Allergy Therapeutics plc
("Allergy Therapeutics", "ATL" or the "Group")

Interim Results for the six months ended 31 December 2020

- *Record level of operating profit pre-R&D (£20.5m) supported by robust sales and operational efficiency*
- *Strong cash position with Grass MATA MPL Phase III programme and Peanut Phase I fully funded*
- *Pivotal clinical programmes for Virus Like Particle (VLP) Peanut and Grass MATA MPL on track despite challenging environment*
- *Pre-Investigational New Drug (IND) meeting with FDA for VLP Peanut programme scheduled for H1 2021*

3 March 2021 Allergy Therapeutics plc (AIM: AGY), the fully integrated commercial biotechnology company specialising in allergy immunotherapy, today announces its unaudited interim results for the six months ended 31 December 2020.

Highlights

Financial highlights

- Revenue increased by 7% in actual terms and 5% at constant rate* to £54.0m (H1 2020: £50.5m)
- 18.5% growth in pre-R&D operating profit to £20.5m (H1 2020: £17.3m) largely as a result of continued sales growth and operational efficiency
- Operating profit pre-R&D margin of 38% (H1 2020 34%)
- R&D expenditure higher at £4.7m (H1 2020: £1.3m, which included £3.2m received from litigation settlement with Inflamax)
- Strong cash balance of £48.3m (30 June 2020: £37.0m). Net cash of £44.5m (30 June 2020: £33.2m)

Operational highlights

- Robust growth across all key products in the portfolio with stronger growth in Northern Europe due to standalone clinics less impacted by Covid-19 restrictions
- First stage of Grass MATA MPL Phase III programme is on track with patients fully recruited
- VLP Peanut *ex-vivo* biomarker study with Imperial College London progressing well and manufacturing batch scale up to 400 litres achieved
- Venomil registration granted in Austrian market
- ImmunoBON product with patented breakthrough technology for multiple allergies launched in Germany, January 2021

Manuel Llobet, CEO at Allergy Therapeutics, stated: *"The Group has made a strong start to the year despite the uncertainty of Covid-19, Brexit and the regulatory and business environment. We continue to perform well commercially with robust growth across all key products in our portfolio and further market share gains thanks to our dedicated workforce. Progressing our growing, high-potential pipeline remains a priority and provides exciting opportunities in the allergy immunotherapy field and the broader immunology space."*

*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 finance review for an analysis of revenue.

This announcement contains inside information for the purposes of Article 7 of Regulatory (EU) No596/2014.

Analyst briefing and webcast today

Manuel Llobet, Chief Executive Officer, Nick Wykeman, Chief Financial Officer, and Alan Bullimore, Head of Business Innovation, will host a virtual presentation for analysts to provide an update on the Group, followed by a Q&A session, at 09.30am GMT.

Webcast link: https://www.lsegissuerservices.com/spark/AllergyTherapeutics/events/27be0274-2be7-4f4d-912d-5ab92e872ea4

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About Allergy Therapeutics

Allergy Therapeutics is an international commercial biotechnology company focussed on the treatment and diagnosis of allergic disorders, including aluminium free immunotherapy vaccines that have the potential to cure disease. The Group sells proprietary and third-party products from its subsidiaries in nine major European countries and via distribution agreements in an additional ten countries. Its broad pipeline of products in clinical development includes vaccines for grass, tree and house dust mite, and peanut allergy vaccine in pre-clinical development. Adjuvant systems to boost performance of vaccines outside allergy are also in development.

Formed in 1999 out of Smith Kline Beecham, Allergy Therapeutics is headquartered in Worthing, UK with more than 11,000m^2 of state-of-the-art MHRA-approved manufacturing facilities and laboratories. The Group, which has achieved over 9% compound annual growth since formation, employs c.600 employees and is listed on the London Stock Exchange (AIM:AGY). For more information, please see www.allergytherapeutics.com.

Joint Statement from the Chairman and Chief Executive Officer

Operating Review

Overview

The Group performed robustly through a challenging period with both Brexit and Covid-19 to deal with. Good progress has been made in research and development with the Grass MATA MPL exploratory trial fully recruited and the *ex-vivo* Peanut study underway at Imperial College London.

