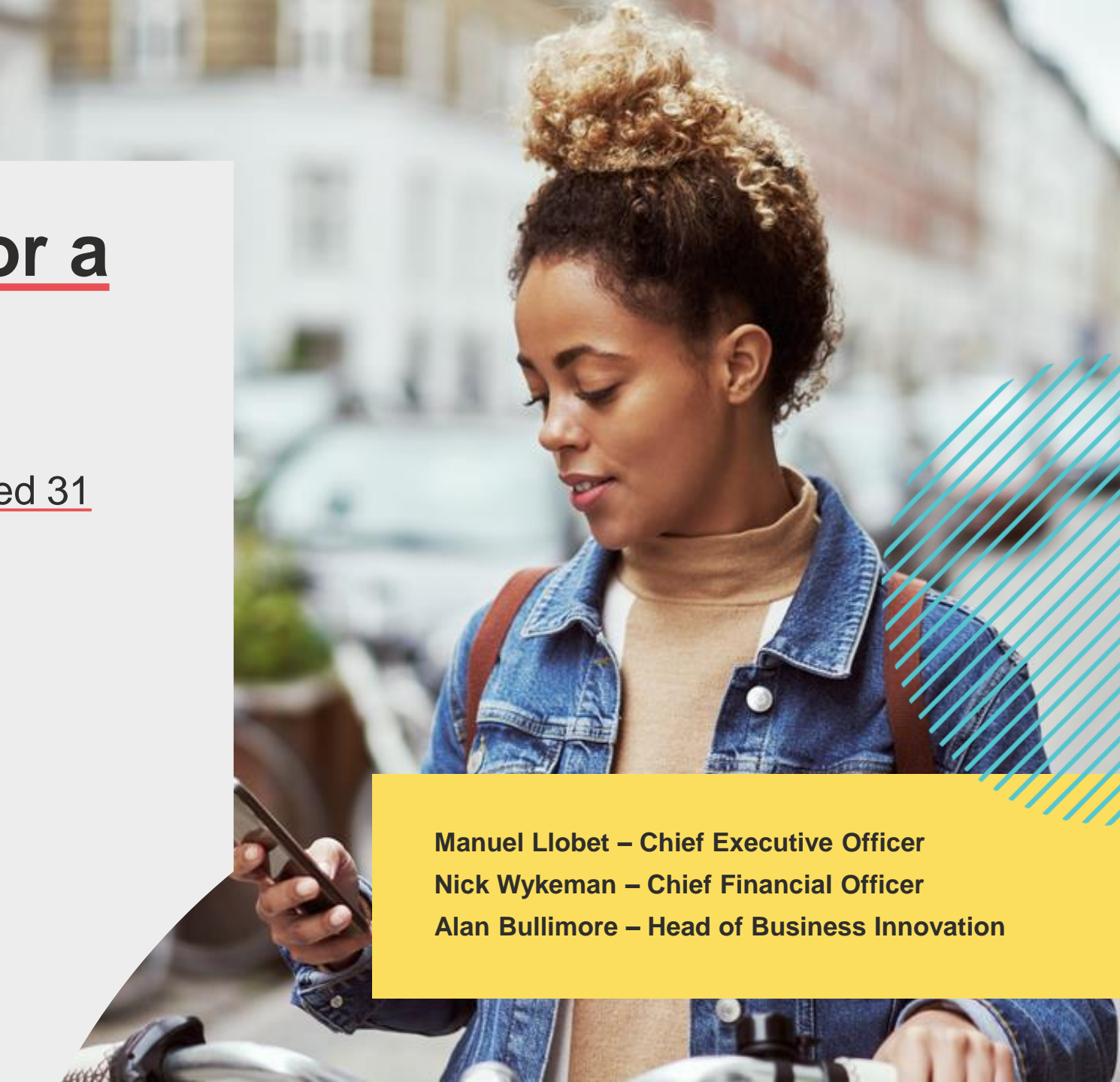




# **Maintaining focus for a pivotal year ahead**

**Interim Results for the six months ended 31  
December 2021**

**Allergy  
Therapeutics** <sup>PLC</sup>



**Manuel Llobet – Chief Executive Officer  
Nick Wykeman – Chief Financial Officer  
Alan Bullimore – Head of Business Innovation**

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# H1 2022 Financial and Operational Highlights

Focus on high value portfolio

## Strategic streamlining

*Enhancing future profitability*

VLP Peanut

## IND clearance

*Phase I trial to start in 2022*

Grass MATA MPL

## Impressive results from exploratory field trial

*Phase III trial to start in Q3 2022*

**£48.7m commercial revenue** (2021 £54.0m)

Short-term decrease of 10% due to streamlining of older products

**4% increase** on a like-for-like product and phasing basis

**Operating profit pre R&D of £12.5m** (2021: £20.5m)

reflecting portfolio streamlining and robust cost control

**Net Profit of £6.7m** (2021: £14.9m)

**Strong cash balance of £41.4m** (2021: £48.3m)

# Delivering across key strategic pillars to growth

**01**

## Strong pipeline

New technologies underpin pipeline breadth and depth

Investment strategy supported by growing revenue stream



**02**

## Expanding in Europe

Strongly performing profitable business

Growing market share and additional product registrations

Drive market position via world class supply chain and increased patient adherence



**03**

## Preparing for US entry

Significant opportunity in largest allergy market

Develop market access approach and relationships

Changing regulatory and reimbursement environment to drive market share towards Allergy's products



