RNS Number : 4174I
Allergy Therapeutics PLC
27 March 2024

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

Interim Results for the six months ended 31 December 2023

Significant clinical and regulatory progress
Financial turnaround on track. Strengthened balance sheet and restructuring plan paves the way to future growth.

- Primary end point met in G306 Pivotal Study for Grass Allergic Patients
- Successful development of VLP Peanut vaccine program underpins the phase I/IIa study.

27 March 2024: Allergy Therapeutics plc (AIM: AGY), the fully integrated commercial biotechnology company specialising in allergy vaccines, announces its unaudited interim results for the six months ended 31 December 2023.

Highlights

Financial
- Completion of the subscription and open offer (the "Equity Financing") to restructure the Group's balance sheet, enhancing financial stability with net assets increasing to £26.5m
- Implementation of ongoing cost reduction strategy, reducing the Group's overheads pre-R&D by 14.9%
- Increased investment in R&D pipeline, demonstrating the Group's commitment to innovation and the development of allergy immunotherapies

Operational
- Primary endpoint of the Group's pivotal Phase III G306 trial for Grass MATA MPL met and discussions with regulators ongoing ahead of planned market authorisation application
- Subcutaneous dosing of peanut allergic patients has begun in the Phase I/IIa PROTECT trial
- Group continues to focus on high value growth products to enhance future profitability

Post Period
- The first £7.5m of the existing £40m Amended Loan Facility (defined below) drawn down from ZQ Capital and Southern Fox (the "Lenders")
- Successful discussions with the Lenders have led to an agreement for a further £15m of the £40m Amended Loan Facility to be drawn down during Q2 calendar year 2024

Manuel Llobet, CEO at Allergy Therapeutics, stated: *2023 has been an important year, marked by a highly focused approach to our business priorities, and a steadfast commitment to our Grass and Peanut allergy R&D programmes. We have navigated the challenges of last year, resulting in more streamlined operations and improved cost-effectiveness. This progress starts to pave the way towards a return to growth.*

The successful completion of the pivotal Phase III G306 trial for Grass MATA MPL, meeting its primary endpoint, and the continuous clinical advancements in our VLP Peanut R&D programme, are a testament to our innovative capabilities. The progress in the development of these two treatments

testament to our innovative capabilities. The progress in the development of these two treatments reaffirms the purpose of our work, to transform the lives of people with allergies and those around them.

None of this could have been achieved without the resilience, commitment, and passion of our R&D team, all employees across the Group and our Board. I am proud of the progress the Company has made in a difficult year.

Finally, thank you to our shareholders who have remained supportive of the Company throughout the period, including in the Equity Financing completed in October.

Financial Review

Revenue for the six months ended 31 December 2023 was £33.6m (2023 H1: £39.9m) representing a reduction of 16% on a reported and constant currency basis. This decrease in revenue is due to the previously reported manufacturing capacity that needed to be allocated to investigational medicinal product batches for use in clinical trials and the ongoing programme of continuous improvement across the supply chain and quality systems paving the way for increased capacity. Demand for the Company's products continues to be robust with the revenue achieved being limited by manufacturing capacity constraints. As previously announced a further increase in investment in plant and equipment is also planned to support the continuing improvements in manufacturing and quality which will be a multi-year investment. The focus has been on higher value products and markets, which are expected to enhance future profitability.

Cost of sales reduced to £13.1m (2023 H1: £14.1m) as a consequence of the reduced volumes allocated to manufacturing commercial sales batches.

Sales, marketing and distribution costs were lower than the prior period at £10.2m (2023 H1: £13.2m) mainly as a result of reduced marketing and promotional activity. Administrative expenses reduced to £11.1m (2023 H1: £11.9m) due to continued cost control initiatives. Exceptional costs were £0.4m (2023 H1: £0.4m) as a result of the ongoing review of funding options.

The operating loss pre-R&D and exceptional costs was £0.1m (2023 H1: £1.0m operating profit pre-R&D and exceptional costs). This loss was mitigated by the successful efforts to reduce distribution and administrative costs through cost control initiatives implemented over the past year.

Research and development costs increased to £11.4m (2023 H1: £8.5m) mainly due to the Group's pivotal G306 Phase III trial of Grass MATA MPL which successfully met its primary endpoint as previously announced on 14 November 2023.

The operating loss was £11.9m (2023 H1: £8.0m), and the loss before tax was £14.9m (2023 H1: £8.2m). The tax charge of £0.7m (2023 H1: £0.3m) relates to the overseas subsidiaries.

