Allergy Therapeutics PLC

Allergy Therapeutics plc
("Allergy Therapeutics", "ATL" or the "Group")
Interim Results for the six months ended 31 December 2019

- *Record level of operating profit pre R&D supported by strong sales*
- *Strong cash position with Grass MATA MPL Phase III programme fully funded for H2 2020 start*
- *Publication of promising preclinical data from VLP Peanut candidate*

4 March 2020 Allergy Therapeutics plc (AIM: AGY), the fully integrated commercial biotechnology company specialising in allergy immunotherapy, today announces its unaudited interim results for the six months ended 31 December 2019.

Highlights

Financial highlights
- Revenue increased by 9% at constant rate* and 8% in actual terms to £50.5m (H1 2019: £46.7m)
- 10% growth in pre-R&D operating profit to £17.3m (H1 2019: £15.7m) largely as a result of continued sales growth
- Operating profit pre R&D margin of 34% (H1 2019 34%)
- R&D expenditure lower at £1.3m (H1 2019: £5.0m) due to receipt of Inflamax legal costs (£3.2m)
- Strong cash balance of £39.7m (30 June 2019: £27.4m)

Operational highlights
- Good growth across all key products in the portfolio with small increase in market share in European business
- First stage of Grass MATA MPL Phase III programme to start in H2 2020 in EU and USA
- Preclinical VLP Peanut data published in highly respected journal post period end

Manuel Llobet, CEO at Allergy Therapeutics, stated: *"The Group has made a steady start to the year with good sales growth supporting our strategy. The regulatory environment remains uncertain but we continue to perform well commercially and to progress our high potential pipeline."*

*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 finance review for an analysis of revenue.

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

- ENDS -

Analyst briefing and webcast today

Manuel Llobet, Chief Executive Officer, and Nick Wykeman, Chief Financial Officer, will host a meeting and webcast for analysts to provide an update on the Group, followed by a Q&A session, at 09.30am GMT today at the offices of Panmure Gordon & Co, One New Change, London, EC4M 9AF.

Dial-in details are:

Webcast link: https://edge.media-server.com/mmc/p/mhc6ku2o

UK dial-in: +44 (0) 2071 928000
US dial-in: +16315107495
Conference ID: 3622619

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Notes for editors:

About Allergy Therapeutics

Allergy Therapeutics is an international commercial biotechnology company focussed on the treatment and diagnosis of allergic disorders, including aluminium free immunotherapy vaccines that have the potential to cure disease. The Group sells proprietary and third party products from its subsidiaries in nine major European countries and via distribution agreements in an additional ten countries. Its broad pipeline of products in clinical development 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^2 of state-of-the-art MHRA-approved manufacturing facilities and laboratories. The Group, which has achieved over 9% compound annual growth since formation, employs c.600 employees and is listed on the London Stock Exchange (AIM:AGY). For more information, please see www.allergytherapeutics.com.

Joint Statement from the Chairman and Chief Executive Officer

Operating Review

Overview

The Group performed well in a challenging market and continued to drive growth in operating profit before R&D (10% up on 2019). There has been increased regulatory activity across Europe in the period creating uncertainty in the market. The growth achieved in the last six months highlights the quality and convenience of our products, our robust supply chain and strong marketing and sales team.

The Market

Allergy Therapeutics achieved sales growth in constant terms[1] of 9% (8% at actual rates). This growth came from across the portfolio with particularly strong performances by Pollinex, Venomil and Pollinex Quattro. The strong 2019 tree season has driven a strong demand for our tree allergy products while the grass season was less pronounced.

We have seen a strong performance in H1 2020 from Germany, Spain, Netherlands and Switzerland, driven by improved market positions, promotion of our ultra-short course products and more focus on key products in the portfolio. The market is generally becoming more aware of the importance of data-driven products, which benefits the Group's products which use advanced science and technology to validate performance.

Regulatory Affairs & Clinical Development

The first half of FY 2020 has been a very busy time for the clinical team with the analysis of the Birch MATA MPL Phase III (B301) trial results leading to a revised approach to the Grass MATA MPL trial. The upcoming Grass development study will now take a stepwise approach, with two stages covering both the 2021 and 2022 pollen seasons. The stepwise approach has been designed with input from regulatory consultants. It enables a phase III-scale development to begin in 2020 and includes a data review to gain insights into the trial, before continuing to the second part of the Phase III development. The first stage of the Grass MATA MPL phase III programme will start in the autumn of this year with read out in 2021.

