Allergy Therapeutics PLC

Interim Results for the six months ending 31 December 2019

Presentation and global webcast, 4 March 2020

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Agenda

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- **Financial and operational highlights**
- **Commercial overview**
- **Pipeline progress – Polyvac peanut and Grass MATA MPL**
- **Financial results**
- **Summary and outlook**

Financial and operational highlights

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9% increase in constant* revenue to **£50.5m** (H1 2019 £46.7m)

10% increase in operating profit pre R&D**

Strong cash balance of **£39.7m** (30 June 2019 £27.4m)

Clinical progress of key assets

Polyvac Peanut

Key preclinical data published in *JACI*

Grass MATA MPL

First stage of PhIII trial to start in H2 2020

*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.

**Operating Profit (pre R&D) is calculated by adding back R&D expenditure for the year to the operating profit of the year to arrive at operating profit (pre R&D) of £17.3m (H1 2019: £15.7m)

N.B. All financial dates refer to the financial year. All clinical dates refer to the calendar year.

European business shows robust revenue stream

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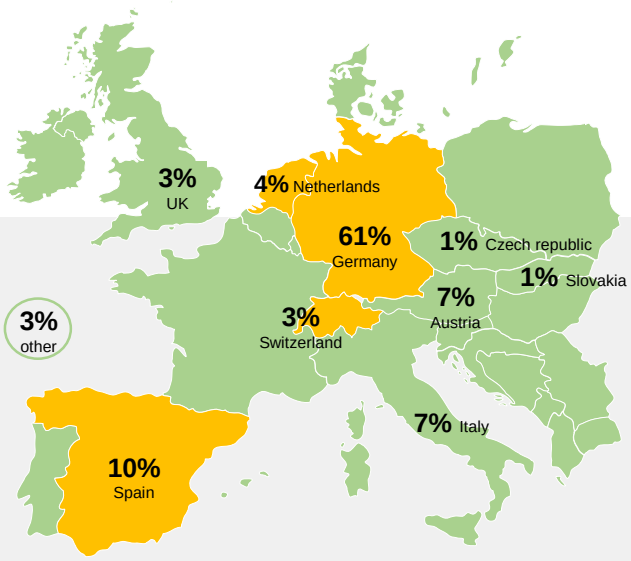
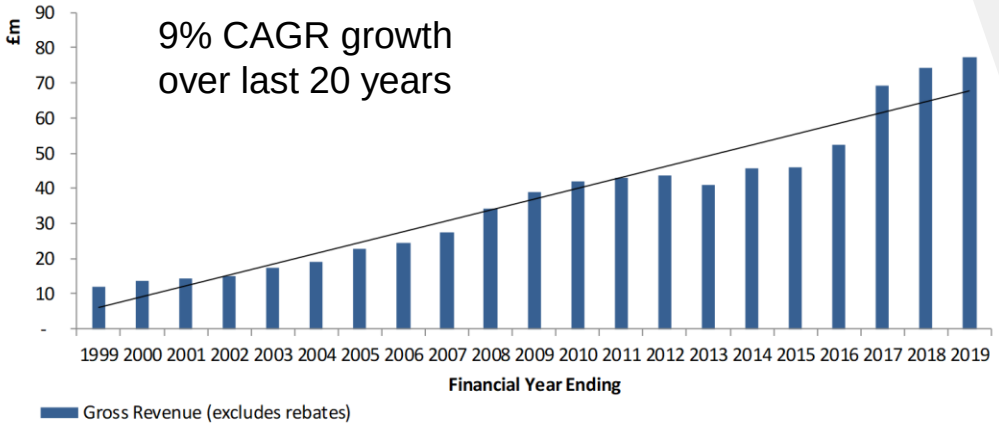
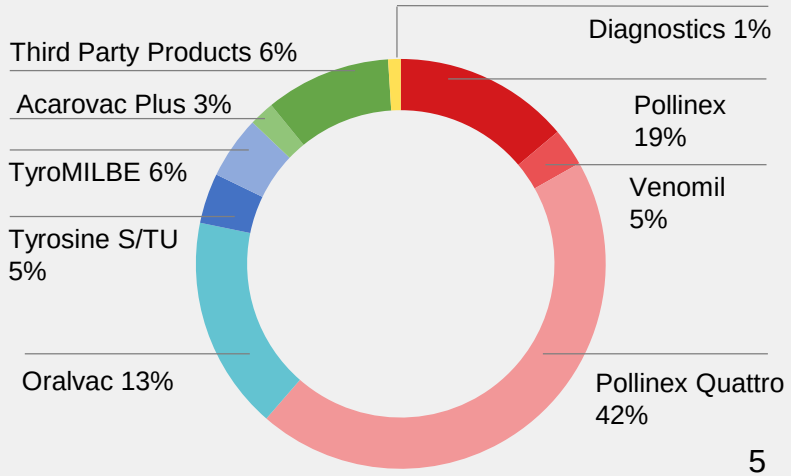
Good sales growth of **8%**

