

Allergy Therapeutics plc  
Dominion Way  
Worthing  
West Sussex  
BN14 8SA

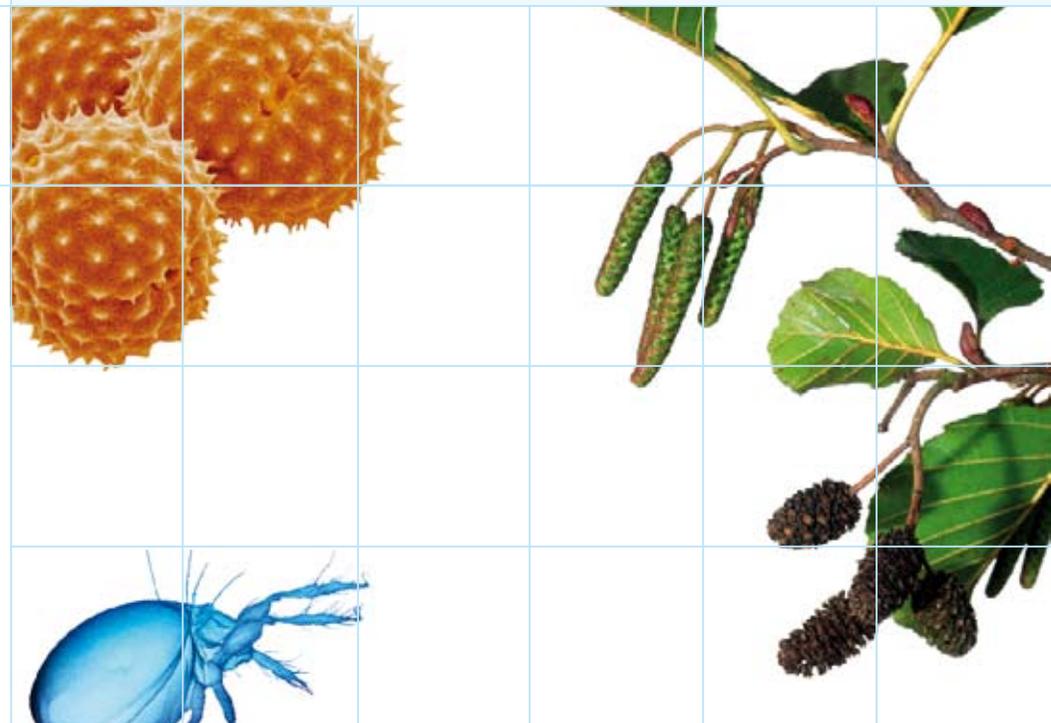
T: +44 (0)1903 844720  
F: +44 (0)1903 844726

# Allergy Therapeutics plc

Consolidated Interim Statements

For six months ended 31 December 05

[www.allergytherapeutics.com](http://www.allergytherapeutics.com)



## Highlights

Significant progress in the clinical development programmes:

- Positive outcome of Pollinex® Quattro Ragweed pivotal study in Canada, paving the way for registration in Canada
- Six phase I and II studies completed

10% growth in Pollinex® Quattro sales

German rebates lower at £0.5m (six months to 31 December 2004 (H1 2004): £2.0m), net sales up 17% to £14.2m (H1 2004: £12.1m)

Operating profit, before development costs, up 23% to £4.8m (H1 2004, pre-exceptional costs: £3.9m)

Expansion of EU sales and marketing infrastructure in Poland, Austria, the UK, and the Czech and Slovak Republics

Board and senior management team strengthened with three key appointments

New bank facilities agreed for £4m

Extensive manufacturing upgrade commenced

### Contents

01	Joint Statement from the Chairman and Chief Executive Officer
04	Consolidated Profit and Loss Account
05	Consolidated Balance Sheet
06	Consolidated Cash Flow Statement
06	Reconciliation of Net Cash Flow to Movement in Net Funds
07	Notes to the Interim Reports

# Joint Statement from the Chairman and Chief Executive Officer



We are pleased to report that the Company has made substantial progress in the six months ended 31 December 2005 (the period) and that it has continued to accomplish its financial and business objectives.

