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

Interim Results for the six months ended 31 December 2018

- *Continued good sales growth and strong operating profit*
- *Pipeline progressing well with PQ Birch results due Q1 and house dust mite results due in H1*

6 March 2019 Allergy Therapeutics plc (AIM:AGY), the fully integrated specialty pharmaceutical group specialising in allergy vaccines, announces its unaudited interim results for the six months ended 31 December 2018.

Highlights

Financial highlights

- Revenue increased by 10.6% (both reported and constant rate*) to £46.7m (H1 2018: £42.2m)
- 27% growth in pre-R&D operating profit to £15.7m (H1 2018: £12.3m) largely as a result of investment in the commercial business last year and a higher gross margin
- R&D expenditure lower at £5.0m (H1 2018: £5.9m) due to lower level of activity
- Cash balance of £31.6m (30 June 2018: £15.5m)
- Oversubscribed equity raise of £10.6m gross in July 2018 to support the development of the Group's clinical pipeline

Operational highlights

- Increased market share in Germany to 14.5%** (2018: 13.7%)
- Breadth of portfolio demonstrated by strong performance from ultra-short course products as well as venom and modified allergen house dust mite therapies
- Completion of PQ Birch Phase III trial, with data readout expected before the end of Q1 2019
- Scale up of Polyvac Peanut progressing well with intention to begin first in human trial in 2019
- Modified allergen house dust mite Phase I trial completed last patient last treatment with readout expected in H1 2019

Commenting on the interim results, Manuel Llobet, Chief Executive Officer, said: *"The Group has made a strong start to the financial year. Our ultra-short course products continue to drive good sales growth in a relatively flat market and the Group's pre-R&D operating profit has increased as a result of investment into our commercial business last year and our focused sales and marketing strategy. 2019 will be a very important year for the Group and, in particular, our ultra-short course technology platform, with the start of the pivotal Phase III Grass MATA MPL trial for the US and Europe. With an increasing market share, a healthy balance sheet, and an exciting clinical pipeline nearing key value inflection points, we look to the future with confidence."*

* 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.

** Market data and internal estimates for the 12 months ended 31 December 2018 of Allergy Therapeutics' direct sales in Germany.

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

- ENDS -

Analyst briefing and webcast today

Manuel Llobet, Chief Executive Officer, and Nick Wykeman, Chief Financial Officer, will host a meeting and webcast for analysts to provide an update on the Group, followed by a Q&A session, at 09.30am GMT today at the offices of Panmure Gordon & Co, One New Change, London, EC4M 9AF. **Dial-in details are:**

Webcast link: https://edge.media-server.com/m6/p/9wmz6jyi

UK dial-in: +44 (0) 2071 928000

US dial-in: +16315107495

Conference ID: 6619359

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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 include 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 double digit compound annual revenue growth since formation, employs c. 500 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 has performed strongly in a relatively flat market and has continued to leverage its infrastructure to achieve significant growth in operating profit before R&D (27% growth over H1 2018). Despite a mixed pollen season and the continued challenges of the regulatory environment, the Group has achieved market share gains through new sales channels and further penetration in mature markets. The performance of the Northern European business has been strong.

The Market

Allergy Therapeutics continues to perform well with revenue growth of 10.6% (both reported and constant rate), and taking market share. This continued growth reflects the quality of the Allergy Therapeutics portfolio, the efficiency and strength of the supply chain and the quality of sales and marketing. The growth in sales has been across most markets with the main contributors being Germany, Austria, Switzerland and Netherlands benefiting from key investments in the sales team. Spain has also recovered well from the removal of all bacterial products from the market with substitution to other products partially filling the gap.

The European spring and summer seasons of 2018 were strong for tree pollens while the exceptionally warm weather last summer dampened the impact of early strong grass pollen. The house dust mite season was weaker, although our house dust mite products continued to perform well in the circumstances (Data: Insight Health Germany July – Nov 2018).

Regulatory Affairs & Clinical Development

The manufacturing scale up of the Group's peanut product, Polyvac Peanut, which is critical to ensure the product can be manufactured commercially in a consistent manner for clinical trials and in GMP conditions, is progressing well. The Group expects to start the first-in-human trial before the end of calendar year 2019. The modified allergen + MPL house dust mite Phase I trial remains on track and due to report in H1 2019.

