RNS Number: 0740D Allergy Therapeutics PLC 19 June 2023

Allergy Therapeutics PLC

Allergy Therapeutics plc

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

Interim Results for the six months ended 31 December 2022 and Lifting of Suspension in Trading

19 June 2023: Allergy Therapeutics plc (AIM: AGY), the integrated commercial biotechnology company specialising in allergy vaccines, announces its unaudited interim results for the six months ended 31 December 2022 and expected restoration of trading in the Company's ordinary shares on AIM with effect from 7.30am today.

Financial Review

Revenue for the first half of the financial year was 18% lower at £39.9m (2022 H1: £48.7m) as a consequence of the short-term pause in production in October 2022.

Cost of sales increased to £14.1m (2022 H1: £12.8m), with an ongoing programme of continuous improvement across the supply chain and quality systems, together with higher labour costs.

Gross profit decreased by 28% to £25.8m (2022 H1: £35.9m), which represents a gross margin of 65% (2022 H1: 74%), reflecting reduced absorption of fixed production overheads on lower revenue.

Sales, marketing and distribution costs were slightly higher at £13.2m (2022 H1: £13.1m) as a result of higher labour costs offset by cost savings. Administrative expenses increased to £11.9m (2022 H1: £10.6m), resulting from increased IT spend to improve productivity and security. Research and development costs increased to £8.5m (2022 H1: £5.0m), including initiation of the G306 Pollinex Quattro grass study. Exceptional costs were £0.4m (2022 H1: £nil) from the ongoing review of funding options.

The operating profit pre-R&D of £0.5m (2022 H1: £12.5m) reflects the decline in revenue caused by the short-term pause in production, together with increased manufacturing, administrative and exceptional costs.

Research and development costs increased to £8.5m (2022 H1: £5.0m), mainly due to initiation of the G306 Pollinex Quattro grass study and preparation for the P101 peanut study.

The operating loss was £8.0m (2022 H1: £7.4m, profit), and the loss before tax was £8.2m (2022 H1: £7.3m, profit). The tax charge of £0.3m (2022 H1: £0.6m) relates to the overseas subsidiaries. The basic loss per share was 1.29 pence per share (2022 H1: 1.04 pence per share, gain).

Property, plant and equipment increased to £22.1m (30 June 2022: £20.2m), mainly as a result of ongoing construction of the energy centre in the UK, offset by depreciation.

The investment in the retirement benefit asset increased to £7.0m (30 June 2022: £6.0m), reflecting investment returns and corporate contributions. Retirement benefit obligations relating to the German pension scheme were slightly lower at £8.2m (30 June 2022: £8.3m).

Net assets excluding cash have increased to £22.8m (30 June 2022: £17.9m), mainly due to capital investment and changes to pension assets and liabilities.

There was an energiting each cutflow of £7.5m caused by the decline in profitability. After capital expanditure of

£2.9m, gross share proceeds of £7.0m, financing costs of £0.5m and repayment of loans of £0.5m, there was a net decrease in cash and cash equivalents of £5.4m.

At 31 December 2022, the Group had cash of £15.2m (30 June 2022: £20.5m) and debt of £2.0m (30 June 2022: £2.4m).

Pursuant to the subscription and debt financing announced in September 2022, the Company received £6.5m of net share proceeds from the issue of new ordinary shares in October 2022 and received £10m from the issue of loan notes on 28 February 2023, together with the issue of 33,333,332 warrants to subscribe for new ordinary shares at a warrant exercise price of 30 pence per warrant.

On 6 April 2023, the Group entered into a senior secured facility agreement in an aggregate principal amount of £40.75m to refinance the existing £10 million loan notes issued on 28 February 2023, to continue key clinical trials, to finance trading and to provide working capital. The NatWest revolving credit facility has been cancelled to provide security for the new funding.

In conjunction with the senior secured facility agreement, the Company also entered into an equity commitment agreement to raise gross proceeds of £40.75m, which will be principally used to repay the amounts owed pursuant to the senior secured facility agreement.

The Company also entered into an agreement with the lenders to pay a substantial finance premium on the principal amount outstanding in the event that there is a successful G306 data read-out, and the Company intends to complete the equity financing and repay all amounts outstanding under the facility agreement to avoid the contingent payment, subject to various conditions.

