



Allergy Therapeutics plc
Interim Report for the six months
ended 31 December 2012

www.allergytherapeutics.com
www.pollinex.com





Highlights

At a Glance

- Revenue £25.7m (H1 2012: £28.5m) impacted principally by foreign exchange movements
- At constant currency gross revenue (excludes rebate) £29.8m (H1 2012: £29.8m)
 - o Revenue outside of Germany (excluding milestones) increased 5% at constant currency to £9.8m (H1 2012: £9.4m)
 - o Decline in gross revenues (before rebate) in Germany of 6% at constant currency to £19.2m (H1 2012: £20.4m)

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- Cash Balance improved to £3.5m (H1 2012: £2.0m) with no bank debt (H1 2012: £9.4m)
 - FDA Clinical Hold Lifted in August 2012 on Company's grass pollen allergy vaccine (Grass MATA MPL/ Pollinex® Quattro Grass 0.5ml)
 - o Partnering strategy underway to commercialise Pollinex® Quattro in US
 - Pollinex® Ragweed distribution agreement signed with Paladin Labs, in Canada in December 2012

Post-period events

- US Patent approved for sublingual administration of MPL adjuvant and vaccine antigens in March 2013



Operating Review

At the beginning of the financial year we were pleased to report that the clinical hold on the Company's development program for Pollinex® Quattro in the United States had been formally lifted by the US FDA (Food and Drug Administration). Allergy Therapeutics is subsequently focused on securing a suitable partner with whom it intends to complete late stage clinical development, submit a BLA (Biologics License Application) to the FDA, and ultimately launch Pollinex® Quattro in the important US market. Discussions are on-going and the Company will provide an update on Pollinex® Quattro commercialisation developments during the second half of 2013.

With a suitable partner, Pollinex® Quattro could be the first registered subcutaneous vaccine to be launched in the US market, which is predominantly a subcutaneous market. The product could revolutionise treatment for grass related allergic rhinitis in the US by providing effective, fast-acting treatment to allergy sufferers. Pollinex® Quattro involves four pre-

seasonal allergy vaccine injections administered over a month, making it an attractive alternative to the prolonged course of weekly to monthly injections over three years that is currently available with the allergen extract vaccines used in the United States.

In Europe the Company is pleased to report that it has increased its market share across a number of key markets including Germany, Austria, Italy, the Netherlands and the UK. Revenue growth outside of Germany (excluding milestones) increased 5% at constant currency to £9.8m. This was achieved despite very challenging market conditions reflecting the broader macro economy, governmental austerity measures and the new regulatory environment in Europe. In Germany, revenue growth was impacted by various factors resulting in gross sales at constant currency of £19.2m (H1 2012: £20.4m).

The Company anticipates regulatory news in Germany and Switzerland, where it submitted a Marketing Authorisation Application (MAA) for Pollinex® Quattro Grass 0.5 ml to the Paul Ehrlich Institute (PEI) and Swissmedic respectively. PEI



has not disclosed when an update on the review process can be expected but the Company is hopeful of an update during the first half of 2013. Assuming approval in this timeframe the Company expects to launch the new presentation of Pollinex® Quattro to coincide with part of the 2013 grass pollen season.

In December 2012 the Company announced the termination of its distribution agreement with Lincoln Medical Limited for the distribution rights to Anapen®, an epinephrine auto-injector product. Allergy Therapeutics terminated its arrangement due to problems related to the voluntary recall of Anapen® by Lincoln Medical, originally announced by Allergy Therapeutics in May 2012. Although it is disappointing to lose a product line, overall the Anapen® contract delivered a net positive return to the Company.

Allergy Therapeutics has one of the most competitive product portfolios in the European immunotherapy market. The Company remains committed to preserving this position by diversifying its portfolio and expanding its presence in new and existing markets.

Our Americas business has also seen good progress. In Canada we signed a new distribution agreement with Paladin Labs, one of Canada's leading specialty pharmaceutical companies with extensive experience marketing in-licensed products. We are confident that this new agreement will increase Pollinex® Ragweed market share in Canada. In South America we have made progress with the launch of operations in a number of markets, albeit at a slower rate than originally planned.

Financial Review

Net revenue was £25.7m (H1 2012: £28.5m). Despite weak allergy vaccine markets in Europe and the loss of Anapen® sales, gross sales, excluding the German rebate, at constant currency were unchanged at £29.8m (H1 2012: £29.8m). The Company recognised milestone revenue of £0.8m in relation to signing a new distributor for Canada. During the period under review (6 months to December 2012) the Company was subject to the full rebate charge in Germany, although it



benefited from an exemption to the increase in the German rebate for the period January to June 2012. However, the net impact of the rebate was an increase in costs to the Company of £0.4m taking the rebate charge for the period to £1.7m (H1 2012: £1.3m). If an exemption is granted for the current period, the Company will be entitled to a refund of £1.1m.

