



Allergy Therapeutics

**Preliminary results
for the year ending
30 June 2016**

September 2016



Financial highlights

- 19% increase in revenue at constant currency to £51.5m (2015: £43.2m)*
- 12% increase in revenue to £48.5m (£43.2m)
- Core business excluding R&D shows 11% increase in Operating Profit to £4.3m (2015: £3.8m)
- Ramp up on R&D investment with £16.2m (2015: £3.1m) spent, reflecting investment in PQ registration and pipeline
- Successfully raised £11.5m (gross) to fund new product development and organic and inorganic growth opportunities
- Strong cash balance of £23.4m at year end (2015: £21.2m)

** 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.*



Operational highlights

- Increased market share in our main European markets to 12% (2015: 10%)
- Achieved primary endpoint for PQ Birch Phase II Study in Europe and with dose selected which will be used in Phase III starting in 2017
- Inconclusive results of Phase II dosing study in the US for Pollinex Quattro Grass
- Acarovac Plus™ one-year study showed statistically significant improvement for patients
- Acquisition of Virus Like Particle technology licence for the development of a potential new injectable vaccine immunotherapy treatment for allergy sufferers with peanut as lead project



Competitive landscape

Eventful year for the industry:

- SLIT competitor manufacturing shutdown
- UK Biotech phase III study failure for cat allergen
- Key German competitor put up for sale
- MSD (Merck) dissolution of partnership in North America with European SLIT manufacturer

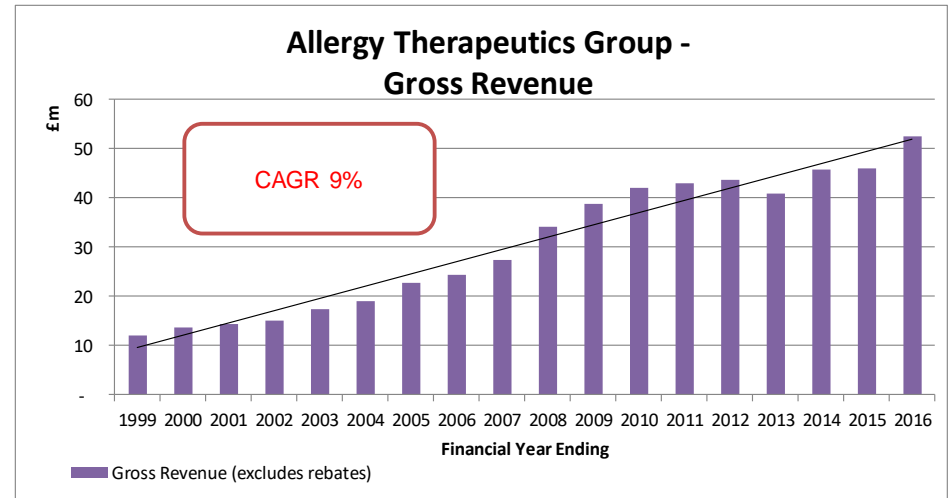


Strategy

September 2016

Strategy

- European business momentum increasing
- US opportunity opens up a potential \$2bn* SIT market
- New therapeutic areas progressing according to plan



