Allergy Therapeutics PLC

2021 set to be an important year

Interim Results for the six months ending 31 December 2020

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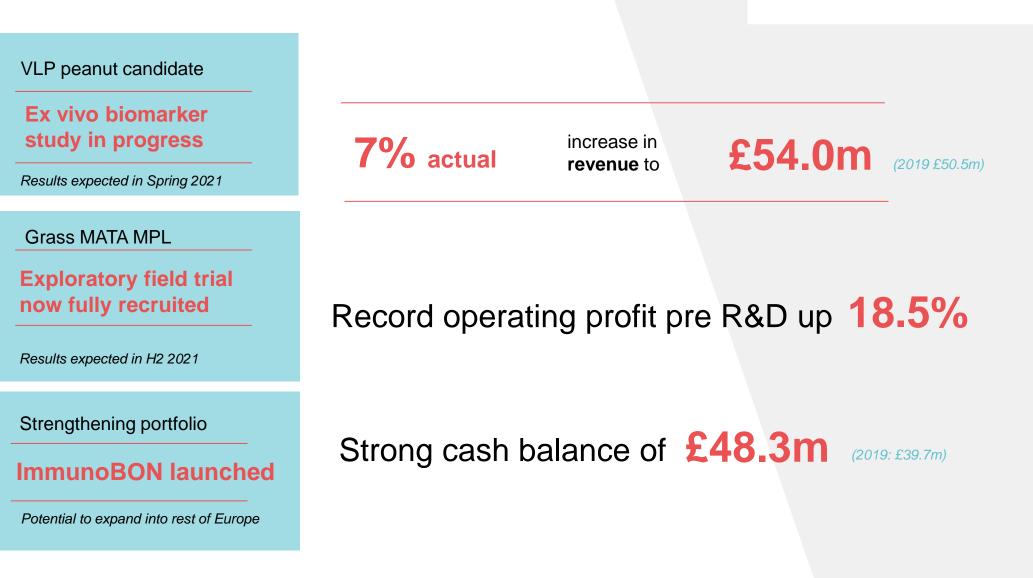
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Financial and operational highlights





Three Pillars to Growth: Advancing a Leading Allergy Immunotherapy Company

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Strong pipeline

New technologies underpin pipeline breadth and depth

Investment strategy supported by growing revenue stream

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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

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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



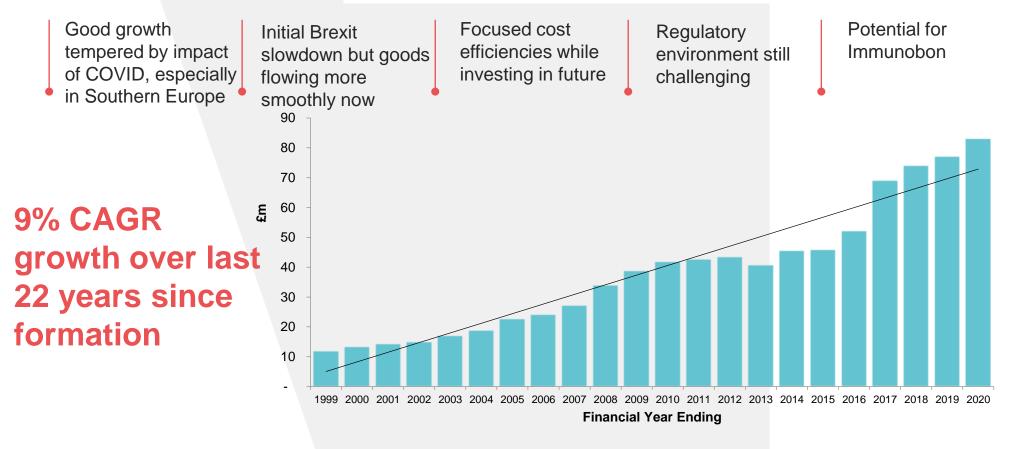






European Business – 2021 Half Year Results

Solid sales growth of 7% at actual rates in 2021



Innovative, Broad Pipeline and Marketed Products

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	Pre-clinical	Phase I	Phase II	Phase III	Market/Registered	Also available as a Named Patient Product
Grass MATA		Short-course SC	NT			
Tree MATA	Ŏ	Short-course SC	IT I		1	
Ragweed MATA	*	Short-course SC	'т	I		
Bee Venom SCIT		Short-course SC	' TI	1		
Wasp Venom SCIT		Short-course SC	іт			
Grass MATA MPL		Short-course Gr	ass SCIT with MPL		\rightarrow	
Birch MATA MPL		Short-course Bir	ch SCIT with MPL	1		
Ragweed MATA MPL		Short-course Ra	gweed SCIT with MPL	-		
Trees MATA MPL		Short-course Tre	ee SCIT with MPL			
Oral Grass, Trees & House Dust Mite	Sublingual in	nmunotherapy wit	th flexible-dosing			
Modified Mite Platform	Short-course HDM SCIT +	e modified Allerge · MPL	n			
Peanut SCIT	Short-course Peanut SCIT					