At 31 December 2023, the Group had cash of £13.5m (30 June 2023: £14.8m) and debt of £1.6m (30 June 2023: £27.1m). This debt reduction was achieved through the successful completion of the Equity Financing to restructure the Group's balance sheet.

The operating cash outflow was £10.8m and investing outflow £1.8m, offset by a net inflow of £11.2m from the net proceeds of the issue of equity shares and repayment of shareholder loans.

The Company completed the £40.75m Equity Financing on 13 October 2023, proceeds of which were used to repay amounts drawn at that time under the original loan facility ("Loan Facility") arranged with the Lenders.

The Loan Facility agreement was amended twice (the "Amended Loan Facility"), as first announced in a circular on 27 September 2023 and subsequently on 27 December 2023.

The Amended Loan Facility provides £40m available to be drawn down from 15 January 2024 until 15 January 2026 with interest payable semi-annually at 12 per cent. per annum and a repayment date of 15 January 2027. Under the attached warrant instrument, on each drawdown under the Amended Loan Facility the Lenders are issued 25 warrants for each £1 drawn down up to a maximum of 1,000,000,000 warrants. The warrants entitle the holders to subscribe for new ordinary shares at a price of 4 pence

per share and are exercisable in whole or in part from 1 July 2024 until 15 January 2027.

£7.5m is currently drawn down under the Amended Loan Facility. The Lenders and the Company have also agreed to a further drawdown of £15m from the Amended Loan Facility, expected during April 2024. Following this drawdown, the Group expects that additional funding will be required during Q1 FY2025 for trading, working capital, capital expenditure and continuing R&D programmes.

The Directors have applied the going concern principle in preparing the interim results for the six months ended 31 December 2023, however there is material uncertainty due to the need for additional near-term funding and the balance of the Amended Loan Facility currently being uncommitted.

R&D Programme Updates

The Group announced in December 2023 the positive primary and secondary endpoint outcomes of the G306 pivotal Phase III trial investigating Grass MATA MPL. This pivotal Phase III trial assessed efficacy of the Group's wholly owned short-course grass pollen immunotherapy, Grass MATA MPL.

The data gathered was highly consistent with that seen in prior trial data. The Group is collating a full data package for regulatory submission and discussions with regulators ahead of planned market authorisation application are ongoing. The Group expects to be the first company to register SCIT Grass immunotherapy under the Therapie Allergene Verordnung (TAV) programme.

Preparations are also ongoing for the initiation of the G308 combined short-term and long-term paediatric clinical trial that is due to commence in Q2 2024. This trial is designed to support a paediatric indication for the Group's Grass MATA MPL product and to also provide long-term efficacy and disease modifying data. This trial will meet the previously communicated requirements of Paediatric Committee for a paediatric registration in Germany.

The VLP Peanut R&D programme is further advancing and in March 2024 the Group announced that subcutaneous dosing of peanut allergic patients had begun in the Phase I/IIa PROTECT trial without any relevant safety issues. The PROTECT trial is designed to evaluate the novel virus-like particle (VLP)-based peanut allergy vaccine candidate ("VLP Peanut").

The PROTECT trial is being executed in the US and conducted in both healthy volunteers and peanut allergic patients and consists of Part A and Part B.

- Part A of the clinical trial is open-label and involves ascending doses of subcutaneous immunotherapy (SCIT) dosing of VLP Peanut in healthy volunteers (Group A1) and skin-prick testing in peanut allergic patients (Group A2).

- Part B of the clinical trial is double-blind, placebo-controlled and is being conducted in subjects with peanut allergy. Part B includes an innovative biomarker part to support clinical proof of concept, in collaboration with the renowned allergy laboratories at Johns Hopkins University (US) and Imperial College (UK).

Dosing in Group A2 of PROTECT was recently completed and results have been well-received in scientific forums and are submitted for publication in the prestigious Journal of Allergy and Clinical Immunology. Part A1 has progressed well, with 2 cohorts of healthy subjects having successfully completed up-dosing up to 25-fold the starting dose. Following an external safety review committee, it was determined that it was safe to proceed with incremental subcutaneous dosing in healthy subjects in subsequent cohorts and to start dosing in peanut allergic patients in the Phase IIa part of the trial (Group B).

