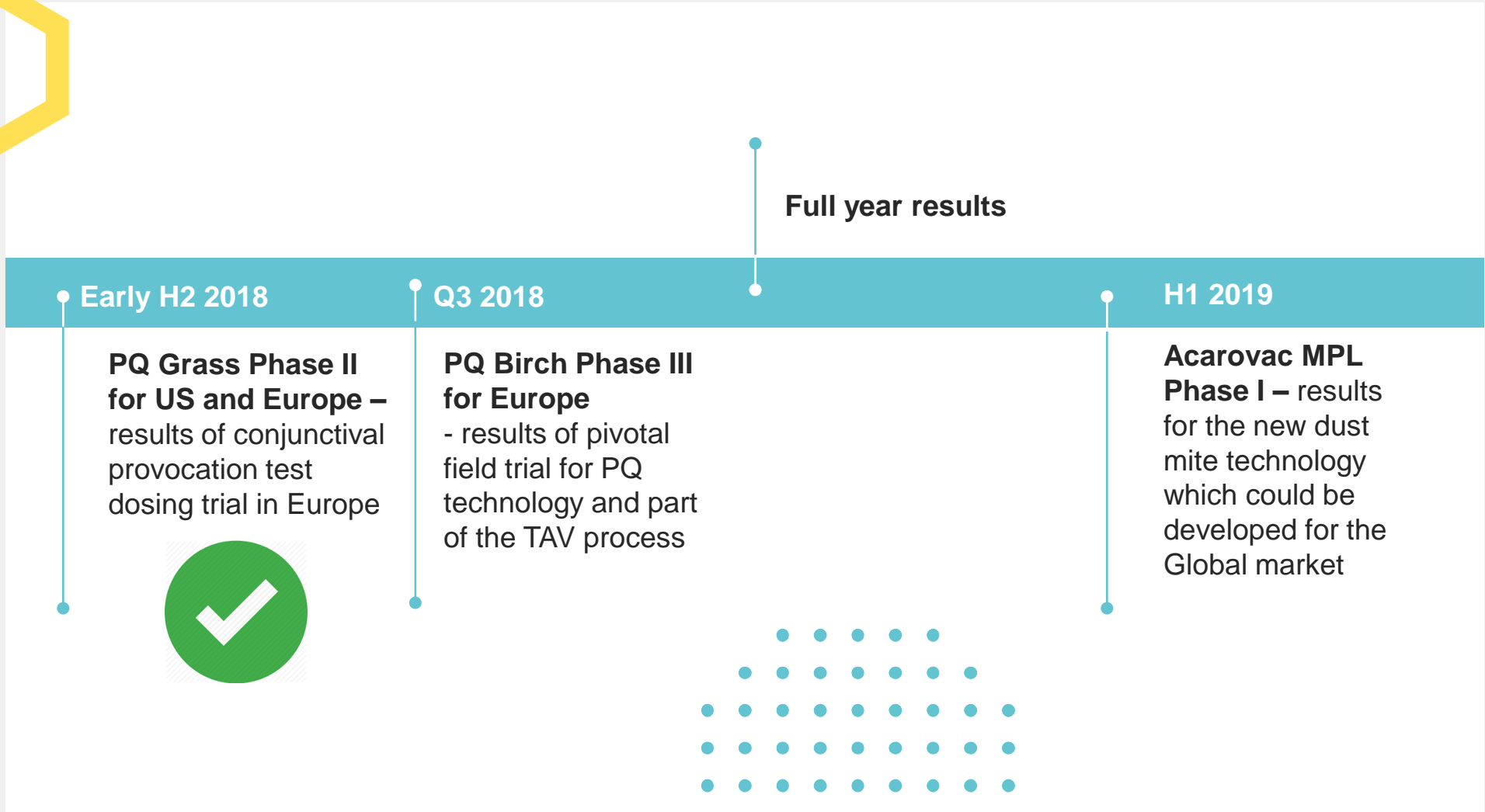
Cash balance of

**£15.5m**

(2017: £22.1m)

\*\*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.