* Piper Jaffray Update on the AR market, Sept. 2008. Datamonitor

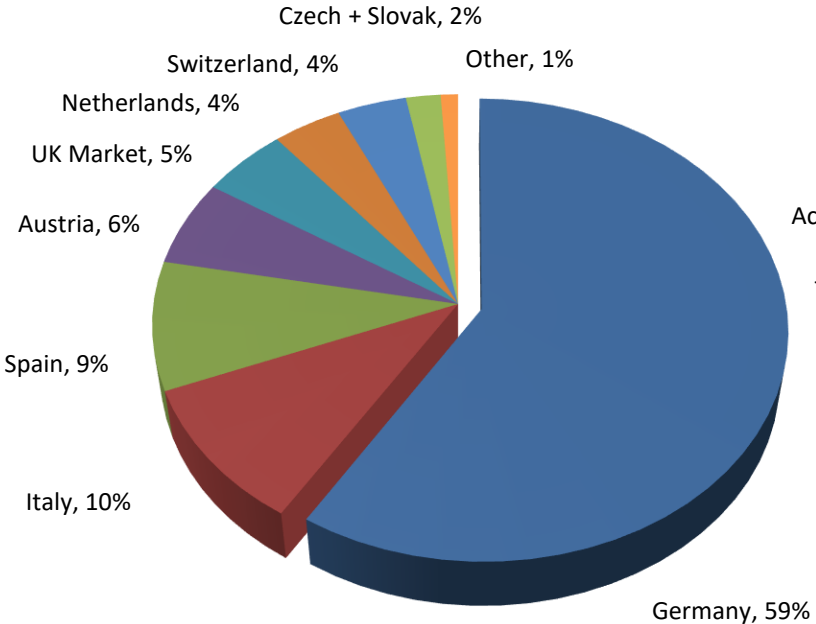


European business

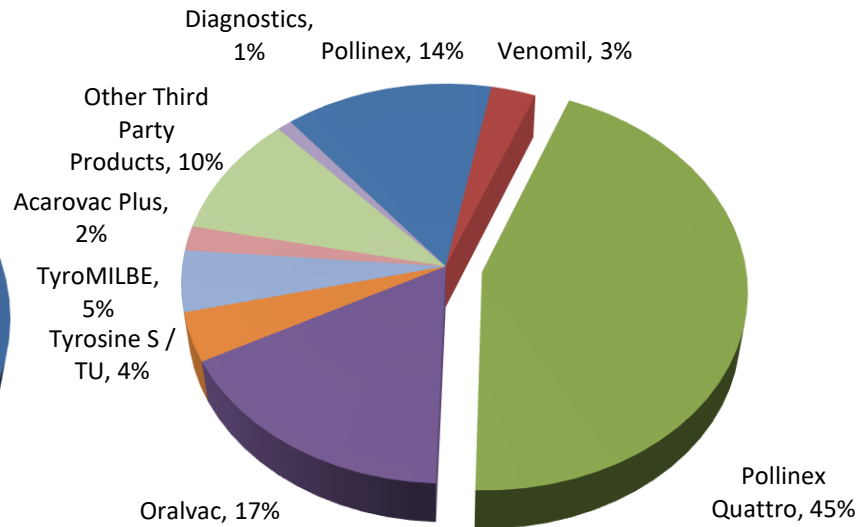
- Growth of 19% at constant rate (12% actual) in broadly flat market
- Gain of 2% market share to 12% this year
- Supply chain integrity and unparalleled customer service
- Alerpharma acquisition fully integrated
- Eventful year in competitive landscape

Sales breakdown

Sales by Country



Sales by Product¹



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



Recent developments in US

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

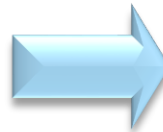


US PQ product opportunity

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

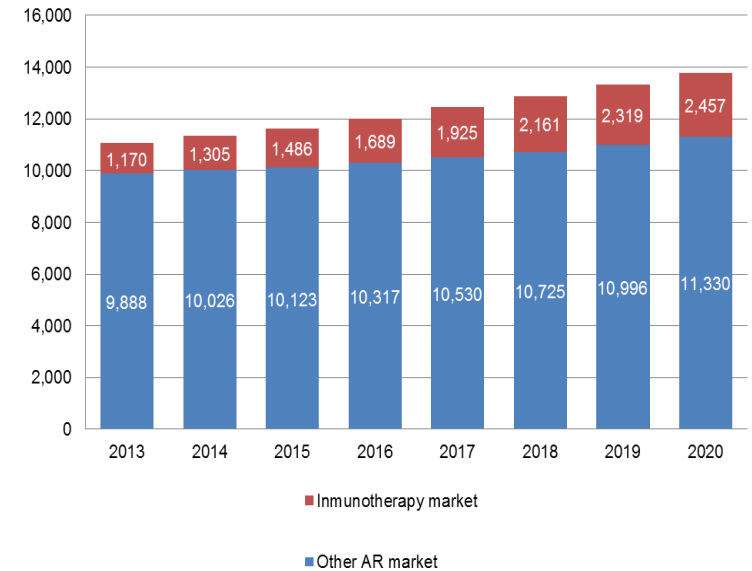
- Ultra- short course treatment:
 - 4 injections
- Efficacy in 3 weeks
- High compliance

The US opportunity

- 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

*Visiongain, AR forecast 2014

**Piper Jaffray Update on the AR market, Sept. 2008. Datamonitor





Phase II Birch dosing study in Europe (B204)