With a weaker Euro: GBP average exchange rate during the period against the prior period, revenues for the period decreased by 10% to £25.7m (H1 2012: £28.5m). The average Euro: GBP exchange rate in the period was 1.25 compared to 1.15 in H1 2012; the weakening Euro adversely impacted revenue by £2.2m.

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

Cost of goods were reduced in the period to £7m (H1 2012: £7.5m) but primarily due to foreign exchange impacts on revenue gross profit

decreased to £18.8m (H1 2012: £21.1m) which represents a gross margin of 73% (H1 2012: 74%).

Management maintained sales and marketing initiatives at levels similar to the previous period and distribution costs at £8.9m (H1 2012: £9.0m) are broadly similar to the previous period. Administration expenses of £3.6m (H1 2012: £3.2m) were up by 12%. Of this net increase, £0.5m represents the cost of ending the distributor agreement in Canada with the previous distributor. A further £0.1m cost was recognised in relation to the termination of the licensing agreement with Lincoln Medical Ltd for the Anapen® device.

Research and development expenditure increased by 12% to £1.0m (H1 2012: £0.9m), due to an increased spend on projects although the overall spend remains lower compared to earlier years.

The Euro denominated loan was repaid in April 2012 which means there is no retranslation difference on the loan in this period (H1 2012: £1.0m credit). The finance expense for this period reflects the interest on the overdraft and German



pension fund finance cost. The overdraft was fully repaid at 31 December 2012.

The tax charge in the period of £0.2m relates mainly to the Italian subsidiary. No other group company is expected to report a material tax charge in this financial year. An R&D tax credit was recognised during the comparative period offsetting the overseas tax charges accrued. This resulted in a net tax credit in H1 2012 of £0.4m.

With the capital investment programme now complete and only a maintenance level of spend now required, property, plant and equipment has fallen from £8.1m to £7.3m as the depreciation charge for the period is higher than new equipment purchases. Goodwill remains broadly even at £2.5m, whilst other intangible assets have fallen by £0.8m due to the termination of the agreement with Lincoln Medical Ltd for the Anapen® device.

Total current assets excluding cash have decreased by £0.3m to £15.5m (H1 2012: £15.8m) primarily due to a lower stock position. Total current liabilities excluding debt financing have decreased by £1.1m to £7.5m (H1 2012: £8.6m).

The cash position has improved by £1.5m with cash standing at £3.5m (H1 2012: £2.0m), whilst gross bank debt has fallen to Nil (H1 2012: £9.4m).

Net cash generated by operating activities was an inflow of £4.1m (H1 2012: £7.6m), significantly lower than the previous period by £3.5m, due principally to lower revenue.





Financing

At the balance sheet date the Company financing facilities consisted of a variable overdraft (maximum available at December 2012 £3.5m). At the balance sheet date this facility was not drawn upon.

The Directors believe that the Company will have access to adequate facilities for the foreseeable future and accordingly have applied the going concern principle in drawing up the financial statements.

Movements in the currency markets between the respective values of the Euro and Sterling have an effect on the Company's operations. The Company manages its cash exposure in this respect by foreign currency hedges. Over 90% of our gross sales are denominated in Euros whereas c.50% of costs are incurred in the United Kingdom and denominated in Sterling.





Outlook

The lifting of the clinical hold by the FDA in August 2012 has allowed the Company to resume our Pollinex® Quattro development programme in the US. With this development alongside the expansion of our commercial activities in emerging markets, and expected regulatory news in Europe, we remain confident of achieving our ambition of building a global franchise of subcutaneous immunotherapy vaccines and becoming the market leader in this allergy segment. Additionally, in our domestic market in Europe we are also moving forward, implementing efficiencies and strengthening our position by winning market share and diversifying our revenue base.

