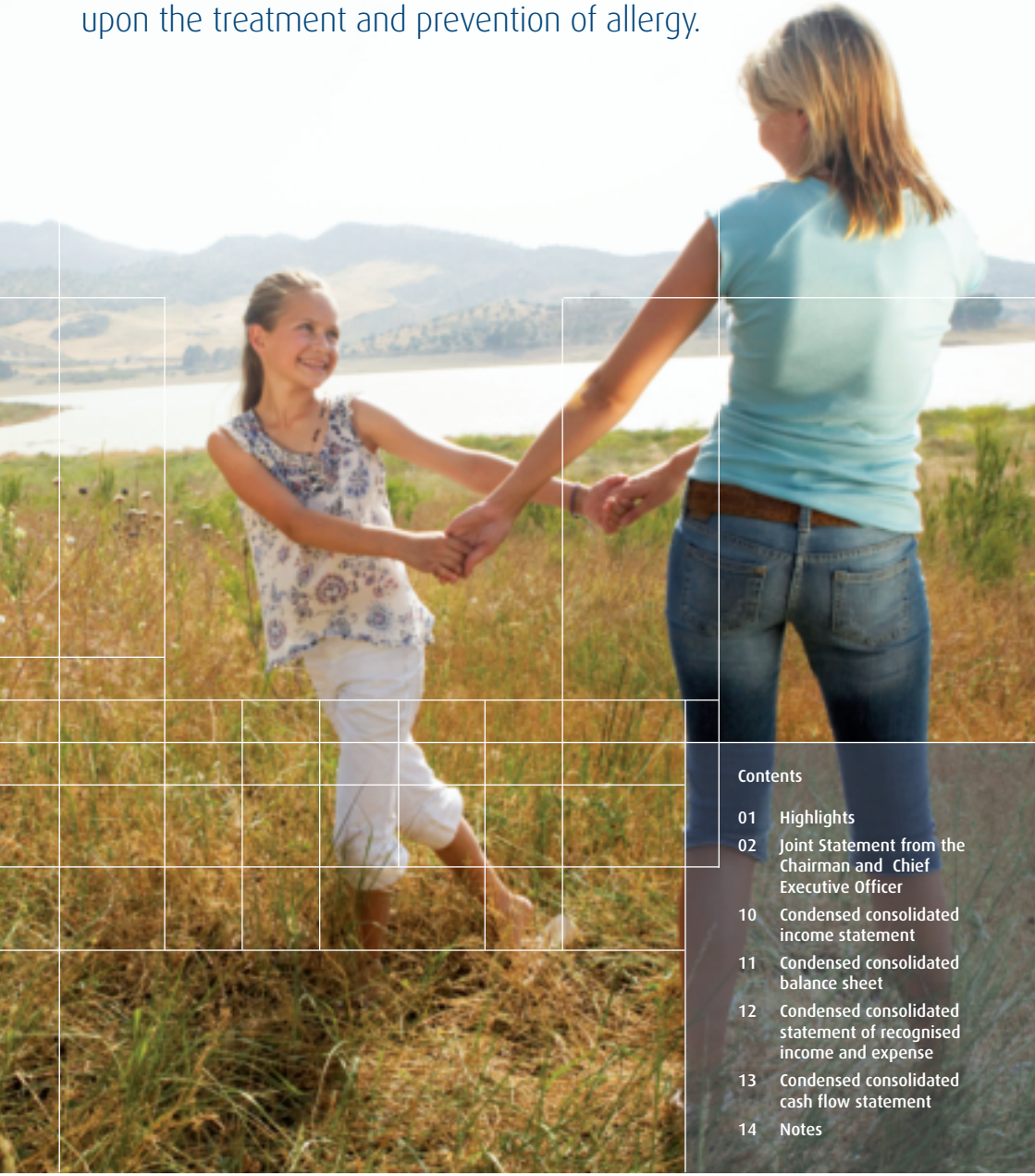
Allergy Therapeutics plc

Interim Report for the six months ended 31 December

Allergy Therapeutics®
Transforming Allergy Treatment

Allergy Therapeutics is a European based specialty pharmaceutical company focussed upon the treatment and prevention of allergy.