The Directors have applied the going concern principle in preparing the interim results for the six months ended 31 December 2022, however there is material uncertainty for the following reasons:

- the need for additional near-term funding;
- the risk that existing investors are unwilling or unable to provide further funds;
- the risk that foreign direct investment clearance required for the equity raise is not obtained meaning that the Group is unable to repay the loan or the contingent payment for the successful G306 read-out.
- the risk that the results of the G306 read-out are unsuccessful meaning that the required additional near-term funding is not able to be raised;

Outlook

Owing to the seasonality of the pollen allergy market, approximately one third of revenue is generated in the second half of the financial year. Compared to the prior comparable period, the Group expects sales for the second half year to 30 June 2023 to continue at a slightly improved trend when compared with the trend seen for the first half of the year, with correspondingly lower gross margins. Overheads before R&D and exceptionals are expected to be similar to the first half year.

As a result of the manufacturing capacity that needs to be allocated to clinical batches, sales for the financial year to 30 June 2024 are expected to be slightly lower than the comparable period, with consequently reduced gross margins, while overheads before R&D and exceptionals are expected to be similar. The investment in clinical trials for the G306 grass study, G308 paediatric study, B302 birch study and P101 peanut study will result in a stepped increase in R&D costs. Further investment in plant and equipment is planned to support the continuing improvements in manufacturing and quality.

With over 90% of revenues and approximately 50% of costs (excluding research and development costs) denominated in euros, and approximately 60% of research and development costs denominated in US dollars, movements in the currency markets have an effect on the Group's operational finances, which are partially managed in the near-term by foreign currency forward contracts.

Notwithstanding the recent loan funding and planned equity refinancing of the loan, the Group expects that additional funding will be required from around September 2023 onwards for trading, working capital, capital expenditure and continuing R&D programmes. Discussions have commenced with certain shareholders on providing additional funding; these discussions are at an early stage with no binding arrangements but have been positive.

Lifting of Suspending in Trading

As a result of publication of the 2022 Annual Report and Accounts and publication of these Interim Results, trading in the Company's ordinary shares on AIM is expected to be restored with effect from 7.30am today.

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.

6 months to 6 months to 12 months

ALLERGY THERAPEUTICS PLC

Consolidated income statement

	6 months to	6 months to	12 months
	31 Dec	31 Dec	to 30 Jun 2022
	2022	2021	
	£'000	£'000	£'000
	Unaudited	Unaudited	Audited
Revenue	39,901	48,696	72,768
Cost of sales	(14,118)	(12,786)	(23,262)
		,	
Gross profit	25,783	35,910	49,506
Calca marketing and distribution costs	(12 227)	(12.000)	(26,004)
Sales, marketing and distribution costs	(13,237)	(13,080)	(26,004)
Administration expenses	(11,863)	(10,630)	(20,828)
Research and development costs	(8,498)	(5,033)	(15,659)
Exceptional costs	(424)	250	740
Other income	282	250	740
Operating (loss)/profit	(7,957)	7,417	(12,245)
Finance income	155	53	257
Finance expense	(398)	(204)	(669)
· ····································	(000)	(=0.)	(000)
(Loss)/profit before tax	(8,200)	7,266	(12,657)
Income tax	(306)	(595)	(1,119)
/I acc \Invalid for the nation	(Q FNA)	£ £71	(12 776)