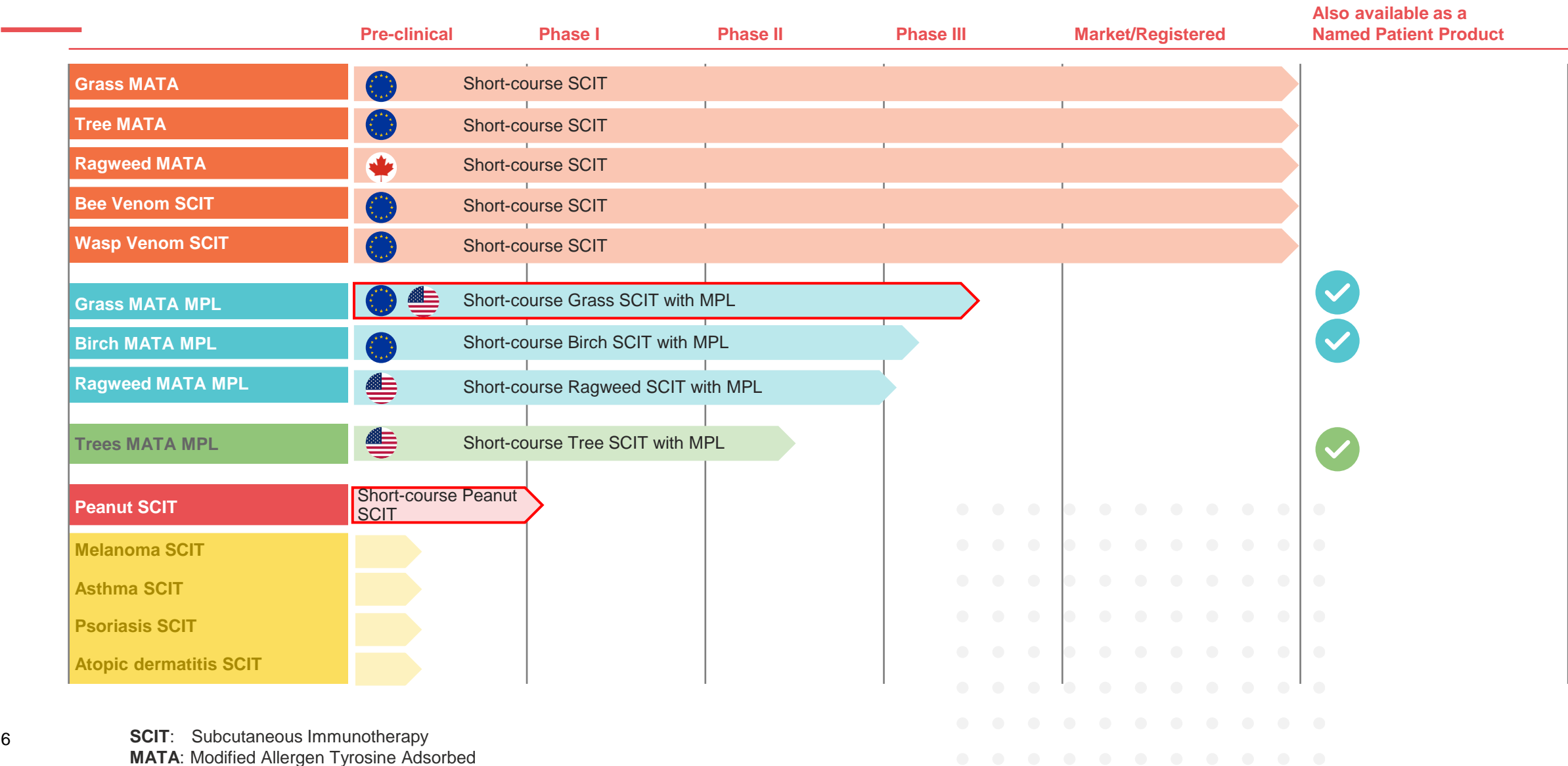




Building an innovative  
immunotherapy portfolio

01

# Innovative, broad pipeline and marketed products



# VLP Peanut: Hypoallergenic potential and protective immune response

Encouraging results provide strong support for human translation of pre-clinical results and strong confidence ahead of planned Phase I PROTECT trial

*Ex-vivo* study at Imperial College London using **blood samples from peanut allergic patients**

**Successful outcome** with positive primary and secondary endpoints

**24-fold reduction** in basophil activation and histamine release after VLP Peanut compared to Ara h 2 (major peanut allergen) – **Target: 10-fold**

Results provide **strong support for hypo-allergic mode of action**

Data demonstrate **potent immune stimulating mode of action** indicative of a beneficial efficacy profile

**Reduced ability to trigger immune cells** associated with the allergic condition compared to whole peanut extract

\*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



# VLP Peanut: A paradigm shift in the future treatment of peanut allergy

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**IND application  
cleared** by US FDA  
January 2022

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**Multiple cohorts:**

- Escalating subcutaneous injection of healthy subjects
- Skin prick tests for peanut allergic patients
- Escalating subcutaneous injection of peanut allergic patients

**First-in-human study  
(PROTECT)** to commence  
in the US in 2022

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**Top line data now  
anticipated in H1 2023** ahead  
of the original intended Q4  
2023 data readout

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**Investigational medicinal  
product (IMP) batch**  
successfully manufactured,  
tested and released

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**New  
opportunity  
in a \$8bn\*  
global food  
allergy  
market**

\*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



# Grass MATA MPL – Impressive efficacy results demonstrating clear treatment effect

Positive exploratory field study (G309) showing **clinically relevant** and **statistically significant efficacy**

- Two short courses of six injections with treatment durations of six and 14 weeks
- Primary endpoint: Combined Symptom Medication Score (CSMS)
- Statistically significant difference between active and placebo in both active treatment groups

	N	Percentage (absolute) Difference versus Placebo	P-value
PQ Grass (conventional*)	41	-33.1% (-0.56)	0.0325
PQ Grass (extended*)	40	-39.5% (-0.67)	0.0112

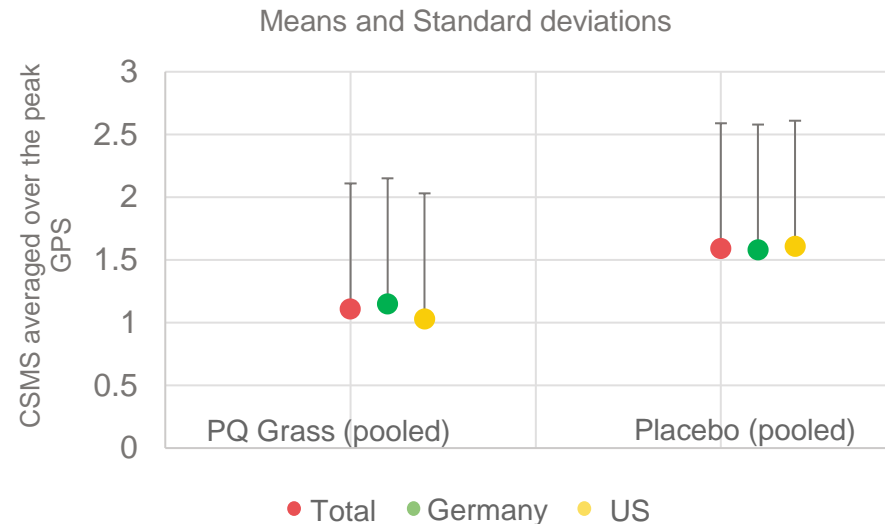
\* Conventional treatment duration: six weeks; extended duration treatment: 14 weeks

# Grass MATA MPL – Impressive efficacy results demonstrating clear treatment effect

Improvement in **rhinoconjunctivitis quality of life** questionnaire (RQLQ) was observed in both active treatment groups

Improvements in the **clinical benefits seen in both US and European populations** were comparable

**Changes in allergen specific IgE and allergen specific IgG4** were consistent with the immunological changes expected following allergen specific immunotherapy