Allergy Therapeutics continued to pursue its strategy as a fully integrated specialist pharmaceutical company based in Europe, building its EU sales and marketing infrastructure, progressing its development pipeline of innovative ultra-short-course allergy vaccines and strengthening its UK manufacturing base. With significant investments of energy, time and money in executing its plans, the Company made progress on many fronts during the period.

## Development

The period saw significant progress in the clinical development programmes. Ten pre-Phase III studies were undertaken with a total of 636 subjects, representing an overall investment of £5.6m in the period and, by the end of the period, six studies had completed their clinical phases and are currently under evaluation. All these studies are designed to provide answers to the questions posed by the US Food and Drug Administration (FDA). The next phase will entail presenting the comprehensive data to the FDA and discussing our Phase III plans for 2006–2007 which are already well advanced. The initial results of the recent studies are expected in the second half of the financial year. Three studies are of special note:

- The **Grass 203** study, part of the Company's development of ultra-short-course allergy vaccines, under the brand name Pollinex® Quattro, relates specifically to the treatment of patients allergic to grass pollen. The successful results of this study were announced on 6 March 2006 and demonstrate that Pollinex® Quattro Grass – Grass M.A.T.A. (Modified Allergen Tyrosine Adsorbate) with MPL®

(Monophosphoryl Lipid A) – was safe and well tolerated at all dosing regimens and increased antibody levels compared to placebo in a dose-dependent manner. MPL® is the Company's innovative TLR4-agonist which acts as an efficient allergy vaccine adjuvant. This study will form an important part of the submissions to the FDA leading up to the Phase III programme for Pollinex® Quattro.

- The pivotal **Ragweed 204** study, the results of which were announced on 24 March 2006, utilised a pollen challenge chamber and demonstrated significant statistical and clinical benefit of the new vaccine. This study is particularly important as, with this positive outcome, we are planning to submit a dossier for registration for an MPL®-based vaccine for allergy to Ragweed pollen in Canada. It is therefore our first pivotal clinical trial with the 4-injection MPL®-containing vaccines. Ragweed pollen is one of the most important causes of allergy across the whole of North America, a target market of approximately 50 million sufferers.
- The oral **Grass 103** study is a Phase I/II trial, incorporating elements of dose-ranging as well as tolerability, and is the first sublingual use of the adjuvant MPL®. Being injection-free efficacious and well-tolerated, allergy vaccines by this route of administration would have considerable commercial potential. Results are expected in the second half of this financial year.

## Operations

In January 2006, the MHRA inspectorate conducted a Good Manufacturing Practice (GMP) audit of the existing facility. There were no critical findings in the audit, a testimony to the integrity of the Company's quality systems.

---

# Joint Statement from the Chairman and Chief Executive Officer

continued

---

As part of the plan for preparing for the FDA requirements, new premises were leased in December, neighbouring the current facility in Worthing. This new facility will be devoted to the production of named-patient products and warehousing, creating the flexibility in the main plant to upgrade and refurbish. Competing demands on manufacturing resources from markets and the clinical development programme caused some supply issues during the last six months. The new facility, due to be operational over the summer of 2006, will permit clearer segregation in these functions.

## Board and senior management

A key component in achieving the Company's strategy is to recruit and retain the right people. Consequently we were delighted that, during the period, Dr Virinder Nohria agreed to join the Board as a Non-Executive Director. His expertise in drug development and dealing with the FDA will be an invaluable support to our excellent and growing internal R&D team as our new MPL<sup>®</sup>-based vaccines move through the late phases of clinical trials. Dr Nohria works as a strategic consultant in international drug development and has led teams in many successful interactions with regulatory bodies in several countries, particularly in the US.