VLP candidates under proof-of-concept evaluation for uses outside allergy including cancer, asthma, psoriasis and atopic dermatitis

Grass MATA MPL

Phased Phase III programme underway to provide data to support US and EU authorisation

Both trials (G309 and G306) fully funded

Exploratory field study (G309) fully recruited with results expected autumn 2021

Efficacy field study (G306) to start H2 2022 incorporating learnings from G309 Just one Phase III efficacy trial and completion of safety database away from filing in US

Key product for US introduction – Ragweed and Birch would be products to follow with INDs already open and Phase II data available



Ultra short-course product with huge potential in US market

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VLP Peanut product

Single dose of virus like particle (VLP) with recombinant peanut allergen successfully protects against anaphylaxis when challenged with peanut in pre clinical model

Data sharing contract signed with VLP partner which could significantly ease development of the peanut product through clinical trials

Safety profile of product evaluated and found **not to induce anaphylaxis** in pre clinical model **Ex vivo biomarker trial** with Imperial College underway and due to read out Spring 2021

Industrial scale-up progressing well (400L batch complete)

Pre IND meeting with FDA planned for H1 2021 and IND submission for H2 2021

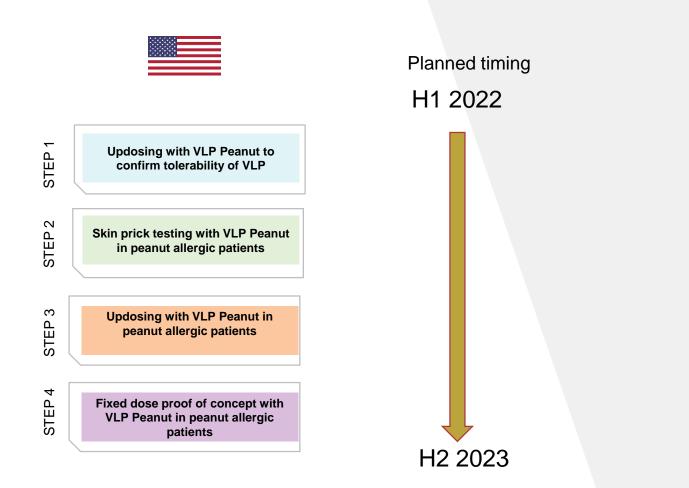
Phase I (P101) trial fully funded and due to begin H1 2022 New opportunity into \$8 billion* worldwide food allergy market

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*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

Draft Trial Protocol for VLP Peanut P101

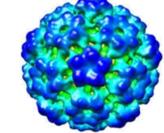
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NB: Subject to regulatory approval

Increased investment in VLP Technology

- Exclusive licence agreements signed to use patented VLP technology platform to develop vaccines targeting oncology and immune conditions –
 - Cancer (Melanoma)
 - Asthma
 - Atopic Dermatitis
 - Psoriasis
- Proof of concept studies underway
- IP registration in progress



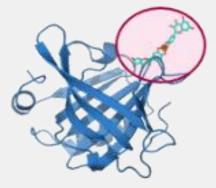
Significant first step into wider Immunotherapy field Allergy Therapeutics PLC

Strengthening a Broad Portfolio

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immunoBON[®] - to treat and prevent allergies by mimicking the "farm effect"

- Uses **Lipocalins**, that are found in raw milk and farm dust, which are proteins that can protect from allergy.
- Treatment for multiple allergens with studies already complete in Birch and House Dust Mite
- Product launched in Germany and Austria
- Early indications good in terms of orders
- **Potential to expand** to other European countries including UK, a very significant OTC market
- Sales channel via pharmacies