Both dosing regimens were **safe and well tolerated**

# Maximising our chances of success in grass pollen immunotherapy

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Learnings from G309 have guided **optimal design** of upcoming pivotal G306 Phase III field trial **to commence in Q3 2022**

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G306 **sample size increased to in excess of 1,000** to increase confidence interval

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If G306 is successful, the only additional trial required for Biological License Application (BLA) will be **completion of safety database**

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Total US allergy immunotherapy market is estimated to be **\$2bn** with around **25% of patients suffering from grass allergy**

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**Potential for peak year sales of \$300-400m\***

\* Internal estimate



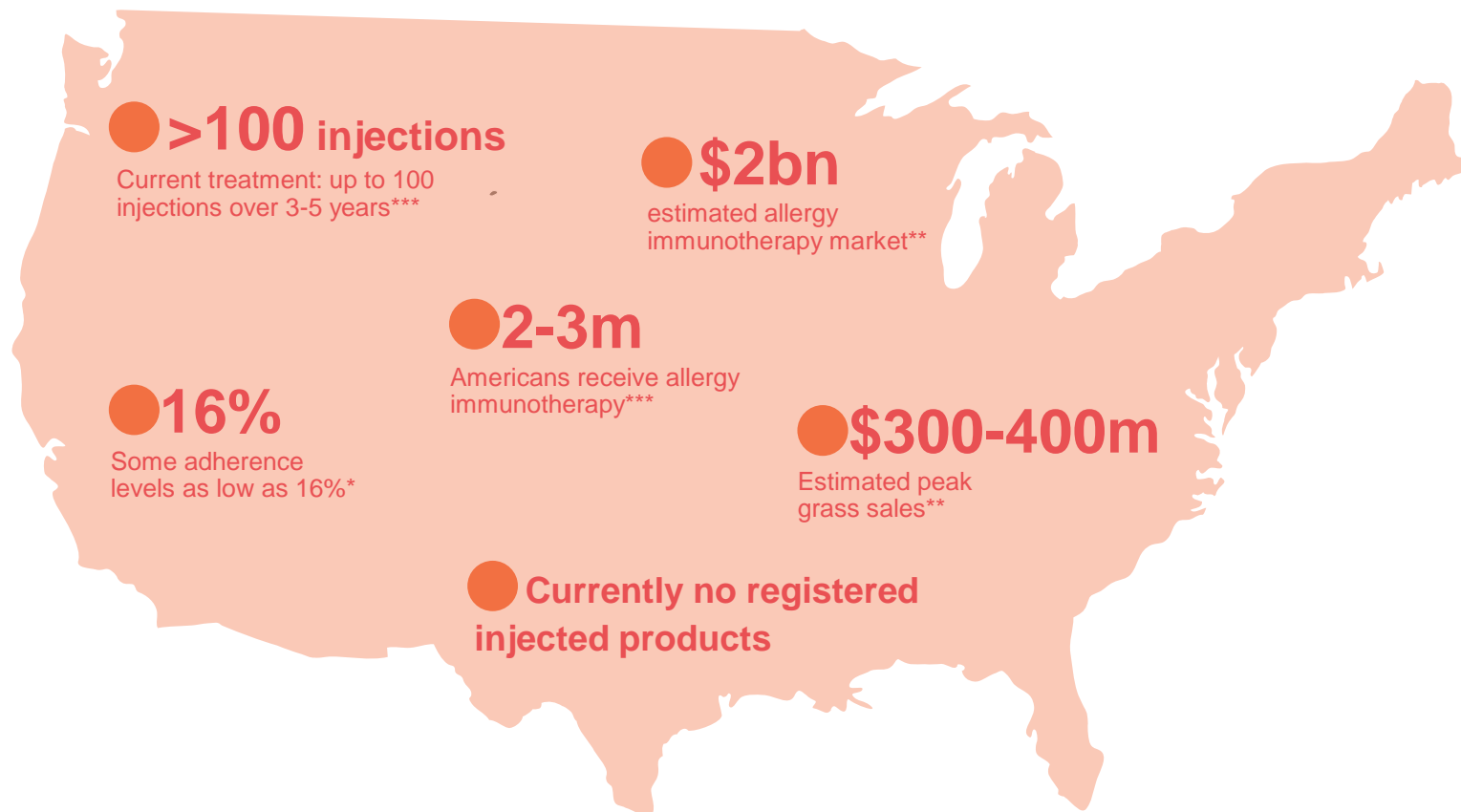


Preparing for success  
in the US market

02



# Why the US remains a key commercial region



## Capturing the opportunity

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

## Building on progress to date

- \$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

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

\*\* Internal estimate

\*\*\* Professor Lawrence DuBuske MD

# Building a portfolio in the US

**Ragweed and Birch/ Trees MATA MPL** product candidates have existing INDs for progression through late-stage development and commercialisation in the US



**Grass  
MATA  
MPL**



**Ragweed  
MATA  
MPL**



**Birch/ Trees  
MATA  
MPL**



**VLP  
Peanut**

These four product candidates form a strong and compelling portfolio that would enable Allergy Therapeutics to lead the allergy immunology market in the US



Maintaining leadership  
in Europe

03

# Continued solid performance in marketplace

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**Strategic streamlining of portfolio** to maintain focus on high value and highly differentiated short course subcutaneous immunotherapies (SCIT) and innovative allergy treatments to drive the growth of the business

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Revenues affected by phasing, headwinds in **Germany** and continuing effect of Covid-19 in Italy and Germany – expected to be short term

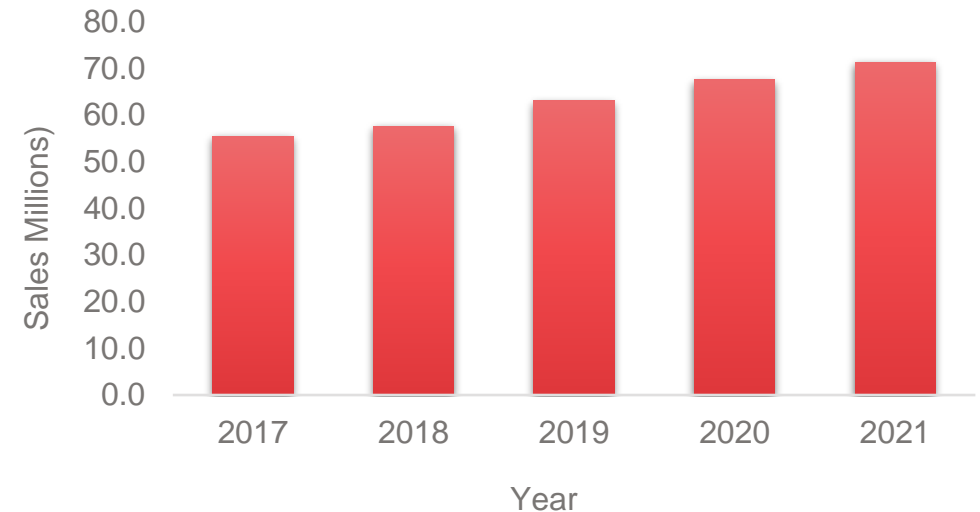
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Double-digit sales growth in **Spain** and strong growth in the **Netherlands, UK, and Rest of World (RoW)**