Strong performances from **Germany**, **Spain**, **Netherlands** and **Switzerland**





FY 19 Sales of £73.7m by product*



* Sales breakdown based on gross sales at budget exchange rates (before freight, rebates and exchange) : £69.3 million.
After deducting rebates, freight charges and foreign exchange adjustments, total sales for FY2019 is £73.7 million

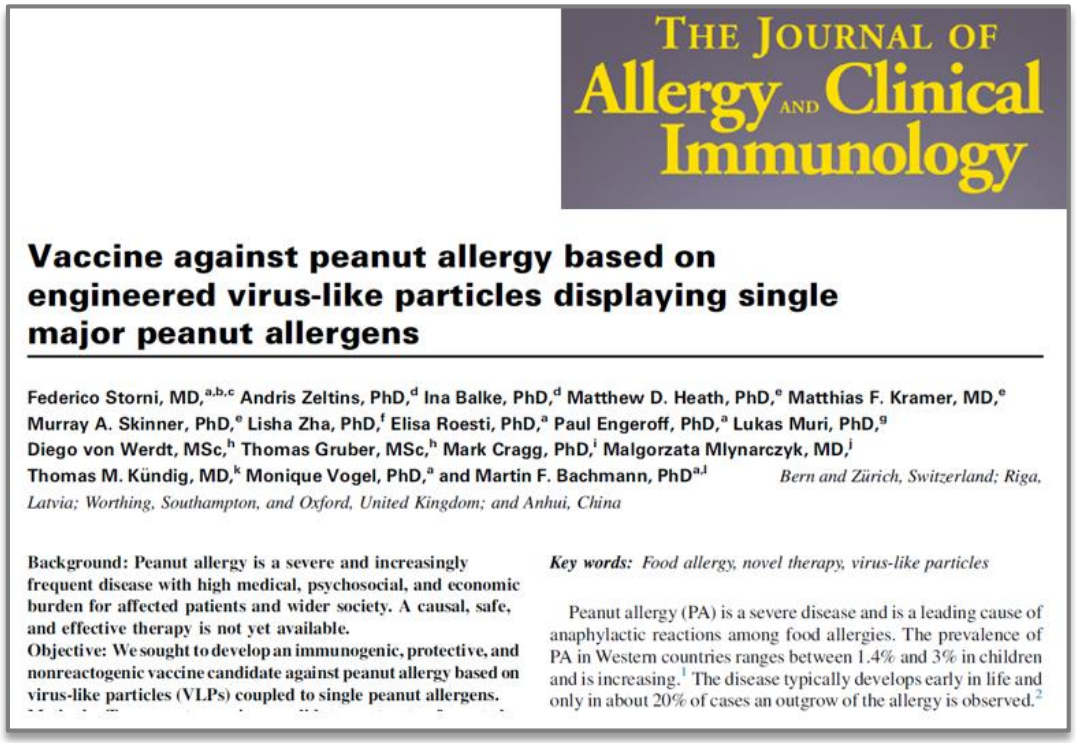
***Allergy Therapeutics currently has no products licensed for sale in the USA**

Polyvac peanut product

Positive preclinical data published in *JACI* *
demonstrates positive safety and efficacy profile reducing systemic and local allergic symptoms in a peanut allergy model

Provides proof of concept
for the generation of sustained immunity and protection through vaccination

Aim is **long-term immunity**



THE JOURNAL OF Allergy AND Clinical Immunology

Vaccine against peanut allergy based on engineered virus-like particles displaying single major peanut allergens

Federico Storni, MD,[a,b,c] Andris Zeltins, PhD,[d] Ina Balke, PhD,[d] Matthew D. Heath, PhD,[e] Matthias F. Kramer, MD,[e] Murray A. Skinner, PhD,[e] Lisha Zha, PhD,[f] Elisa Roesti, PhD,[a] Paul Engeroff, PhD,[a] Lukas Muri, PhD,[g] Diego von Werdt, MSc,[h] Thomas Gruber, MSc,[h] Mark Cragg, PhD,[i] Malgorzata Mlynarczyk, MD,[j] Thomas M. Kündig, MD,[k] Monique Vogel, PhD,[a] and Martin F. Bachmann, PhD[a,l]

Bern and Zürich, Switzerland; Riga, Latvia; Worthing, Southampton, and Oxford, United Kingdom; and Anhui, China

Background: Peanut allergy is a severe and increasingly frequent disease with high medical, psychosocial, and economic burden for affected patients and wider society. A causal, safe, and effective therapy is not yet available.
Objective: We sought to develop an immunogenic, protective, and nonreactogenic vaccine candidate against peanut allergy based on virus-like particles (VLPs) coupled to single peanut allergens.