# 2018/2019 Milestones



# Summary and outlook

## 2018 set to be a pivotal year

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Delivering against our strategy: three pillars to growth

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Robust financials set to continue

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

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Innovative and convenient, allergy vaccines

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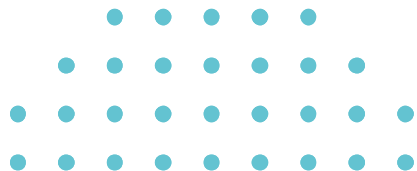
Board remains confident about Group's future prospects

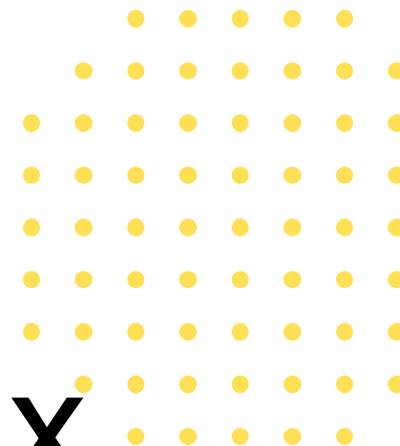
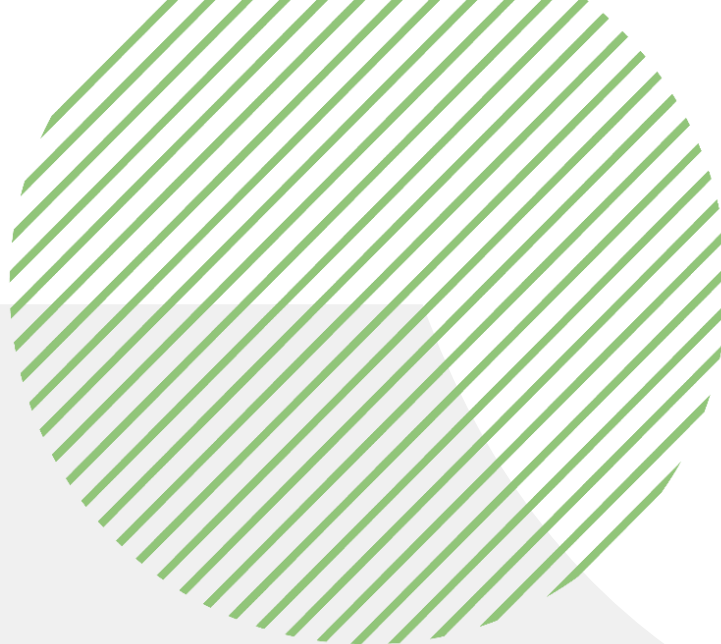
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Focused strategy to be first to market in the US SCIT segment