Outlook

In the second half of the financial year, sales are expected to be slightly higher than the previous year. Consequently, overall sales for the full year ending on 30 June 2024 are expected to be slightly lower than the corresponding period ending 30 June 2023. The Group will continue with cost control initiatives but will undertake selective investments such as the programme of continuous improvement across the supply chain and quality systems paving the way for increased capacity. This is an ongoing multi-year project.

year project.

The Group's R&D programmes, including the G306 Phase III trial, the upcoming G308 paediatric clinical trial, and the PROTECT trial, continue to progress the Company's efforts towards its strategic goals of strengthening our pipeline and expanding in Europe.

The ongoing discussions surrounding further funding, coupled with the financing provided by our major shareholders under the Amended Loan Facility underline the confidence held in the Group and the future potential that can be leveraged from the R&D pipeline. The Group is planning for success, and preparations are underway for relevant health authority submissions that will support the unmet need in the market for allergic patients.

This announcement contains inside information for the purposes of the UK Market Abuse Regulations.

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About Allergy Therapeutics

Allergy Therapeutics is an international commercial biotechnology company, headquartered in the UK, 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, house dust mite and peanut. For more information, please see www.allergytherapeutics.com.

ALLERGY THERAPEUTICS PLC

Consolidated income statement

	6 months to 31 Dec 2023 £'000 Unaudited	6 months to 31 Dec 2022 £'000 Unaudited	12 months to 30 Jun 2023 £'000 Audited
Revenue	33,572	39,901	59,587
Cost of sales	(13,052)	(14,118)	(26,342)
Gross profit	20,520	25,783	33,245

Gross profit	20,520	25,765	53,243
Sales, marketing and distribution costs	(10,222)	(13,237)	(23,705)
Administration expenses	(11,138)	(11,863)	(25,179)
Research and development costs	(11,386)	(8,498)	(20,121)
Exceptional costs - adjustment to provision	-	-	(2,069)
Exceptional fundraising costs	(420)	(424)	(2,681)
Other income	760	282	856
Operating loss	(11,886)	(7,957)	(39,654)
Finance income	159	155	329
Finance expense	(3,189)	(398)	(2,441)
Loss before tax	(14,916)	(8,200)	(41,766)
Income tax	(735)	(306)	(1,305)
Loss for the period	(15,651)	(8,506)	(43,071)
Loss per share			
Basic (pence per share)	(0.58)p	(1.29)p	(6.43)p
Diluted (pence per share)	(0.58)p	(1.29)p	(6.43)p

Consolidated statement of comprehensive income

	6 months to 31 Dec 2023 £'000 Unaudited	6 months to 31 Dec 2022 £'000 Unaudited	12 months to 30 Jun 2023 £'000 Audited
Loss for the period	(15,651)	(8,506)	(43,071)
Items that will not be reclassified subsequently to profit or loss:			
Remeasurement of net defined benefit liability	(749)	479	603
Remeasurement of investments-retirement benefit assets	324	661	(867)
Revaluation gains - freehold land and buildings	-	-	428
Total other comprehensive loss	(425)	1,140	164
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	392	414	193
Total comprehensive loss	(15,684)	(6,952)	(42,714)

ALLERGY THERAPEUTICS PLC

Consolidated balance sheet

	31 Dec 2023 £'000 Unaudited	31 Dec 2022 £'000 Unaudited	30 Jun 2023 £'000 Audited
Assets			
Non-current assets			
Property, plant and equipment	23,392	22,096	23,241
Intangible assets - goodwill	3,364	3,407	3,346
Intangible assets - other	1,626	1,202	1,790
Investment - retirement benefit asset	5,346	7,042	4,866
Total non-current assets	33,728	33,747	33,243
Current assets			
Inventories	11,893	10,971	11,593
Trade and other receivables	9,934	11,697	7,088
Cash and cash equivalents	13,522	15,197	14,845
Total current assets	35,349	37,865	33,526
Total assets	69,077	71,612	66,769
Liabilities			
Current liabilities			
Trade and other payables	(20,088)	(14,299)	(16,683)
Current borrowings	(625)	(775)	(648)

