

# Allergy Therapeutics plc

("Allergy Therapeutics" or "the Group")

## Interim Results for the six months ended 31 December 2017

- Consistent performance driven by market share gains
- Pivotal year with Grass MATA MPL readout due in H2 2018

**7 March 2018** Allergy Therapeutics plc (AIM:AGY), the fully integrated specialty pharmaceutical group specialising in allergy vaccines, announces its unaudited interim results for the six months ended 31 December 2017.

#### Highlights (including post period end highlights)

# Financial highlights

- Reported revenue increased by 4.4% to £42.2m (H1 2017: £40.4m) and to £40.9m at constant currency\*, representing 1.3%\*\* growth despite an abnormally weak pollen season
- R&D expenditure increased to £5.9m (H1 2017: £3.8m) due to investment in the Grass MATA MPL Phase II and PQ Birch Phase III trials
- 12% growth in pre-R&D operating profit to £12.3m (H1 2017: £11.1m) as a result of broad investment in the business and the strength of the euro against sterling
- Strong cash balance of £25.8m (H1 2017: £27.8m)

## **Operational highlights**

- Increased market share in the German market to 14% (2017: 13%)
- Breadth of portfolio demonstrated by strong performance from Venomil and Acarovac Plus
- Completion of recruitment in the pivotal Pollinex Quattro Birch Phase III study for Europe
- Completion of recruitment ahead of schedule for the Grass MATA MPL Phase II dosing trial for the US
- Contract for scaling up the Polyvac<sup>®</sup> Peanut product signed with AGC Biologics, aiming for first in human trials in 2019
- Acarovac Phase I trial continues with readout expected in H1 2019
- Contract for joint development of Oralvac products in the TAV process signed with Ergomed
- Bencard Adjuvant Systems continues to build its IP assets with microcrystalline tyrosine manufacturing process patented in key worldwide markets

Commenting on the interim results, Manuel Llobet, Chief Executive Officer, said: "2018 is set to be a pivotal year for Allergy Therapeutics with the key Grass MATA MPL Phase II trial on course for readout in the second half of the calendar year. This could provide us the platform to expand into the lucrative US market. In the first half of this year, we continued to outperform the wider market and delivered an increase in revenue at constant currency despite an abnormally weak pollen season, demonstrating the strength of our differentiated products. This reflects the quality of the Group's highly convenient, ultra-short course, aluminium-free therapy, enabling us to continue to gain market share."

This announcement contains insider information for the purposes of Article 7 of Regulatory (EU) No596/2014.

<sup>\*</sup> Constant currency uses prior year weighted average exchange rates to translate current year foreign currency denominated revenue to give a year on year comparison excluding the effects of foreign exchange movements. See table in financial review for an analysis of revenue.

<sup>\*\*</sup> Percentage based on figures in thousands (2017: £40.956m, 2016: £40.427m)

## For further information, please contact:

# **Allergy Therapeutics**

+44 (0) 1903 845 820 Manuel Llobet, Chief Executive Officer Nick Wykeman, Finance Director

#### **Panmure Gordon**

+44 (0) 20 7886 2500 Freddy Crossley, Corporate Finance Tom Salvesen, Corporate Broking

### **Consilium Strategic Communications**

+44 20 3709 5700 Mary-Jane Elliott / Ivar Milligan / Philippa Gardner allergytherapeutics@consilium-comms.com

#### **Stern Investor Relations**

+1 212 362 1200 Christina Tartaglia christina@sternir.com

#### Notes for editors:

## **About Allergy Therapeutics**

Allergy Therapeutics is an international specialty pharmaceutical group focussed on the treatment and diagnosis of allergic disorders, including 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 include vaccines for grass, tree and house dust mite, and peanut allergy vaccine in pre-clinical development. Adjuvant systems to boost performance of vaccines outside allergy are also in development.

Formed in 1999 out of Smith Kline Beecham, Allergy Therapeutics is headquartered in Worthing, UK with more than 11,000m<sup>2</sup> of state-of-the-art MHRA-approved manufacturing facilities and laboratories. The Group, which has achieved double digit compound annual growth since formation, employs c.500 employees and is listed on the London Stock Exchange (AIM:AGY). For more information, please see <a href="https://www.allergytherapeutics.com">www.allergytherapeutics.com</a>.