Continued  
gain in market  
share

Successful  
Phase II  
Grass Trial

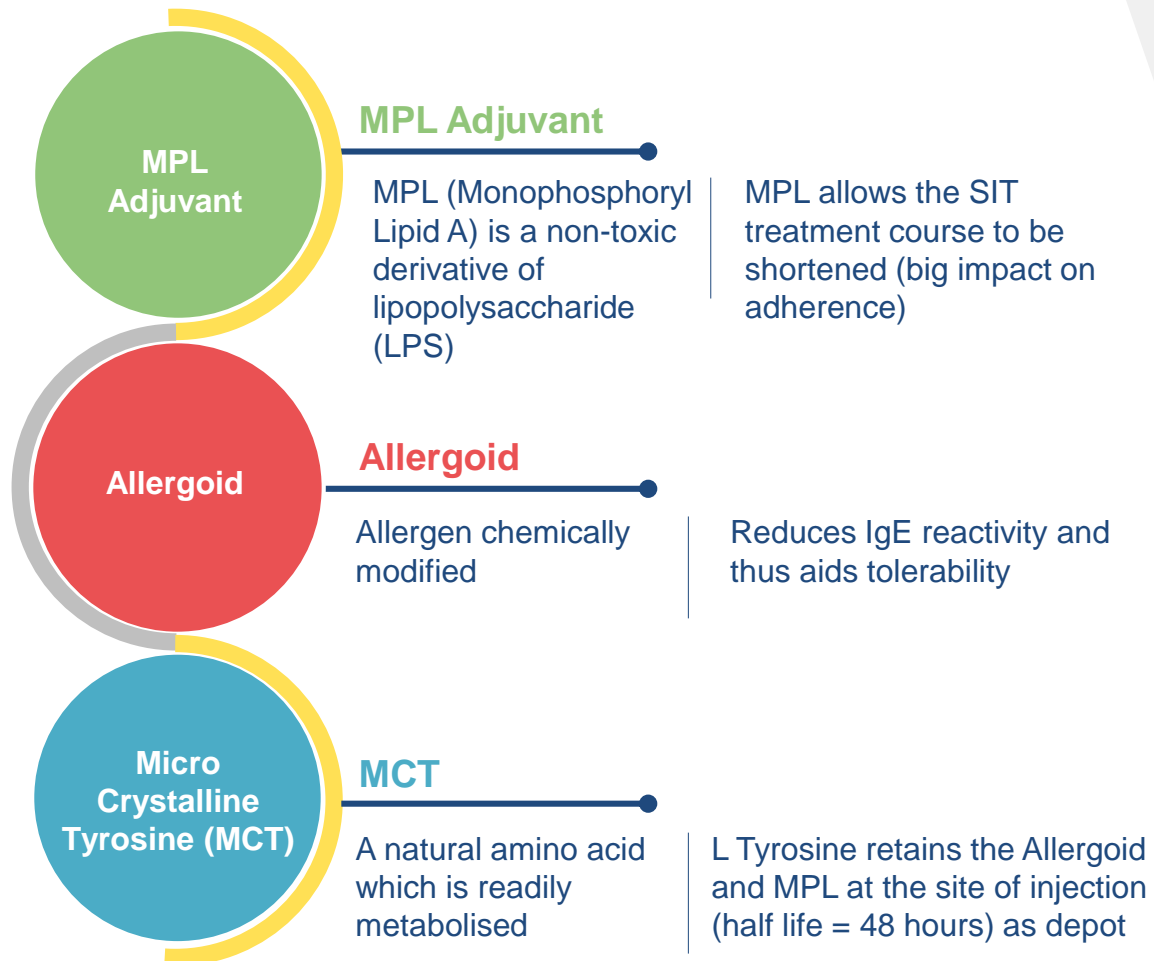




# Appendix

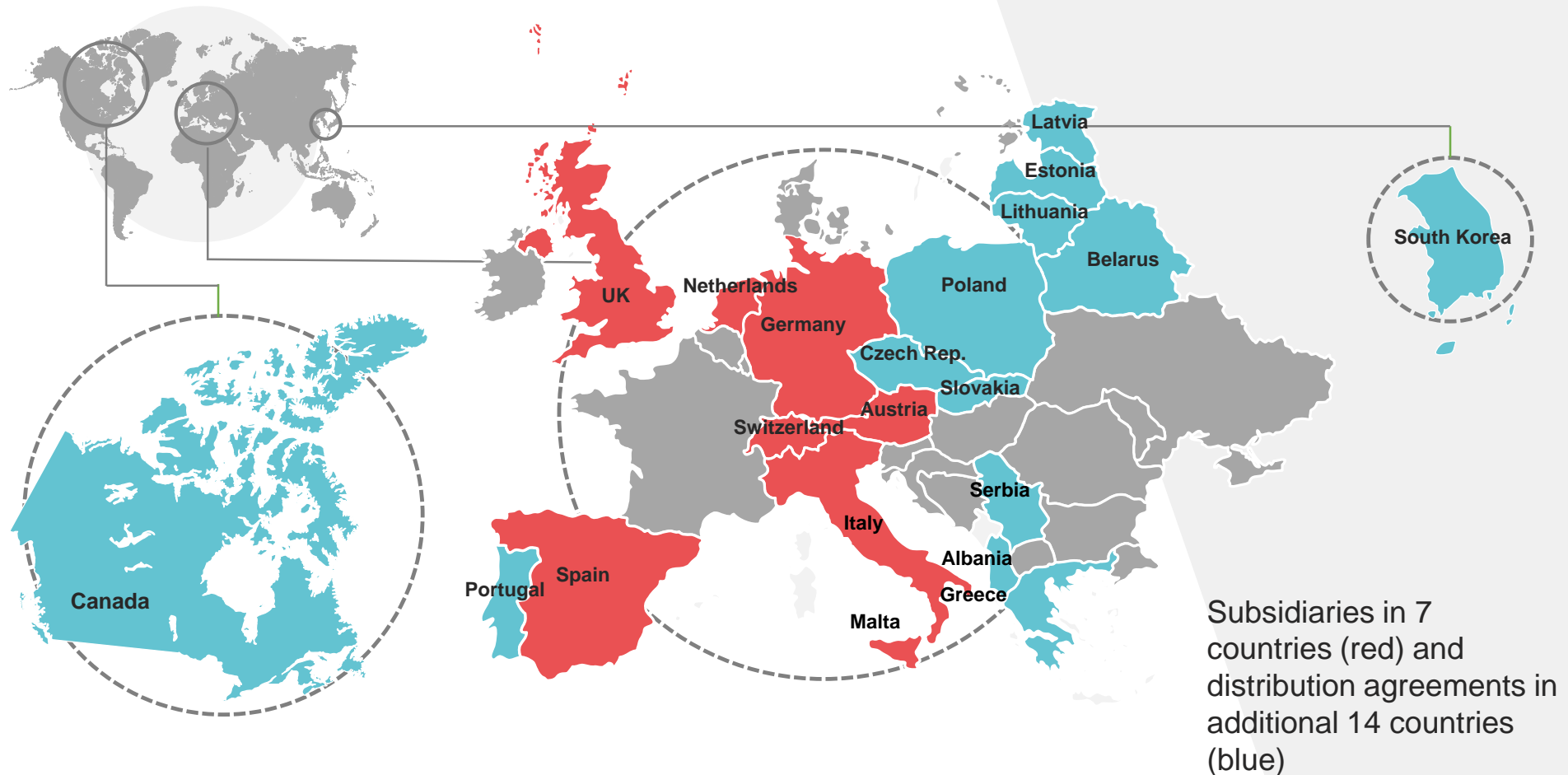


# PQ: Differentiated platform approach enhances compliance, leads to higher efficacy and successful outcomes



# Pharmaceutical Company with Solid Sales and International presence

Sales