The Market

Allergy Therapeutics achieved sales growth in actual terms of 7% (5% at constant rates[1]). This growth came mainly from Northern Europe, with Southern Europe being more affected by Covid-19. Pollinex Quattro, Pollinex and Venomil continued to grow well.

We have seen a solid performance in H1 2021 from Germany, Netherlands and Switzerland, driven by our science-based selling approach and the reliability of our supply chain. In Spain, Italy and the UK sales have been weak due to closure of clinics in hospitals and the diversion of doctors to emergency wards. Despite this, and the challenges of preparation for and implementation of Brexit, the business has performed well. Although, like all other export businesses, Brexit created some delays due to increased paperwork and external system problems, our products are now flowing more smoothly into the EU from the UK. We continue to work to optimise processes.

In January 2021, we launched ImmunoBON in Germany. ImmunoBON is a patented protein-based oral product for the general treatment of allergies based on the lower incidence of allergies shown by people who live near or on a livestock farm, the so-called “farm effect”. This product offers an innovative approach to those with mild allergies.

Regulatory Affairs & Clinical Development

Grass MATA MPL Phase III trial

The first half of FY2021 has seen the start of the Grass MATA MPL exploratory field study (G309) with patients fully recruited and almost all treated, ready for the start of the grass season. Results from this ground-breaking trial are expected in the autumn of 2021and data will be crucial for informing the second stage. The second stage of the Grass MATA MPL Phase III programme will start in the autumn of 2022 with read out in autumn 2023. Both these trials, as well as the Phase I VLP Peanut trial, are fully funded.

The Group continues to work with regulators in relation to the German TAV (Therapy Allergy Ordinance) process. Italy and Spain are implementing similar legislation and, in time, we expect the whole of the EU market to do the same. It is expected that data and studies carried out in Germany should be transferable to the rest of the EU. Venomil, the lifesaving vaccine for bees and wasps venoms, which has already been approved in Germany, has been granted registration in the Austrian market.

VLP Peanut Phase I trial

The Group is currently running an *ex-vivo* biomarker study at Imperial College London evaluating an innovative panel of biomarkers using blood samples from peanut-allergic patients. Results from this study, which will give the first indications of human reaction to the Group’s VLP Peanut allergy vaccine candidate, will be available in the spring of 2021. This study will also form an important part of the submission to the United States Food and Drug Administration (FDA) for the opening of the Investigational New Drug (IND) application in autumn 2021. A Pre-IND meeting with the FDA is scheduled for H1 2021. It is expected that recruitment of patients in the VLP Peanut Phase I clinical trial will begin in early calendar 2022 if there are no regulatory delays.

[1]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 finance review for an analysis of revenue.

The VLP Peanut Phase I trial (P101) will use a stepwise approach given the high allergenicity of peanut. The initial stage will involve healthy patients, followed by skin prick tests in peanut allergy patients before moving to subcutaneous injection of peanut allergic patients.

Adjuvant technology

Our adjuvant technology, which has the potential to create immunotherapies that act faster and work more efficiently than traditional therapies, is a key element of the Group's strategy to develop innovative immunotherapies for allergy patients. In a paper published in a special edition of Frontiers in Immunology in November 2020, the evolution of adjuvants and the potential of adjuvant systems in allergy immunotherapy research is explored. It is the first time that a unified view of Monocrystalline Tyrosine (MCT®) mode-of-action from multiple experiments and adjuvant systems has been collated and will help facilitate future rational design of vaccines while shaping their success.

Work continues on the proof of concept for the four VLP candidates for melanoma, asthma, atopic dermatitis and psoriasis. The Group is also busy securing the intellectual property for these candidates allowing more disclosure of the technology.

Financial Review

Reported revenue for the first half of the financial year was £54.0m (H1 2020: £50.5m), representing a growth of 5% at constant currency (see table below) and 7% in actual terms. The sales growth has been driven primarily by the Group's long-term investment in promoting its scientifically advanced products.

