ASTRAZENECA PLC Form 6-K February 06, 2014

# FORM 6-K

# SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of the Securities Exchange Act of 1934

For the month of February 2014

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# AstraZeneca PLC

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### AstraZeneca PLC

### FOURTH QUARTER AND FULL YEAR RESULTS 2013

London, 06 February 2014

Significant progress made towards achieving scientific leadership.

• Pipeline now includes 11 new molecular entities in Phase III or registration; almost double compared with the previous year.

Pipeline and portfolio bolstered through business development in core therapeutic areas.

• Integration of the Bristol-Myers Squibb share of the diabetes alliance occurring at pace; business combination transaction completed on 1 February 2014.

2013 financial performance in line with our expectations and reflecting continuing impact of loss of exclusivity on several brands.

19 candidates for potential new Phase III starts in 2014-15.

Previously announced restructuring programme expanded to deliver a total \$1.1 billion of annual benefits.

The Company expects a low-to-mid single digit percentage decline in revenue at constant exchange rates (CER) for 2014. Core EPS expected to decline in the teens.

The Board declares a second interim dividend of \$1.90 per share, bringing the dividend for the full year to \$2.80. The Board remains committed to the Company's progressive dividend policy.

# Financial Performance Highlights

Revenue for the full year was \$25,711 million, down 6 percent at CER due to competition from generics.

• The key growth platforms Brilinta, the diabetes franchise, respiratory, Emerging Markets and Japan delivered an incremental \$1.2 billion of revenue at CER in 2013. This was more than offset by the impact of patent expiries, which reduced revenue by \$2.2 billion at CER. In the quarter, revenue in China increased by 21 percent at CER.

Core EPS was \$5.05 for the full year, a 23 percent decline at CER.

• The decline in EPS was greater than the decline in revenue primarily due to the investment in the Company's key growth platforms and strengthened pipeline.

Reported EPS for the full year was down 55 percent at CER to \$2.04.

• The impairment of Bydureon (\$1,758 million) in the fourth quarter reduced Reported earnings per share by \$1.10, resulting in a Reported loss per share for the quarter of \$0.42.

Cash generated from operating activities was \$7.4 billion in 2013, compared with \$6.9 billion in 2012.

Revenue in the fourth quarter down 4 percent at CER to \$6,844 million; Core EPS was down 25 percent at CER to \$1.23.

### **R&D Highlights**

- Farxiga (US) and Xigduo (EU) approved for type 2 diabetes
- Olaparib (EU) and naloxegol (EU & US) submitted for regulatory review
- Benralizumab, selumetinib, olaparib and moxetumomab commenced Phase III trials
- Multiple ongoing trials with innovative immuno-oncology portfolio

### **Financial Summary**

Group	4th Quarter 2013	Actual %	CER %	Full Year 2013 \$m	Actual %	CER %
Revenue Core* Operating Profit	\$m 6,844	(6)	(4)	25,711	(8)	(6)
Operating Profit Earnings per Share Reported	1,983	(29)	(26)	8,390	(25)	(22)
	\$1.23	(28)	(25)	\$5.05	(26)	(23)
Operating (Loss)/Profit	(591)	(130)	(128)	3,712	(54)	(51)
(Loss)/Earnings per Share	(\$0.42)	(135)	(132)	\$2.04	(59)	(55)

<sup>\*</sup> See Operating and Financial Review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.

Pascal Soriot, Chief Executive Officer, commenting on the results, said: "As expected, our financial performance for 2013 reflects the ongoing impact from the loss of exclusivity for several key brands. In the near term these headwinds will remain challenging, however I am confident that we can return to growth faster than anticipated and expect our 2017 revenues will be broadly in line with 2013.

"I'm pleased with the momentum we have built in 2013 against our strategic priorities, in particular our objective of achieving scientific leadership. We continue to focus our organisation on the areas that will drive growth, redeploying our resources to fund the promising late-stage pipeline, which nearly doubled in size over the last 12 months. The acquisition of Bristol-Myers Squibb's share of our diabetes alliance strengthens our position in this important area and I am delighted that the business integration is progressing with such pace. We extend a warm welcome to our new colleagues who will help us maximise the potential of our diabetes portfolio."