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Double-digit growth for key products **Pollinex, Venomil and Acarovac** (constant currency)

## Adjusted Net Sales



Adjusted Net Sales based on constant currency with the portfolio as it is currently





Financials

04

# P&L – six months ended 31 December 2021

**-5%**

Net Sales in constant terms due to streamlining of portfolio

**-4%**

Gross margin percent due to Sales, Covid impact and fx

**£12.5m**

Operating profit pre R&D (2021: £20.5m) due to lower sales, higher CoS and fx

	2022 £'m	2021 £'m	Variance % £'m
Revenue	48.7	54.0	(5.3) -10%
Gross profit	35.9	42.2	(6.3) -15%
Overheads	(23.7)	(22.1)	(1.7) 8%
R&D - Expenditure	(5.0)	(4.7)	(0.3)
Other Income	0.3	0.3	(0.1)
Operating profit	7.4	15.8	(8.3)
Net Financing costs	(0.2)	(0.2)	0.1
Tax	(0.6)	(0.6)	0.0
Profit after tax	6.7	14.9	(8.2)

# Balance sheet at 31 December 2021

£0.5m

Increase in inventory due to  
extended Brexit supply chain

£41.4m

Cash at year end 2021  
(2021 : £48.3m)

£2.9m

Debt. New RCF of £10m in  
place

	2022 £'m	2021 £'m	Variance £'m
Non-current assets			
Property , plant and equipment	19.0	19.5	(0.5)
Intangible assets	4.2	4.4	(0.3)
Investments	5.7	5.9	(0.2)
	28.9	29.8	(1.0)
Current assets			
Inventories	10.6	10.1	0.5
Trade and other receivables	10.8	10.8	0.0
Cash	41.4	48.3	(6.9)
Derivative financial instruments	0.3		0.3
Liabilities			
Financial Liabilities	(2.9)	(3.8)	0.9
Other Liabilities	(34.1)	(36.5)	2.3
Net Assets	55.0	58.7	(3.8)
Equity			
Share capital and share premium	113.2	113.2	0.0
P&L account and other reserves	(58.3)	(54.5)	(3.8)
Total Equity	55.0	58.7	(3.8)

# Cashflow for the six months ended 31 December 2021

Positive net cash pre R&D  
generated

Working capital increase  
due to long supply chain

Strong Cash position  
of £41.4m driven by  
solid performance and  
low costs

	2022		2021	
	£'m	£'m	£'m	£'m
Opening cash balance 1 <sup>st</sup> July		40.3		37.0
Profit before tax	7.3		15.6	
Adjustments re operations	(3.5)		(2.9)	
Net cash generated by operations		3.7		12.7
Tax received		0.1		0.3
Interest paid		(0.2)		(0.2)
Interest received	0.1		0.0	
Investments and acquisitions	(0.2)		(0.1)	
Capital expenditure	(1.0)		(0.7)	
Net cash used in investing activities		(1.2)		(0.8)
Net movement in borrowings	(1.5)		(0.6)	
Net cash used in financing activities		(1.5)		(0.6)
Effects of exchange rates on cash		0.1		(0.1)
Closing Cash Balance 31 December		41.4		48.3





Summary and outlook

05

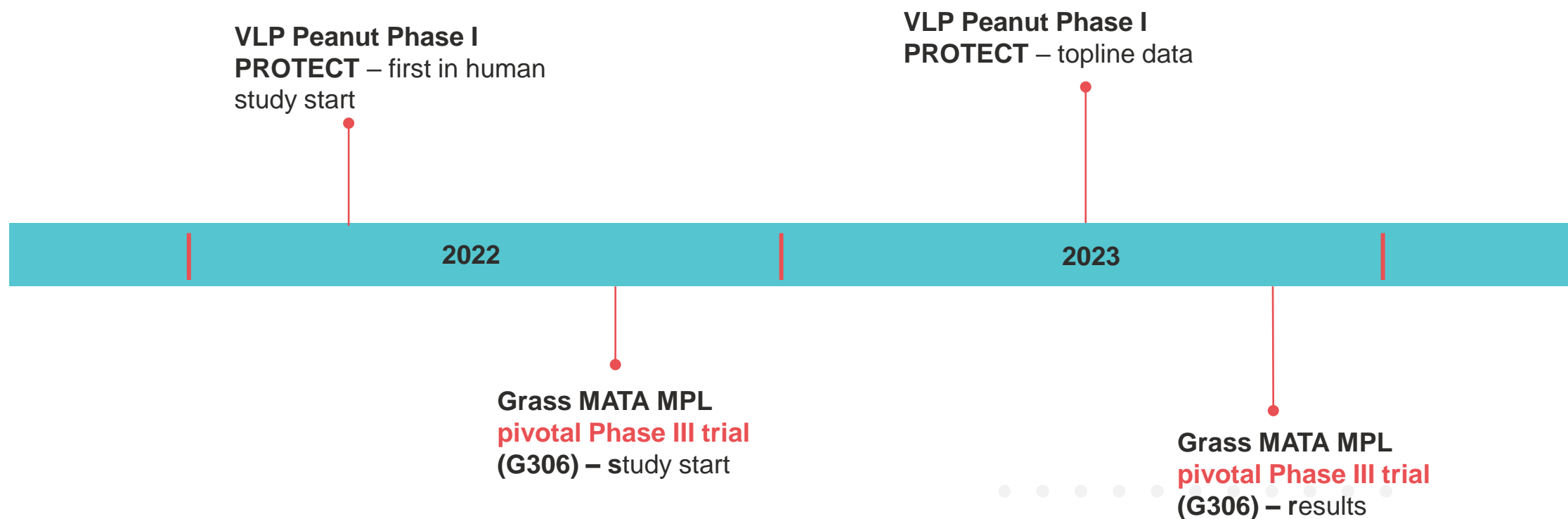
# Well placed for an exciting and pivotal year ahead

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- Commencement of **two important clinical trials in the US**
  - Phase I PROTECT trial VLP Peanut
  - Phase III G306 Grass MATA MPL
- **Continued solid commercial performance in Europe**
- **Maintaining focus on SCIT and innovative approaches** to allergy treatment through strategic streamlining of portfolio



# Key Milestones (Calendar Years)



Interim reports on progress of VLP Peanut Phase I PROTECT trial expected across trial