A reconciliation between reported revenue and revenue in constant currency is provided in the table below:

	6 months to 31-Dec-20 £m	6 months to 31-Dec-19 £m	Increase/ Decrease £m	Increase %
Revenue	54.0	50.5	3.5	6.9%
Adjustment to retranslate to prior year foreign exchange rate	(0.9)	-	(0.9)	
Revenue at constant currency[1]	53.1	50.5	2.6	5.1%
Add rebates at constant currency	2.8	3.3	(0.5)	
Gross revenue at constant currency	55.9	53.8	2.1	3.9%

As in previous years, owing to the seasonality of the pollen allergy market, between 60%-70% of Allergy Therapeutics' revenue is generated in the first half of the financial year and, as a consequence, the Group typically reports profits in the first half of the year and losses in the second half.

Cost of goods sold increased in the period to £11.8m (H1 2020: £11.4m), mainly due to higher volumes being sold. Gross profit increased to £42.2m (H1 2020: £39.1m), which represents a gross margin of 78% (H1 2020: 77%).

Sales, marketing and distribution costs of £12.4m (H1 2020: £13.6m) were lower due to reduced activity caused by Covid-19. The increase in administrative expenses to £9.6m (H1 2020: £8.2m) reflects investment in compliance and infrastructure.

Research and development costs of £4.7m (H1 2020: £1.3m) are in line with last year once the impact on last year of the £3.2m received in settlement of legal costs relating to the Inflamax litigation process is taken into account. The majority of the costs associated with the exploratory Grass MATA MPL trial are expected to be incurred in the remaining part of the 2021 calendar year.

The tax charge in the period of £0.6m (H1 2020: £0.6m) relates to overseas subsidiaries.

Property, plant and equipment decreased by £0.8m to £19.5m (H1 2020: £20.3m) compared with the year before, mainly as a result of a natural reduction in the remaining leasehold period of leased assets. Goodwill was £3.4m (H1 2020: £3.3m) and was higher than the prior year due to changes in foreign exchange rates. Other intangible assets have decreased by £0.3m due to the amortisation charge being in excess of additions.

Total current assets excluding cash have increased by £3.1m to £20.9m (H1 2020: £17.8m) mainly due to increased stock levels to protect against Brexit as well as tax credits.

Retirement benefit obligations, which relate solely to the German pension scheme, increased to £13.4m (H1 2020: £12.3m) due to a decrease in the discount rate primarily as a result of lower corporate bond yields in Germany.

Net cash generated by operations was strongly positive, due to low R&D spending in the first half of the year 2020 as well as the strong trading result, with an inflow of £12.7m (H1 2020: £14.3m).

All periods now are based on IFRS16, the new accounting standard on leased assets. Assets that were previously shown as operating lease assets are now on the balance sheet with an accompanying liability. The measure of earnings before interest, tax and depreciation and amortisation has benefited to the order of £0.9m in comparison with pre IFRS 16 treatment. There is no material impact on the operating profit.

Financing

The Group had cash of £48.3m (30 June 2020 £37.0m) and debt on its balance sheet at the close of the period relating to loans held in the Spanish subsidiary of £3.8m (H1 2020: £2.0m). The seasonal overdraft was not used during the calendar year 2020.

The Directors believe that the Group will have sufficient facilities for the foreseeable future and, accordingly, they have applied the Going Concern principle in preparing these interim financial statements.

Movements in the currency markets between the respective values of the euro and sterling have an effect on the Group's operations. The Group manages its cash exposure in this respect by foreign currency hedges. Over 90% of our gross sales are denominated in euros whereas approximately 60% of costs are incurred in the United Kingdom and denominated in sterling.

Outlook

This is an important calendar year for us, with the results of the peanut *ex-vivo* study expected in the spring of 2021 leading to a potential IND meeting with the FDA in the autumn, as well as expecting the results from the Grass MATA MPL exploratory study towards the end of the year.

The outlook over the second half of the financial year is hard to predict accurately, given the lack of clarity over the ongoing impact of Covid-19. The Board and management team expect that net sales will continue to grow roughly in line with H1 in the second half of the year subject to any worsening of the Covid-19 situation. The gross margin is expected to be lower in the second half of the year compared with the first, similar to previous years, as volumes through the factory are likely to be lower, leaving gross margin for the whole year in line with last year. This is due to seasonality and Brexit stock building. As planned, research and development costs are expected to more than double in the second half of the year compared with the first half, reflecting the period of higher activity of the Grass MATA MPL trial and further work on VLP Peanut studies as well as TAV costs. Other costs for the full year are expected to be in line with market expectations and higher in the second than the first half due to investment in the ImmunoBON launch, phasing, Brexit and various other projects.