Key words: *Food allergy, novel therapy, virus-like particles*

Peanut allergy (PA) is a severe disease and is a leading cause of anaphylactic reactions among food allergies. The prevalence of PA in Western countries ranges between 1.4% and 3% in children and is increasing.[1] The disease typically develops early in life and only in about 20% of cases an outgrow of the allergy is observed.[2]

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

* Storni et al., Vaccine against peanut allergy based on engineered virus-like particles displaying single major peanut allergens. J Allergy Clin Immunol 2019
** 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

Reduced reactogenicity and protection against systemic anaphylaxis

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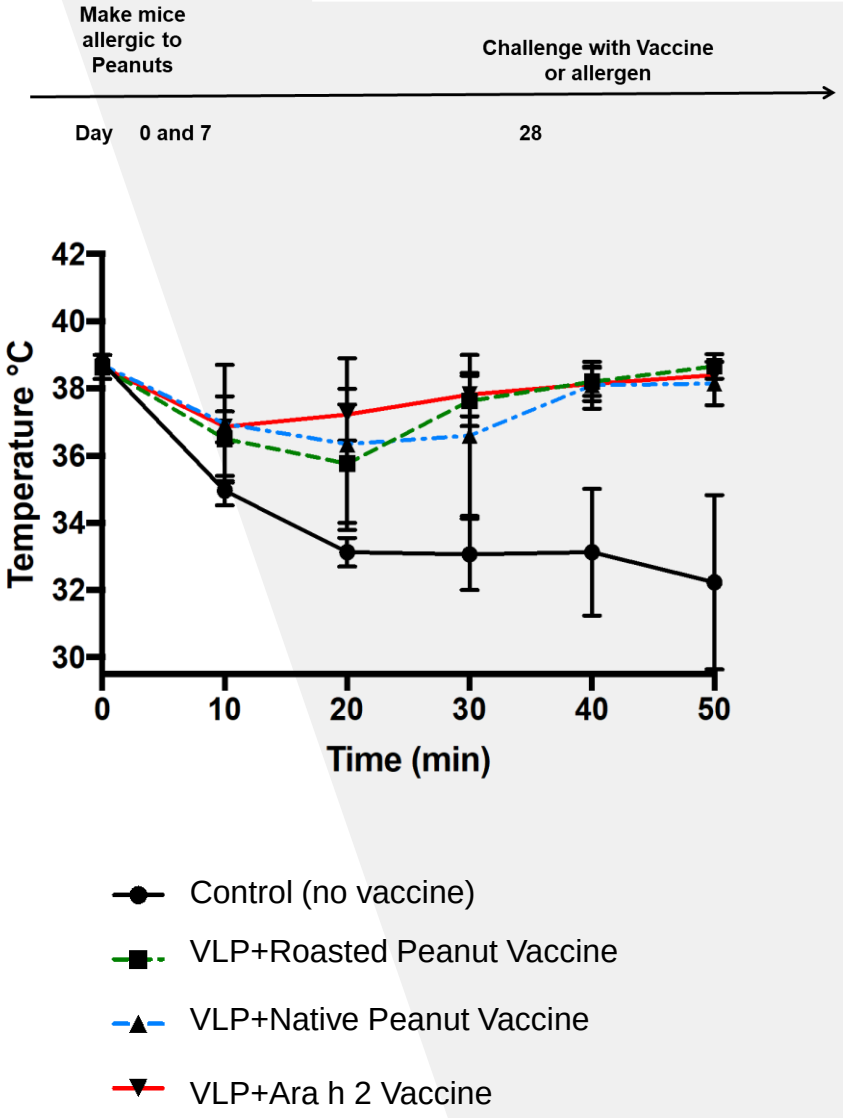
Vaccines require **low reactogenicity** so they do not cause anaphylaxis when administered to patients

Single injection **protected against systemic anaphylaxis**

One injection against **single allergen** sufficient to induce protection against **whole peanut allergen mixture** – never shown before



J Allergy Clin Immunol. 2019. doi: 10.1016/j.jaci.2019.12.007. [Epub ahead of print]

Peanut programme progressing well

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Proof of concept established in animal models for generation of sustained immunity and protection through vaccination

Manufacturing Process (GMP) for clinical studies established at CMO

- First GMP batch manufactured
- Technical batches manufactured and drug product filled
- Stability and toxicology programme commenced