Financial Results

P&L – six months ended 31 December 2020



		2021 £'m	2020 £'m	Variance % £'m	
+7%	Revenue	54.0	50.5	3.5	7%
Robust sales performance Despite COVID-19 and Brexit	Gross profit	42.3	39.1	3.2	8%
	Overheads	(22.1)	(21.8)	(0.3)	1%
+£0.3m	R&D - Expenditure	(4.7)	(4.5)	(0.2)	
Overheads up due to phasing and efficiencies	- Settlement		3.2	(3.2)	
	Other Income	0.3		0.3	
	Operating profit	15.8	16.0	(0.2)	
£20.5m	Net Financing costs	(0.2)	(0.1)	(0.1)	
Operating profit pre R&D (2020: £17.3m) increase due to robust sales and operating efficiencies	Тах	(0.6)	(0.6)	(0.1)	
	Profit after tax	14.9	15.3	(0.3)	

Balance sheet at 31 December 2020

		2021	2020	Variance
		£'m	£'m	£'m
£1.4m	Non-current assets			
Increase in inventory due to	Property , plant and equipment	19.5	20.3	(0.8)
Brexit preparation	Intangible assets	4.4	4.6	(0.2)
	Investments	5.9	5.5	0.4
		29.8	30.4	(0.5)
	Current assets			
£2.0m	Inventories	10.1	8.7	1.4
	Trade and other receivables	10.8	8.8	2.0
Debtor increase due to tax	Cash	48.3	39.7	8.6
R&D and VAT credits	Derivative financial instruments		0.3	(0.3)
	Liabilities			
£48.3m	Financial Liabilities	(3.8)	(2.0)	(1.8)
	Other Liabilities	(36.5)	(34.7)	(1.7)
Cash at 31 Dec 2020	Net Assets	58.7	51.2	7.5
	Equity			
£3.8m	Share capital and share premium	113.2	113.2	0.0
Debt. Seasonal overdraft	P&L account and other reserves	(54.5)	(62.0)	7.5
in place (undrawn)	Total Equity	58.7	51.2	7.5

Cashflow for the six months ended 31 December 2020

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		2021		2020	
		£'m	£'m	£'m	£'m
Positive net cash generated by good sales, cost phasing and control	Opening cash balance 1 st July		37.0		27.4
	Profit before tax	15.6		15.9	
	Adjustments re operations	(2.9)		(1.6)	
	Net cash generated by operations		12.7		14.3
	Tax received		0.3		0.6
Good working capital control	Interest paid		(0.2)		(0.3)
	Interest received	0.0		0.2	
	Investments and acquisitions	(0.1)		(0.1)	
	Capital expenditure	(0.7)		(1.1)	
	Net cash used in investing activities		(0.8)		(1.0)
Strong cash position of £48.3m driven by trading performance	Net movement in borrowings	(0.6)		(1.0)	
	Net cash used in financing activities		(0.6)		(1.0)
	Effects of exchange rates on cash		(0.1)		(0.3)
	Closing Cash Balance 31 December		48.3		39.7

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Summary and outlook

2021 set to be an important year

Delivering against our strategy: three pillars to growth

Drive further growth in sales and maximise ImmunoBON launches

Results from Grass MATA MPL exploratory field study (G309) in autumn 2021

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

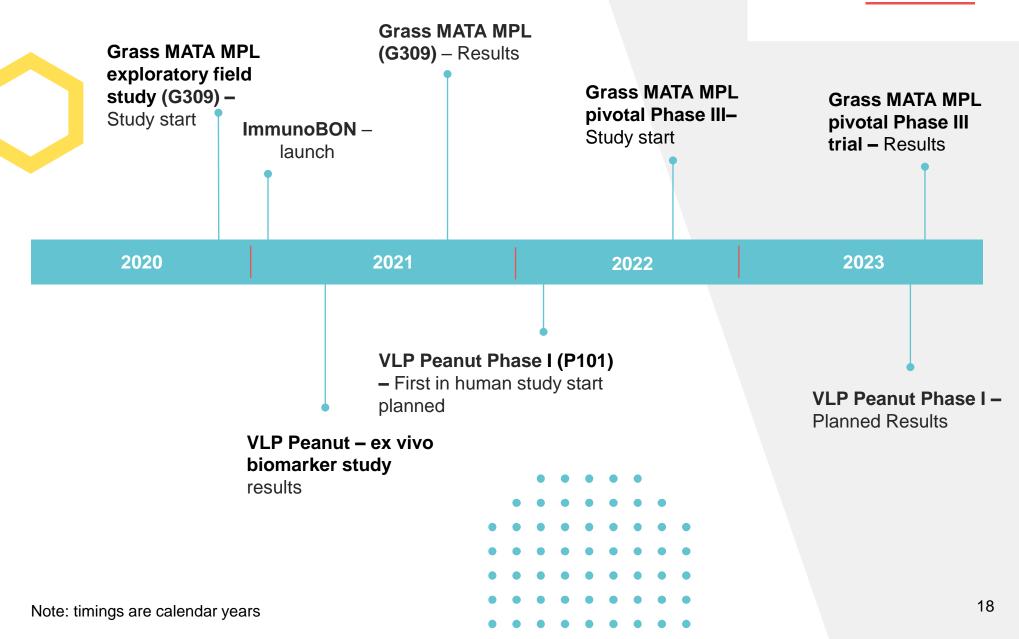
Results of Peanut ex vivo study to support IND meeting with FDA ahead of Phase I (P101) in 2022