Two further key positions were filled in November 2005, strengthening the senior management team: Ray Keeling, 46, an experienced pharmaceutical manufacturing and supply executive with particular expertise in sterile manufacture and meeting the requirements of the US FDA, joined as Head of Supply Operations. Prior to joining the Company, Ray held senior supply operations positions at Aventis. Dr Manjit Rahelu, 38, who has a PhD in immunology and over seven years' experience in business development in the pharmaceutical industry, joined the Company as Head of Business Development. Prior to joining the Company, Manjit was a senior business development executive at UCB.

Including these key appointments, the headcount across the Company increased to 279 by the end of the period (H1 2004: 226) reflecting the significant investment required in building the commercialisation infrastructure, upgrading manufacturing and preparing for initiation of the Phase III development programme during 2006 and for potential commercial launches.

## Financial review

The results for the six months to 31 December 2005 have been very encouraging and have continued the progress shown in previous years.

At present, approximately 77% of Allergy Therapeutics' sales are generated in Germany, so the reduction of the compulsory rebate from 16% to 6% in January 2005 was beneficial to the Company with a reduction in the charge to £0.5m (H1 2004: £2m) in the period. Consequently, after the rebate, Group net sales increased by 17% to £14.2m (H1 2004: £12.1m). Gross sales (before the rebate in Germany) for the period were £14.7m (H1 2004: £14.1m). This represents an increase of 4% over the previous period, driven primarily by growth of 10% in named-patient sales of Pollinex<sup>®</sup> Quattro, the Group's 4-injection allergy vaccine. Year-on-year improvement in operating profit was inhibited by some manufacturing issues, resulting primarily from the demands made on all manufacturing resources in meeting the needs of both the markets and the clinical trials. We are confident that the investments and actions initiated over the period will prevent a recurrence of these problems.

Owing to the seasonality of the allergy market, some 60-70% of Allergy Therapeutics' sales are generated in the first half of the Company's financial year and, as a consequence, the interim results give a better indication than normal for the full-year performance.



Gross profit grew by 21% to £11.4m, representing a gross margin of 80% of sales, compared with £9.4m and 78% in the same period last year. This was an expected trend because of the decrease in German rebates. The initiation of the investment programme in the manufacturing facility and further investment in manufacturing headcount to maintain compliance with good manufacturing practice will reduce the gross margin in the short term.

Marketing expenses, the major component of distribution costs, have increased in line with our budgets as we have set up new markets in Poland, Austria, the UK and the Czech and Slovak Republics and intensified the promotional spend on our high-margin products. Costs increased to £5.0m (H1 2004: £3.8m), an increase of 33% over the previous period. Returns on these revenue investments are anticipated in coming years. Administration costs of £1.7m (H1 2004: £2.0m) were lower by 13%, benefiting by the release in the period of a bad debt provision.

Research and development expenditure increased during the period to £5.5m (H1 2004: £0.7m) as the development activity for the MPL®-based vaccine range was progressed.

The operating loss for the period was £0.7m (H1 2004 profit: £2.6m) but before development costs, the operating profit was £4.8m (H1 2004, pre-exceptional costs: £3.9m).

Capital expenditure for the period was £0.6m (H1 2004: £0.5m) and mainly represents upgrades to plant and machinery. Net current assets excluding cash were up to £3.2m (H1 2004: £2.2m), reflecting higher activity levels.

Net assets of £19.7m (H1 2004: £24.8m) show a net decrease of £5.1m against the previous period end, due primarily to the investment in R&D over the period.

Net cash outflow before financing for the period was £4.2m (H1 2004 inflow: £1.7m), less than the previous period by £5.9m due principally to the accelerated investment in R&D in the period.

### Funding

New funding lines were agreed in March 2006 with the Company's bank, RBOS, to provide a facility of £4m. This facility will be used to fund the investment required to prepare the production facilities for the US launch of its products and to support working capital requirements as the Company grows.

### Outlook

Trading remains on track with market expectation and excellent opportunities lie ahead for the Company in the second half of the financial year with the successful outcome of Ragweed 204. The next target is a successful outcome of the oral Grass 103 trials as well as the continued marketing and expansion of existing products into the European markets. The most exciting phase of growth, however, will come when regulatory clearance is achieved to sell Pollinex® Quattro in the chosen markets and the Company's efforts and resources are focused on this objective.