Optimal strain of *E.coli* identified to express the VLP-peanut proteins

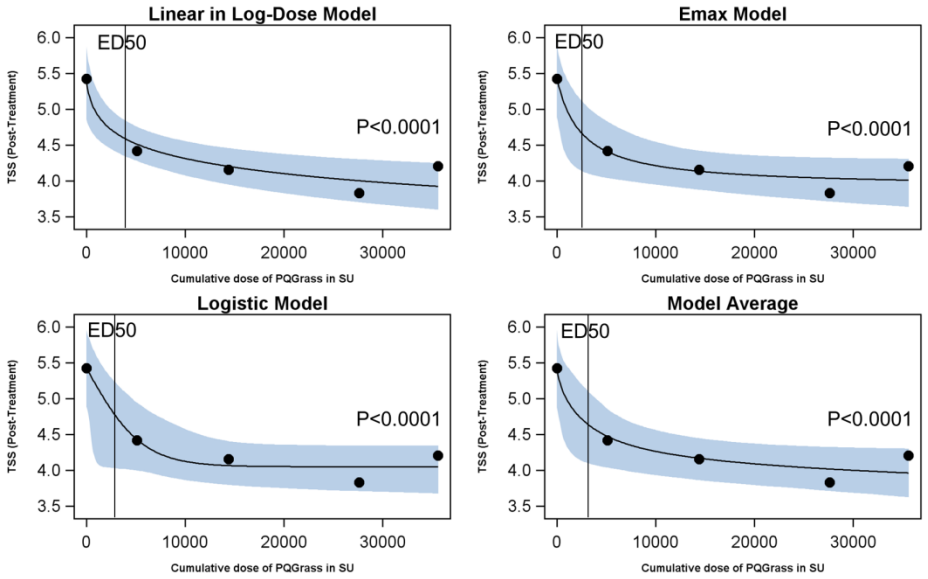
Successful Scientific Advice Meetings held with three European regulators

- Agreed in principal with the proposed development programme

Submission of clinical trial application anticipated 2021

Grass MATA MPL programme

In the Phase II (G205) study, a **highly statistically significant dose response** (p<0.0001) was shown for the range of cumulative doses from 5100 SU to 35600 SU



Stepwise approach enables phase III development to begin in 2020 with data review to gain insights ahead of stage 2

G309 Phase III study Europe + USA
(2020/2021)

G306 Phase III study Europe + USA
(2021/2022)

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Financial Results

P&L – six months ended 31 December 2019

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+8%

Good sales performance
in mixed pollen season (underlying figures)

+£0.2m

Overheads up
due to phasing and efficiencies

£17.3m

Operating profit pre R&D
(2019: £15.7m) increase due to good sales and operating efficiencies

	2020 £'m	2019 £'m	Variance £'m	%
Revenue	50.5	46.7	3.8	8%
Gross profit	39.1	37.3	1.8	5%
Overheads	(21.8)	(21.6)	(0.2)	1%
R&D - Expenditure	(4.5)	(5.0)	0.5	
- Settlement	3.2		3.2	
Operating profit	16.0	10.7	5.3	
Net Financing costs	(0.1)	(0.0)	(0.1)	
Tax	(0.6)	(0.4)	(0.2)	
Profit after tax	15.3	10.3	5.0	

Sales – six months ended 31 December 2019

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Good sales growth driven by good performance in Northern Europe

Growth in Pollinex, Pollinex Quattro and Venomil

Most markets performing robustly

Small FX impact in this period as exchange rates similar

	2020 £'m	2019 £'m	Variance £'m	%
Gross Revenue at Constant Exchange Rate	54.1	49.1	5.0	10%
Rebate at Constant Exchange Rate	(3.3)	(2.4)	(0.9)	
Net Revenue at Constant Exchange Rate	50.8	46.7	4.1	9%
Effect of Foreign Exchange	(0.3)		(0.3)	
Net Revenue	50.5	46.7	3.8	8%
*Constant exchange rate Euro/£	1.12			
Current exchange rate Euro/£	1.13	1.12		

* 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.

Balance sheet at 31 December 2019

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IFRS 16*

Operating lease assets (£9m) and lease creditors (£9m) on balance sheet

(£1.6m)

Debtor drop due to reduction in debtor days

£39.7m

Cash at 31 Dec 2019

£2.0m

Debt. Seasonal overdraft in place (undrawn)

	2020 £'m	2019 £'m	Variance £'m
Non-current assets			
Property , plant and equipment	11.3	10.0	1.3
Right of use assets*	9.0		9.0
Intangible assets	4.6	4.9	(0.3)
Investments	5.5	5.4	0.1
	30.4	20.3	10.1
Current assets			
Inventories	8.7	9.0	(0.3)
Trade and other receivables	8.8	10.3	(1.6)
Cash	39.7	31.6	8.1
Derivative financial instruments	0.3		0.3
Liabilities			
Financial Liabilities	(2.0)	(2.8)	0.8
Lease liabilities*	(9.0)		(9.0)
Other Liabilities	(25.8)	(24.0)	(1.7)
Net Assets	51.2	44.5	6.7
Equity			
Share capital and share premium	113.2	113.2	0.0
P&L account and other reserves	(62.0)	(68.7)	6.7
Total Equity	51.2	44.5	6.7