(Loss)/profit for the period	(0,000)	U,U <i>I</i> I	(13,110)
(Loss)/earnings per share Basic (pence per share) Diluted (pence per share)	(1.29)p (1.29)p	1.04p 0.97p	(2.14)p (2.14)p
Consolidated statement of comprehensive income	6 months to	6 months to	12 months
	31 Dec	31 Dec	to 30 Jun 2022
	2022 £'000 Unaudited	2021 £'000 Unaudited	£'000 Audited
(Loss)/profit for the period Items that will not be reclassified subsequently to profit or loss:	(8,506)	6,671	(13,776)
Remeasurement of net defined benefit liability Remeasurement of investments-retirement benefit assets Total other comprehensive income/(loss) Items that may be reclassified subsequently to profit or	479 661 1,140	(498) (58) (556)	3,094 (193) 2,901
loss: Exchange differences on translation of foreign operations	414	1	265
Total comprehensive (loss)/income ALLERGY THERAPEUTICS PLC	(6,952)	6,116	(10,610)
Consolidated balance sheet			
	31 Dec 2022 £'000 Unaudited	31 Dec 3 2021 £'000 Unaudited	0 Jun 2022 £'000 Audited
Assets Non-current assets Property, plant and equipment Intangible assets - goodwill Intangible assets - other	22,096 3,407 1,202	18,992 3,374 791	20,190 3,347 1,688
Investment - retirement benefit asset	7,042	5,726	5,962
Total non-current assets	33,747	28,883	31,187
Current assets Inventories Trade and other receivables Cash and cash equivalents Derivative financial instruments	10,971 11,697 15,197	10,602 10,773 41,385 330	11,410 10,468 20,515
Total current assets	37,865	63,090	42,393
Total assets	71,612	91,973	73,580
Liabilities Current liabilities Trade and other payables	(14,299)	(14,942)	(15,669)
Current borrowings Lease liabilities	(775) (1,132)	(1,008) (654)	(952) (1,316)
Derivative financial instruments	(847)		(116)
Total current liabilities	(17,053)	(16,604)	(18,053)
Net current assets	20,812	46,486	24,340
Non-current liabilities Retirement benefit obligations Deferred taxation liability Non-current provisions Lease liabilities Long term borrowings	(8,179) (402) (152) (6,669) (1,199)	(11,590) (387) (150) (6,398) (1,870)	(8,319) (406) (144) (6,764) (1,497)
Total non-current liabilities	(16,601)	(20,395)	(17,130)
Total liabilities	(33,654)	(36,999)	(35,183)
Net assets	37,958	54,974	38,397
Equity Capital and reserves Issued share capital Share premium Merger reserve Reserve - share based payments	689 119,029 40,128 2,824	652 112,576 40,128 3,015	654 112,576 40,128 2,799

ALLERGY THERAPEUTICS PLC

Consolidated statement of changes in equity

							1	
	Issued share Capital	Share premium	Merger reserve	Reserve - share based payment	Revaluation reserve	Foreign exchange reserve	Retained earnings	Total equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
At 31 December 2021	652	112,576	40,128	3,015	1,073	(1,187)	(101,283)	54,974
Exchange differences on translation of foreign operations Valuation gains taken to equity (land and buildings) - net of	-	-	-	-	-	264	-	264
deferred tax	-	-	-	-	-	-	-	-
Remeasurement of net defined benefit liability Remeasurement of	-	-	-	-	-	-	3,592	3,592
investments - retirement benefit assets		-		-		-	(135)	(135)
Total other comprehensive income	-	-	-	-	-	264	3,457	3,721
Loss for the period		-	-	-	-	-	(20,447)	(20,447)
Total comprehensive income	-	-	-	-	-	264	(16,990)	(16,726)
Share based payments	-	-	-	147	-	-	-	147
Shares issued Transfer of lapsed options	2	-	-	- (200)	-	-	-	2
To retained earnings Transfer of depreciation	-	-	-	(363)	-	-	363	-
on revalued property		-	-	-	-	-	-	
At 30 June 2022	654	112,576	40,128	2,799	1,073	(923)	(117,910)	38,397
Exchange differences on translation of foreign operations	_	_	_	_	_	414	_	414
Remeasurement of net defined benefit liability Remeasurement of	-	-	-	-	-	-	479	479
investments - retirement benefit assets		-				-	661	661
Total other comprehensive income	-	-	-	-	-	414	1,140	1,554
Loss for the period		-	-	-	-	-	(8,506)	(8,506)
Total comprehensive income	-	-	-	-	-	414	(7,366)	(6,952)
Share based payments	-	_	-	25	-	-	-	25
Shares issued	35	6,965	-	-	-	-	-	7,000
Share issue costs		(512)		-	-			(512)
At 31 December 2022	689	119,029	40,128	2,824	1,073	(509)	(125,276)	37,958