Key milestones

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Appendix

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Unique Selling Point - Ultrashort course treatment technology platforms

Potential to cure, not just treat symptoms

Only truly innovating business in broad allergy market of biotechnology

Large US market potential in peanut, allergic rhinitis and immunotherapy Successful trading model - 9% annual revenue growth over the last 22 years

Leading aluminium-free subcutaneous allergy vaccines

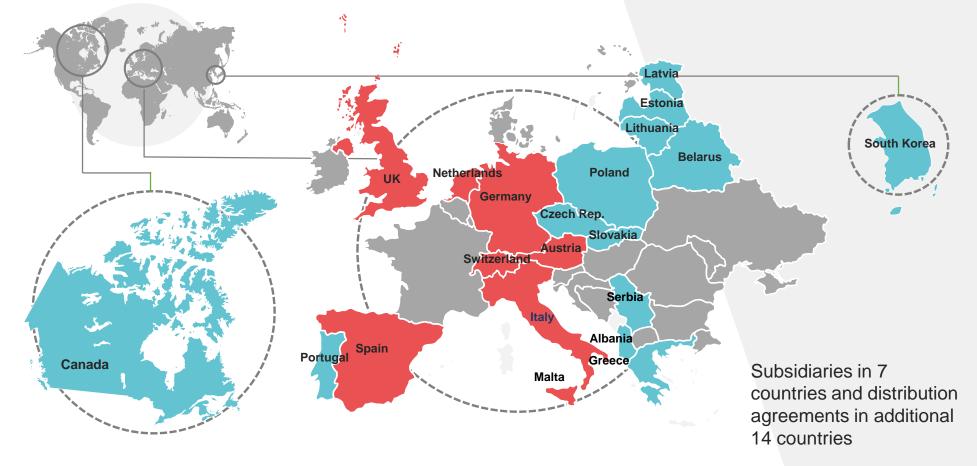
Rich pipeline with both near market and early stage candidates

Listed on London Stock Exchange (AIM) R&D pipeline focussing on peanut allergy with VLP technology Allergy Therapeutics PLC

Allergy Therapeutics: Company with Solid Sales and Global presence

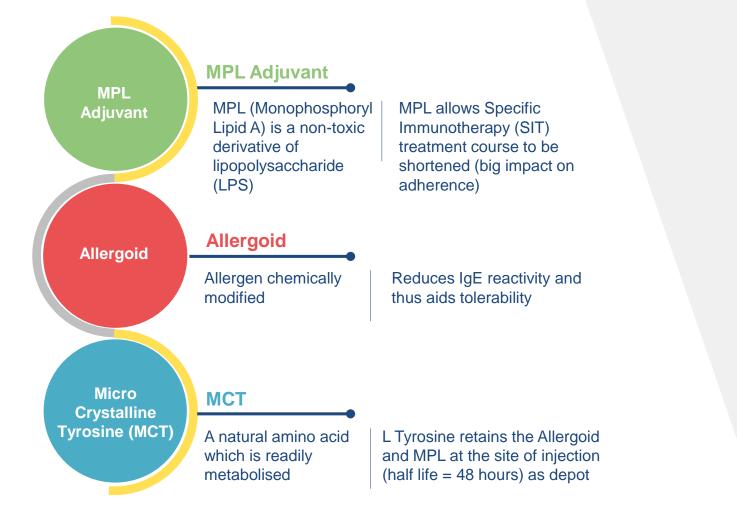
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Sales and marketing network comprising c.140 European sales force



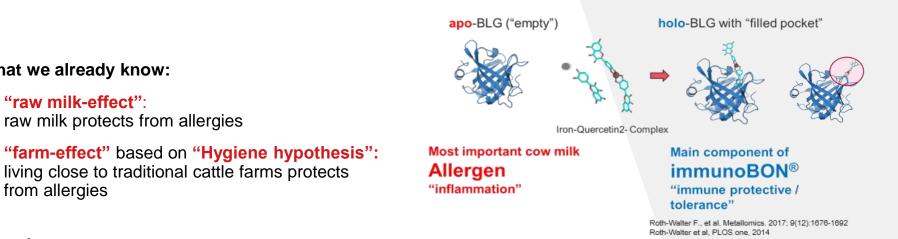
PQ: Differentiated platform approach enhances compliance, leads to higher efficacy and successful outcomes

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Science of immunoBON[®]

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What is new:

- >Lipocalins, that are found in raw milk and farm dust, are proteins that can protect from allergy.
- B-lactoglobulin (BLG) in its holo-form binds iron.