- Positive top-line results for Phase II Birch dosing study
- Randomised 371 patients into six cumulative dosing regimes plus placebo
- Conjunctival provocation test
- Primary endpoint to demonstrate a statistically significant dose response for 5,000 to 27,000 standardised unit met
- Dose response closely followed and extended the findings of previous dose response study (PQ Birch 203)
- PQ Birch well-tolerated and no safety concerns were reported in any treatment arm



Phase II Grass dosing study in the US (G204)

- Exploratory Phase II dose-ranging study for US Grass MATA MPL clinical development program
- Results inconclusive and could not determine suitable dose
 - Investigation of reasons for results underway
 - Trial used mobile challenge chambers
- Further Phase II dosing trial using Conjunctival Provocation Tests (CPT) to be undertaken in 2017 subject to agreement from FDA
- Further Phase II (CPT) trial has put back expected launch date to 2020/2021
- Funding in place to carry out current, planned Phase III trial

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 top selling 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
- Developing Acarovac Quattro, an ultra-short course therapy utilising the adjuvant monophosphoryl lipid A (MPL), as used in successful Pollinex Quattro product range.
- CTA approval expected for Acarovac Quattro Phase I expected Q4 2016



The peanut allergy opportunity

- Allergy acquired the exclusive right in November 2015 to develop Virus Like Particles (VLP) technology for allergy vaccines
- Carrier system to present allergens to immune system
- First development will be for peanut allergy
 - Currently no established and safe treatment available
- 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



*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



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



Financial Results

September 2016

P&L – Year to 30 June 2016

<u>Audited</u>	2016	2015	Variance	%
	£'m	£'m	£'m	
Revenue	48.5	43.2	5.3	12%
Gross profit	34.4	31.1	3.4	11%
Overheads	(30.3)	(27.3)	(3.0)	(11%)
R&D	(16.2)	(3.1)	(13.1)	
Other Income	0.2	0.1	0.1	
Operating profit	(12.0)	0.7	(12.7)	
Net Financing costs	(0.1)	(0.1)	(0.1)	
Tax	(1.0)	(0.5)	(0.5)	
Profit after tax	<u>(13.1)</u>	<u>0.1</u>	<u>(13.2)</u>	

- Strong sales performance in all markets despite weaker euro
- Strong sales drives gross profit growth and gross profit % up on constant basis
- Overheads
 - non-cash credit of £2.4m re. revaluation \$
 - £2.0m charge for hedging contracts
- Significant R&D investment in US Grass Study and PQ Birch in Europe
- Operating loss of £12m (2015: £0.7m profit) due to R&D investment

Sales – Year to 30 June 2016

<u>Audited</u>	2016 £'m	2015 £'m	Variance £'m	%
Gross Revenue at Constant Exchange Rate	55.7	46.1	9.6	21%
Rebate at Constant Exchange Rate	<u>(4.2)</u>	<u>(2.9)</u>	<u>(1.3)</u>	(45%)
Net Revenue at Constant Exchange Rate	51.5	43.2	8.3	19%
Effect of Foreign Exchange	<u>(3.0)</u>	<u>0.0</u>	<u>(3.0)</u>	
Net Revenue	<u>48.5</u>	<u>43.2</u>	<u>5.3</u>	12%

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

1.27
1.36 1.27

- Significant improvement in sales against flat markets
- All markets performing well
- Strong growth in Pollinex Quattro and Oralvac
- Germany 59% of total sales
- Rebates up due to increase in prices in Germany
- FX impact due to weaker Euro for most of year

Balance sheet at 30 June 2016

<u>Audited</u>	2016	2015	Var
	<u>£'m</u>	<u>£'m</u>	<u>£'m</u>
Non-current assets			
Property, plant and equipment	9.7	8.7	1.0
Intangible assets	5.4	5.0	0.4
Investments	4.0	3.2	0.8
	<u>19.1</u>	<u>16.9</u>	<u>2.2</u>
Current Assets			
Trade and other receivables	6.5	5.1	1.4
Inventories	7.7	6.7	1.0
Cash	23.4	21.2	2.2
Other assets	-	0.8	(0.8)
Liabilities			
Financing liabilities	(3.4)	(1.7)	(1.7)
Other liabilities	(23.0)	(14.5)	(8.5)
Net assets	<u>30.3</u>	<u>34.5</u>	<u>(4.2)</u>
<u>Equity</u>			
Share capital and share premium	103.0	92.0	11.0
P&L account and other reserves	(72.7)	(57.5)	(15.2)
	<u>30.3</u>	<u>34.5</u>	<u>(4.2)</u>