#### Joint Statement from the Chairman and Chief Executive Officer

## **Operating Review**

#### Overview

The Group has continued to outperform in most markets, with Spain and the Emerging Markets being the largest contributors. During the first six months of the year, the Group's revenues grew by 1.3% at constant currency and 4.4% in actual terms, notwithstanding an abnormally weak pollen season in Central European markets which affected Germany, Austria and Switzerland. The continued growth in these more challenging market conditions reflects the quality of the Group's highly convenient, aluminium-free therapy and enabled the Group to continue to gain market share.

Furthermore, one of the management team's stated aims is to leverage the Group's current infrastructure, and this is demonstrated by continued expansion of pre-R&D operating profit, growing 12% to £12.3m (H1 2017: £11.1m).

## The Market

Allergy Therapeutics continues to gain market share in its core European markets. In the year to 31 December 2017, our German market share grew to 14% compared to 13% in the year ended 30 June 2017. The revenue growth achieved in the first half of the year clearly shows the strength and continued penetration of the Pollinex portfolio in testing circumstances experienced across the market. The advantage of the breadth of our innovative portfolio has also been illustrated with continued strong growth in Venomil, the Group's leading bee

and wasp venom product, and Acarovac Plus<sup>™</sup>. Acarovac Plus<sup>™</sup> is now the best-selling Group product in the Spanish market. The results are in line with the Group's target of achieving 20% market share in the coming years on the basis of the focused sales and marketing strategy and continued growth of the newer products in our portfolio.

The abnormally weak pollen season that occurred last year usually occurs every few years and management currently expects that the 2018 pollen season should return to normal levels. Weather patterns and pollution mainly determine the strength of a pollen season and we are pleased that despite the weakness of the season in 2018, we have continued to achieve growth.

The benefits of the investments made in the broader supply chain to ensure high quality and robustness continues to be shown. The Group expects that the markets and the associated regulatory environment will continue to evolve as further countries within the EU enact legislation similar to the TAV process in Germany.

## **Regulatory Affairs & Clinical Development**

Good progress continues to be made in the German TAV (Therapy Allergy Ordinance) process. As disclosed in January, the Group has now completed recruitment and started treating patients in its pivotal Phase III Pollinex Quattro Birch study in Europe (B301), which is expected to read out in H2 2018. If successful, and if approved, the next step is expected to lead to a market authorisation.

With the Oralvac products in the TAV process, the Group has signed a co-development agreement with Ergomed plc and expects to announce the start of Phase I trials within the calendar year.

We are pleased to report that all ten of the Group's products which were submitted to the TAV process are still in development. In terms of the wider competitive landscape, the data available show that 40% of all the products that were on the market and submitted for the TAV process have dropped out and are no longer allowed to be sold in Germany (PEI Seminar, Bad Homberg, 6-9 Sept 2017).

As announced in February, the Grass MATA MPL Phase II dosing study for the US (G205) using conjunctival provocation has completed recruitment ahead of schedule and the enrolled patients have started treatment. The trial is taking place in Europe and is expected to read out in early H2 2018 ahead of a planned pivotal Phase III trial (G306). This product, if it successfully completes clinical trials and gains approval, will form the platform for expansion into the lucrative US market.

The Phase I trial for Acarovac MPL (AM101), a subcutaneous house dust mite immunotherapy using the Pollinex Quattro technology platform, has begun and is expected to read out in H1 2019, slightly later than previously reported.

Bencard Adjuvant Systems continues to build its IP assets with microcrystalline tyrosine (MCT) manufacturing process patented in key worldwide markets including the US, EU, China and Japan.

#### **Polyvac Peanut**

In February 2018, the Group also announced that it has signed an agreement with AGC Biologics to scale up Polyvac Peanut manufacturing in advance of first clinical trials. The Group still expects to begin Phase I trials in 2019, subject to successful scale-up, dosing analysis and discussions with the regulatory authorities. This product uses the virus-like particles (VLP) technology which is new in the allergy field but has been successfully applied in other fields of immunology such as with a hepatitis B vaccine.

The US peanut allergy market is potentially worth U\$8bn (The Journal of Allergy and Clinical Immunology, 2016). Unlike other candidate products that require a long treatment period, Polyvac Peanut is being developed as an ultra-short course treatment that will improve adherence and convenience consistent with the rest of the Group portfolio.