Contents

01 Highlights

02 Joint Statement from the Chairman and Chief Executive Officer

10 Condensed consolidated income statement

11 Condensed consolidated balance sheet

12 Condensed consolidated statement of recognised income and expense

13 Condensed consolidated cash flow statement

14 Notes

Highlights

Pollinex® Quattro Grass dossier submitted

for EU Regulatory Review in March

- Pollinex Quattro Grass would become the first ultra short course vaccine for hayfever registered across Europe

Revenues increased

by 24% to £24.2 million (2007: £19.6m)

- Pollinex Quattro named-patient sales increased by 31% to £13.7 million

Gross profit increased

by 22% to £17.3 million (2007: £14.2m)

Operating loss reduced

to £0.8m (2007: £4.4 m)

R&D expenditure reduced

to £3.2 million (2007: £10.2m)

- No further significant investment in R&D without the support of a partner

"We have completed our independent clinical development of Pollinex® Quattro - the world's first 'ultra-short course' allergy vaccine"

Operating Review

Overview

Allergy Therapeutics plc had a strong first half with sales growth in all of its core markets: Germany, Italy, Spain, Austria and the United Kingdom. Revenues grew by 24% (8% on a constant currency basis) over the comparative period last year (£24.2m in 2008 vs. £19.6m in 2007). Sales of Pollinex Quattro grew by 31%. This was an excellent performance particularly as the pollen count last year was unusually low, which tends to reduce the overall market growth rate.

Sales of Pollinex Quattro grew by 31%

Operating profit before R&D costs fell by 59% to £2.4m (2007: £5.8m), primarily due to non-cash fair valuation of the forward foreign exchange contracts of £4.2m (2007: nil) and the Group had cash of £3.0 million at the period end. The current financial year will be the last in which Allergy Therapeutics incurs large-scale R&D clinical costs without a partner to fund them, so in future periods the Company's profit and loss account will be strengthened as R&D spend falls to a low 'maintenance' level.

We have completed our independent clinical development of Pollinex® Quattro - the world's first 'ultra-short course' allergy vaccine, requiring just four injections over three weeks. During the period under review, we announced the positive outcome of our Phase III clinical trial in Pollinex Quattro Ragweed which prevents the symptoms of allergy to the pervasive ragweed pollen, a widespread problem in North America. This study confirmed the results of G301, the pivotal Phase III efficacy and tolerability study on our vaccine against the hayfever caused by grass pollen, which reported a positive outcome in May 2008.

In short, after years of investment and with an attractive, technically advanced product on the market in a growing part of a large therapy area we are well-placed to continue to build on our record of 10 years of consecutive sales growth. However the continuing FDA clinical hold has delayed the Group's partnering expectations and led to higher than originally planned debt. Consequently the Company intends to seek opportunities in 2009 to address its capital structure.

Business Model and Market

Allergy Therapeutics is a fully integrated pharmaceuticals company specialising in allergy

"We are well placed to continue to build on our record of 10 years of consecutive sales growth"

We have been actively investing in all operational areas

vaccines; we manufacture them, sell them, and market them across Europe and beyond, directly and through distributors. We have been actively investing in all operational areas for the past four years to develop and improve the operational infrastructure and management systems across the Group. This process continued in the first half of this financial year and these are durable investments in our future.

Allergy vaccination is an attractive therapeutic approach to the treatment and prevention of allergy. By redressing the imbalances of the allergic immune system, allergy vaccines not only reduce the suffering associated with the symptoms of allergy but also offer the prospect of long term benefit with continued protection after the treatment has been completed. The current £7 billion allergic rhinitis market is dominated by symptomatic drugs - antihistamines, steroids and leukotreine inhibitors - which do not offer patients a long term benefit. In the developed world approximately 20% of the population suffers from allergies. However, the proportion of allergic patients currently treated with allergy vaccines is very low, for example approximately 1% of grass allergy sufferers receive allergy vaccines in Europe. It is widely expected that this 'niche' will grow, especially as a result of Pollinex Quattro, a more patient-friendly product, becoming more widely available.