Current borrowings	(635)	(775)	(648)
Lease liabilities	(1,115)	(1,132)	(1,155)
Provisions	(3,434)	-	-
Derivative financial instruments	-	(847)	(79)
Total current liabilities	(25,272)	(17,053)	(18,565)
Net current assets	10,007	20,812	14,961
Non-current liabilities			
Retirement benefit obligations	(8,685)	(8,179)	(7,917)
Deferred taxation liability	(463)	(402)	(454)
Provisions	(95)	(152)	(3,581)
Lease liabilities	(7,152)	(6,669)	(7,747)
Long term borrowings	(948)	(1,199)	(26,439)
Total non-current liabilities	(17,343)	(16,601)	(46,138)
Total liabilities	(42,615)	(33,654)	(64,703)
Net assets	26,462	37,958	2,066
Equity			
Capital and reserves			
Issued share capital	4,776	689	689
Share premium	154,672	119,029	119,030
Merger reserve	40,128	40,128	40,128
Reserve - share based payments	-	2,824	2,906
Revaluation reserve	1,501	1,073	1,501
Reserve - warrants	412	-	412
Foreign exchange reserve	(338)	(509)	(730)
Retained earnings	(174,689)	(125,276)	(161,870)
Total equity	26,462	37,958	2,066

ALLERGY THERAPEUTICS PLC

Consolidated statement of changes in equity

	Issued share Capital	Share premium	Merger reserve	Reserve - share based payment	Revaluation reserve	Reserve - warrants	Foreign exchange reserve	Retained earnings	Total equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
At 31 December 2022	689	119,029	40,128	2,824	1,073	-	(509)	(125,276)	37,958
Exchange differences on translation of foreign operations	-	-	-	-	-	-	(221)	-	(221)
Valuation gains taken to equity (land and buildings) - net of deferred tax	-	-	-	-	428	-	-	-	428
Remeasurement of net defined benefit liability	-	-	-	-	-	-	-	124	124
Remeasurement of investments - retirement benefit assets	-	-	-	-	-	-	-	(2,160)	(2,160)
Total other comprehensive loss	-	-	-	-	428	-	(221)	(2,036)	(1,829)
Loss for the period after tax	-	-	-	-	-	-	-	(34,565)	(34,565)
Total comprehensive loss	-	-	-	-	428	-	(221)	(36,601)	(36,394)
Share based payments	-	-	-	89	-	-	-	-	89
Shares issued	-	1	-	-	-	-	-	-	1
Transfer of lapsed options						-			

to retained earnings	-	-	-	(7)	-		-	7	-
Warrants issued	-	-	-	-	-	412	-	-	412
At 30 June 2023	689	119,030	40,128	2,906	1,501	412	(730)	(161,870)	2,066
Exchange differences on translation of foreign operations	-	-	-	-	-	-	392	-	392
Remeasurement of net defined benefit liability	-	-	-	-	-	-	-	(749)	(749)
Remeasurement of investments - retirement benefit assets	-	-	-	-	-	-	-	324	324
Total other comprehensive loss	-	-	-	-	-	-	392	(425)	(33)
Loss for the period after tax	-	-	-	-	-	-	-	(15,651)	(15,651)
Total comprehensive loss	-	-	-	-	-	-	392	(16,076)	(15,684)
Share based payments	-	-	-	351	-	-	-	-	351
Transfer of lapsed options to retained earnings	-	-	-	(3,257)	-	-	-	3,257	-
Shares issued	4,087	36,672	-	-	-	-	-	-	40,759
Share issue costs	-	(1,030)	-	-	-	-	-	-	(1,030)
At 31 December 2023	4,776	154,672	40,128	-	1,501	412	(338)	(174,689)	26,462

ALLERGY THERAPEUTICS PLC

Consolidated cash flow statement

	6 months to 31 Dec 2023 £'000 Unaudited	6 months to 31 Dec 2022 £'000 Unaudited	12 months to 30 Jun 2023 £'000 Audited
Cash flows from operating activities			
Loss before tax	(14,916)	(8,200)	(41,766)
Adjustments for:			
Finance income	(159)	(155)	(329)
Finance expense	3,189	398	2,441
Non-cash movements on defined benefit pension plan	(160)	(142)	(79)
Depreciation and amortisation	2,114	2,102	4,224
Net monetary value of above the line R&D tax credit	(760)	(282)	(856)
Charge for share based payments	351	25	114
Payments for retirement benefit investments	-	-	(159)
Movement in fair value of derivative financial instruments	(79)	731	(37)
(Increase)/decrease in trade and other receivables	(3,307)	(1,042)	3,380
(Increase) in inventories	(255)	611	(183)
Increase in trade and other payables	3,174	(1,405)	4,818
Net cash used by operations	(10,808)	(7,359)	(28,432)
Income tax received/(paid)	34	(92)	(449)
Net cash used by operating activities	(10,774)	(7,451)	(28,881)
Cash flows from investing activities			
Interest received	69	18	82
Payments for intangible assets	-	(630)	-
Payments for property plant and equipment	(1,865)	(2,255)	(4,669)