## **Financial Review**

Reported revenues for the first half of the financial year were £42.2m (H1 2017: £40.4m), representing a growth of 1.3% at constant currency, despite the abnormally weak pollen season in Central Europe. The growth rate reported after taking into account currency movements was 4.4% with the positive impact on revenues from the strengthening euro being £1.3m (H1 2017: £6.2m). The sales growth has been driven primarily by the Group's investment in infrastructure and broadening of the product portfolio as it continues to increase its market share in all of its main markets.

A reconciliation between reported revenues and revenues in constant currency is provided in the table below:

	6 months to	6 months to	Increase	Increase
	31-Dec-17	31-Dec-16		
	£m	£m	£m	%
Revenue	42.2	40.4	1.8	4%
Adjustment to retranslate to prior year foreign exchange rate	(1.3)	-		
Revenue at constant currency	40.9	40.4	0.5	1%
Add rebates at constant currency	4.0	3.9	0.1	
Gross revenue at constant currency	44.9	44.3	0.6	1%

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

Cost of goods sold decreased marginally in the period to £8.7m (H1 2017: £8.9m), mainly due to cost efficiencies with higher volumes in the factory in advance of manufacturing of the clinical trial products. Gross profit increased to £33.5m (H1 2017: £31.5m), which represents a gross margin of 79% (H1 2017: 78%), reflecting lower costs of goods.

Sales, marketing and distribution costs of £14.2m (H1 2017: £13.8m) were higher than the previous period due to the impact of the strong euro. Administration expenses of £7.1m (H1 2017: £6.6m) also rose due to the impact of the euro and inflation.

Research and development costs of £5.9m (H1 2017: £3.8m) reflected the higher level of activity in H1 2018 due to the Grass MATA MPL Phase II and the PQ Birch Phase III trials.

The tax charge in the period of £0.4m (H1 2017: £0.4m) relates to overseas subsidiaries.

Property, plant and equipment was unchanged in the period but increased by £0.1m to £9.8m compared to the year before, mainly as a result of investment in new plant and equipment to increase capacity and efficiency and improvements to the Worthing offices. The depreciation charge increased by £0.2m, reflecting this investment in the plant. Goodwill remained broadly unchanged at £3.4m (H1 2017: £3.4m), whilst other intangible assets have decreased by £0.3m.

Total current assets excluding cash have increased by £1.6m to £19.3m (H1 2017: £17.7m). This is mainly due to an increase in debtors reflecting the higher sales and the different sales channel used for Synbiotics.

Retirement benefit obligations, which relate solely to the German pension scheme, increased to £10.1m (H1 2017: £9.6m) as a result of the movement in the sterling-euro exchange rate as well as the reduction in the discount rate.

Net cash generated by operations was positive although lower than last year, due to higher R&D spending in H1 2018 as well as the strong trading result helped by the sterling-euro exchange rate, with a reported inflow of £4.3m (H1 2017: £5.4m).

## **Financing**

The Group had debt on its balance sheet at the close of the financial year relating to loans held in the Spanish subsidiary of £3.2m (H1 2017: £3.4m). The seasonal overdraft was not used during the calendar year 2017 but the Group expects to renew its banking facilities when they are due for review in April 2018. The Group did not draw down any debt from its facility in Spain during the period (H1 2017: £0.1m).

The Directors believe that the Group will have adequate facilities for the foreseeable future and, accordingly, they have applied the going concern principle in preparing these interim financial statements.

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

#### **Other Matters**

As disclosed in Note 4 (Contingent liabilities), on 23 February 2015, the Company received notification that The Federal Office for Economics and Export ("BAFA") had made a decision to reverse its preliminary exemption to the increased manufacturers rebate in Germany for the period July to December 2012. The Company was granted a preliminary exemption to the increased rebate for this period by BAFA in 2013. The Company recognised revenue of €1.4m (£1.1m at that time, now £1.2m) against this exemption in the year ended 30 June 2013. All other preliminary exemptions (granted for periods up to 30 June 2012) have previously been ratified as final by BAFA. After taking legal advice, the Company has lodged an appeal against this decision and is confident that the exemption will be re-instated. Therefore, as at 31 December 2017, no provision has been recognised for the repayment of the rebate refund. This position will be kept under review.