Cashflow for the six months ended 31 December 2019

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Positive net cash generated by good sales, cost phasing and control

Good working capital control

Strong cash position of £39.7m driven by trading performance

	2020		2019	
	£'m	£'m	£'m	£'m
Opening cash balance 1st July		27.4		15.5
Profit before tax	15.9		10.7	
Adjustments re operations	(1.6)		(4.0)	
Net cash generated by operations		14.3		6.8
Tax received		0.6		0.4
Interest paid		(0.3)		(0.1)
Interest received	0.2		0.1	
Investments and acquisitions	(0.1)		(0.2)	
Capital expenditure	(1.1)		(0.7)	
Net cash used in investing activities		(1.0)		(0.8)
Net movement in borrowings	(0.4)		(0.3)	
Net Proceeds of equity raise			10.2	
IFRS repayment	(0.7)			
Net cash (used in)/generated in financing activities		(1.0)		9.9
Effects of exchange rates on cash		(0.3)		0.1
Closing Cash Balance 31 December		39.7		31.6

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Summary and outlook

Three Pillars to Growth

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01

Europe

Continue good growth via marketing and supply chain as well as better adherence

Continue expansion of key products across region

Look for new markets for current products

02

Strong pipeline

New technologies underpin pipeline breadth and depth

Looking for further opportunities to extend pipeline

Investment strategy supported by growing revenue stream

03

US Market

Significant opportunity in largest allergy market

Preparing for stepwise Phase III Grass MATA MPL trial

2020 set to be a key year

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Consistent sales growth outperforming the market

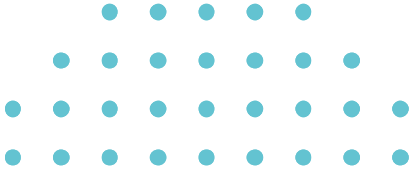
Continued gain in market share

First stage of Grass MATA MPL Phase III trial start

Continued progress of Peanut vaccine programme ahead of CTA submission in 2021

Delivering against our strategy: three pillars to growth

Groundwork to capture the US market opportunity



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Q&A

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Appendix

Solid Sales and Global presence

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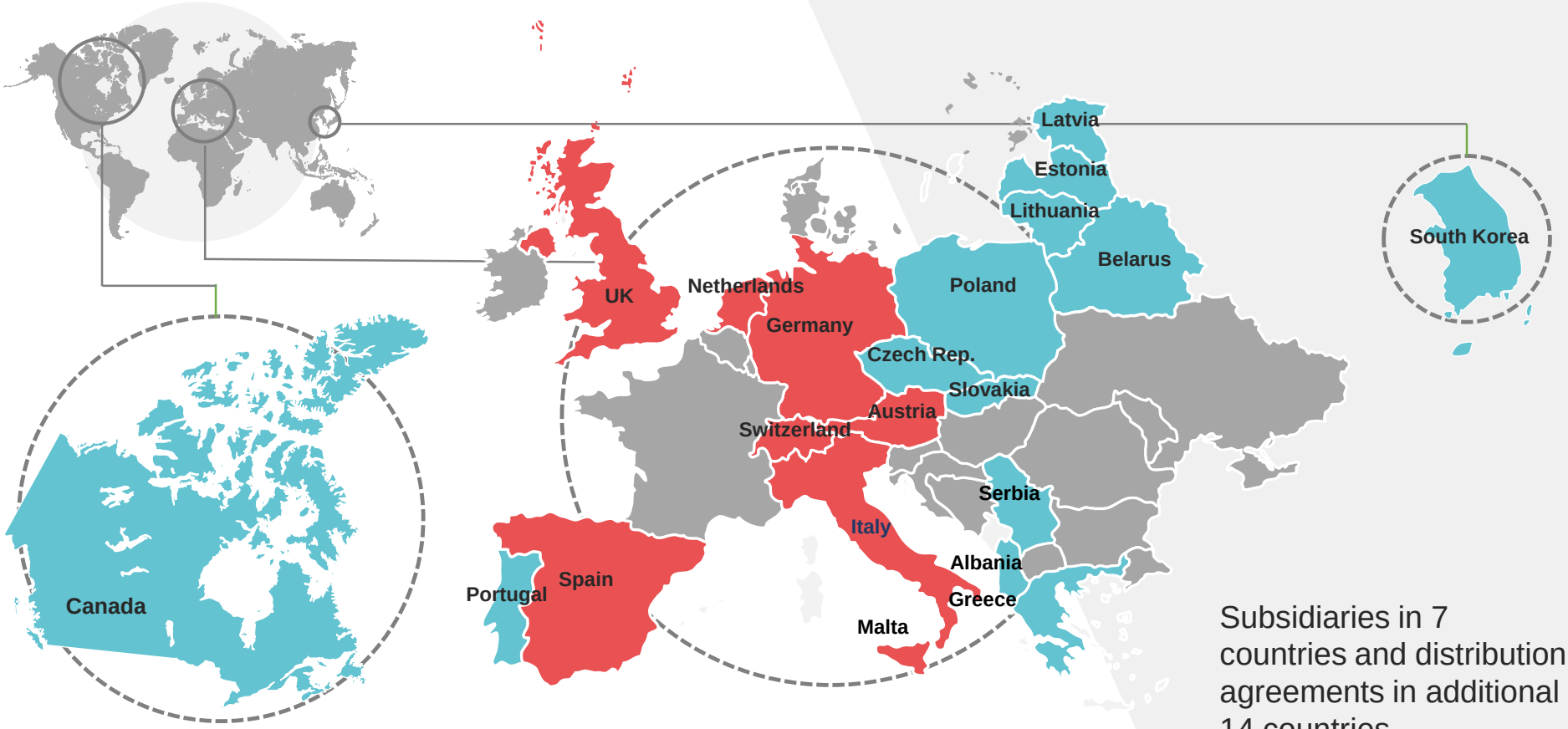
Sales and marketing network comprising c.140 European sales force