# Appendix

06



# Allergy Therapeutics

**Allergy  
Therapeutics** <sup>PLC</sup>

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Leading, fully integrated  
biopharmaceutical company  
based in the UK

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

---

PQ® Platform enabling ultra-  
short course treatment for  
grass, tree and ragweed  
allergies

---

Headquartered in  
Worthing, Sussex  
with around 600  
employees

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9% compound  
annual revenue  
growth achieved  
over the last 23 years

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Leading provider of  
subcutaneous aluminium-  
free allergy vaccines

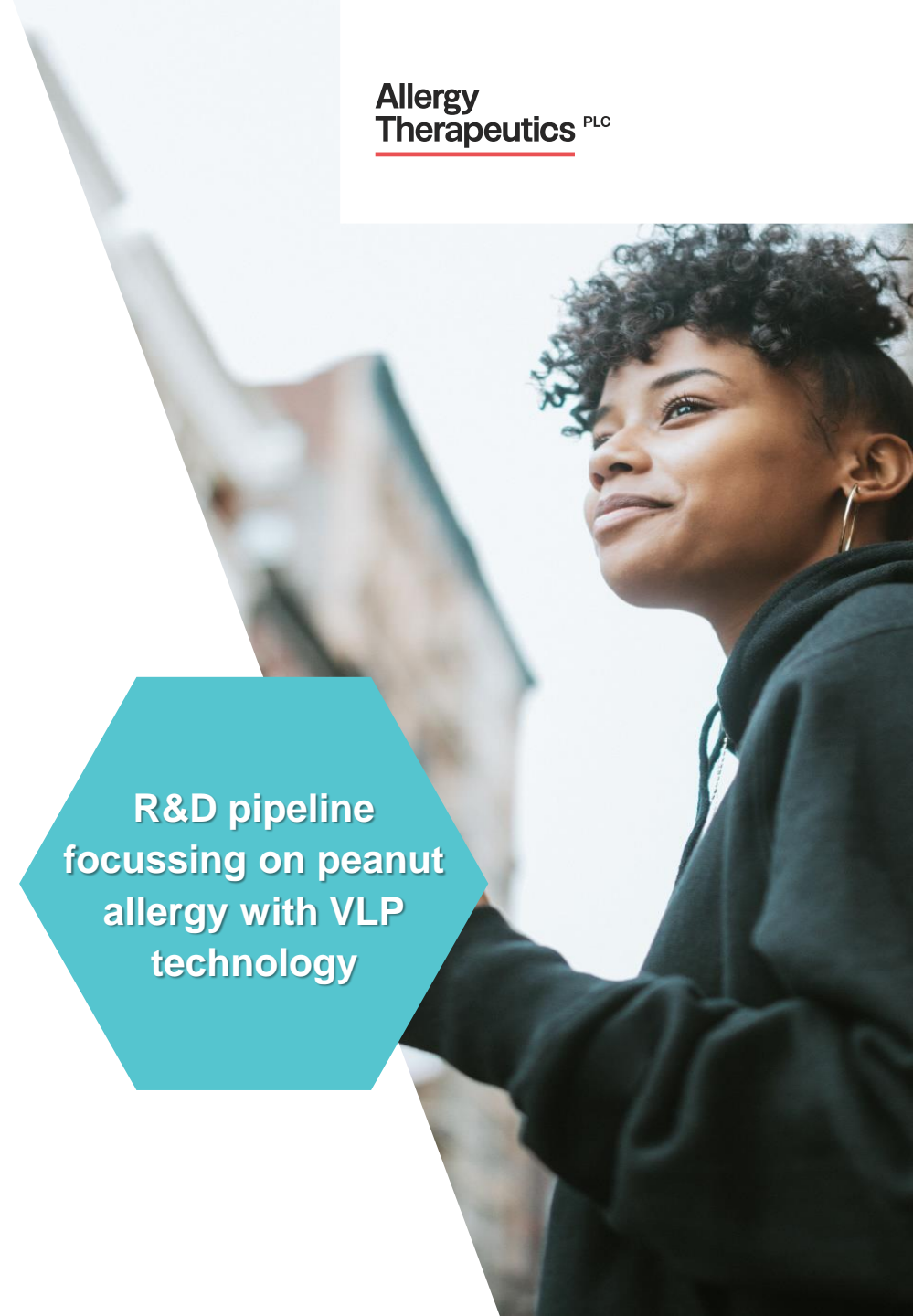
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Spun out of Smith Kline  
Beecham in 1999

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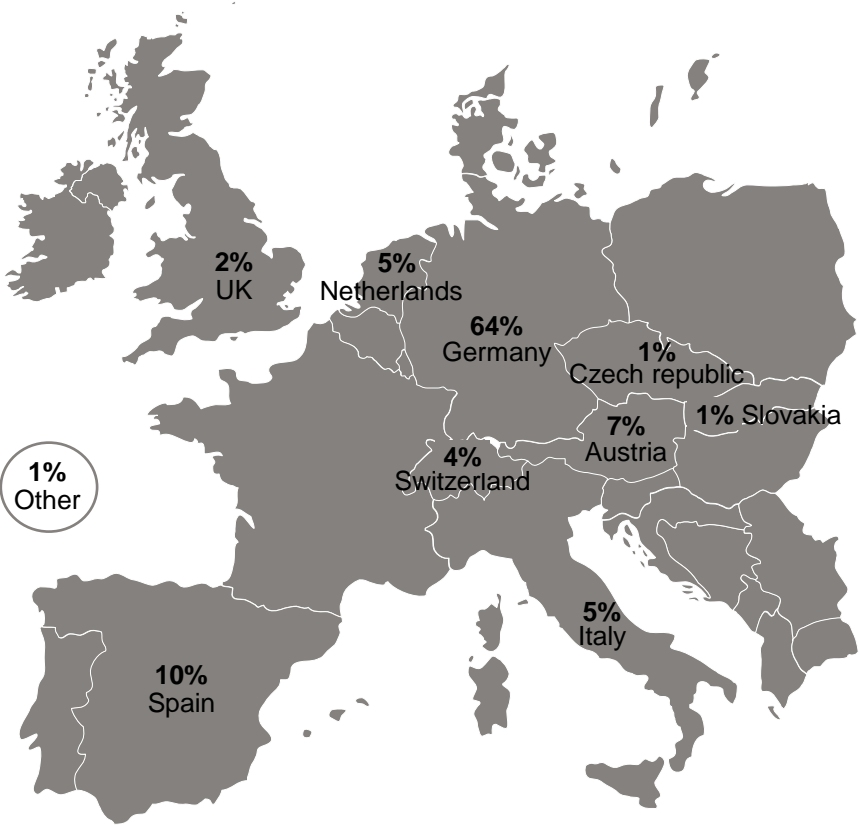
Market capitalisation of  
about £166m, AIM ticker  
LSE:AGY