Pollinex® Quattro

Pollinex Quattro is currently sold across a number of European countries on a named patient basis. Completion of the regulatory process outlined below will open up new markets to Pollinex Quattro and enable Allergy Therapeutics to improve pricing and market share in those countries where named patient sales are currently possible.

Allergen immunotherapy exists in a number of forms. Most prescriptions are for 'traditional immunotherapy' products, which involve a great many injections (up to 40 in the first year) over an extended period of 3 to 5 years. Newer product offerings include tablet form sub-lingual immunotherapy, requiring very long courses of daily dosing under the tongue starting four months before the pollen season. Compared with these existing treatments, we believe that Pollinex Quattro, with its innovative

"The Pollinex Quattro formulations have been taken through extensive clinical trials culminating in the successful Phase III Studies G301 (Grass) and R301 (Ragweed)"

adjuvant system containing MPL® requiring just four pre-seasonal injections over a short period of time, is very attractive.

The clinical programme and regulatory approach

Pollinex Quattro formulations treating Grass, Ragweed and Tree allergies have been taken through extensive clinical trials culminating in the successful Phase III studies, G301(Grass) and R301 (Ragweed). Clinical trials are designed in agreement with the appropriate regulatory authorities with the objective of proving that the product is efficacious and well tolerated in a context approximating to real life. Like everything in pharmaceutical development, the standards are becoming increasingly rigorous.

The most demanding studies are large scale 'randomised double-blind placebo-controlled' trials:

- 'Large scale' trials exclude the possibility that the study shows a chance result as a consequence of unrepresentative local conditions.
- 'Randomised placebo controlled' means that a sufficient proportion of the patients in the trial are randomly allotted to a group given a placebo - an inactive substitute for the study drug resembling it in every way possible. This allows the trial to measure the effect of the study drug versus the placebo, very important in case the placebo effect is large. In the case of allergy trials it is estimated that the placebo effect is in the order of 50%.
- 'Double blind' means that neither physician nor patient can know whether the patient is receiving active study drug or placebo. Without this, especially with allergy where the symptoms monitored are subjective, it is likely that the results would be biased in favour of the active study drug.

Once the data has been collected there are contrasting ways in which it can be analysed. The most demanding standard is to insist on an 'intent to treat' ('ITT') analysis, meaning that all the patients must be evaluated regardless of whether all patients complete the study protocol. Uniquely in recent large-scale allergy vaccine studies, in G301 the ITT covered in the primary analysis was 100% of patients enrolled in the study. The

"We are confident of a successful outcome for our European Submission for the new Pollinex Quattro vaccine"

"The G301 and R301 trials were designed to meet and exceed the most demanding modern Good Clinical Practice Criteria"

compliance levels - patients receiving the treatment as specified - is also vitally important to the reliability of a study. All our experience with Pollinex Quattro, not just in clinical trials but in real life use, confirms a very high compliance to the ultra short regime of treatment, because of its convenience.

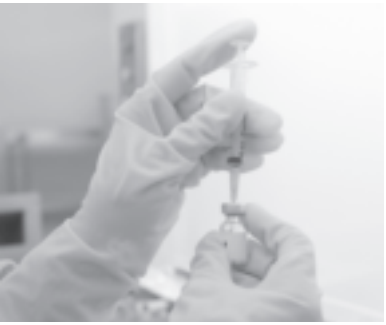
The G301 and R301 trials were designed to meet and exceed the most demanding modern Good Clinical Practice criteria for randomised double blind placebo controlled studies as partially set out above. In terms of technical quality, these two studies were the largest and possibly the most rigorous ever conducted in the allergy vaccine field, and both showed a clear efficacy benefit over placebo and excellent tolerability for Pollinex Quattro. Efficacy and tolerability are the key considerations of the regulatory authorities when they review a marketing authorisation application dossier for a product, taken in the context of the disease condition treated and the product's benefit/risk profile.

We are therefore confident of a successful outcome for our European Union submission for the new Pollinex Quattro Grass vaccine which, as previously announced, was made in early March.