- Increase in non current assets driven by currency movements and investment in infrastructure
- Trade debtors higher due to FX and timing of significant receipt
- Strong cash position of £23.4m
- Fundraising £11m net November 2015
- Debt in Alerpharma £1.7m plus bank loan. Seasonal overdraft in place (undrawn)
- Other liabilities increase due to fx, R&D creditors and hedging liability

Funds Flow for Year to 30 June 2016

<u>Audited</u>	2016		2015	
	<u>£'m</u>	<u>£'m</u>	<u>£'m</u>	<u>£'m</u>
Opening cash balance 1st July		21.2		2.0
(Loss)/Profit before tax	(12.1)		0.7	
Adjustments re operations	0.6		2.9	
Net cash (used)/ generated by operations		(11.5)		3.6
Tax paid		0.0		(0.2)
Interest Paid		(0.4)		(0.3)
Investments and acquisitions	(0.3)		(1.5)	
Capital Expenditure	(1.2)		(1.1)	
Net cash used in investing activities		(1.5)		(2.6)
Proceeds from issue of shares	11.0		20.1	
Net movement in borrowings	1.6		0.0	
Net cash generated in financing activities		12.6		20.1
Effects of exchange rates on cash		3.0		(1.4)
Closing Cash Balance 30 June		<u>23.4</u>		<u>21.2</u>

- Net use of cash in operations driven by R&D investment
- Fundraising for new product development plus organic/inorganic opportunities
- Bank loan
- Weakness of sterling at end of year boosted US dollar holdings



Summary

September 2016



Summary

- Strong trading in the 2015/16 financial year: +19% revenue growth at constant currency with gain in market share of competitive markets from 10% to 12%
- Moving forward R&D and regulatory maintenance projects
- Exciting pipeline progressing
- US opportunity delayed about 1 year, all additional costs to be self-financing but still expected to be first to launch SCIT product in US market
- Significant progress towards our long-term strategic plans



Outlook

- We expect to submit BLA for Pollinex Quattro Grass in 2020 with commercial launch in 2020/2021
 - We expect to be the first to market in the US SCIT segment with a registered product
 - We aim to be market leaders in the SCIT allergy segment by 2020
- Phase III PQ Birch trial for Europe to commence in 2017
- Phase I study for Acarovac Quattro due to start before end of Q2 2017
- We will be actively developing our M&A strategy
- We look forward to the future with confidence
 - Continued growth and expansion in European business
 - Future product development pipeline
 - Geographic expansion opportunities



2016 expected newsflow

Nov 2016	Capital Markets Day	
Q4 2016	Europe – clinical trial approval for PQ Birch 301	
Q4 2016	CTA approval for Acarovac Quattro Phase I trials	
Jan 2017	Trading update	
Mar 2017	Half year results	