Net cash used in investing activities	(1,796)	(2,867)	(4,587)
Cash flows from financing activities			
Net proceeds from issue of equity shares	39,731	6,488	6,489
Repayment of bank loan borrowings	(333)	(533)	(961)
Interest paid on loan borrowings	(1,646)	(137)	(2,117)
Repayment of principal on lease liabilities	(409)	(761)	(1,281)
Interest paid on lease liabilities	(159)	(160)	(334)
Proceeds from shareholder loan	14,075	-	36,000
Repayment of shareholder loan	(40,075)	-	(10,000)
Net cash generated in financing activities	11,184	4,897	27,796
Net decrease in cash and cash equivalents	(1,386)	(5,421)	(5,672)
Effects of exchange rates on cash and cash equivalents	63	103	2
Cash and cash equivalents at the start of the period	14,845	20,515	20,515
Cash and cash equivalents at the end of the period	13,522	15,197	14,845

1. Interim financial information

The unaudited consolidated interim financial information is for the six months ended 31 December 2023. 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 2023, which were prepared under International Financial Reporting Standards (IFRS) in issue as adopted by the UK and with those parts of the Companies Act 2006 that are relevant to the Group preparing its accounts in accordance with UK-adopted IFRS.

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.

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 in the annual financial statements for the year to 30 June 2023. 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 financial statements have been prepared on a going concern basis after considering the Group's and the Company's current cash position and reviewing budgets and cash flow forecasts for a period of at least 12 months from the date of approval of these financial statements.

On 27 December the Group announced a second amendment to the Amended Loan Facility which provided for a £40m loan facility of which £7.5m would be initially committed, the remaining £32.5m uncommitted. The committed portion, being £7.5m, was drawdown in Q1 calendar year 2024. Successful discussions with the Lenders, post period, have led to an agreement for a further £15m of the £40m Amended Loan Facility to be drawn down during Q2 calendar year 2024. Interest accrues on the loan at 12% per annum with interest payments due every 6 months. Full repayment of the interest and principal is due by 15 January 2027.

The Directors have prepared cash flow forecasts for the period to 30 June 2025, which assume that the Group will be able to undertake additional financing activities. £7.5 million is currently drawn under the Amended Loan Facility. Following future drawdown of the recently agreed further £15m from the Amended Loan Facility, the Group expects that additional funding will be required during Q1 FY2025 onwards for trading, working capital, capital expenditure and continuing R&D programmes. The remaining uncommitted portion of the Amended Loan Facility, should it become committed, would

remaining uncommitted portion of the Amended Loan Facility, should it become committed, would provide sufficient funds for the 12-month going concern review period.

The Directors acknowledge that a material uncertainty exists over the Group's ability to access additional sources of finance, which will be required to fund trading, working capital, capital expenditure and continuing R&D programme.

The Directors have reasonable expectations that additional financing can be obtained for the Group and Company. Accordingly, they have prepared these financial statements on a going concern basis.

3. Loss per share

	6 months to 31 Dec 2023 Unaudited	6 months to 31 Dec 2022 Unaudited	12 months to 30 Jun 2023 Audited
Loss after tax attributable to equity shareholders (£'000)	(15,651)	(8,506)	(43,071)
Issued ordinary shares at start of the period ('000)	679,105	644,105	644,105
Ordinary shares issued in the period ('000)	4,087,335	35,000	35,000
Issued ordinary shares at end of the period ('000)	4,766,440	679,105	679,105
Weighted average number of shares in issue for the period	2,720,224	661,605	670,355
Weighted average number of shares for diluted earnings	2,720,224	661,605	670,355
Basic earnings per ordinary share (pence)	(0.58)p	(1.29)p	(6.43)p
Diluted earnings per ordinary share (pence)	(0.58)p	(1.29)p	(6.43)p

The diluted loss per share for 2023 does not differ from the basic loss per share as the exercise of share options would have the effect of reducing the loss per share and is therefore not dilutive under the terms of IAS 33.

4. Events after the balance sheet date

There were no disclosable events after the balance sheet date other than the drawdown of funds and agreement for further drawdown discussed in note 2 to the unaudited consolidated interim financial information above.

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