The PQ Birch product has been injected more than 26,000 times between 2005-2018 across Europe. Since the beginning of the TAV process in Germany in 2010, two successful Phase II trials have been completed and the PQ Birch Phase III trial will read out before the end of Q1 2019. The delay has been caused by a longer than expected time needed by the Group's trial service providers to audit, review and consolidate data from the field trial. Allergy Therapeutics remains blinded to the data package and management looks forward to receiving the data.

Discussions with the Paul Ehrlich Institut (PEI) and the FDA continue regarding the upcoming PQ Grass Phase III field trial, which is due to start in the autumn of 2019. The Group is confident in its preparations for this pivotal trial which will be conducted in the US and Europe.

The German TAV (Therapy Allergy Ordinance) process remains underway for all of the ten Allergy Therapeutics' products that started the process. Latest data suggest 65 of the original 123 products from all market participants now remain in the process. The first oral therapy Phase IIa trial is expected to start this calendar year.

Financial Review

Reported revenues for the first half of the financial year were £46.7m (H1 2018: £42.2m), representing a growth of 10.6% at constant currency and in actual terms. The growth rate reported after taking into account currency movements of nil (H1 2018: £1.3m) was 10.6%. The sales growth has been driven primarily by the Group's investment in infrastructure and broadening of the product portfolio as it continues to increase its market share in all of its main markets. Rebates were lower this period due to changes in product composition that may not continue in 2019.

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

	6 months to 31-Dec-18 £m	6 months to 31-Dec-17 £m	Increase £m	Increase %
Revenue	46.7	42.2	4.5	10.6%
Adjustment to retranslate to prior year foreign exchange rate	-	-		
Revenue at constant currency	46.7	42.2	4.5	10.6%
Add rebates at constant currency	2.4	4.1	(1.7)	
Gross revenue at constant currency	49.1	46.3	2.8	5.9%

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

Cost of goods sold increased in the period to £9.4m (H1 2018: £8.7m), mainly due to higher volumes being sold. Gross profit increased to £37.3m (H1 2018: £33.5m), which represents a gross margin of 80% (H1 2018: 79%)

Sales, marketing and distribution costs of £13.6m (H1 2018: £14.2m) were lower than the previous period. This is due to phasing of major campaigns and will reverse over the second half. Administration expenses of £8.1m (H1 2018: £7.1m) rose due to higher share based payment charges and one-off employee related costs.

Research and development costs of £5.0m (H1 2018: £5.9m) reflected the lower level of activity in H1 2019.

The tax charge in the period of £0.4m (H1 2018: £0.4m) relates to overseas subsidiaries.

Property, plant and equipment increased by £0.2m to £10.0m compared to the year before, mainly as a result of investment in new storage facilities as part of our Brexit contingency planning. The depreciation charge decreased by £0.1m. Goodwill remained unchanged at £3.4m (H1 2018: £3.4m), whilst other intangible assets have decreased by £0.2m.

Total current assets excluding cash have remained the same as the year before at £19.3m (H1 2018: £19.3m) with an increase in stock due to Brexit planning offset by a reduction in debtors driven by improved collection of trade debtors.

Retirement benefit obligations, which relate solely to the German pension scheme, increased to £10.5m (H1 2018: £10.1m) as a result of increased accrued benefit to scheme members not being matched by an increase in scheme assets.

Net cash generated by operations was strongly positive, due to lower R&D spending in the first half of the year as well as the strong trading result, with an inflow of £6.8m (H1 2018: £4.3m).

The Group is in a legal process with one of its suppliers over potential cost overruns on one of its clinical trials that may lead to additional expense for the Group (see note 4, contingent liabilities).

Financing

In July 2018, we completed a successful placing and subscription of 40m shares, raising £10.6m gross. The Group now has sufficient capital to fully fund an extended Phase III Grass trial in the US and EU.

The Group had debt on its balance sheet at the close of the period relating to loans held in the Spanish subsidiary of £2.8m (H1 2018: £3.2m). The seasonal overdraft was not used during the calendar year 2018 but the Group expects to renew its banking facilities when they are due for review in August 2019.