# Operating and Financial Review

All narrative in this section refers to growth rates at constant exchange rates (CER) and on a Core basis unless otherwise indicated. Core measures, which are presented in addition to our Reported financial information, are non-GAAP measures which management believe useful to enhance understanding of the Group's underlying financial performance of our ongoing business and the key business drivers thereto. Core financial measures are adjusted to exclude certain significant items, such as charges and provisions related to our global restructuring programmes, all intangible asset amortisation charges and impairments, except for IS-related intangibles, and other specified items, principally legal settlements and acquisition related costs. More detail on the nature of these measures is given on pages 88 and 97 of our Annual Report and Form 20-F Information 2012.

Core results for 2012 have been restated according to the Group's updated definition of Core financial measures, which has been implemented with effect from the first quarter 2013 results. Reported and Core results have also been restated to reflect adoption of the amendments to IAS 19 Employee Benefits, which is effective from 1 January 2013.

Fourth Quarter

All financial figures, except earnings per share, are in \$ millions. Weighted average shares in millions.

					Legal		Restated		
	Reported		Intangible	Intangible	_		Core A	Actual	CER
	2013 F	Restructuring	Amortisation I	mpairments	& Other	2013	2012	%	%
Revenue	6,844	-	-	_	-	6,844	7,282	(6)	(4)
Cost of Sales	(1,440)	22	129	-	-	(1,289)	(1,210)		
Gross Profit	5,404	22	129	-	-	5,555	6,072	(9)	(7)
% sales	79.0%					81.2%	83.4%	-2.2	-2.4
Distribution	(72)	-	-	-	-	(72)	(79)	(9)	(7)
% sales	1.1%					1.1%	1.1%	-	-
R&D	(1,429)	84	15	143	(18)	(1,205)	(1,180)	2	2
% sales	20.9%					17.6%	16.2%	-1.4	-1.0
SG&A	(4,642)	279	233	1,662	(15)	(2,483)	(2,204)	13	14
% sales	67.8%					36.3%	30.3%	-6.0	-5.7
Other Income	148	-	40	-	-	188	186	1	1
% sales	2.2%					2.8%	2.6%	+0.2	+0.1
Operating (Loss)/Profit	(591)	385	417*	1,805	(33)	1,983	2,795	(29)	(26)
% sales	-8.6%					29.0%	38.4%	-9.4	-9.0
Net Finance Expense	(124)	-	-	-	-	(124)	(128)		
(Loss)/Profit before Tax	(715)	385	417	1,805	(33)	1,859	2,667	(30)	(28)
Taxation	195	(70)	(59)*	(385)	4**	(315)	(529)		
(Loss)/Profit after Tax	(520)	315	358	1,420	(29)	1,544	2,138	(28)	(25)
Non-controlling Interests	(4)	-	-	-	-	(4)	(13)		
Net (Loss)/Profit	(524)	315	358	1,420	(29)	1,540	2,125	(28)	(25)
Weighted Average Shares	1,254	1,254	1,254	1,254	1,254	1,254	1,246		
(Loss)/Earnings per Share	(0.42)	0.26	0.28	1.13	(0.02)	1.23	1.71	(28)	(25)

<sup>\*</sup> Intangible amortisation includes Merck related amortisation, of which \$98 million carries no tax adjustment.

<sup>\*\*</sup> Legal Provisions & Other includes \$14 million which carries no tax adjustment.

Revenue in the fourth quarter was down 4 percent at CER and declined by 6 percent on an actual basis as a result of the negative impact of exchange rate movements. The Company's key growth platforms contributed \$190 million in revenue growth on a CER basis, an increase of 6 percent compared with last year but this was more than offset by the revenue impact from products which have recently lost exclusivity.

US revenues were down 7 percent in the fourth quarter. Loss of exclusivity accounted for around half of the decline, with the balance being driven by Crestor and Nexium, partially offset by growth of Symbicort, the diabetes franchise and Brilinta. The overall negative impact of US healthcare reform on fourth quarter revenue and costs was approximately \$318 million in total.