and marketing network comprising c.160 European sales force



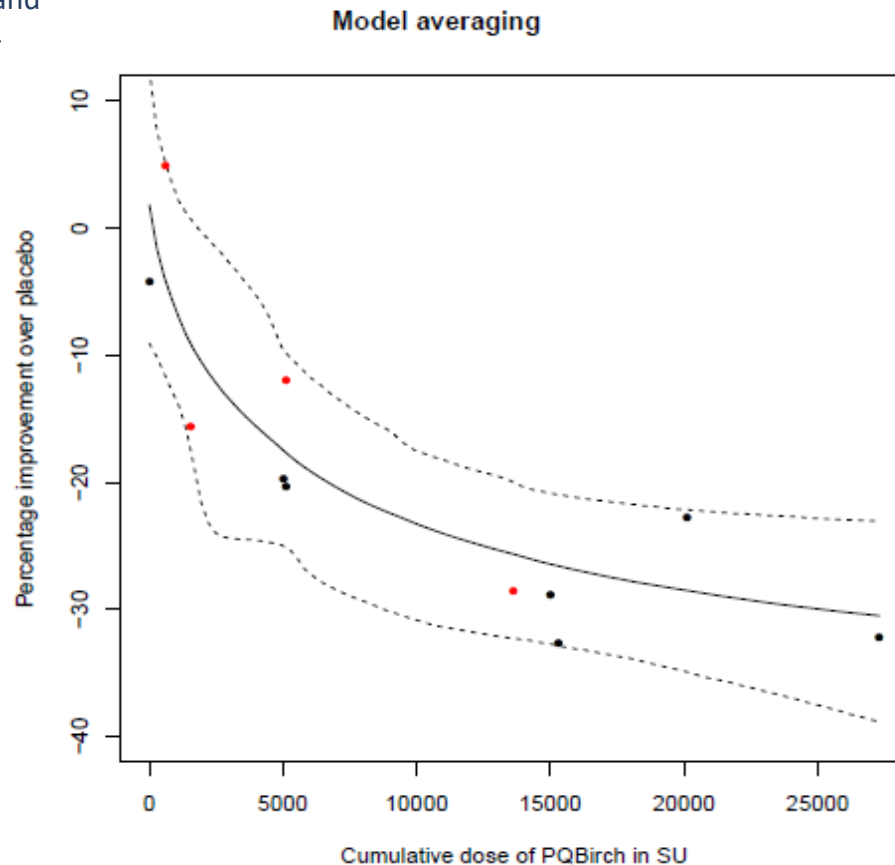
# Platform Technologies

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

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

# Pooled data from PQ Birch Phase II trials (B203 and B204) showing efficacy difference between each dose and placebo (PPS)