≻Holo-BLG:

What we already know:

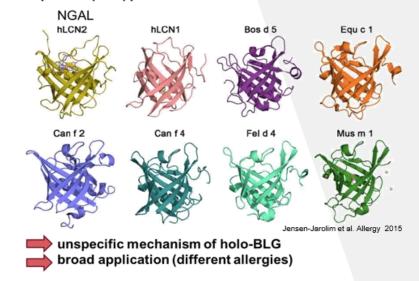
raw milk protects from allergies

"raw milk-effect":

from allergies

- immune response ↓
- allergies ↓

Lipocalin (-like) proteins with similar structure:

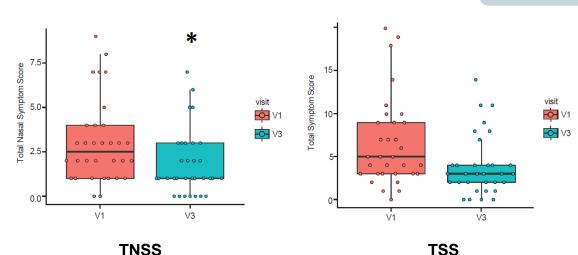


immunoBON[®] clinical studies

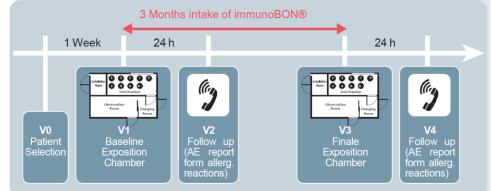
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Study overview:

We assessed the effect of a new dietary supplement (immunoBON[®]) containing whey proteins such as BLG, iron, retinoic acid, zinc and polyphenols on participants suffering from house dust mite (HDM) induced allergic rhinoconjunctivitis.



Study Design:



The primary endpoint (total nasal symptom score "TNSS") revealed significant improvement after intake of immunoBON[®].

The Median TNSS was decreased by 60% (*p*=0.0034) and the Median Total Symptom Score "TSS" by 40% (*p*=0.0026)

This is the first evaluation of a novel immune modulating dietary supplement (immunoBON[®]) in a highly standardized allergen exposure chamber (AEC) setting, demonstrating beneficial effects especially on nasal, ocular and bronchial symptoms in HDM allergic patients. After an intake period of only 3 months the primary endpoint defined as the change in Median Total Nasal Symptom Score (TNSS) after 120 minutes of HDM exposure in the AEC was significantly reduced by 60%.

Bergmann K.C. et al., Impact of a novel immune-modulating dietary supplement on house dust mite induced allergic rhinoconjunctivitis - first evaluation in an allergen exposure chamber. ePoster-Nummer **P7.10** - Deutscher Allergiekongress 2020 in Wiesbaden

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Results:

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



The changing US regulatory landscape offers potential for significant commercial growth

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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

Preparing for US entry

>100 injections

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

estimated allergy immunotherapy market**

2-3m Americans receive allergy

immunotherapy***

Some adherence levels as low as 16%*

16%

\$300-400m

Estimated peak grass sales**

Currently no registered injected products

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

*** Professor Lawrence DuBuske MD

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

Sales – six months ended 31 December 2020

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0		2021	2020 Variance		0/
		£'m	£'m	£'m	m %
Good sales growth driven by good performance in Northern Europe	Gross Revenue at Constant Exchange Rate	55.9	53.8	2.1	4%
Growth in Pollinex, Pollinex	Rebate at Constant Exchange Rate	(2.8)	(3.3)	0.5	
Quattro and Venomil	Net Revenue at Constant Exchange Rate	53.1	50.5	2.6	5%
Noted impact in	Effect of Foreign Exchange	0.9		0.9	
Southern Europe from COVID-19	Net Revenue	54.0	50.5	3.5	7%
Small FX impact in this	*Constant exchange rate Euro/£	1.13			
period as exchange rates similar	Current exchange rate Euro/£	1.11	1.13		

* 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.