R&D pipeline  
focussing on peanut  
allergy with VLP  
technology



# Sales breakdown for FY 2021

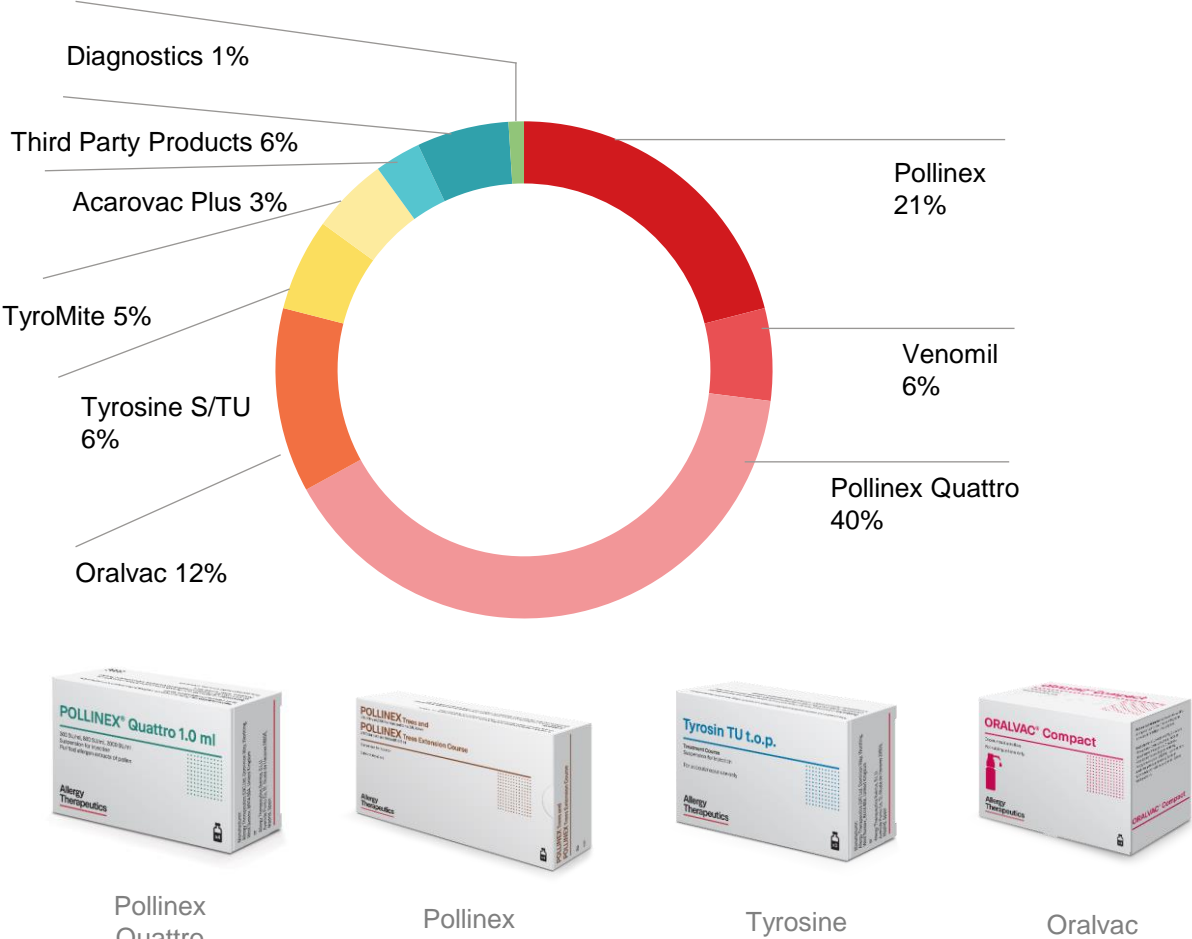
## Sales by country



<sup>1</sup> Sales breakdown based on gross sales at budget exchange rates (before freight, rebates and exchange) : £84.0 million.  
After deducting rebates, freight charges and foreign exchange adjustments, total sales for FY2021 is £84.3million

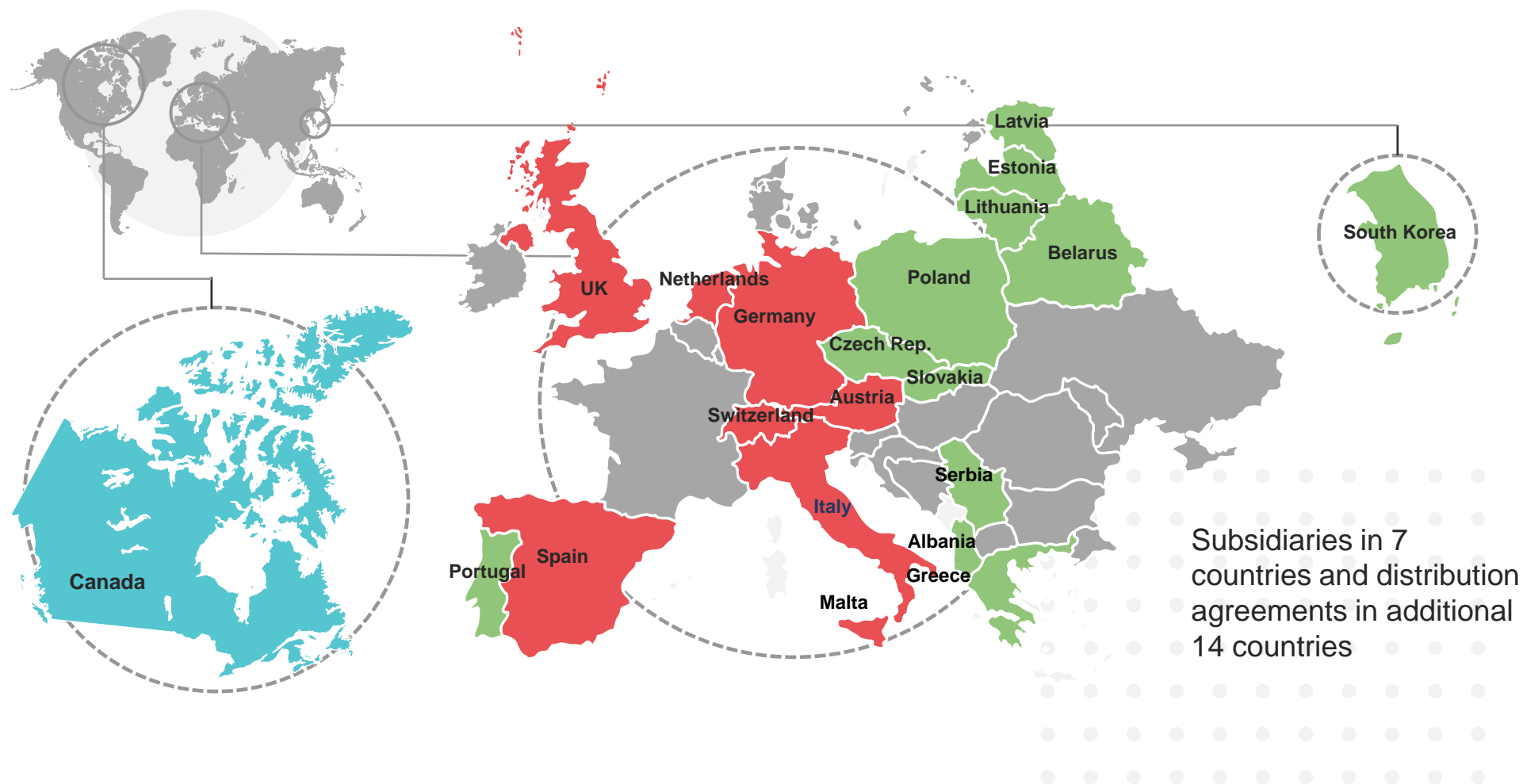
**\*Allergy Therapeutics currently has no products licensed for sale in the USA**