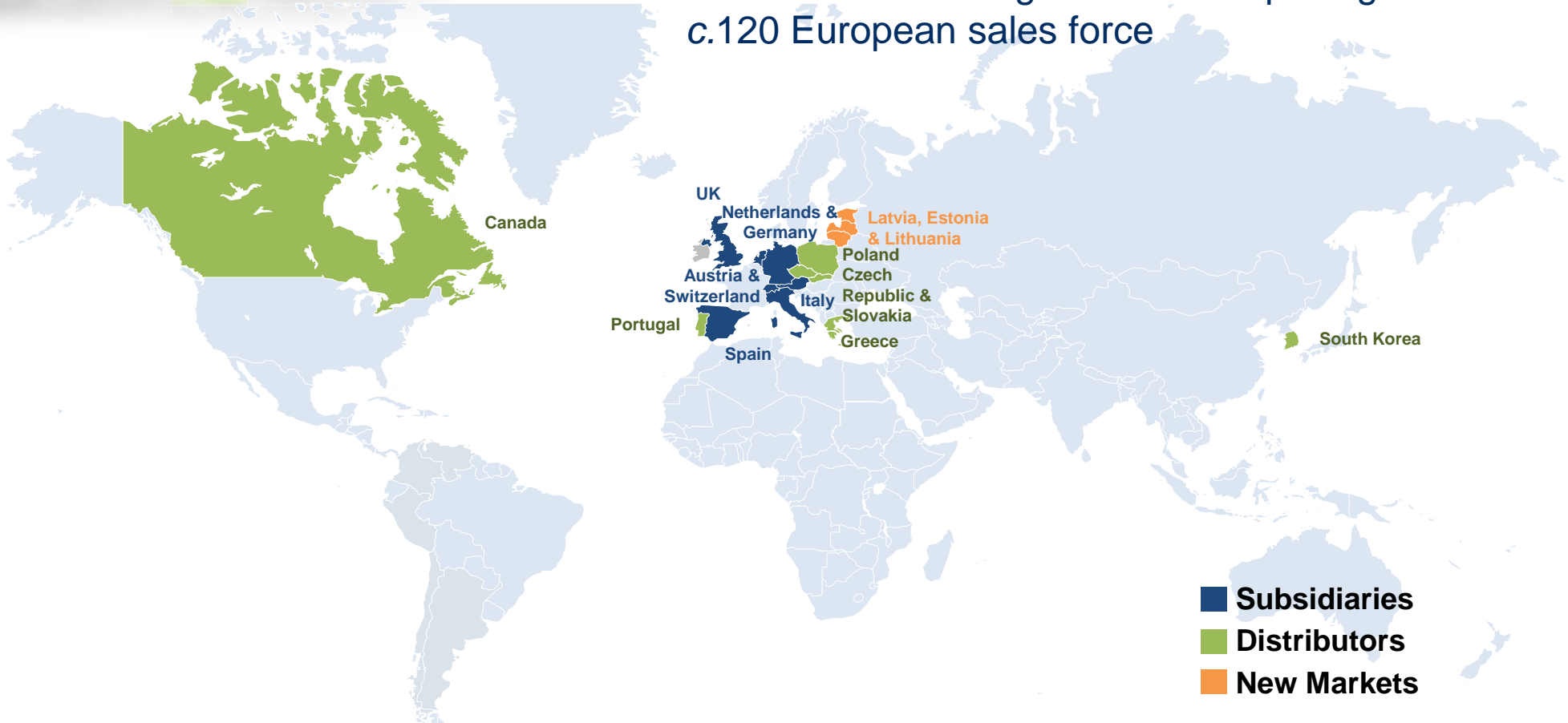
Appendix

September 2016



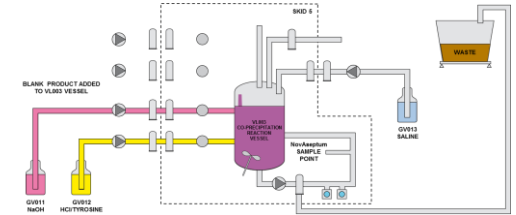
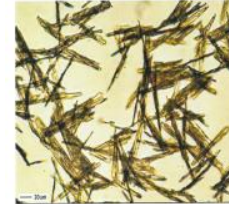
Global presence

- Sales and marketing network comprising c.120 European sales force



Subsidiaries in 7 countries and distribution agreements in additional 7 countries

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 optimized 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



PQ: An unique Platform Technology in the US

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

Allergoid

- Allergen chemically modified with glutaraldehyde
- Reduces IgE reactivity vs. that induced by native allergens used in SIT
- Retains IgG-allergen stimulating properties

MPL Adjuvant

- MPL (Monophosphoryl Lipid A) is a non-toxic derivative of lipopolysaccharide (LPS)
- Acts locally as a TLR4 agonist and increases IgG production
- Regulates expression of co-stimulatory molecules on antigen-presenting cells
- MPL allows the SIT treatment course to be shortened (big impact on adherence)

Micro Crystalline Tyrosine (MCT)

- A natural amino acid which is readily metabolized
- 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



Keys to Success for PQ in the US

- Proprietary Technology
- IP Protected
- De-risked opportunity
 - Treated more than 250,000 patients and marketed in 7 countries
- 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
- Strategic fit for US market*
 - Pollinex Quattro is an injected product for an injected market
- First mover advantage
 - First to market in the seasonal injected segment
 - High entry barriers: regulatory requirements for extensive trials on efficacy and safety

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



Key investment highlights

- 1 Lead product Pollinex Quattro, a proven, unique and highly differentiated allergy vaccination
- 2 Integrated, efficient and scalable platform technology
- 3 Strong late stage pipeline of aluminium-free allergy products
- 4 Well established European commercial presence through direct sales force & distributors
- 5 MHRA-approved manufacturing facility with significant headroom
- 6 Strong financial performance with trend over 16 years of gross sales growth
- 7 Focused on the US opportunity & strengthening position in European allergy rhinitis market