Red PQB203 and  
black PQB204



**The reduction of  
symptoms with each dose  
relative to placebo**

5100 SU: -20.88%

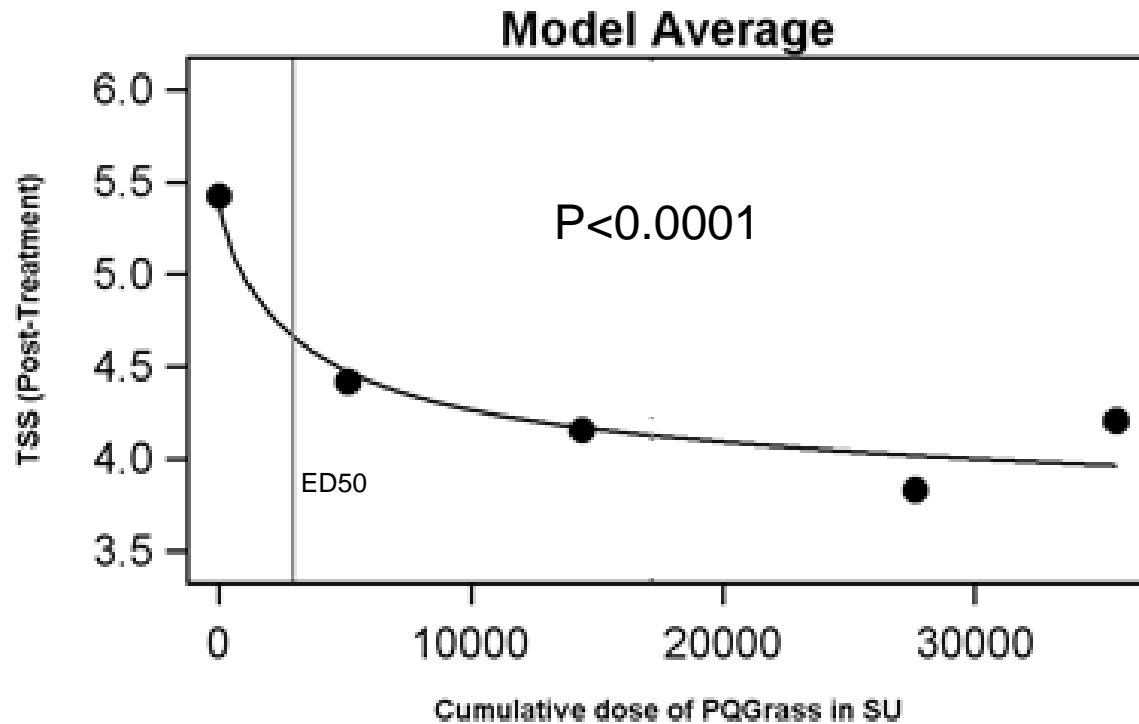
15300 SU: -28.33%

20100 SU: -30.21%

27300 SU: -32.33%

- B203 completed in 2014 and B204 in 2016
- Data shows increasing efficacy with increased dosing

# Grass Phase II Dosing Study :Primary Efficacy Analysis: Model Averaging (mFAS)



**The reduction of symptoms with each dose relative to placebo**

Treatment Group Estimated\* mean post-treatment TSS relative to Placebo

\*Estimates from the model (curve fitting), not the descriptive point estimates  
ED50: The minimum dose that achieves 50% of the full effect size over Placebo