The dossier was submitted to the German authority, the Paul Ehrlich Insitut ("PEI"), recognised to be the European authority most expert in the allergy vaccine field. The PEI has agreed to act as 'Reference Member State' for Europe-wide registration under the European Union Mutual Recognition Procedure ('MRP'). Following the German national phase, which usually takes one year, the MRP will commence. We have elected in this initial phase to apply for authorisation in the markets of largest potential for the product and approvals can be expected during 2010. Allowing for pricing and reimbursement discussions, the launch of the product is intended to be during the 2010 to 2012 period. Following launch our potential markets will be much more extensive, almost doubling of the population we currently serve within existing markets where named patient sales have been possible to date; furthermore we will have the potential to improve pricing and market share in those existing markets.

Following launch our potential markets will be much more extensive

"Experience and acceptance of adjuvants outside the United States is accumulating fast"



FDA update

The FDA clinical hold on our development programmes has now been in place for over 18 months. When it was imposed the FDA had never approved a product containing an adjuvant and there were several adjuvant-containing vaccines in development, the most advanced of which contained MPL® - including Allergy Therapeutics' programmes. MPL and other vaccine adjuvants are widely approved elsewhere; for example, GlaxoSmithKline's vaccines containing MPL have achieved approvals in over 60 countries.

Today the situation remains that the FDA wishes to complete a thorough review of vaccine adjuvants before progressing. Experience and acceptance of adjuvants outside the United States is in the meantime accumulating fast, as millions of doses of vaccines containing adjuvants are administered safely in those markets and ongoing clinical trials, including our own, continue to produce results supporting the improved efficacy of products containing adjuvants. It is widely expected that GlaxoSmithKline will resubmit its MPL containing vaccine Cervarix® to the FDA during 2009. A Cervarix approval which is anticipated by most analysts, would be a positive change in the environment for Allergy Therapeutics' US development plans.

In December 2008 the FDA and NIAID (part of the National Institutes of Health) held a vaccine adjuvant workshop. Allergy Therapeutics joined attendees from all the major vaccine companies including GlaxoSmithKline, Novartis, Merck, Sanofi Pasteur, Pfizer and CSL. The meeting was positive with acceptance of the need for and utility of adjuvants and further assurance on their safety. We will continue to participate in future meetings and we believe that the FDA will ultimately reach a favourable conclusion to its adjuvant review.

This would give Allergy Therapeutics a valuable, late-phase development asset for partnering which would represent a significant further upside for the value of the business.

"Gross sales for the period were £25.0m"

The results for the six months to 31 December 2008 have continued the encouraging trend shown in previous years

Gross profit increased by 22% to £17.3m

Financial Review

The results for the six months to 31 December 2008 have continued the encouraging trend shown in previous years.

Gross sales for the period, before the rebate in Germany of £0.7m, were £25.0m (H1 2007: £21.6m). This represents an increase of 16% over the previous period. If a licensee milestone receipt of £2.7m which occurred in the previous year is excluded, the growth rate increases to 32%. This growth is driven primarily by an increase of 31% in named-patient sales of Pollinex Quattro, and by the increasing strength of the Euro which added £2.9m to the sales over the prior period.

At present, approximately 77% of Allergy Therapeutics' sales are generated in Germany, so a decrease in the compulsory rebate to levels prior to the temporary increases imposed in the previous year, reduced the rebate paid to £0.7m (H1 2007: £2.1m). After the rebate, group net sales increased by 24% to £24.2m (H1 2007: £19.6m).

Owing to the seasonality of the pollen allergy market, some 60 to 70% of Allergy Therapeutics' sales are generated in the first half of the financial year and, as a consequence, the interim results present a better performance than can be expected over the course of a full year.

Gross profit increased by 22% to £17.3m, representing a gross margin of 71% of sales, compared with £14.2m and 72% in the same period last year. This is a strong performance especially in light of the receipt of a licensee milestone in the previous year which benefited gross margin.