The Directors believe that the Group will have adequate 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.

Board Changes

In November 2018, the Group announced that Jeff Barton retired from the Board as the nominated Abbott director and was replaced by Scott Leinenweber, Vice President of Investor Relations and Licensing and Acquisitions at Abbott Laboratories, Inc.

Outlook

This calendar year is set to be pivotal for Allergy Therapeutics particularly with the Grass MATA MPL Phase III trial due to start in the second half of the calendar year which will help to provide us with the platform to potentially expand into the highly attractive US market.

The Board and management team expect that net sales will continue to grow in line with market expectations in the second half of the year and have great confidence in the future of the business. The gross margin is expected to be lower in the second half as the first half of the year was boosted by additional production in the manufacturing facility to build up stocks before the Brexit deadline date of 29 March 2019. Volumes through the factory are likely to be lower in second half. As planned, research and development costs are expected to double in the second half of the year compared to the first half, reflecting the period of higher activity of the Grass MATA MPL Phase III field trial as well as the start of the oral therapy trials. Other costs for the full year are expected to be in line with market expectations due to phasing and Brexit costs.

As noted in the Group Risks section of the 2018 Annual Report, management has taken action to try and mitigate the impact of Brexit, though the Group expects sales would be impacted in the event of a hard Brexit.

The Group is well positioned to continue to grow the European business while developing the pipeline for the US market and the food allergy field.

We look forward to the future with confidence.

Peter Jensen
Chairman

Manuel Llobet
Chief Executive Officer

6 March 2019

Consolidated income statement

	Note	6 months to 31 Dec 2018 £'000 unaudited	6 months to 31 Dec 2017 £'000 unaudited	12 months to 30 Jun 2018 £'000 audited
	2			
Revenue		46,713	42,241	68,346
Cost of sales		(9,411)	(8,720)	(17,013)
Gross profit		37,302	33,521	51,333
Sales, marketing and distribution costs		(13,563)	(14,246)	(27,133)
Administration expenses – other		*(8,063)*	*(7,140)*	*(15,543)*
Research and development costs		*(4,968)*	*(5,913)*	*(16,017)*
Administration expenses		(13,031)	(13,053)	(31,560)
Other income		31	200	630
Operating profit/(loss)		10,739	6,422	(6,730)
Finance income		118	110	154
Finance expense		(124)	(129)	(320)
Profit/(loss) before tax		10,733	6,403	(6,896)
Income tax		(408)	(377)	(637)
Profit/(loss) for the period		10,325	6,026	(7,533)
Earnings/(loss) per share	**3**			
Basic (pence per share)		1.64p	1.01p	(1.27p)
Diluted (pence per share)		1.55p	0.99p	(1.27p)

Consolidated statement of comprehensive income

	6 months to 31 Dec 2018 £'000 unaudited	6 months to 31 Dec 2017 £'000 unaudited	12 months to 30 Jun 2018 £'000 audited
Profit/(loss) for the period	10,325	6,026	(7,533)
Items that will not be reclassified subsequently to profit or loss:			
Remeasurement of net defined benefit liability	206	(229)	(278)
Remeasurement of investments-retirement benefit assets	(83)	(60)	(39)
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	131	(114)	(68)
Total comprehensive income/ (loss)	10,579	5,623	(7,918)