**Ignace Goethals**

Chairman  
24 March 2006

**Keith Carter**

Chief Executive Officer  
24 March 2006

# Consolidated Profit and Loss Account

for the six month period ended 31 December 2005

	Note	6 months to 31 Dec 2005 £'000	6 months to 31 Dec 2004 £'000	Year ended 30 June 2005 £'000
Turnover	2	14,200	12,140	20,606
Cost of sales		(2,807)	(2,709)	(4,853)
<b>Gross profit</b>		<b>11,393</b>	<b>9,431</b>	<b>15,753</b>
Distribution costs		(4,974)	(3,750)	(8,012)
Administrative expenses – other		(1,729)	(1,978)	(4,303)
Research and development costs		(5,493)	(665)	(5,620)
Exceptional costs		–	(614)	(614)
Administrative expenses		(7,222)	(3,257)	(10,537)
Other operating income		133	160	378
<b>Operating (loss)/profit</b>		<b>(670)</b>	<b>2,584</b>	<b>(2,418)</b>
Interest receivable and similar income		245	163	531
Interest payable on loans and overdrafts		–	(39)	(42)
<b>(Loss)/profit on ordinary activities before tax</b>		<b>(425)</b>	<b>2,708</b>	<b>(1,929)</b>
<b>Tax on (loss)/profit on ordinary activities</b>		<b>–</b>	<b>–</b>	<b>–</b>
Retained (loss)/profit for the financial period		(425)	2,708	(1,929)
Basic (loss)/earnings per share	3	(0.7p)	5.2p	(3.4p)
Diluted (loss)/earnings per share	3	(0.7p)	4.5p	(3.4p)

All amounts relate to continuing activities.

# Consolidated Balance Sheet

at 31 December 2005

	Note	31 Dec 2005 £'000	31 Dec 2004 £'000	30 June 2005 £'000
<b>Fixed assets</b>				
Intangible assets				
Goodwill		2,484	2,850	2,617
Other intangible assets		893	1,013	951
		3,377	3,863	3,568
Tangible assets		2,414	1,926	2,111
		5,791	5,789	5,679
<b>Current assets</b>				
Stocks		3,242	2,185	2,741
Debtors: amounts falling due within one year		4,023	3,832	3,160
Cash at bank and in hand		10,912	17,234	15,080
		18,177	23,251	20,981
<b>Creditors: amounts falling due within one year</b>		(4,011)	(3,801)	(6,121)
<b>Net current assets</b>		14,166	19,450	14,860
<b>Total assets less current liabilities</b>		19,957	25,239	20,539
<b>Creditors: amounts falling due after one year</b>		(226)	(459)	(455)
<b>Net assets</b>	4	19,731	24,780	20,084
<b>Capital and reserves</b>				
Called up share capital		73	73	73
Share premium account		14,924	14,945	14,924
Other reserves – share premium on shares issued by subsidiary		40,128	40,128	40,128
Other reserves – shares held in Employee Benefit Trust		(296)	(346)	(322)
Profit and loss account		(35,098)	(30,020)	(34,719)
<b>Shareholders' funds – equity</b>		19,731	24,780	20,084

# Consolidated Cash Flow Statement

for the six month period ended 31 December 2005

	Note	6 months to 31 Dec 2005 £'000	6 months to 31 Dec 2004 £'000	Year ended 30 June 2005 £'000
Cash (outflow)/inflow from operating activities	5	(3,857)	2,057	(15)
<b>Returns on investment and servicing of finance</b>				
Interest received		245	163	531
Interest paid		-	(39)	(42)
		245	124	489
<b>Capital expenditure and financial investment</b>				
Purchase of fixed assets		(582)	(456)	(903)
Sale of tangible fixed assets		-	3	-
		(582)	(453)	(903)
<b>Cash (outflow)/inflow before financing</b>		<b>(4,194)</b>	<b>1,728</b>	<b>(429)</b>
<b>Financing</b>				
Gross funds raised on AIM		-	16,000	16,000
Bank loans repaid		-	(945)	(945)
Sale of EBT shares		26	27	51
Expenses paid in connection with issue of shares		-	(1,033)	(1,054)
		26	14,049	14,052
<b>(Decrease)/increase in cash in period</b>		<b>(4,168)</b>	<b>15,777</b>	<b>13,623</b>