Sales and marketing expenses, the major component of distribution costs, have increased in line with our budgets due to the new sales and marketing infrastructure in Germany which was set up in the previous year. Costs increased to £7.6m (H1 2007: £6.1m), an increase of 24% over the previous period. Administration costs of £7.3m (H1 2007: £2.3m) were higher by £5m mainly due to foreign exchange effects including the cost of the fair valuation on forward foreign exchange contracts.

Research and development expenditure decreased significantly during the period to £3.2m (H1 2007: £10.2m) as the development activity for the MPL based vaccine range is now completing its current programme.

"Recent trends in the currency markets have been favourable to the company's operations."

The operating loss for the period was £0.8m (H1 2007: £4.4m) but before development costs operating profit was £2.4m (H1 2007: £5.8m); lower mainly due to foreign exchange effects as noted above and the receipt of a £2.7m licensee milestone in the previous year.

Finance expense costs for the period were £7.7m (H1 2007: £2.4m) with the increase being principally due to the RBS Euro loan liability increasing as a result of the strengthening Euro exchange rate. The loss for the period was £8.5m (2007: £6.7m).

Capital expenditure for the period was £1.1m (H1 2007: £1.6m) and mainly represents upgrades to the facilities in preparation for launching Pollinex Quattro. Net current assets excluding cash show a liability of £3.4m (H1 2007: net assets of £3.1m), lower due to the increase in short-term debt facilities; within net assets, trade and other receivables have increased by £2.2m to £6.5m primarily due to higher December sales.

Net liabilities of £19.4m (H1 2007: net assets of £2.2m) show a decrease in assets of £21.6m against the previous period end, due primarily to the investments in R&D over the period and the corresponding increase in debt facilities.

Net cash used in operating activities for the period was an inflow of £2.1m (H1 2007: outflow £9.2m), better than the previous period by £11.3m due principally to the lower R&D spend in the period.

Financing

As a pharmaceutical company operating mainly in a state-reimbursed healthcare environment, we anticipate that Allergy Therapeutics will be relatively protected from the worst of the effects of the global economic downturn. Furthermore, recent trends in the currency markets have been favourable to the Company's operations. Over 90% of our sales are denominated in Euros whereas 70% of costs are incurred in the United Kingdom and denominated in Sterling. The current economic conditions created volatility in the exchange rate between the Euro and Sterling and uncertainty particularly over the future availability of bank finance due to the current banking liquidity crisis.

The Group meets its financing obligations through a combination of bank overdraft, asset-backed

"As the market in Europe for allergy vaccination develops we expect to increase revenues and for Pollinex Quattro to continue to win market share"

facility and a term loan facility of €40m. The Company announced on 20 March that it is in discussion with its bank with the aim of renegotiating its debt facilities. The discussions are progressing well and although the Company has not finalised the terms of the agreement the Board is confident based on current negotiations that the Company will be in a position to announce the revised terms shortly. The directors believe that the Company and the Group will have access to adequate facilities for the foreseeable future and accordingly, they continue to adopt the going concern basis in preparing the Interim Results.

Outlook

Pollinex Quattro is a unique and valuable product. We are confident of achieving regulatory approval across Europe from 2010 onwards and also expect to see some progress with our discussions with the FDA. As the market in Europe for allergy vaccination develops we expect to increase revenues and for Pollinex Quattro to continue to win market share although the current economic climate may affect certain markets where products are not fully reimbursable and pollen flights continue to be unpredictable. The Company also needs to conclude negotiations with its lender.

On a positive note, we are in discussions regarding the possibility of out-licensing Pollinex Quattro in several new territories and going forward as the major R&D spend of the past few years has now ended. If the prevailing exchange rates continue Allergy Therapeutics will also benefit from the relative strength of the Euro against Sterling.