Consolidated balance sheet	31 Dec 2018 £'000 unaudited	31 Dec 2017 £'000 unaudited	30 Jun 2018 £'000 audited
Assets			
Non-current assets			
Property, plant and equipment	10,034	9,798	10,096
Intangible assets - goodwill	3,438	3,412	3,406
Intangible assets - other	1,437	1,696	1,543
Investment - retirement benefit asset	5,369	4,854	5,043
Total non-current assets	20,278	19,760	20,088
Current assets			
Inventories	9,033	8,393	8,808
Trade and other receivables	10,324	10,939	6,587
Cash and cash equivalents	31,642	25,812	15,533
Total current assets	50,999	45,144	30,928
Total assets	71,277	64,904	51,016
Liabilities			
Current liabilities			
Trade and other payables	(12,892)	(14,691)	(13,890)
Current borrowings	(664)	(395)	(644)
Derivative financial instruments	(65)	(384)	(97)
Total current liabilities	(13,621)	(15,470)	(14,631)
Net current assets	37,378	29,674	16,297
Non-current liabilities			
Retirement benefit obligations	(10,477)	(10,131)	(10,346)
Deferred taxation liability	(304)	(325)	(309)
Non-current provisions	(306)	(279)	(282)
Long term borrowings	(2,092)	(2,798)	(2,414)
Total non-current liabilities	(13,179)	(13,533)	(13,351)
Total liabilities	(26,800)	(29,003)	(27,982)
Net assets	44,477	35,901	23,034
Equity			
Capital and reserves			
Issued share capital	646	604	606
Share premium	112,576	102,420	102,420
Merger reserve – shares issued by subsidiary	40,128	40,128	40,128
Reserve – share based payments	2,324	1,213	1,656
Revaluation reserve	949	974	949
Foreign exchange reserve	(844)	(1,021)	(975)
Retained earnings	(111,302)	(108,417)	(121,750)
Total equity	44,477	35,901	23,034

Consolidated statement of changes in equity

	Issued 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 2017	604	102,420	40,128	1,213	974	(1,021)	(108,417)	35,901
Exchange differences on translation of foreign operations	-	-	-	-	-	46	-	46
Remeasurement of net defined benefit liability	-	-	-	-	-	-	(49)	(49)
Remeasurement of investments – retirement benefit assets	-	-	-	-	-	-	21	21
Total other comprehensive income	-	-	-	-	-	46	(28)	18
Loss for the period after tax	-	-	-	-	-	-	(13,559)	(13,559)
Total comprehensive income	-	-	-	-	-	46	(13,587)	(13,541)
Share based payments	-	-	-	672	-	-	-	672
Shares issued	2	-	-	-	-	-	-	2
Transfer of lapsed options to retained earnings	-	-	-	(229)	-	-	229	-
Transfer of depreciation on revalued property	-	-	-	-	(25)	-	25	-
At 30 June 2018	**606**	**102,420**	**40,128**	**1,656**	**949**	**(975)**	**(121,750)**	**23,034**
Exchange differences on translation of foreign operations	-	-	-	-	-	131	-	131
Remeasurement of net defined benefit liability	-	-	-	-	-	-	206	206
Remeasurement of investments – retirement benefit assets	-	-	-	-	-	-	(83)	(83)
Total other comprehensive income	-	-	-	-	-	131	123	254
Profit for the period after tax	-	-	-	-	-	-	10,325	10,325
Total comprehensive income	-	-	-	-	-	131	10,448	10,579
Share based payments	-	-	-	668	-	-	-	668
Shares issued	40	10,560	-	-	-	-	-	10,600
Share issue costs	-	(404)	-	-	-	-	-	(404)
At 31 December 2018	**646**	**112,576**	**40,128**	**2,324**	**949**	**(844)**	**(111,302)**	**44,477**

Condensed consolidated cash flow statement

	6 months to 31Dec 2018 £'000 unaudited	6 months to 31Dec 2017 £'000 unaudited	12 months to 30Jun 2018 £'000 audited
Cash flows from operating activities			
Profit/(loss) before tax	10,733	6,403	(6,896)
Adjustments for:			
Finance income	(118)	(110)	(154)
Finance expense	124	129	320
Non cash movements on defined benefit pension plan	79	95	381
Depreciation and amortisation	1,014	1,127	2,020
Impairment of intangible assets	-	-	224
Loss on disposal of fixed assets	-	-	5
Net monetary value of above the line R&D tax credit	(31)	(200)	(630)
Charge for share based payments	668	313	985
Movement in fair value of derivative financial instruments	(32)	20	(307)
Foreign exchange revaluation on US dollar cash deposits	4	3	(10)
(Increase)/decrease in trade and other receivables	(4,024)	(3,566)	3,303
Increase in inventories	(183)	(915)	(1,330)
(Decrease)/increase in trade and other payables	(1,441)	994	(1,762)
Net cash generated by operations	6,793	4,293	(3,851)
Bank loan fees and Interest paid	(124)	(129)	(318)
Income tax received	353	699	367
Net cash generated/(used) by operating activities	7,022	4,863	(3,802)
Cash flows from investing activities			
Interest received	119	110	48
Payments for retirement benefit investments	(231)	(187)	(367)
Payments for intangible assets	(7)	(4)	(179)
Payments for property plant and equipment	(722)	(993)	(2,005)
Net cash used in investing activities	(841)	(1,074)	(2,503)
Cash flows from financing activities			
Share issue proceeds from issue of equity shares (net of issue costs)	10,196	1	2
Repayment of borrowings	(346)	(107)	(398)
Proceeds from borrowings	-	-	102
Net cash generated from/(used by) financing activities	9,850	(106)	(294)
Net increase/(decrease) in cash and cash equivalents	16,031	3,683	(6,599)
Effects of exchange rates on cash and cash equivalents	78	7	10
Cash and cash equivalents at the start of the period	15,533	22,122	22,122
Cash and cash equivalents at the end of the period	31,642	25,812	15,533