## Sales of £84.3m by product<sup>1\*</sup>

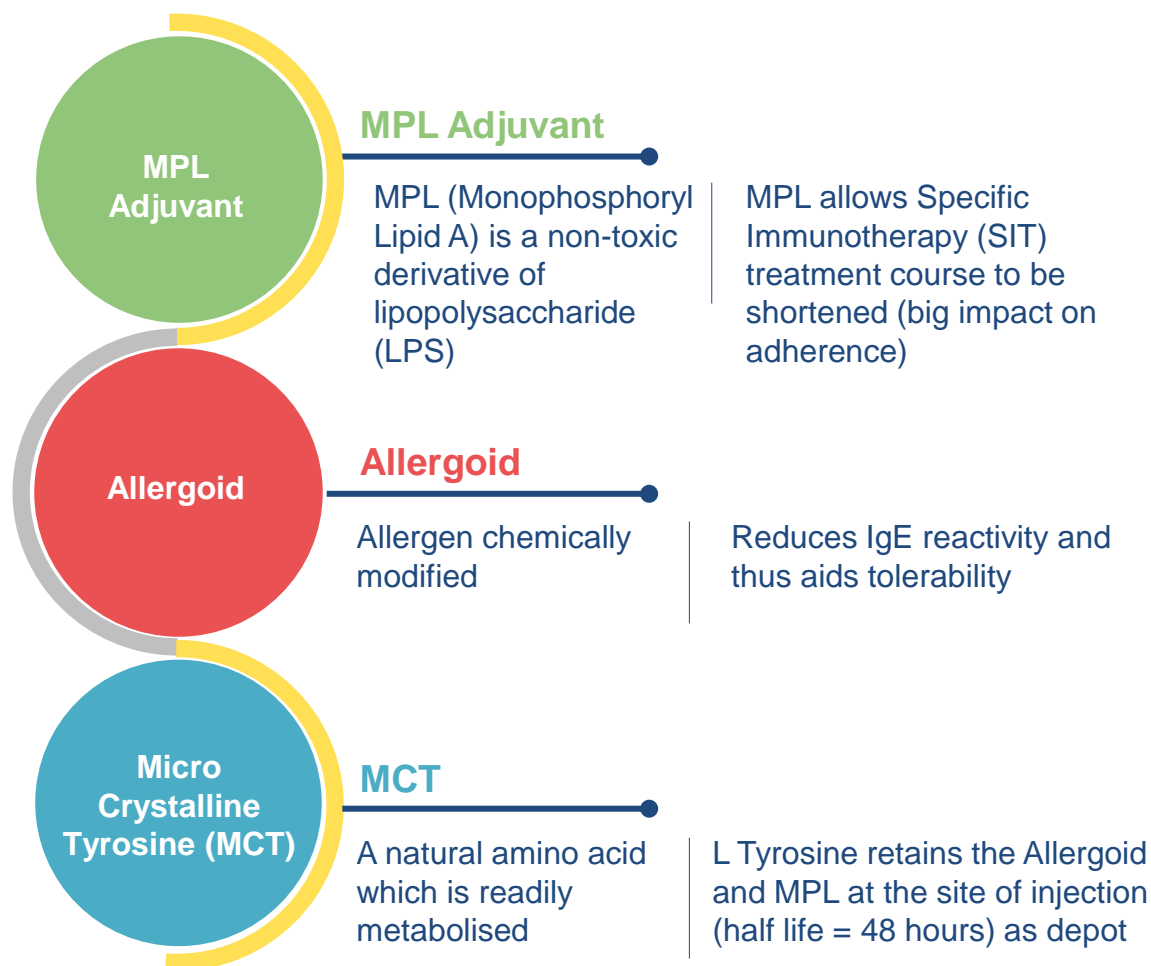


# Allergy Therapeutics: Company with Solid Sales and Global presence

Sales and marketing network comprising c.140 European sales force

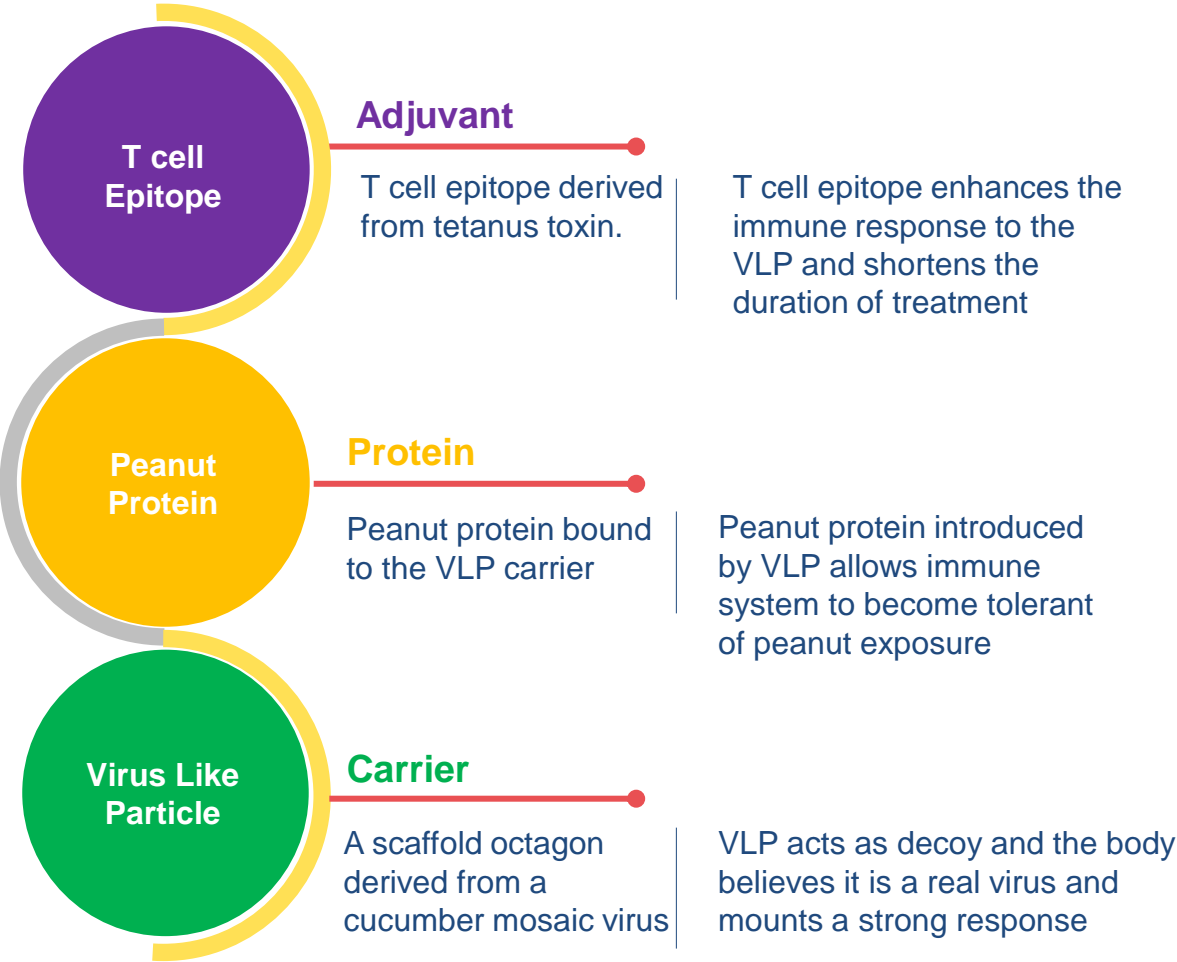


# PQ: Differentiated platform approach enhances compliance, leads to higher efficacy and successful outcomes





# Peanut VLP



# Cutting-edge Platform Technologies

	Modified Allergen (Allergoid)	Native Allergen	Recombinant Allergen	Microcrystalline Tyrosine (MCT)	Monophosphoryl Lipid A (MPL)	Virus-Like Particles (VLP)	Lipocalin Technology
MATA	✓			✓			
MATA MPL (PQ)	✓			✓	✓		
Sublingual		✓					
Mite SCIT	✓			✓			
ImmunoBON							✓
Venom SCIT		✓					
Peanut*				✓	✓	✓	

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

# 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

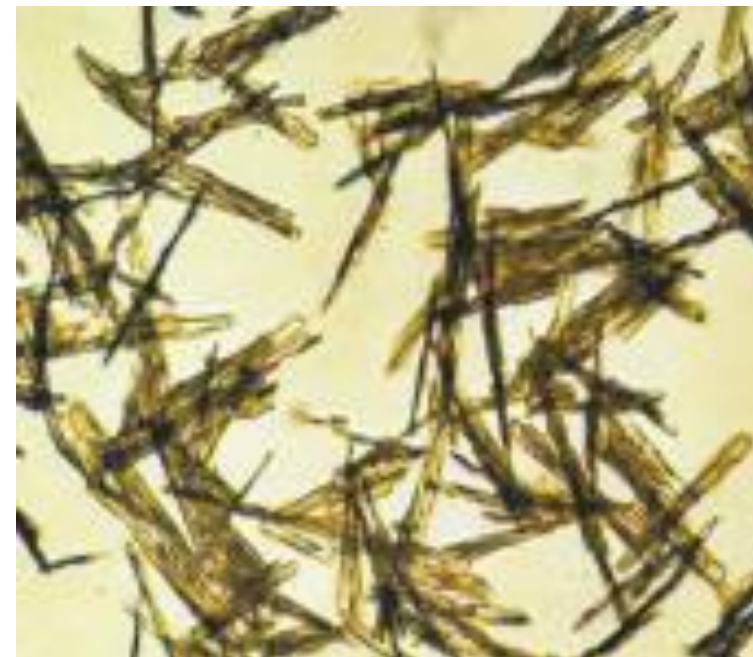
### Studies have been completed supporting MCT use as a depot immunomodulator in each application:

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



# 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:  
**6** injections for optimal product profile
- **Efficacy** in 3 weeks
- **High** compliance



# Virus like particle (VLP) platform

— **VLP** platform has potential in many different allergy areas.

## **Sophisticated technology with potential to treat severe and extreme allergies**

- Engineered with a T-cell epitope derived from the tetanus toxin
- Leads to activation of memory cells
- Increased antibody response

When bound with an allergen, the immune system reacts to the virus not the allergen.

Therefore protective immunity is induced, enabling shorter therapy duration with an enhanced tolerability profile.