Ignace Goethals
Chairman
31 March 2009

Keith Carter
Chief Executive Officer
31 March 2009

We are confident of achieving regulatory approval across Europe from 2010

Condensed consolidated income statement

	6 months to 31 Dec 2008 £'000 unaudited	6 months to 31 Dec 2007 £'000 unaudited	12 months to 30 Jun 2008 £'000 audited
Revenue	**24,208**	19,572	31,022
Cost of sales	**(6,939)**	(5,378)	(10,865)
Gross profit	**17,269**	14,194	20,157
Distribution costs	**(7,559)**	(6,098)	(12,852)
Administration expenses - other	***(7,320)***	*(2,320)*	*(6,640)*
Research and development costs	***(3,166)***	*(10,200)*	*(16,300)*
Administration expenses	**(10,486)**	(12,520)	(22,940)
Other income	**0**	0	42
Operating loss	**(776)**	(4,424)	(15,593)
Finance income	**26**	93	201
Finance expense	**(7,671)**	(2,414)	(4,852)
Loss before tax	**(8,421)**	(6,745)	(20,244)
Income tax	**(52)**	0	(53)
Loss for the period	**(8,473)**	(6,745)	(20,297)
Loss per share			
Basic & diluted (pence per share)	**(10.3p)**	(8.2p)	(24.8p)

Condensed consolidated balance sheet

	31 Dec 2008 £'000 unaudited	31 Dec 2007 £'000 unaudited	30 Jun 2008 £'000 audited
Assets			
Non-current assets			
Property, plant and equipment	**7,260**	6,902	6,883
Intangible assets - Goodwill	**2,735**	2,380	2,468
Intangible assets - Other	**1,167**	653	1,073
Investments	**1,916**	1,217	1,400
Derivative financial instruments	**0**	0	42
Total non-current assets	**13,078**	11,152	11,866
Current assets			
Trade and other receivables	**6,490**	4,277	3,199
Derivative financial instruments	**0**	0	3
Inventory	**6,065**	6,014	5,817
Cash and cash equivalents	**3,013**	5,752	2,298
Total current assets	**15,568**	16,043	11,317
Total assets	**28,646**	27,195	23,183
Liabilities			
Current liabilities			
Trade and other payables	**(6,033)**	(6,718)	(4,760)
Current borrowings	**(6,545)**	0	(2,422)
Derivative financial instruments	**(3,364)**	0	(923)
Other financial liabilities	**0**	(452)	0
Total current liabilities	**(15,942)**	(7,170)	(8,105)
Net current (liabilities) / assets	**(374)**	8,873	3,212
Non current liabilities			
Retirement benefit obligation	**(2,961)**	(2,439)	(2,324)
Non current borrowings	**(26,762)**	(15,170)	(23,413)
Derivative financial instruments	**(2,065)**	0	(382)
Non current provisions	**(323)**	(217)	(249)
Total non current liabilities	**(32,111)**	(17,826)	(26,368)
Total liabilities	**(48,053)**	(24,996)	(34,473)
Net (liabilities) / assets	**(19,407)**	2,199	(11,290)
Equity			
Capital and reserves			
Issued capital	**92**	92	92
Share premium	**33,173**	33,173	33,173
Merger reserve - shares issued by subsidiary	**40,128**	40,128	40,128
Reserve - shares held by EBT	**(1)**	(31)	(1)
Reserve - share based payments	**1,156**	886	1,031
Revaluation reserve	**195**	212	165
Foreign exchange reserve	**(504)**	(54)	(628)
Retained earnings	**(93,646)**	(72,207)	(85,250)
Total equity	**(19,407)**	2,199	(11,290)

Condensed consolidated statement of recognised income and expense

	6 months to 31 Dec 2008 £'000 unaudited	6 months to 31 Dec 2007 £'000 unaudited	6 months to 30 Jun 2008 £'000 audited
Loss for the period	**(8,473)**	(6,745)	(20,297)
Actuarial gain on defined benefit pension scheme	**77**	60	576
Exchange differences on translation of foreign operations	**124**	(6)	(495)
Revaluation gains and (losses)	**30**	(14)	(61)
Total recognised income and (expense)	**(8,242)**	(6,705)	(20,277)