ALLERGY THERAPEUTICS PLC

Cash flows from operating activities			
(Loss)/profit before tax	(8,200)	7,266	(12,657)
Adjustments for:			
Finance income	(155)	(53)	(257)
Finance expense Non-cash movements on defined benefit pension plan	398 (142)	204 29	669 (23)
Depreciation and amortisation	2,102	2,400	4,166
Net monetary value of above the line R&D tax credit	(282)	(250)	(740)
Charge for share based payments	25	322	`469
Movement in fair value of derivative financial instruments	731	150	641
(Profit)/loss on disposal of fixed asset (Increase) in trade and other receivables	- (1,042)	(4,971)	8 (4,246)
Decrease/(increase) in inventories	(1,042) 611	(4,971)	(572)
(Decrease) in trade and other payables	(1,405)	(1,385)	(1,067)
Net code (code)/componented by components	(7.050)	2.744	(42,000)
Net cash (used)/generated by operations	(7,359)	3,744	(13,609)
Income tax (paid)/received	(92)	119	(213)
Net cash (used)/generated by operating activities	(7,451)	3,863	(13,822)
Cash flows from investing activities			
Interest received	18	53	58
Payments for retirement benefit investments	-	(87)	(179)
Payments for intangible assets	(630)	(151)	-
Payments for property plant and equipment	(2,255)	(996)	(3,056)
Net cash used in investing activities	(2,867)	(1,181)	(3,177)
Cash flows from financing activities			
Net proceeds from issue of equity shares	6,488	1	3
Repayment of bank loan borrowings	(533)	(466)	(957)
Interest paid on bank loan borrowings	(137)	(204)	(168)
Repayment of principal on lease liabilities Interest paid on lease liabilities	(761) (160)	(878) (140)	(1,311) (373)
interest paid on lease liabilities	(100)	(140)	(373)
Net cash generated/(used) in financing activities	4,897	(1,687)	(2,806)
Net (decrease)/ increase in cash and cash equivalents	(5,421)	995	(19,805)
Effects of exchange rates on cash and cash equivalents	103	117	47
Cash and cash equivalents at the start of the period	20,515	40,273	40,273
Cash and cash equivalents at the end of the period	15,197	41,385	20,515

1. Interim financial information

The unaudited consolidated interim financial information is for the six months ended 31 December 2022. 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 2022, 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.

The annual report and accounts for the year ended 30 June 2022 included a qualification for limitation of scope in respect of the carrying value of insurance policy assets related to the pension scheme of the Group's German subsidiary. The Board of Directors made relevant enquiries of the scheme's insurer and were unable to obtain all of the relevant information required under IAS (UK) 500 about the controls and valuation of the underlying assets at 30 June 2022, therefore were unable to obtain sufficient, appropriate audit evidence.

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 2022. 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 4 October 2022, the Group announced that it had proactively paused production at the Freeman facility, part of its Worthing, UK manufacturing site, in order to accelerate ongoing site improvements and to maintain regulatory compliance. The pause in manufacturing occurred during a period of peak production prior to the start of the pollen season in the Spring. As a consequence, the production pause will have a material impact upon the Group's revenue and cashflow for the year ending 30 June 2023.

Despite the completion of the £7m equity raise and £10m of loan notes announced on 17 October 2022, the manufacturing pause resulted in the Group requiring additional funding to continue with the planned R&D clinical trials. In addition, at the expected reduced levels of underlying profit, excluding research and development costs, the terms of the £10m NatWest revolving credit facility would not allow use of the facility.

As a result, on 6 April 2023, the Group announced it had signed a loan agreement with certain shareholders for £40.75m, incurring interest at 18% per annum and with full repayment of the principal outstanding and any accrued interest in December 2025. The loan is fully secured against substantially all assets of the Company and its subsidiaries incorporated in England and Wales by way of an English-law governed debenture. The NatWest revolving credit facility has been cancelled to release the necessary security.

The Directors have prepared cash flow forecasts for the period to 30 June 2024, which assume that the Group will be able to undertake a planned equity financing of £40.75m during the going concern period to re-finance the £40.75m shareholder loan, however the Group expects that additional financing will be required from around September 2023 onwards.

The Directors acknowledge that a material uncertainty exists over the Group's ability to access additional sources of finance, which will be required regardless of the outcome of the Phase III G306 trial and regardless of the planned equity financing after obtaining the necessary foreign direct investment ("FDI") regulatory approvals.

Under the terms of a contingent payment letter entered into with the lenders of the shareholder loan, the Group will be obligated to pay a substantial finance premium ("G306 contingent payment") equal to 250% of the principal amount of the loan outstanding on a successful data read-out of the Phase III G306 trial, if any principal remains outstanding under the terms of the loan agreement at 6 January 2024.

The planned equity financing for £40.75m is conditional on obtaining certain foreign direct investment ("FDI") regulatory approvals and completing the equity refinancing by 6 January 2024 and, if not obtained prior to the read-out of the Phase III G306 trial, the equity financing is also conditional on a successful Phase III G306 outcome. Should the equity financing not proceed, it is unlikely that the Group will be able to pay the G306 contingent payment should it crystallise. If the Group is unable to secure an alternative funding solution to repay the amounts due under the shareholder loan, the Group may be subject to, inter alia, possible insolvency and loss of ownership of its assets, over which security has been granted pursuant to the loan.