Subsidiaries in 7 countries and distribution agreements in additional 14 countries

Preparing for US entry

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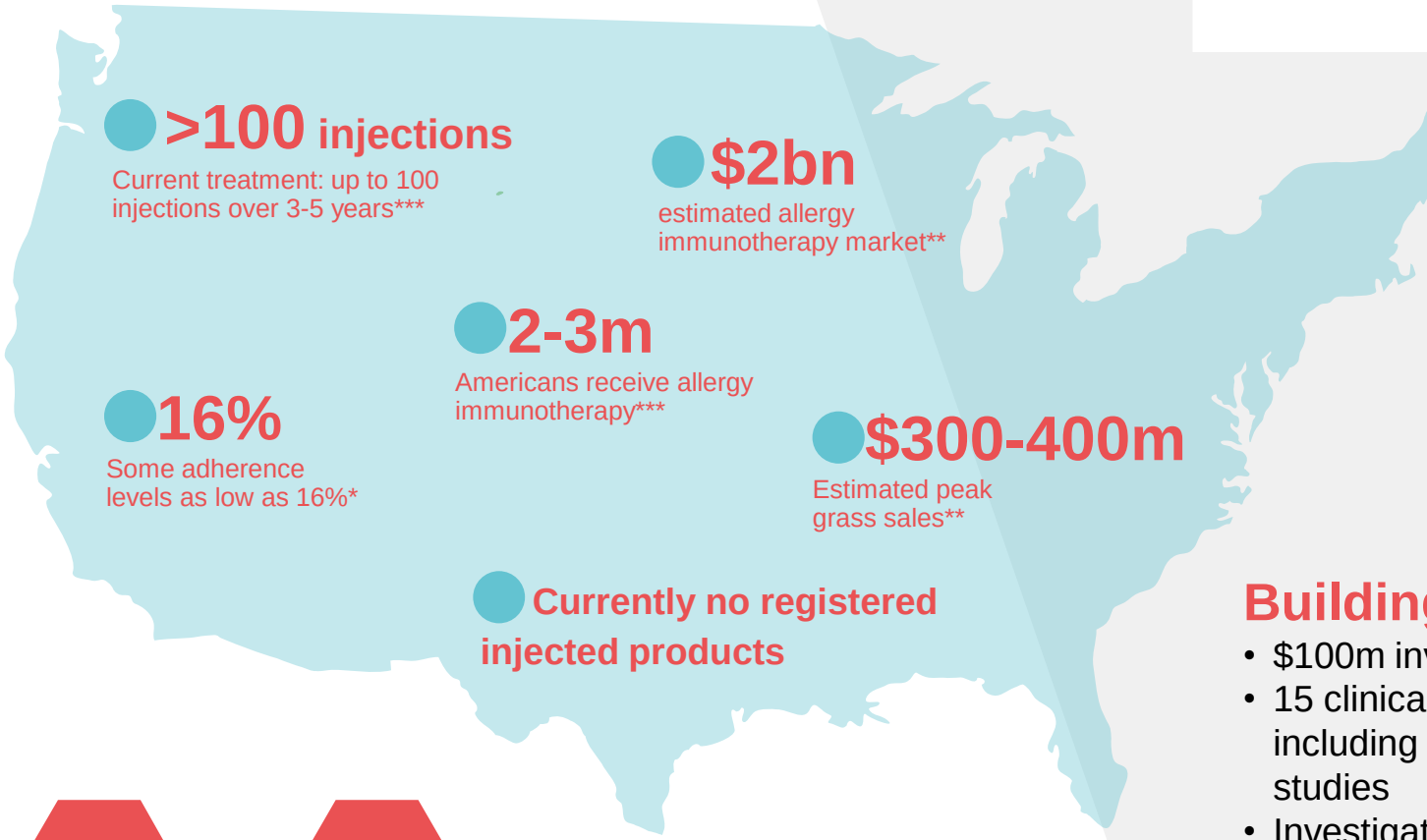