A significant amount of work has been carried out by the Group in relation to the German TAV (Therapy Allergy Ordinance) process and the products that are part of that process. The German TAV process is in response to EU legislation relating to named patient products which requires immunotherapies to the most common allergens to undergo a market authorisation process. This is also starting to apply to the Italian and Spanish markets and is likely, in time, to affect the whole EU market. Further trials are not expected to be needed for each additional country.

The Group is in dialogue with the German regulatory authorities about the results of the Birch MATA MPL Phase III trial. The team will focus first on applying the lessons to the Grass MATA MPL trials before returning to a further clinical trial in relation to Birch.

The Group announced the publication, in January 2020, of encouraging preclinical results of its peanut allergy vaccine candidate in *The Journal of Allergy and Clinical Immunology (JACI),* the most frequently cited allergy and immunology journal in the field.

The study, which used the Group's novel virus like particle (VLP) platform, potentially offers an effective way to treat peanut allergies and prevent anaphylaxis. It provided validation of proof of concept for the generation of sustained immunity and protection through vaccination. The study illustrated that a single injection protected against systemic anaphylaxis, as demonstrated via subsequent *in vivo* challenge, skin prick testing and oral challenge.

[1]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 finance review for an analysis of revenue.

With manufacturing scale-up of the product now underway and following agreement with several regulatory authorities on the clinical trial design, the programme to initiate first-in-human studies is progressing well. Given the importance of the trial and scale of the opportunity, the Group is implementing robust protocols with the regulatory authorities and plans to introduce additional *in vitro* human cell testing to its preclinical programme to ensure the initial studies will support global registration plans. Submission of the clinical trial application is anticipated in 2021.

The Group is evaluating further opportunities in the immunology field that could utilise VLP technology alongside the adjuvant systems that the Group owns.

Financial Review

Reported revenues for the first half of the financial year were £50.5m (H1 2019: £46.7m), representing a growth of 9% at constant currency (see table below) and 8% in actual terms. The sales growth has been driven primarily by the Group's investment in marketing and sales teams and broadening of the product portfolio as it continues to increase its market share in all of its main markets. Rebates were higher this period due to increased sales and price rises of certain products.

A reconciliation between reported revenues and revenues in constant currency[1] is provided in the table below:

	6 months to 31-Dec-19	6 months to 31-Dec-18	Increase	Increase
	£m	£m	£m	%
Revenue	50.5	46.7	3.8	8.1%
Adjustment to retranslate to prior year foreign exchange rate	0.3	-	0.3	
Revenue at constant currency[1]	50.8	46.7	4.1	8.8%
Add rebates at constant currency	3.3	2.4	0.9	
Gross revenue at constant currency	54.1	49.1	5.0	10.2%

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 reports profits in the first half of the year and losses in the second half.

Cost of goods sold increased in the period to £11.4m (H1 2019: £9.4m), mainly due to higher volumes being sold, Brexit costs and reversal of stock provisions in the prior year. Gross profit increased to £39.1m (H1 2019: £37.3m), which represents a gross margin of 77% (H1 2019: 80%).

Sales, marketing and distribution costs of £13.6m (H1 2019: £13.6m) were in line with the previous period. Administration expenses of £8.2m (H1 2019: £8.1m) were broadly in line with the previous period.

Research and development costs of £1.3m (H1 2019: £5.0m) reflected the lower level of activity in H1 2020 with the key Grass MATA MPL trials starting in autumn 2020 and included the £3.2m received in settlement of legal costs relating to the litigation with Inflamax.

The tax charge in the period of £0.6m (H1 2019: £0.4m) relates to overseas subsidiaries. It should be noted that IFRIC 23 (Uncertainty over income tax treatment) has been implemented in the period ended 31 December 2019. The Group prepares provisions against uncertain tax positions in accordance with IFRIC 23. IFRIC 23 has been adopted by the Group with effect from 1 July 2019, with the modified retrospective approach being applied (i.e. the cumulative effect of initially applying the Interpretation is recognised as an adjustment to the opening balance of retained earnings, with no change being made to the prior year comparative numbers).

The effect of IFRIC 23 provisions in these interim financial statements amounts to £0.7m and this has been dealt with through retained earnings.

Property, plant and equipment excluding IFRS16 increased by £1.3m to £11.3m compared to the year before, mainly as a result of investment in new storage facilities as part of our Brexit contingency planning. IFRS16 additions amounted to £9m and depreciation of £0.7m. Goodwill was £3.3m (H1 2019: £3.4m) and was lower than the prior year due to changes in the foreign exchange rates. Other intangible assets have decreased by £0.2m due to the amortisation charge being in excess of additions.