The European Commission has concluded its investigation into whether the exemption of pharmaceutical manufacturers from the increase in rebates in Germany constitutes state aid. The European Commission has determined that the exemptions do not constitute state aid. Subsequent to this announcement, the Group has been advised that an appeal has been lodged at the EU Court against this decision. If successful, and the exemptions are determined to be illegal state aid, then the exemption refunds may have to be repaid. The maximum sum to be repaid would be approximately £5m (including the £1.2m referred to above); however, the Group considers this to be an unlikely outcome and consequently has not recognised any provision as a result.

The Group is in a legal process with one of its suppliers and their lawyers over potential cost overruns on one of its clinical trials which may lead to additional expense for the Group.

#### Outlook

This year is set to be pivotal for Allergy with the key Grass MATA MPL Phase II trial on course for readout in the second half of the calendar year as expected. This could provide us the platform to expand into the lucrative US market.

The Board and management team expect that growth in net sales will continue ahead of wider market trends in the second half of the year and have great confidence in the future of the business. As planned, research and development costs are expected to double in the second half of the year compared to the first half, reflecting the period of maximum activity of two major trials (US Grass MATA MPL Phase II and PQ Birch Phase III) with the intention of significantly expanding our addressable market. Our continued focus on new product development is illustrated by our work on Polyvac Peanut. Whilst at an early stage, we believe that our well-established, innovative approach to immunising patients from allergy symptoms could provide a new approach to combating this severe affliction. Other costs are expected to be slightly higher than H1 2018.

The Group is well positioned to continue to grow the European business while developing the pipeline for the US market and expanding into other allergy fields.

We look forward to the future with confidence.

Peter Jensen Chairman

Manuel Llobet
Chief Executive Officer

7 March 2018

# **ALLERGY THERAPEUTICS PLC**

Consolidated income statement				
	Note 2	6 months to 31 Dec 2017 £'000	6 months to 31 Dec 2016 £'000	12 months to 30 Jun 2017 £'000
	_	unaudited	unaudited	audited
Revenue Cost of sales		42,241 (8,720)	40,427 (8,924)	64,138 (16,771)
Gross profit		33,521	31,503	47,367
Sales, marketing and distribution costs		(14,246)	(13,842)	(26,888)
Administration expenses – other Research and development costs Administration expenses		(7,140) (5,913) (13,053)	(6,611) (3,820) (10,431)	(13,778) (9,296) (23,074)
Other income		200	-	<u> </u>
Operating profit/(loss)		6,422	7,230	(1,896)
Finance income Finance expense		110 (129)	90 (112)	151 (225)
Profit/(loss) before tax Income tax		6,403 (377)	7,208 (367)	(1,970) (511)
Profit/(loss) for the period		6,026	6,841	(2,481)
Earnings/(loss) per share Basic (pence per share) Diluted (pence per share)	3	1.01p 0.99p	1.16p 1.10p	(0.42p) (0.42p)
Consolidated statement of comprehensive income		6 months to 31 Dec	6 months to 31 Dec	12 months to 30 Jun
		2017 £'000 unaudited	2016 £'000 unaudited	2017 £'000 audited
Profit/(loss) for the period  Items that will not be reclassified subsequently to profit		6,026	6,841	(2,481)
or loss: Remeasurement of net defined benefit liability		(229)	1,105	1,500
Remeasurement of investments-retirement benefit assets		(60)	(78)	(91)
Items that may be reclassified subsequently to profit or loss:  Exchange differences on translation of foreign operations		(114)	(81)	(23)
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Total comprehensive income/ (loss)		5,623	7,787	(1,095)