Peter Jensen
Chairman

Manuel Lobet
Chief Executive Officer

25 March 2013



Consolidated income statement

	Note 6 months to 31 Dec 2012 £'000 unaudited	6 months to 31 Dec 2011 £'000 unaudited	12 months to 30 June 2012 £'000 audited
Revenue	25,749	28,526	41,280
Cost of sales	(7,021)	(7,455)	(13,670)
Gross profit	18,728	21,071	27,610
Distribution costs	(8,862)	(9,021)	(17,881)
<i>Administration expenses – other</i>	<i>(3,621)</i>	<i>(3,178)</i>	<i>(6,542)</i>
<i>Research and development costs</i>	<i>(968)</i>	<i>(867)</i>	<i>(2,095)</i>
Administration expenses	(4,589)	(4,045)	(8,637)
Other income	-	-	-
Operating profit	5,277	8,005	1,092
Finance income	15	1	5
Retranslation gain on Euro denominated borrowing facilities	-	966	999
Finance expense	(154)	(782)	(1,456)
Profit before tax	5,138	8,190	640
Income tax	(189)	372	183
Profit for the period	4,949	8,562	823
Earnings per share	3		
Basic (pence per share)	1.22p	2.76p	0.25p
Diluted (pence per share)	1.17p	2.66p	0.24p

Consolidated statement of comprehensive income

	6 months to 31 Dec 2012 £'000 unaudited	6 months to 31 Dec 2011 £'000 unaudited	12 months to 30 June 2012 £'000 audited
Profit for the period	4,949	8,562	823
Actuarial gain/(loss) on defined benefit pension scheme	86	104	(734)
Exchange differences on translation of foreign operations	19	(432)	(431)
Revaluation gains	72	31	50
Total comprehensive income	5,126	8,265	(292)

Consolidated balance sheet

	31 Dec 2012 £'000 unaudited	31 Dec 2011 £'000 unaudited	30 June 2012 £'000 audited
Assets			
Non-current assets			
Property, plant and equipment	7,317	8,147	7,555
Intangible assets - Goodwill	2,489	2,536	2,489
Intangible assets - Other	1,332	2,175	2,107
Investment - Retirement benefit asset	2,811	2,473	2,569
Total non-current assets	13,949	15,331	14,720
Current assets			
Trade and other receivables	9,222	8,663	4,997
Derivative financial instruments	24	278	483
Inventory	6,298	6,845	6,651
Cash and cash equivalents	3,513	1,960	903
Total current assets	19,057	17,746	13,034
Total assets	33,006	33,077	27,754
Liabilities			
Current liabilities			
Trade and other payables	(7,424)	(8,589)	(6,312)
Current borrowings	(114)	(3,153)	(1,426)
Derivative financial instruments	(70)	-	(9)
Total current liabilities	(7,608)	(11,742)	(7,747)
Net current assets	11,449	6,004	5,287
Non current liabilities			
Retirement benefit obligation	(4,884)	(3,907)	(4,717)
Non current borrowings	(97)	(6,223)	(97)
Derivative financial instruments	-	(276)	(162)
Deferred taxation	(161)	(176)	(165)
Non current provisions	(292)	(287)	(274)
Total non current liabilities	(5,434)	(10,869)	(5,415)
Total liabilities	(13,042)	(22,611)	(13,162)
Net assets	19,964	10,466	14,592
Equity			
Capital and reserves			
Issued capital	420	321	417
Share premium	67,714	58,705	67,571
Merger reserve – shares issued by subsidiary	40,128	40,128	40,128
Reserve – shares held by EBT	67	67	67
Reserve – share based payments	1,596	1,459	1,496
Reserve – convertible loan notes	3,652	-	3,652
Revaluation reserve	1,369	1,297	1,297
Foreign exchange reserve	112	92	93
Retained earnings	(95,094)	(91,603)	(100,129)
Total equity	19,964	10,466	14,592

Consolidated statement of changes in equity

	Issued capital	Share premium	Merger reserve shares issued by subsidiary	Reserve shares held in EBT	Reserve share based payments	Reserve convertible Loan note	Revaluation reserve	Foreign exchange reserve	Retained earnings	Total equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
At 31 December 2011	321	58,705	40,128	67	1,459	-	1,297	92	(91,603)	10,466
Exchange differences on translation of foreign operations								1		1
Actuarial losses									(838)	(838)
Valuation gains taken to equity							19			19
Net income recognised directly in equity	-	-	-	-	-	-	19	1	(838)	(818)
Loss for the period after tax									(7,739)	(7,739)
Total recognised income and expense	-	-	-	-	-	-	19	1	(8,577)	(8,557)
Share based payments					69					69
Shares issued	96	8,866				3,652				12,614
Transfer of depreciation on revalued property							(19)		19	-
Transfer of lapsed options to retained reserves					(32)				32	-
At 30 June 2012	417	67,571	40,128	67	1,496	3,652	1,297	93	(100,129)	14,592
Exchange differences on translation of foreign operations								19		19
Actuarial gains									86	86
Valuation gains taken to equity							72			72
Net income recognised directly in equity	-	-	-	-	-	-	72	19	86	177
Profit for the period after tax									4,949	4,949
Total recognised income and expense	-	-	-	-	-	-	72	19	5,035	5,126
Share based payments					100					100
Shares issued	3	143								146
Transfer of depreciation on revalued property										-
Transfer of lapsed options to retained reserves										-
At 31 December 2012	420	67,714	40,128	67	1,596	3,652	1,369	112	(95,094)	19,964