Total current assets excluding cash have decreased by £1.6m to £17.8m (H1 2019: £19.4m) mainly due to a reduction in debtor days.

Retirement benefit obligations, which relate solely to the German pension scheme, increased to £12.3m (H1 2019: £10.5m) due to a decrease in the discount rate primarily as a result of lower corporate bond yields in Germany.

Net cash generated by operations was strongly positive, due to lower R&D spending in the first half of the year 2020 as well as the strong trading result, with an inflow of £14.3m (H1 2019: £6.8m).

It should be noted that the financial results for H1 2020 now incorporate IFRS16, the new accounting standard on leased assets. This requires companies reporting under International Accounting Standards to place operating lease assets on the balance sheet with an accompanying liability. Furthermore, depreciation is charged on these assets (£0.7m) as well as a finance charge (£0.2m) with removal of lease charges (£0.9m). The impact of this is that lease costs in the P&L reduce and depreciation increases. Hence, the measure of earnings before interest, tax and depreciation and amortisation has benefited to the order of £0.9m. There is no material impact on the operating profit.

Financing

The Group had cash of £39.7m (30 June 2019 £27.4m) and debt on its balance sheet at the close of the period relating to loans held in the Spanish subsidiary of £2.0m (H1 2019: £2.8m). The seasonal overdraft was not used during the calendar year 2019 but the Group expects to renew its banking facilities when they are due for review in August 2020.

The Directors believe that the Group will have sufficient 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 60% of costs are incurred in the United Kingdom and denominated in sterling.

Outlook

This calendar year is key in order to prepare for several important trials for the 2021 financial year.

The Board and management team expect that net sales will continue to grow in line with market expectations in the second half of the year and have confidence in the future of the business. The gross margin is expected to be lower in the second half of the year compared with the first, as volumes through the factory are likely to be lower, leaving gross margin for the whole year in line with last year. As planned, research and development costs, excluding the Inflamax legal cost recovery, are expected to double in the second half of the year compared with the first half, reflecting the period of higher activity of the Grass MATA MPL trial and further work on peanut study as well as TAV costs. Other costs for the full year are expected to be in line with market expectations due to phasing and Brexit.

As noted in the Group Risks section of the 2019 Annual Report, management has taken action to try to mitigate the impact of Brexit. It will be difficult to determine precisely what impact Brexit will have on the business until a trade deal is concluded.

The Group continues to grow well while developing a very exciting and valuable pipeline of products.

The regulatory environment is a challenge but the Group is best placed to meet it with its strong portfolio of products and high potential pipeline.

Peter Jensen
Chairman

Manuel Llobet
Chief Executive Officer

4 March 2020

Consolidated income statement

	Note	6 months to 31 Dec 2019 £'000 unaudited	6 months to 31 Dec 2018 £'000 unaudited	12 months to 30 Jun 2019 £'000 audited
	2			
Revenue		50,472	46,713	73,717
Cost of sales		(11,414)	(9,411)	(18,379)
Gross profit		39,058	37,302	55,338
Sales, marketing and distribution costs		(13,614)	(13,563)	(26,995)
Administration expenses – other		*(8,177)*	*(8,063)*	*(17,595)*
Research and development costs (includes £3.2m received relating to the litigation with Inflamax. FY19:£6.0m received)		*(1,273)*	*(4,968)*	*(6,950)*
Administration expenses		(9,450)	(13,031)	(24,545)
Other income		-	31	593
Operating profit		15,994	10,739	4,391
Finance income		152	118	103
Finance expense		(291)	(124)	(201)
Profit before tax		15,855	10,733	4,293
Income tax		(579)	(408)	(826)
Profit for the period		15,276	10,325	3,467
Earnings per share	**3**			
Basic (pence per share)		2.40p	1.64p	0.55p
Diluted (pence per share)		2.27p	1.55p	0.52p

Consolidated statement of comprehensive income

	6 months to 31 Dec 2019 £'000 unaudited	6 months to 31 Dec 2018 £'000 unaudited	12 months to 30 Jun 2019 £'000 audited
Profit for the period	15,276	10,325	3,467
Items that will not be reclassified subsequently to profit or loss:			
Remeasurement of net defined benefit liability	(1,060)	206	(906)
Remeasurement of investments-retirement benefit assets	65	(83)	(42)
Revaluation gains – freehold land and buildings	-	-	312
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	(286)	131	130
Total comprehensive income	13,995	10,579	2,961