Consolidated balance sheet	31 Dec 2017 £'000	31 Dec 2016 £'000	30 Jun 2017 £'000
Assets	unaudited	unaudited	audited
Non-current assets			
Property, plant and equipment	9,798	9,708	9,673
Intangible assets - goodwill	3,412	3,382	3,390
Intangible assets - other	1,696	2,038	2,069
Investment - retirement benefit asset	4,854	4,291	4,592
Total non-current assets	19,760	19,419	19,724
Current assets	0.000	7.005	7 40 4
Inventories Trade and other receivables	8,393	7,025	7,484
Trade and other receivables Cash and cash equivalents	10,939 25,812	10,653 27,763	7,853 22,122
Cash and Cash equivalents	25,612	21,103	22,122
Total current assets	45,144	45,441	37,459
Total assets	64,904	64,860	57,183
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Liabilities			
Current liabilities			
Trade and other payables	(14,691)	(12,375)	(13,225)
Current borrowings	(395)	(306)	(391)
Derivative financial instruments	(384)	(486)	(404)
Total current liabilities	(15,470)	(13,167)	(14,020)
Net current assets	29,674	32,274	23,439
Non-current liabilities			
Retirement benefit obligations	(10,131)	(9,553)	(9,619)
Deferred taxation liability	(325)	(315)	(352)
Non-current provisions	(279)	(291)	(291)
Long term borrowings	(2,798)	(3,071)	(2,936)
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Total non-current liabilities	(13,533)	(13,230)	(13,198)
Total liabilities	(29,003)	(26,397)	(27,218)
Net assets	35,901	38,463	29,965
Equity			
Capital and reserves			
Issued share capital	604	603	604
Share premium	102,420	102,420	102,420
Merger reserve – shares issued by subsidiary	40,128	40,128	40,128
Reserve – share based payments Revaluation reserve	1,213 974	1,061 1,254	900 1 254
		1,254	1,254 (907)
Foreign exchange reserve Retained earnings	(1,021) (108,417)	(965) (106,038)	(907) (114,434)
Notainou Garriings	(100,417)	(100,030)	(117,404)
Total equity	35,901	38,463	29,965

# Consolidated statement of changes in equity

	Issued Capital	Share premium	Merger reserve – shares issued by subsidiary	Reserve - share based payment	Revaluation reserve	Foreign exchange reserve	Retained earnings	Total equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
At 31 December 2016	603	102,420	40,128	1,061	1,254	(965)	(106,038)	38,463
Exchange differences on translation of foreign operations	-	-	-	-	-	58	-	58
Remeasurement of net defined benefit liability	-	-	-	-	-	-	395	395
Remeasurement of investments – retirement benefit assets	-	-				-	(13)	(13)
Total other comprehensive income		-	-	-	-	58	382	440
Profit for the period after tax	-	-	-			-	(9,322)	(9,322)
Total comprehensive income	-	-	-	-	-	58	(8,940)	(8,882)
Share based payments	-	-	-	383	-	-	-	383
Shares issued	1	-	-	-	-	-	-	-
Transfer of lapsed options to retained earnings	-	-	-	(544)	-	-	544	-
At 30 June 2017	604	102,420	40,128	900	1,254	(907)	(114,434)	29,965
Exchange differences on translation of foreign operations	-	-	-	-	-	(114)	-	(114)
Remeasurement of net defined benefit liability	-	-	-	-	-	-	(229)	(229)
Remeasurement of investments – retirement benefit assets		-	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	(60)	(60)
Total other comprehensive income	-	-	-	-	-	(114)	(289)	(403)
Profit for the period after tax	-	-	-	-	-	-	6,026	6,026
Total comprehensive income	-	-	-	-	-	(114)	5,737	5,623
Share based payments	-	-	-	313	-	-	-	313
Transfer of depreciation on revalued property	-	-	-	-	(280)	-	280	-
At 31 December 2017	604	102,420	40,128	1,213	974	(1,021)	(108,417)	35,901