Capturing the opportunity

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

Innovative, Broad Pipeline and Marketed Products

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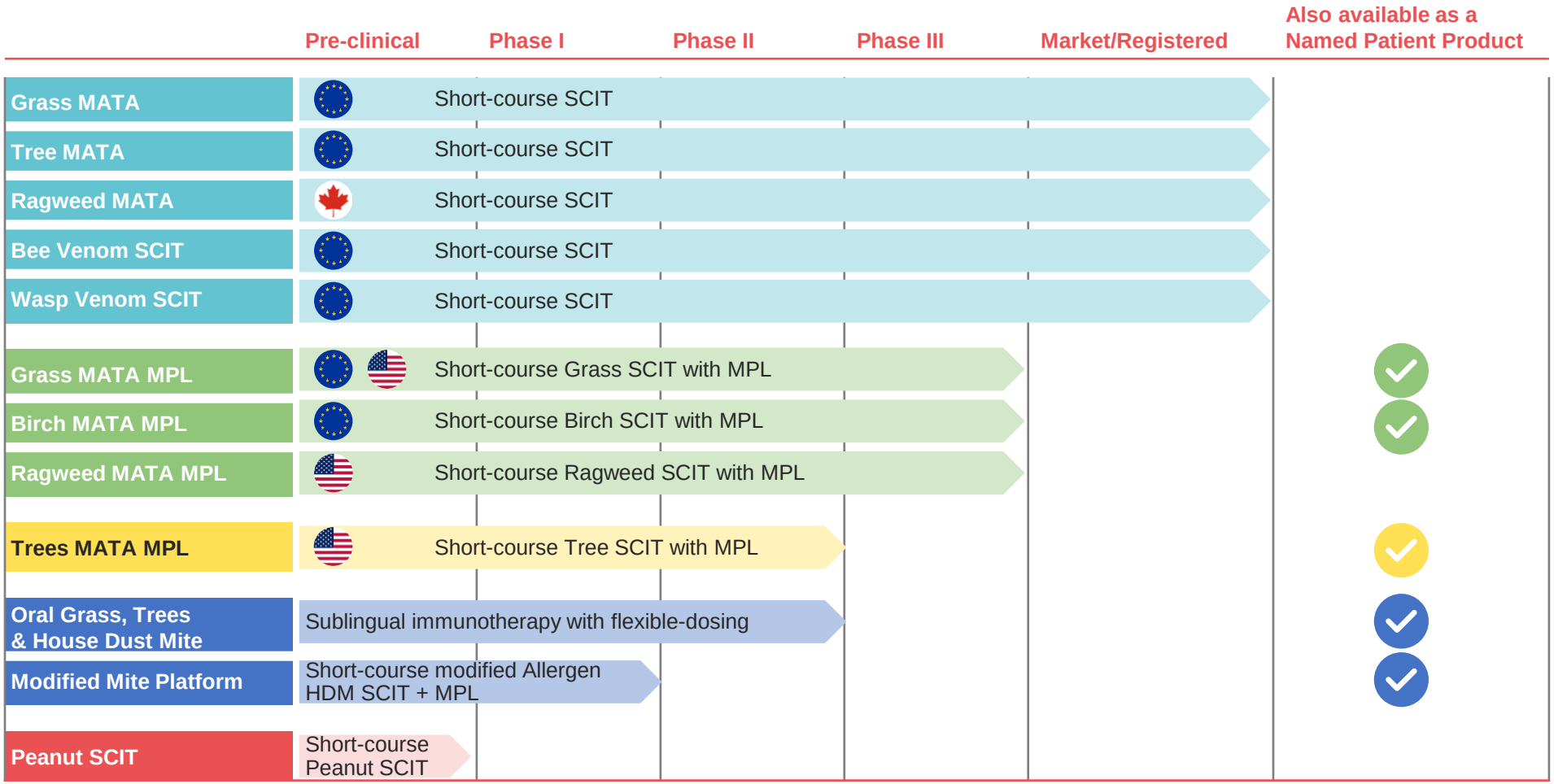