Condensed consolidated cash flow statement

	6 months to 31 Dec 2012 £'000 unaudited	6 months to 31 Dec 2011 £'000 unaudited	12 months to 30 June 2012 £'000 audited
Cash flows from operating activities			
Profit before tax	5,138	8,190	640
Adjustments for:			
Finance income	(15)	(1)	(5)
Finance expense	154	782	1,456
Revaluation (gain)/loss on loan	-	(966)	(999)
Non cash movements on defined benefit pension plan	84	69	164
Depreciation and amortisation	683	948	1,892
Charge for share based payments	100	62	131
Financial derivative instruments	460	(1,083)	(1,280)
Disposal of property, plant and equipment	601	-	8
(Increase)/decrease in trade and other receivables	(4,175)	(1,616)	1,287
Decrease/(increase) in inventories	401	97	272
Increase/(decrease) in trade and other payables	828	1,273	(642)
Net cash generated by/(used in) operations	4,259	7,755	2,924
Interest paid	(151)	-	(51)
Income tax (paid)/received	(8)	(189)	7
Net cash generated by/(used in) operating activities	4,100	7,566	2,880
Cash flows from investing activities			
Interest received	15	1	5
Investments	(127)	(124)	(311)
Payments for intangible assets	(12)	(663)	(829)
Payments for property plant and equipment	(227)	(218)	(432)
Net cash used in investing activities	(351)	(1,004)	(1,567)
Cash flows from financing activities			
Proceeds from issue of equity shares	146	-	12,614
Repayment of borrowings	-	(9,362)	(22,623)
Proceeds from borrowings	-	4,366	7,680
Bank loan fees and interest paid	-	(592)	(406)
Net cash generated by/(used in) financing activities	146	(5,588)	(2,735)
Net increase/(decrease) in cash and cash equivalents	3,895	974	(1,422)
Effects of exchange rates on cash and cash equivalents	27	(62)	(35)
Cash and cash equivalents at the start of the period	(409)	1,048	1,048
Cash and cash equivalents at the end of the period	3,513	1,960	(409)
Cash at bank and in hand	3,513	1,960	903
Bank overdraft	-	-	(1,312)
Cash and cash equivalents at the end of the period	3,513	1,960	(409)

1. Interim financial information

The unaudited consolidated interim financial information is for the six month period ended 31 December 2012. 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 Company for the year ended 30 June 2012, 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 2012 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 2012 as described in those financial statements.

Going Concern

The Group has been profit making in the six months to 31 December 2012, as it was in the corresponding period ending 31 December 2011 and has made operating profits in the years ending 30 June 2010 onwards.

Detailed budgets have been prepared, including cash flow projections for the periods ending 30 June 2013 and 30 June 2014. These projections include assumptions on the trading performance of the operating business and the continued

availability of the existing debt facilities. 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 Company's funding plans, the Directors continue to believe that the Company will have adequate resources to continue in operational existence for the foreseeable future and accordingly have applied the going concern principle in drawing up these financial statements. In reaching this view, the Directors have considered and prioritised the actions that could be taken to offset the impact of any shortfall in operating performance.



3. Earnings per share

	6 months to 31 Dec 2012 £'000 unaudited	6 months to 31 Dec 2011 £'000 unaudited	12 months to 30 June 2012 £'000 audited
Profit after tax attributable to equity shareholders	4,949	8,562	823
	Shares '000	Shares '000	Shares '000
Issued ordinary shares at start of the period	406,913	310,772	310,757
Ordinary shares issued in the period	2,930	-	96,141
Issued ordinary shares at end of the period	409,843	310,772	406,913
Weighted average number of shares in issue for the period	407,157	310,772	326,795
Weighted average number of shares for diluted earnings per share	424,688	321,360	340,051
Basic earnings per share (pence)	1.22p	2.76p	0.25p
Diluted earnings per share (pence)	1.17p	2.66p	0.24p



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