# Condensed consolidated cash flow statement

Condensed consolidated cash flow statement	6 months to 31Dec 2017 £'000 unaudited	6 months to 31Dec 2016 £'000 unaudited	12 months to 30Jun 2017 £'000 audited
Cash flows from operating activities			
Profit/(loss) before tax	6,403	7,208	(1,970)
Adjustments for: Finance income Finance expense Non cash movements on defined benefit pension plan Depreciation and amortisation Impairment of intangible assets Loss on disposal of fixed assets Net monetary value of above the line R&D tax credit Charge for share based payments Movement in fair value of derivative financial instruments Foreign exchange revaluation on US dollar cash deposits (Increase)/decrease in trade and other receivables (Increase)/decrease in inventories	(110) 129 95 1,127 - (200) 313 20 3 (3,566) (915)	(90) 112 122 955 - - 320 (694) (296) (4,202) 743	(151) 225 322 1,936 69 42 (699) 703 (776) (361) 1,004 334
Increase in trade and other payables	994	1,263	823
Net cash generated by operations	4,293	5,441	1,501
Bank loan fees and Interest paid Income tax received/(paid)	(129) 699	(112) (6)	(222) (1,101)
Net cash generated by operating activities	4,864	5,323	178
Cash flows from investing activities Interest received Investments Payments for intangible assets Payments for property plant and equipment	110 (187) (4) (993)	90 (148) (22) (1,341)	41 (258) (226) (1,500)
Net cash used in investing activities	(1,074)	(1,421)	(1,943)
Cash flows from financing activities Share options exercised Repayment of borrowings Proceeds from borrowings	1 (107)	32 (161) 77	33 (297) 76
Net cash used by financing activities	(106)	(52)	(188)
Net increase/(decrease) in cash and cash equivalents Effects of exchange rates on cash and cash equivalents Cash and cash equivalents at the start of the period	3,683 7 22,122	3,850 507 23,406	(1,953) 669 23,406
Cash and cash equivalents at the end of the period	25,812	27,763	22,122

#### 1. Interim financial information

The unaudited consolidated interim financial information is for the six month period ended 31 December 2017. 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 2017, 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 2017 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 2017 as described in those financial statements. 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 Group has been profit making in the six months to 31 December 2017, as it was in the corresponding period ending 31 December 2016.

Detailed budgets have been prepared, including cash flow projections for the periods ending 30 June 2018 and 30 June 2019. These projections include assumptions on the trading performance of the operating business and the continued availability of the existing bank facilities. The Group had a cash balance of £25.8m at 31 December 2017 and expects to renew its banking facilities when they are due for renewal in April 2018. 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 Group's funding plans, the Directors continue to believe that the Group will have adequate resources to continue in operational existence for the foreseeable future and accordingly have applied the going concern principle in preparing these interim financial statements.

#### 3. Earnings per share

	6 months to	6 months to	12 months to
	31 Dec 2017	31 Dec 2016	30 Jun 2017
	unaudited	unaudited	audited
	£'000	£'000	£'000
Profit/(loss) after tax attributable to equity shareholders	6,026	6,841	(2,481)
	Shares	Shares	Shares
	'000	'000	'000
Issued ordinary shares at start of the period	594,118	589,159	589,159
Ordinary shares issued in the period	-	4,285	4,959
Issued ordinary shares at end of the period	594,118	593,444	594,118
Weighted average number of shares in issue for the period	594,118	591,415	592,192
Weighted average number of shares for diluted earnings per share	610,995	624,470	592,192
			(2.42.)
Basic earnings per ordinary share/(loss) (pence)	1.01p	1.16p	(0.42p)
Diluted earnings per ordinary share/(loss) (pence)	0.99p	1.10p	(0.42p)

## 4. Contingent liabilities

On 23 February 2015, the Company received notification that The Federal Office for Economics and Export ("BAFA") had made a decision to reverse their preliminary exemption to the increased manufacturers rebate in Germany for the period July to December 2012. The Company was granted a preliminary exemption to the increased rebate for this period by BAFA in 2013. The Company recognised revenue of €1.4m (£1.1m at that time, now £1.2m) against this exemption in the year ended 30 June 2013. All other preliminary exemptions (granted for periods up to 30 June 2012) have previously been ratified as final by BAFA. After taking legal advice, the Company has lodged an appeal against this decision and is confident that the exemption will be re-instated. Therefore, as at 31 December 2017, no provision has been recognised for the repayment of the rebate refund. This position will be kept under review.

The European Commission has concluded its investigation into whether the exemption of pharmaceutical manufacturers from the increase in rebates in Germany constitutes state aid. The European Commission has determined that the exemptions do not constitute state aid. Subsequent to this announcement, the Group has been advised that an appeal has been lodged at the EU Court against this decision. If successful, and the exemptions are determined to be illegal state aid, then the exemption refunds may have to be repaid. The maximum sum to be repaid would be approximately £5m (including the £1.2m referred to above); however, the Group considers this to be an unlikely outcome and consequently has not recognised any provision as a result.