SCIT: Subcutaneous Immunotherapy
MATA: Modified Allergen Tyrosine Adsorbed

Cutting-edge Platform Technologies

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

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

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

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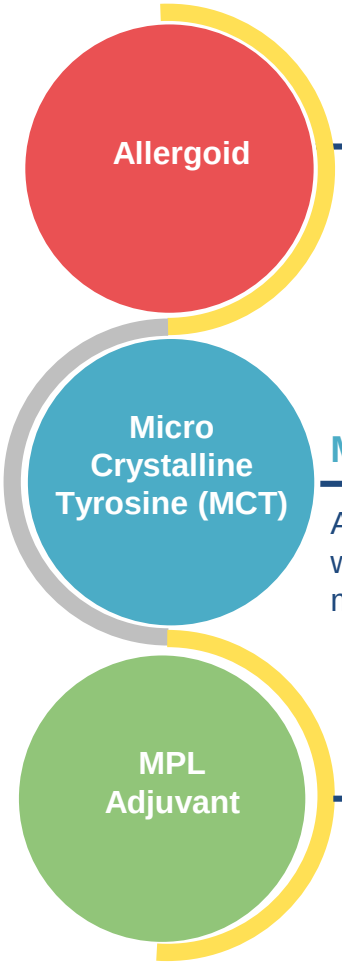


Allergoid

Allergen chemically modified

Reduces IgE reactivity and thus aids tolerability

MCT

A natural amino acid which is readily metabolised

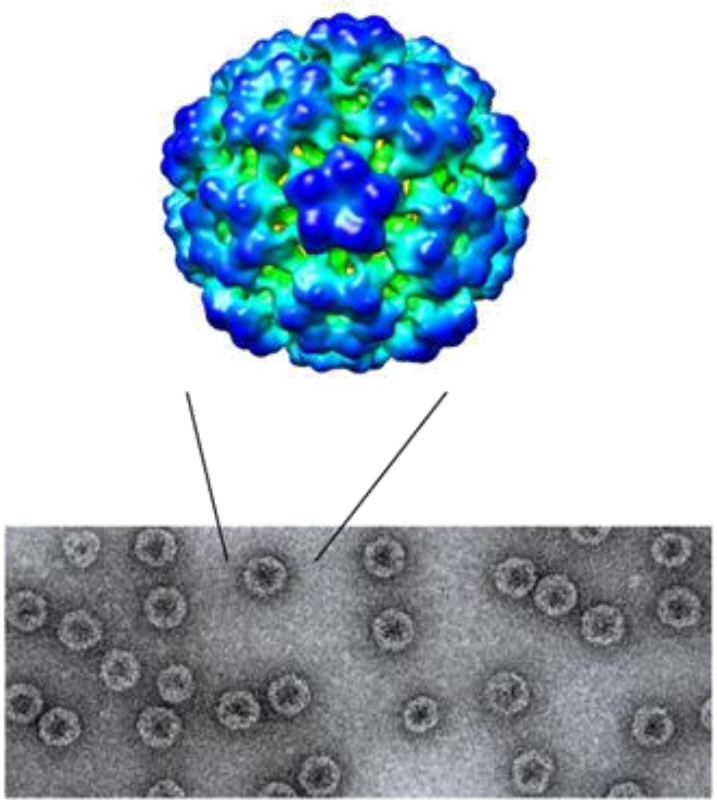
L Tyrosine retains the Allergoid and MPL at the site of injection (half life = 48 hours) as depot

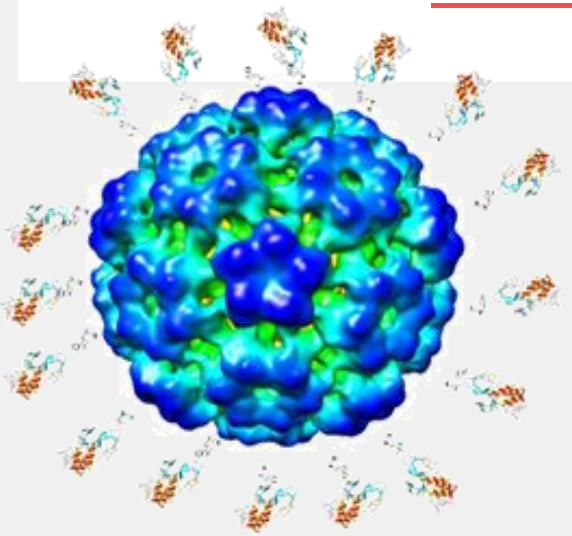
MPL Adjuvant

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

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

VLP technology





- Make the allergen look like a virus to the immune system
- Consequently induces a strong cellular and humoral immune response
- Antagonizing the Th2 driven allergy = protective immunity

VLP + allergen = optimized immunotherapy:

Th2 → **Th1**