**Potential allergy areas** include peanut, mixed nuts, cat, mould, mite and venoms

**Initial peanut results  
show potential of  
technology**

# Adopting an ESG Framework

## Environmental

- Become a Net Zero Carbon emission Company by 2030
- Manufacturing sites have reduced all single use plastic and are reusing water
- Planning permission granted to build energy centre in Worthing
- Working towards paperless offices across all sites (fully paperless in Spain and Italy)
- Using biodegradable adjuvants (MCT)

## Social

- Set gender diversity targets for our Board and Executive Team - 30% Board and 50% Exec Team by 2025
- Work closely with local schools in Worthing area to raise awareness of careers in STEM
- Introduced mental health first aiders across group
- Focussed on better employee engagement and wellbeing introducing a 'wellness day off' and fitness challenges

## Governance

- Created a more robust compliance framework with additional controls relating to ethical decision-making and anti-bribery
- Annual review of effectiveness and twice a year assessment of Board composition to ensure that it is right to achieve our future goals
- Improve risk management processes for consistency across the Group and more robust systems of internal controls

## Focus areas and expected actions in 2021-2022

- Introduce ESG framework which will include an Executive ESG Steering Committee
- ESG materiality assessment finalised
- UN Sustainable Development Goals adopted to align with AGY strategy and help guide policy and decision making
- Sustainability strategy approved by Board and communicated to stakeholders
- Net Zero Carbon emission pathway fully costed and timelines defined to 2030
- Measurable targets and actions for Diversity, Equity & Inclusion agreed

• Measurable targets and actions for Diversity, Equity & Inclusion agreed