Condensed consolidated cash flow statement

	6 months to 31 Dec 2008 £'000 unaudited	6 months to 31 Dec 2007 £'000 unaudited	6 months to 30 Jun 2008 £'000 audited
Cash flows from operating activities			
Loss before tax	**(8,421)**	(6,745)	(20,244)
Adjustments for:			
Foreign exchange (gain) / loss	**(21)**	(169)	(495)
Finance income	**(26)**	(93)	(201)
Finance expense	**1,418**	2,237	1,972
Revaluation loss on loan	**6,253**	0	2,880
Non cash movements on defined benefit pension plan	**76**	97	158
Depreciation and amortisation	**688**	655	1,159
Charge for share based payments	**125**	211	356
Financial derivative instruments	**4,169**	0	1,261
Disposal of property, plant and equipment	**(26)**	0	(1)
(Increase) / decrease in trade and other receivables	**(3,291)**	(888)	174
Increase in inventories	**(248)**	(1,103)	(906)
(Decrease) / increase in trade and other payables	**1,439**	(3,388)	(5,246)
Net cash used in operations	**2,135**	(9,186)	(19,133)
Interest paid	**(13)**	(96)	(136)
Income tax paid	**(52)**	0	(53)
Net cash used in operating activities	**2,070**	(9,282)	(19,322)
Cash flows from investing activities			
Interest received	**26**	77	201
Investments	**(132)**	0	(256)
Payments for intangible assets	**(222)**	0	(151)
Payments for property plant and equipment	**(917)**	(1,613)	(2,472)
Net cash used in investing activities	**(1,245)**	(1,536)	(2,678)
Cash flows from financing activities			
Proceeds from issue of equity shares	**0**	5	35
Net proceeds from borrowings	**1,177**	11,865	20,411
Bank loan fees and interest paid	**(1,287)**	(996)	(1,844)
Net cash generated by financing activities	**(110)**	10,874	18,602
Net increase / (decrease) in cash and cash equivalents	**715**	56	(3,398)
Cash and cash equivalents at the start of the period	**2,298**	5,696	5,696
Cash and cash equivalents at the end of the period	**3,013**	5,752	2,298

Notes

1. Interim financial information

The unaudited consolidated interim financial information is for the six month period ended 31 December 2008. 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 2008, which were prepared under International Financial Reporting Standards (IFRS) as adopted by the European Union (EU).

The accounting policies adopted in this report are consistent with those of the annual financial statements for the year to 30 June 2008 as described in those financial statements.

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 240 of the Companies Act 1985. The group's statutory financial statements for the year ended 30 June 2008 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 237(2) of the Companies Act 1985.

2. 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 2008 annual report and financial statements.

3. Loss per share

	6 months to 31 Dec 2008 unaudited £'000	6 months to 31 Dec 2007 unaudited £'000	6 months to 30 Jun 2008 audited £'000
Loss for the period attributable to equity shareholders	**(8,473)**	(6,745)	(20,297)
	Shares '000	Shares '000	Shares '000
Weighted average number of shares in issue for the period.	**81,951**	81,951	81,951
Basic and diluted loss per share (pence)	**(10.3p)**	(8.2p)	(24.8p)

The diluted loss per share 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.

Notes

4. 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	Revaluation reserve	Foreign exchange reserve	Retained earnings	Total equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
At 31 December 2007	**92**	**33,173**	**40,128**	**(31)**	**886**	**212**	**(54)**	**(72,207)**	**2,199**
Exchange differences on translation of foreign operations							(574)		(574)
Actuarial gains								516	516
Valuation losses taken to equity						(47)			(47)
Net income recognised directly in equity						(47)	(574)	516	(105)
Loss for the period after tax								(13,559)	(13,559)
Total recognised income and expense					145	(47)	(574)	(13,043)	(13,664)
Share based payments				30					145
Sale of shares by Employee Benefit Trust									30
At 30 June 2008	**92**	**33,173**	**40,128**	**(1)**	**1,031**	**165**	**(628)**	**(85,250)**	**(11,290)**
Exchange differences on translation of foreign operations							124		124
Actuarial gains								77	77
Valuation losses taken to equity						30			30
Net income recognised directly in equity						30	124	77	231
Loss for the period after tax								(8,473)	(8,473)
Total recognised income and expense						30	124	(8,396)	(8,242)
Share based payments					125				125
At 31 December 2008	**92**	**33,173**	**40,128**	**(1)**	**1,156**	**195**	**(504)**	**(93,646)**	**(19,407)**

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