RNS Number: 6716V Allergy Therapeutics PLC

06 April 2023

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Allergy Therapeutics PLC

Allergy Therapeutics plc

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

Trading and Business Update Update on Annual Report and Accounts

6 April 2023: Allergy Therapeutics plc (AIM: AGY), the fully integrated commercial biotechnology company specialising in allergy vaccines, is today providing a trading and business update.

<u>2022 Accounts</u> On 29 September 2022, the Company announced its unaudited preliminary results for the year ended 30 June 2022 (the "Preliminary Results") and a £17 million financing consisting of a subscription for new ordinary shares to raise £7 million and an issue of loan notes to raise £10 million (with the loan notes being issued on 28 February 2023).

Subsequent to the financing in September 2022, the Company announced a material reduction in revenue as a consequence of a short-term pause in production and the requirement for significant additional near-term funding. The Company has had ongoing funding discussions and expects to make a further announcement shortly regarding

The Company is actively working with its auditors to finalise the audit and publication of its annual report and accounts for the year ended 30 June 2022 (the "2022 Accounts"), which have been delayed pending new funding. Once new funding has been secured, the Directors expect to finalise the 2022 Accounts on a going concern basis but subject to material uncertainty in view of the need for additional funding within the next 12 months to support operations and the continuing R&D programme.

While the Company is not aware of any material change that will be required to be made to the Preliminary Results, the 2022 Accounts may include 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, Bencard Allergy GmbH ("Bencard"). The pension scheme assets are recorded in the Bencard accounts based on valuations that are acceptable under German GAAP, however the auditors have been unable to obtain sufficient, appropriate audit evidence in relation to the valuation of the insurance policy assets in the Group accounts under IFRS, which the Company is working to resolve. As in previous years, the 2022 Accounts are expected to include a note regarding a contingent liability in respect of rebates on sales of certain products in Germany. The national health insurance association has recently contacted Bencard regarding these rebates and the level of rebates incurred by Bencard is expected to reduce reported group revenue moderately from the second half of the financial year to 30 June 2023.

<u>Half Year and Current Trading Update</u>
As previously announced, the unaudited interim results for the six months ended 31 December 2022 are expected to record revenue of £39.9 million (2021: £48.7 million), with the reduction in revenue primarily caused by the unplanned short-term pause in production during October and November 2022. Operating profit pre-R&D is expected to be £0.5 million (2021: £12.5 million) reflecting lower revenue, together with increased manufacturing and regulatory costs. The operating loss after R&D costs is expected to be £8.0 million (2021: £7.4 million profit), reflecting the increased development costs. The fully diluted loss per share is expected to be 1.29 pence per share (2021: 0.97 pence profit per share).

Compared to the prior comparable period, the Group expects sales for the second half year to 30 June 2023 to continue at a similarly reduced level as for the first half year, with correspondingly lower gross margins, while overheads before R&D are expected to be similar.

R&D Programme Updates

The VLP Peanut R&D programme is progressing, with the first application of the Group's innovative, short-course peanut allergy vaccine candidate in peanut allergic patients commencing in the Phase I PROTECT trial in March 2023. The first in human study is being conducted in several phases with safety, tolerability and preliminary proof of efficacy data for the unblinded cohorts expected by Q4 2023.

The pivotal Phase III G306 trial evaluating efficacy of the Group's wholly owned short-course grass pollen immunotherapy, Grass MATA MPL, began in Q3 2022, and the interim trial results are expected in Q4 2023. Recruitment of patients has been completed with expected numbers achieved in Germany, but lower numbers in other countries where recruitment started later than planned. The achieved number of randomised patients is comparable to other pivotal Phase III studies which were successful, and the powering of the study remains high. The Group remains positive as to the outcome of the G306 trial given the success of the G309 trial. Over two-thirds of the injections for the G306 trial have been completed.

The Group is starting preparations for a paediatric clinical study evaluating the efficacy of Grass MATA MPL in children to meet the previously communicated requirements of the German TAV regulatory framework (Therania опшате со тност ито ртомовому вознитичноваем точинатисть от ито вознаст или точинасту натнемогь (тнагарие Alleraene Verordnung).

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 for the next two financial years. The continued investment in these important trials forms part of our future regulatory commitments and, subject to completion of a safety database, enable access to the very significant US market.

<u>Manufacturing</u>
Following the resumption of manufacturing after the unplanned pause in production, the Group has been implementing a programme of continuous improvements across its supply chain and quality systems, which is designed to improve efficiency and enable future growth. With the transition from a named patient product framework towards a registered product portfolio, the facilities are being adapted to an increased emphasis on bulk manufacturing. Investment in plant and equipment is planned to increase significantly over the next two years to support the continuing improvements in manufacturing and quality.

Financial Position

At 2 April 2023, the Group had cash of £12.6 million after receiving £10 million from the issue of loan notes. Cash outflows in the second half year to 30 June 2023 are expected to be high due to seasonal operational losses and R&D costs, resulting in the Group having a short cash runway without additional funding.

Notwithstanding imminent additional funding, the Group will require further funding within the next 12 months and beyond for trading, working capital, capital expenditure and the continuing R&D programme. Work is continuing on cost control and tight working capital management.

At the reduced level of underlying profit excluding R&D costs, the terms of the NatWest revolving credit facility will not allow its use, and therefore the facility has been cancelled to facilitate the new funding.

Admission to Trading on AIM

The Company's shares are currently suspended from trading on AIM, pending publication of the 2022 Accounts. While the interim results for the six months ended 31 December 2022 (the "Interim Results") were required to be announced no later than 31 March 2023, these can only be finalised and issued once the audit of the 2022 Accounts has been completed. For reasons outlined above, this audit was not completed before 31 March 2023, therefore the Company's shares remain suspended from trading on AIM until after both the 2022 Accounts and the Interim Results have been finalised and published. The Company is unable to provide specific dates for the publication of the 2022 Accounts and the Interim Results, but expects these results to be announced before 30 June 2023 and will update the market as soon as the timing for this is known. In the event that the Company is unable to publish its 2022 Accounts by 30 June 2023, the admission of the Company's shares to trading on AIM will be cancelled in accordance with Rule 41 of the AIM Rules for Companies.

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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.

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