The Group continues to grow well, despite the challenging regulatory environment and issues related to Covid-19, by developing an innovative and valuable pipeline of products.

Peter Jensen
Chairman

Manuel Llobet
Chief Executive Officer

3 March 2021

ALLERGY THERAPEUTICS PLC

Consolidated income statement

	Note	6 months to 31 Dec 2020 £'000 unaudited	6 months to 31 Dec 2019 £'000 unaudited	12 months to 30 Jun 2020 £'000 audited
	2			
Revenue		54,032	50,472	78,204
Cost of sales		(11,788)	(11,414)	(20,201)
Gross profit		42,244	39,058	58,003
Sales, marketing and distribution costs		(12,413)	(13,614)	(24,853)
Administration expenses – other		*(9,637)*	*(8,177)*	*(19,627)*
Research and development costs (FY 20 includes £3.2m received relating to the litigation with Inflamax)		*(4,695)*	*(1,273)*	*(5,848)*
Administrative expenses		(14,332)	(9,450)	(25,475)
Other income		280	-	634
Operating profit		15,779	15,994	8,309
Finance income		36	152	266
Finance expense		(242)	(291)	(504)
Profit before tax		15,573	15,855	8,071
Income tax		(634)	(579)	(1,013)
Profit for the period		14,939	15,276	7,058
Earnings per share	**3**			
Basic (pence per share)		2.34p	2.40p	1.11p
Diluted (pence per share)		2.19p	2.27p	1.05p

Consolidated statement of comprehensive income

	6 months to 31 Dec 2020 £'000 unaudited	6 months to 31 Dec 2019 £'000 unaudited	12 months to 30 Jun 2020 £'000 audited
Profit for the period	14,939	15,276	7,058
Items that will not be reclassified subsequently to profit or loss:			
Remeasurement of net defined benefit liability	45	(1,060)	(1,287)
Remeasurement of investments-retirement benefit assets	(13)	65	(23)
Revaluation gains – freehold land and buildings	-	-	364
Deferred tax movement – freehold land and buildings	-	-	(146)
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	(126)	(286)	160
Total comprehensive income	14,845	13,995	6,126

Consolidated balance sheet	31 Dec 2020 £'000 unaudited	31 Dec 2019 £'000 unaudited	30 Jun 2020 £'000 audited
Assets			
Non-current assets			
Property, plant and equipment	19,503	20,340	20,417
Intangible assets - goodwill	3,438	3,324	3,467
Intangible assets - other	980	1,245	1,269
Investment - retirement benefit asset	5,927	5,479	5,902
Total non-current assets	29,848	30,388	31,055
Current assets			
Inventories	10,092	8,716	10,132
Trade and other receivables	10,772	8,769	8,076
Cash and cash equivalents	48,289	39,725	36,962
Derivative financial instruments	2	324	-
Total current assets	69,155	57,534	55,170
Total assets	99,003	87,922	86,225
Liabilities			
Current liabilities			
Trade and other payables	(14,152)	(12,903)	(15,148)
Current borrowings	(800)	(659)	(829)
Lease liabilities	(1,400)	(1,457)	(1,435)
Derivative financial instruments	-	-	(815)
Total current liabilities	(16,352)	(15,019)	(18,227)
Net current assets	52,803	42,515	36,943
Non-current liabilities			
Retirement benefit obligations	(13,388)	(12,299)	(13,526)
Deferred taxation liability	(439)	(284)	(470)
Non-current provisions	(304)	(264)	(304)
Lease liabilities	(6,769)	(7,536)	(6,988)
Long term borrowings	(3,023)	(1,317)	(2,927)
Total non-current liabilities	(23,923)	(21,700)	(24,215)
Total liabilities	(40,275)	(36,719)	(42,442)
Net assets	58,728	51,203	43,783
Equity			
Capital and reserves			
Issued share capital	651	646	647
Share premium	112,576	112,576	112,576
Merger reserve – shares issued by subsidiary	40,128	40,128	40,128
Reserve – share based payments	3,200	3,368	3,104
Revaluation reserve	974	1,207	974
Foreign exchange reserve	(811)	(1,131)	(685)
Retained earnings	(97,990)	(105,591)	(112,961)
Total equity	58,728	51,203	43,783