# Unique depot Microcrystalline tyrosine (MCT) provides aluminium alternative as well as adjuvant properties

## 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

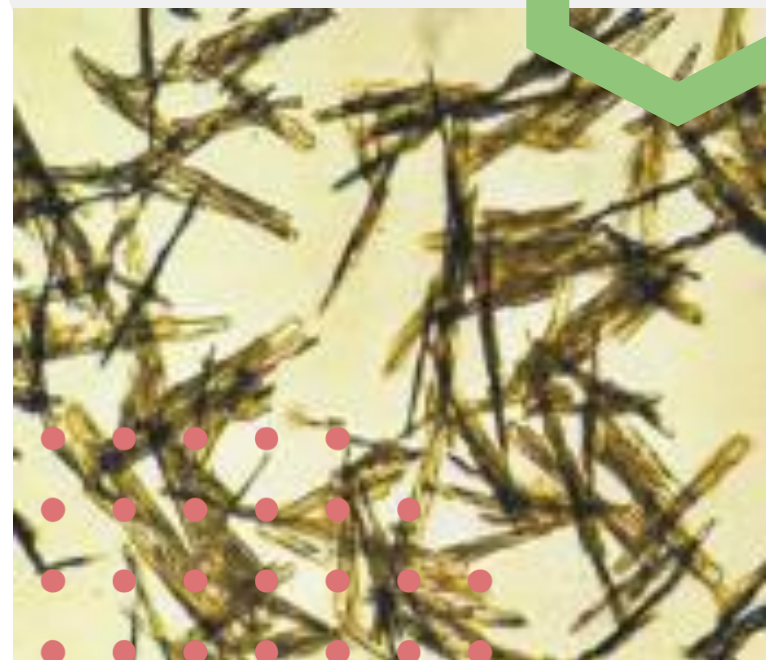
Within the last 12 months, studies have been completed supporting MCT use as a depot immunomodulator in each application:

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



# Portfolio of products offer a strategic advantage to capture US opportunity

Grass



Ragweed



Trees



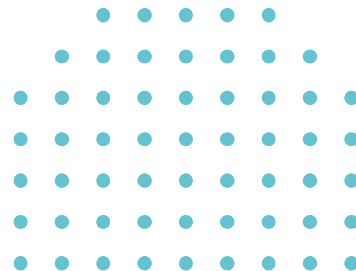
Mites



Peanut



- Proprietary, IP protected technology
- De-risked opportunity
  - Treated more than 250,000 patients and marketed in 7 countries (pollen)
- 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:
  - \$100m 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



# P&L – six months ended 31 December 2017

£12.3m

Operating profit pre R&D

(H1 2017: £11.1m) due to investment,  
leveraging solid sales

Up

Overheads up

due to FX and investment

Solid

sales performance

in abnormally weak pollen season

	H1 2018 £'m	H1 2017 £'m	Variance £'m	%
Revenue	42.2	40.4	1.8	4%
Gross profit	33.5	31.5	2.0	6%
Overheads	(21.4)	(20.5)	(0.9)	(4%)
R&D	(5.9)	(3.8)	(2.1)	
Other Income	0.2		0.2	
Operating profit	6.4	7.2	(0.8)	
Net Financing costs	(0.0)	(0.0)	0.0	
Tax	(0.4)	(0.4)	(0.0)	
Profit after tax	6.0	6.8	(0.8)	



# Balance sheet at 31 December 2017

£25.8m

Cash position

£3.2m

Debt. Seasonal overdraft  
in place (undrawn)

Increase

Increase in non-current  
assets driven by increase  
in pension investments

Other liabilities increase  
due to R&D creditors

Higher

Inventory higher due to  
preparation for clinical trial material

	H1 2018 £'m	H1 2017 £'m	Variance £'m
<b>Non-current assets</b>			
Property, plant and equipment	9.8	9.7	0.1
Intangible assets	5.1	5.4	(0.3)
Investments	4.9	4.3	0.6
	19.8	19.4	0.4
<b>Current Assets</b>			
Trade and other receivables	10.9	10.7	0.2
Inventories	8.4	7.0	1.4
Cash	25.8	27.8	(2.0)
<b>Liabilities</b>			
Financing liabilities	(3.2)	(3.4)	0.2
Other liabilities	(25.8)	(23.0)	(2.8)
<b>Net assets</b>	35.9	38.5	(2.6)
<b>Equity</b>			
Share capital and share premium	103.0	103.0	0.0
P&L account and other reserves	(67.1)	(64.5)	(2.6)
	35.9	38.5	(2.6)