Consolidated balance sheet	31 Dec 2019 £'000 unaudited	31 Dec 2018 £'000 unaudited	30 Jun 2019 £'000 audited
Assets			
Non-current assets			
Property, plant and equipment	11,336	10,034	11,481
Right of use assets (property, plant and equipment)	9,004	-	-
Intangible assets - goodwill	3,324	3,438	3,432
Intangible assets - other	1,245	1,437	1,408
Investment - retirement benefit asset	5,479	5,369	5,551
Total non-current assets	30,388	20,278	21,872
Current assets			
Inventories	8,716	9,033	9,409
Trade and other receivables	8,769	10,324	9,776
Cash and cash equivalents	39,725	31,642	27,440
Derivative financial instruments	324	-	-
Total current assets	57,534	50,999	46,625
Total assets	87,922	71,277	68,497
Liabilities			
Current liabilities			
Trade and other payables	(12,903)	(12,892)	(15,736)
Current borrowings	(659)	(664)	(694)
Lease liabilities	(1,457)	-	-
Derivative financial instruments	-	(65)	(429)
Total current liabilities	(15,019)	(13,621)	(16,859)
Net current assets	42,515	37,378	29,766
Non-current liabilities			
Retirement benefit obligations	(12,299)	(10,477)	(11,747)
Deferred taxation liability	(284)	(304)	(318)
Non-current provisions	(264)	(306)	(273)
Lease liabilities	(7,536)	-	-
Long term borrowings	(1,317)	(2,092)	(1,742)
Total non-current liabilities	(21,700)	(13,179)	(14,080)
Total liabilities	(36,719)	(26,800)	(30,939)
Net assets	51,203	44,477	37,558
Equity			
Capital and reserves			
Issued share capital	646	646	646
Share premium	112,576	112,576	112,576
Merger reserve – shares issued by subsidiary	40,128	40,128	40,128
Reserve – share based payments	3,368	2,324	3,023
Revaluation reserve	1,207	949	1,207
Foreign exchange reserve	(1,131)	(844)	(845)
Retained earnings	(105,591)	(111,302)	(119,177)
Total equity	51,203	44,477	37,558

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 2018	646	112,576	40,128	2,324	949	(844)	(111,302)	44,477
Exchange differences on translation of foreign operations	-	-	-	-	-	(1)	-	(1)
Valuation gains taken to equity (land and buildings)	-	-	-	-	312	-	-	312
Remeasurement of net defined benefit liability	-	-	-	-	-	-	(1,112)	(1,112)
Remeasurement of investments – retirement benefit assets	-	-	-	-	-	-	41	41
Total other comprehensive income	-	-	-	-	312	(1)	(1,071)	(760)
Loss for the period after tax	-	-	-	-	-	-	(6,858)	(6,858)
Total comprehensive income	-	-	-	-	312	(1)	(7,929)	(7,618)
Share based payments	-	-	-	699	-	-	-	699
Transfer of depreciation on revalued property	-	-	-	-	(54)	-	54	-
At 30 June 2019	**646**	**112,576**	**40,128**	**3,023**	**1,207**	**(845)**	**(119,177)**	**37,558**
Exchange differences on translation of foreign operations	-	-	-	-	-	(286)	-	(286)
Remeasurement of net defined benefit liability	-	-	-	-	-	-	(1,060)	(1,060)
Remeasurement of investments – retirement benefit assets	-	-	-	-	-	-	65	65
Total other comprehensive income	-	-	-	-	-	(286)	(995)	(1,281)
Profit for the period after tax	-	-	-	-	-	-	15,276	15,276
Total comprehensive income	-	-	-	-	-	(286)	14,281	13,995
Share based payments	-	-	-	345	-	-	-	345
IFRIC 23 tax provision (See Note 2)	-	-	-	-	-	-	(695)	(695)
At 31 December 2019	**646**	**112,576**	**40,128**	**3,368**	**1,207**	**(1,131)**	**(105,591)**	**51,203**