Consolidated statement of changes in equity

	Issued share Capital	Share premium	Merger reserve – shares issued by subsidiary	Reserve - share based payment	Revaluation reserve	Foreign exchange reserve	Retained earnings	Total equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
At 31 December 2019	646	112,576	40,128	3,368	1,207	(1,131)	(105,591)	51,203
Exchange differences on translation of foreign operations	-	-	-	-	-	446	-	446
Valuation gains taken to equity (land and buildings)	-	-	-	-	218	-	-	218
Remeasurement of net defined benefit liability	-	-	-	-	-	-	(228)	(228)
Remeasurement of investments – retirement benefit assets	-	-	-	-	-	-	(88)	(88)
Total other comprehensive income	-	-	-	-	218	446	(316)	348
Loss for the period	-	-	-	-	-	-	(8,218)	(8,218)
Total comprehensive income	-	-	-	-	218	446	(8,534)	(7,870)
Share based payments	-	-	-	449	-	-	-	449
Shares issued	1	-	-	-	-	-	-	1
Transfer of lapsed options To retained earnings	-	-	-	(713)	-	-	713	-
Transfer of depreciation on revalued property	-	-	-	-	(451)	-	451	-
At 30 June 2020	**647**	**112,576**	**40,128**	**3,104**	**974**	**(685)**	**(112,961)**	**43,783**
Exchange differences on translation of foreign operations	-	-	-	-	-	(126)	-	(126)
Remeasurement of net defined benefit liability	-	-	-	-	-	-	45	45
Remeasurement of investments – retirement benefit assets	-	-	-	-	-	-	(13)	(13)
Total other comprehensive income	-	-	-	-	-	(126)	32	(94)
Profit for the period	-	-	-	-	-	-	14,939	14,939
Total comprehensive income	-	-	-	-	-	(126)	14,971	14,845
Share based payments	-	-	-	96	-	-	-	96
Shares issued	4	-	-	-	-	-	-	4
At 31 December 2020	**651**	**112,576**	**40,128**	**3,200**	**974**	**(811)**	**(97,990)**	**58,728**

Consolidated cash flow statement

	6 months to 31Dec 2020 £'000 unaudited	6 months to 31Dec 2019 £'000 unaudited	12 months to 30Jun 2020 £'000 audited
Cash flows from operating activities			
Profit before tax	15,573	15,855	8,071
Adjustments for:			
Finance income	(36)	(152)	(266)
Finance expense	242	291	504
Non cash movements on defined benefit pension plan	67	81	192
Depreciation and amortisation	2,033	1,922	3,914
Net monetary value of above the line R&D tax credit	(280)	-	(634)
Charge for share based payments	96	345	794
Movement in fair value of derivative financial instruments	(818)	(753)	386
Foreign exchange revaluation on US dollar cash deposits	(155)	53	(154)
(Increase)/decrease in trade and other receivables	(3,702)	(178)	3,694
Decrease/(increase) in inventories	3	571	(706)
Decrease in trade and other payables	(334)	(3,727)	(2,399)
Net cash generated by operations	12,689	14,308	13,396
Bank loan fees and Interest paid	(242)	(291)	(489)
Income tax received/(paid)	340	572	(897)
Net cash generated by operating activities	12,787	14,589	12,010
Cash flows from investing activities			
Interest received	36	152	266
Payments for retirement benefit investments	(96)	(101)	(228)
Payments for intangible assets	(33)	(53)	(283)
Payments for property plant and equipment	(665)	(998)	(2,264)
Net cash used in investing activities	(758)	(1,000)	(2,509)
Cash flows from financing activities			
Proceeds from issue of equity shares	4	-	1
Repayment of bank loan borrowings	(424)	(350)	(654)
Repayments of lease creditor	(720)	(683)	(1,343)
Proceeds from borrowings	541	-	1,886
Net cash used in financing activities	(599)	(1,033)	(110)
Net increase in cash and cash equivalents	11,430	12,556	9,391
Effects of exchange rates on cash and cash equivalents	(103)	(271)	131
Cash and cash equivalents at the start of the period	36,962	27,440	27,440
Cash and cash equivalents at the end of the period	48,289	39,725	36,962