1. Interim financial information

The unaudited consolidated interim financial information is for the six-month period ended 31 December 2018. 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 2018, 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 2018 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

The interim financial statements have been prepared in accordance with applicable accounting standards and under the historical cost convention except for land and buildings and derivative financial instruments which have been measured at fair value. The accounting policies adopted in this report are consistent with those of the annual financial statements for the year to 30 June 2018 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.

IFRS 15 was issued in May 2014 and was implemented by the Group from 1 July 2018 using the modified retrospective approach.

The standard provides a principles-based approach to the recognition of revenue, following a five-step procedure.

The Group has reviewed its contracts with customers under the five-step method using a portfolio approach, treating all sales as having substantially the same terms and conditions attached. Sales in specific territories that have differentiating factors have been considered as exceptions.

The Group's revenues are almost entirely derived from the sale of allergy vaccines and probiotics products. The Group considers that all of its performance obligations have been fulfilled once the products have been delivered to customers and will continue to recognise revenue at that point.

The Group does not currently maintain a warranty returns provision as the historical experience shows that returns are insignificant. The Group does not provide extended warranties that are considered to represent a separate performance obligation with respect to the sale of goods and therefore do not recognise warranty revenues separately. The Group will continue to monitor warranty returns and will create a returns provision if necessary in future periods.

The Group has concluded that the new standard has not had a material impact on the amount or timing of recognition of reported revenue for periods up to 30 June 2018. The amounts reported under IFRS 15 were the same as those that would have been reported under IAS18, therefore no transitional adjustment is required in these interim financial statements.

Going Concern

The Group has been profit making in the six months to 31 December 2018, as it was in the corresponding period ending 31 December 2017.

Detailed budgets have been prepared, including cash flow projections for the periods ending 30 June 2019 and 30 June 2020. 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 £31.6m at 31 December 2018 and expects to renew its banking facilities when they are due for renewal in August 2019. 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 adequate 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 2018 unaudited £'000	6 months to 31 Dec 2017 unaudited £'000	12 months to 30 Jun 2018 audited £'000
Profit/(loss) after tax attributable to equity shareholders	10,325	6,026	(7,533)
	Shares '000	Shares '000	Shares '000
Issued ordinary shares at start of the period	596,169	594,118	594,118
Ordinary shares issued in the period	40,000	-	2,051
Issued ordinary shares at end of the period	636,169	594,118	596,169
Weighted average number of shares in issue for the period	629,502	594,118	595,099
Weighted average number of shares for diluted earnings per share	667,845	610,995	595,099
Basic earnings per ordinary share/(loss) (pence)	1.64p	1.01p	(1.27p)
Diluted earnings per ordinary share/(loss) (pence)	1.55p	0.99p	(1.27p)

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 £1.2m) 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 2018, 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 revenue of up to £3.5m (2017: £Nil) recorded in the periods up to and including December 2018 may be subject to a retrospective change. This is due to the level of rebate being applied.

The Group is in litigation with one of its third party contractors. The Group is claiming $22m from the third party contractor in damages, and additionally, interest and legal fees. The third party contractor is counterclaiming $4.3m in what it claims are unpaid invoices, plus interest and legal fees. The Group is of the opinion that it has a strong claim against the contractor and a full defence to the counterclaim. No liabilities or assets have been recognised in these interim financial statements in relation to these claims.