The Directors have reasonable expectations that the Phase III G306 trial will be successful and that appropriate additional financing can be obtained for the Group and Company. Accordingly, they have prepared these financial statements on a going concern basis.

There are, however, currently no binding arrangements in place for additional funding over and above the equity financing and no guarantees that existing shareholders will be willing, or able, to provide further funds.

It is therefore considered that material uncertainties exist which may cast significant doubt on the Group's and the Company's ability to continue as a going concern and therefore they may be unable to realise their assets and discharge their liabilities in the normal course of business. The financial statements do not include any adjustments that would result from the basis of preparation being inappropriate.

	6 months to	6 months to	12 months to
	31 Dec 2022	31 Dec 2021	30 Jun 2022
	Unaudited	Unaudited	Audited
(Loss)/profit after tax attributable to equity shareholders (£'000)	(8,506)	6,671	(13,776)
Issued ordinary shares at start of the period ('000)	644,105	641,773	641,773
Ordinary shares issued in the period ('000)	35,000	1,824	2,332
Issued ordinary shares at end of the period ('000)	679,105	643,597	644,105
Weighted average number of shares in issue for the period Weighted average number of shares for diluted earnings	661,605	641,794	642,990
	661,605	686,135	642,990
Basic earnings per ordinary share (pence) Diluted earnings per ordinary share (pence)	(1.29)p	1.04p	(2.14)p
	(1.29)p	0.97p	(2.14)p

The diluted loss per share for 2022 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. Contingent liabilities

In a letter dated 3 February 2023, the Group's German subsidiary received notification from the German national health insurance association which indicated that manufacturer's rebates are due on sales of certain products launched on the market from 1 September 2017. After taking legal advice, the Group considers the likelihood of any payment of a rebate or other cash outflow in relation to this matter, in respect of the period prior to 30 June 2022, to be below 50% and no provision has been made in the financial statements for the six months ended 31 December 2022. In respect of net revenue relating to certain products, there is a risk that up to £13.6m cumulative revenue recognised in periods up to and including 31 December 2022 may be reversed due to the level of rebate being applied.

5. Events after the balance sheet date

On 6 April 2023, the Company entered into a senior secured facility agreement pursuant to which the Company's existing substantial shareholders ZQ Capital Management Limited (acting through its affiliate SkyGem International Holdings Limited) and Southern Fox Investments Limited, agreed to make available to the Company a secured term loan facility in an aggregate principal amount of £40.75 million. The purpose of the facility was to refinance the existing £10 million loan notes issued on 28 February 2023, to facilitate the continuation of the Group's pivotal Phase III G306 trial for Grass MATA MPL, to continue other key clinical trial activities including the Phase I study for Peanut allergy and to finance trading and provide working capital. The NatWest revolving credit facility has been cancelled to facilitate the new funding.

In conjunction with the facility agreement, the Company also entered into an equity commitment agreement with ZQ Capital Management Limited (acting through its affiliate SkyGem International Holdings Limited) and Southern Fox Investments Limited to conditionally subscribe for new ordinary shares of 0.1 pence each in the capital of the Company at an issue price of 1 pence per new share to raise gross proceeds of £40.75 million. The equity financing is comprised of a direct subscription by each of ZQ Capital Management Limited and Southern Fox Investments Limited for, in aggregate, 3,385,510,000 new shares at the issue price and an open offer, where qualifying shareholders (excluding the three largest shareholders ZQ Capital Management Limited, Southern Fox Investments Limited and Abbott Laboratories (together Abbott Laboratories (Chile) Holdco SPA and Yissum Holdings Limited)) will be offered the opportunity to subscribe for up to 689,490,000 new shares at the issue price. The proceeds of the equity financing will be principally used to repay the amounts owed under the facility agreement, including principal amounts and accrued interest.

Under the terms of a contingent payment letter entered into between the Company and the Lenders in connection with the facility agreement, the Company will be obligated to pay a substantial finance premium equal to 250 per cent of the principal amount of the loan outstanding under the facility to the Lenders on a successful G306 data read-out if at such time any principal remains outstanding under the terms of the facility agreement. The Company therefore intends, subject to satisfaction (or waiver, if capable of being waived) of the equity conditions, to complete the equity financing and repay all amounts outstanding under the facility agreement within nine months of the date of the facility agreement, thereby avoiding the contingent payment being triggered.

On 27 April 2023, the Company received shareholder approval for the issue of equity, but the equity funding remains conditional on FDI clearances.

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