## Reconciliation of Net Cash Flow to Movement in Net Funds

	6 months to 31 Dec 2005 £'000	6 months to 31 Dec 2004 £'000	Year ended 30 June 2005 £'000
(Decrease)/increase in cash in the period	(4,168)	15,777	13,623
Net loans repaid	-	945	945
<b>Movement in net funds in period</b>	<b>(4,168)</b>	<b>16,722</b>	<b>14,568</b>
Net funds at beginning of period	15,080	512	512
<b>Net funds at end of period</b>	<b>10,912</b>	<b>17,234</b>	<b>15,080</b>

# Notes to the Interim Reports

## for the six month period ended 31 December 2005

### 1 Basis of preparation

The interim financial statements have been prepared in accordance with applicable accounting standards and under the historical cost convention. The principal accounting policies of the Group have remained unchanged from those set out in the Group's June 2005 annual report and financial statements. The financial information set out in this interim report is unaudited and does not constitute statutory accounts as defined in section 240 of the Companies Act 1985.

### 2 Analysis of turnover

	6 months to 31 Dec 2005 £'000	6 months to 31 Dec 2004 £'000	Year ended 30 June 2005 £'000
<b>Turnover by destination</b>			
Germany	10,956	9,017	14,175
Rest of Europe	3,056	2,939	4,714
North America	39	12	1,371
Asia	149	172	346
	<b>14,200</b>	<b>12,140</b>	<b>20,606</b>
<b>Turnover by origin</b>			
Germany	10,963	9,017	14,175
Rest of Europe	2,039	1,861	3,481
UK	1,198	1,262	2,950
	<b>14,200</b>	<b>12,140</b>	<b>20,606</b>

### 3 (Loss)/earnings per share

	6 months to 31 Dec 2005	6 months to 31 Dec 2004	Year ended 30 June 2005
(Loss)/earnings for the period (£'000)	(425)	2,708	(1,929)
Weighted number of shares in issue	62,950,632	51,991,728	57,471,180
Diluted weighted number of shares in issue	n/a	60,787,224	n/a
Basic (loss)/earnings per share (pence)	(0.7)	5.2	(3.4)
Diluted (loss)/earnings per share (pence)	(0.7)	4.5	(3.4)

# Notes to the Interim Reports

## Continued

### 4 Reconciliation of movement in shareholders' funds

	6 months to 31 Dec 2005 £'000	6 months to 31 Dec 2004 £'000	Year ended 30 June 2005 £'000
(Loss)/profit for the financial period	(425)	2,708	(1,929)
Other recognised gains and losses relating to the period (net)	46	2	(60)
Issue of shares	-	16,000	16,000
Sale of shares by EBT	26	27	51
Expenses paid in connection with issue of shares	-	(1,033)	(1,054)
Net (decrease)/increase in shareholders' funds	(353)	17,704	13,008
Opening shareholders' funds	20,084	7,076	7,076
Closing shareholders' funds	19,731	24,780	20,084

### 5 Reconciliation of operating (loss)/profit to operating cash flow

	6 months to 31 Dec 2005 £'000	6 months to 31 Dec 2004 £'000	Year ended 30 June 2005 £'000
Operating (loss)/profit	(670)	2,584	(2,418)
Depreciation	287	203	436
Amortisation of intangibles	225	228	448
Loss/(gain) on disposal of fixed assets	5	(3)	5
Effect of foreign exchange rate changes	(1)	(95)	(58)
(Increase)/decrease in stocks	(501)	(360)	(916)
(Increase)/decrease in debtors	(863)	(1,547)	(875)
Increase/(decrease) in creditors	(2,339)	1,047	3,363
Net cash (outflow)/inflow from continuing activities	(3,857)	2,057	(15)