Condensed consolidated cash flow statement

	6 months to 31Dec 2019 £'000 unaudited	6 months to 31Dec 2018 £'000 unaudited	12 months to 30Jun 2019 £'000 audited
Cash flows from operating activities			
Profit before tax	15,855	10,733	4,293
Adjustments for:			
Finance income	(152)	(118)	(103)
Finance expense	291	124	201
Non cash movements on defined benefit pension plan	81	79	273
Depreciation and amortisation	1,922	1,014	2,090
Net monetary value of above the line R&D tax credit	-	(31)	(593)
Charge for share based payments	345	668	1,367
Movement in fair value of derivative financial instruments	(753)	(32)	332
Foreign exchange revaluation on US dollar cash deposits	53	4	(36)
(Increase) in trade and other receivables	(178)	(4,024)	(1,864)
Decrease/(increase) in inventories	571	(183)	(543)
(Decrease)/increase in trade and other payables	(3,727)	(1,441)	162
Net cash generated by operations	14,308	6,793	5,579
Bank loan fees and Interest paid	(291)	(124)	(204)
Income tax received	572	353	225
Net cash generated by operating activities	14,589	7,022	5,600
Cash flows from investing activities			
Interest received	152	119	151
Payments for retirement benefit investments	(101)	(231)	(405)
Payments for intangible assets	(53)	(7)	(289)
Payments for property plant and equipment	(998)	(722)	(2,810)
Net cash used in investing activities	(1,000)	(841)	(3,353)
Cash flows from financing activities			
Proceeds from issue of equity shares	-	10,600	10,600
Share issue costs	-	(404)	(404)
Repayment of bank loan borrowings	(350)	(346)	(651)
Repayments of lease creditor	(683)	-	-
Net cash (used in)/generated by financing activities	(1,033)	9,850	9,545
Net increase in cash and cash equivalents	12,556	16,031	11,792
Effects of exchange rates on cash and cash equivalents	(271)	78	115
Cash and cash equivalents at the start of the period	27,440	15,533	15,533
Cash and cash equivalents at the end of the period	39,725	31,642	27,440

1. Interim financial information

The unaudited consolidated interim financial information is for the six month period ended 31 December 2019. 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 2019, 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 2019 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 2019 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 except for IFRS16 "Leases" and IFRIC 23, "Uncertainty over income tax treatments" as below.

<u>IFRS16 "Leases"</u>

IFRS 16 "Leases" was published by the IASB and adopted by the EU. It came into effect from 1 January 2019. The Group adopted the standard with effect from 1 July 2019 and included related transactions in these interim financial statements.

The effects of IFRS16 on the balance sheet at the reporting date is to increase lease liabilities by £9.0m of which £7.5m are within non-current liabilities and £1.5m within current liabilities and correspondingly a Right-of-Use Asset of £9.0m under tangible assets net of related depreciation costs of £0.7m.

The impact of IFRS16 on the income statement in these interim financial statements is an increase in EBITDA*** of £0.9m with no net effect on the profit before tax.

<u>IFRIC 23 "Uncertainty over income tax treatments"</u>

The Group prepares provisions against uncertain tax positions in accordance with IFRIC 23. IFRIC 23 has been adopted by the Group with effect from 1 July 2019, with the modified retrospective approach being applied (i.e. the cumulative effect of initially applying the interpretation is recognised as an adjustment to the opening balance of retained earnings, with no change being made to the prior year comparative numbers).

The effect of IFRIC 23 provisions in these interim financial statements amounts to a £0.7m adjustment dealt with through opening retained earnings and a current period additional tax charge of £0.1m.

Going Concern

The Group has been profit making in the six months to 31 December 2019, as it was in the corresponding period ending 31 December 2018.

Detailed budgets have been prepared, including cash flow projections for the periods ending 30 June 2020 and 30 June 2021. 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 £39.7m at 31 December 2019 and expects to renew its banking facilities when they are due for renewal in August 2020. 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 sufficient resources to continue in operational existence for the foreseeable future and accordingly have applied the going concern principle in preparing these interim financial statements.

***EBITDA Profit before interest, tax, depreciation and amortisation.

3. Earnings per share

	6 months to 31 Dec 2019 unaudited £'000	6 months to 31 Dec 2018 unaudited £'000	12 months to 30 Jun 2019 audited £'000
Profit after tax attributable to equity shareholders	15,276	10,325	3,467
	Shares '000	Shares '000	Shares '000
Issued ordinary shares at start of the period	636,169	596,169	596,169
Ordinary shares issued in the period	-	40,000	40,000
Issued ordinary shares at end of the period	636,169	636,169	636,169
Weighted average number of shares in issue for the period	636,169	629,502	632,835
Weighted average number of shares for diluted earnings per share	672,321	667,845	669,703
Basic earnings per ordinary share (pence)	2.40p	1.64p	0.55p
Diluted earnings per ordinary share (pence)	2.27p	1.55p	0.52p

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 2019, no provision has been recognised for the repayment of the rebate refund. This position will be kept under review.

In respect of net revenue relating to certain products, there is a risk that up to £5.8m cumulative revenue (2019: £3.5m) recorded in periods up to and including December 2019 may be subject to a retrospective change. This is due to the level of rebate being applied.