1. Interim financial information

The unaudited consolidated interim financial information is for the six month period ended 31 December 2020. The financial information does not include all the information required for full annual financial statements and should be read in conjunction with the consolidated financial statements of the Group for the year ended 30 June 2020, which were prepared under International Financial Reporting Standards (IFRS) as adopted by the European Union (EU).

The interim financial information has not been audited nor has it been reviewed under ISRE 2410 of the Auditing Practices Board. The financial information set out in this interim report does not constitute statutory accounts as defined in Section 434 of the Companies Act 2006. The Company's statutory financial statements for the year ended 30 June 2020 prepared under IFRS have been filed with the Registrar of Companies. The auditor's report on those financial statements was unqualified and did not contain a statement under Section 498(2) of the Companies Act 2006.

2. Basis of preparation

As permitted, this Interim Report has been prepared in accordance with the AIM rules and not in accordance with IAS 34 "Interim Financial Reporting". The accounting policies adopted in this report are consistent with those of the annual financial statements for the year to 30 June 2020 as described in those financial statements. There are no accounting standards that have become effective in the current period that would have a material impact upon the financial statements.

Going Concern

The Group has been profit making in the six months to 31 December 2020, as it was in the corresponding period ended 31 December 2019.

Detailed budgets have been prepared, including cash flow projections for the periods ending 30 June 2021 and 30 June 2022. These projections include assumptions on the trading performance of the operating business and the continued availability of the existing bank facilities. The Group had a cash balance of £48.3m at 31 December 2020 and expects to renew its banking facilities when they are due for renewal in August 2021. After making appropriate enquiries, which included a review of the annual budget and latest forecast, by considering the cash flow requirements for the foreseeable future and the effects of sales and other sensitivities on the Group's funding plans, the Directors continue to believe that the Group will have sufficient resources to continue in operational existence for the foreseeable future and accordingly have applied the Going Concern principle in preparing these interim financial statements.

3. Earnings per share

	6 months to 31 Dec 2020 unaudited	6 months to 31 Dec 2019 unaudited	12 months to 30 Jun 2020 audited
	£'000	£'000	£'000
Profit after tax attributable to equity shareholders	14,939	15,276	7,058
	Shares '000	Shares '000	Shares '000
Issued ordinary shares at start of the period	637,286	636,169	636,169
Ordinary shares issued in the period	3,506	-	1,117
Issued ordinary shares at end of the period	640,792	636,169	637,286
Weighted average number of shares in issue for the period	637,286	636,169	636,169
Weighted average number of shares for diluted earnings per share	681,352	672,321	673,492
Basic earnings per ordinary share (pence)	2.34p	2.40p	1.11p
Diluted earnings per ordinary share (pence)	2.19p	2.27p	1.05p

4. Contingent liabilities

On 23 February 2015, the Company received notification that The Federal Office for Economics and Export ("BAFA") had made a decision to reverse their preliminary exemption to the increased manufacturers rebate in Germany for the period July to December 2012. The Company was granted a preliminary exemption to the increased rebate for this period by BAFA in 2013. The Company recognised revenue of €1.4m (£1.1m at that time, now £1.3m) against this exemption in the year ended 30 June 2013. All other preliminary exemptions (granted for periods up to 30 June 2012) have previously been ratified as final by BAFA. After taking legal advice, the Company has lodged an appeal against this decision and is confident that the exemption will be re-instated. Therefore, as at 31 December 2020, no provision has been recognised for the repayment of the rebate refund. This position will be kept under review.

In respect of net revenue relating to certain products, there is a risk that up to £10.0m cumulative revenue (2020: £7.4m) recorded in periods up to and including December 2020 may be subject to a retrospective change. This is due to the level of rebate being applied.