Revenue in the Rest of World (ROW) was down 2 percent in the fourth quarter. Revenue in Europe was down 2 percent. Loss of exclusivity on several products including Seroquel IR, Atacand, Nexium and Merrem drove revenue declines with these losses being partially offset by Brilique, Byetta and Bydureon. Revenue in Established ROW was down 10 percent, largely as a result of generic competition for Crestor in Australia and Seroquel IR in Japan which was adversely affected by partner ordering patterns. Revenue in Emerging Markets was up 6 percent. Revenue increased by 21 percent in China and 17 percent in South Korea but these strong performances were offset by a decline in Mexico due to inventory adjustments. Excluding these adjustments, growth in Emerging Markets was 8 percent in the quarter.

Core gross profit in the fourth quarter declined by 7 percent. Core gross margin was 81.2 percent, 240 basis points lower than last year. An unfavourable product mix contributed to the decline.

Core R&D expense was up 2 percent in the fourth quarter as continued benefits from restructuring and other savings were more than offset by investment behind in-licensed, acquired or partnered projects.

Expenditure in Core SG&A was \$2,483 million, 14 percent higher than the fourth quarter last year. This increase was driven by increased investment behind key growth platforms, notably Brilinta, the diabetes franchise and Emerging Markets. The excise fee imposed by the enactment of US healthcare reform measures amounted to 2.4 percent of Core SG&A expense in the quarter.

Core other income increased by 1 percent in the fourth quarter to \$188 million.

Core operating profit in the fourth quarter was down 26 percent to \$1,983 million, which was significantly greater than the decline in revenue due to the investment behind the growth platforms and the enlarged late stage pipeline. Core operating margin was 29.0 percent, 900 basis points lower than last year.

Core earnings per share in the fourth quarter were down 25 percent to \$1.23, broadly in line with the decline in Core operating profit.

As a result of the \$1,758 million intangible impairment related to Bydureon (\$1.10 per share), the Company recorded a Reported loss per share of \$0.42 and a Reported operating loss of \$591 million in the fourth quarter.

Full Year

All financial figures, except earnings per share, are in \$ millions. Weighted average shares in millions.

			Legal	R	estated			
Reported	Intangible	Intangible F	Provisions	Core	Core	Actual	CER	
2013 Restructuring	Amortisation In	mnairments	& Other	2013	2012	%	%	

Revenue	25,711	-	-	-	- 25,711	27,973	(8)	(6)
Cost of Sales	(5,261)	126	502	-	- (4,633)	(4,932)		
Gross Profit	20,450	126	502	-	- 21,078	23,041	(9)	(7)
% sales	79.5%				82.0%	82.4%	-0.4	-0.5
Distribution	(306)	-	-	-	- (306)	(320)	(4)	(3)
% sales	1.2%				1.2%	1.2%	-	-
R&D	(4,821)	490	30	50	(18) (4,269)	(4,241)	1	1
% sales	18.7%				16.6%	15.1%	-1.5	-1.1
SG&A	(12,206)	805	902	1,662	(28) (8,865)	(8,389)	6	7
% sales	47.5%				34.5%	30.0%	-4.5	-4.3
Other Income	595	-	157	-	- 752	1,068	(30)	(30)
% sales	2.3%				2.9%	3.8%	-0.9	-1.0
Operating Profit	3,712	1,421	1,591*	1,712	(46) 8,390	11,159	(25)	(22)
% sales	14.4%				32.6%	39.9%	-7.3	-6.9
Net Finance Expense	(445)	-	-	-	- (445)	(502)		
Profit before Tax	3,267	1,421	1,591	1,712	(46) 7,945	10,657	(25)	(23)
Taxation	(696)	(302)	(256)*	(364)	7** (1,611)	(2,022)		
Profit after Tax	2,571	1,119	1,335	1,348	(39) 6,334	8,635	(27)	(24)
Non-controlling Interests	(15)	-	-	-	- (15)	(30)		
Net Profit	2,556	1,119	1,335	1,348	(39) 6,319	8,605	(27)	(24)
Weighted Average Shares	1,252	1,252	1,252	1,252	1,252 1,252	1,261		
Earnings per Share	2.04	0.90	1.06	1.08	(0.03) 5.05	6.83	(26)	(23)

<sup>\*</sup> Intangible amortisation includes Merck related amortisation, of which \$392 million carries no tax adjustment.

Revenue for the year was down 6 percent at CER and declined by 8 percent on an actual basis as a result of the negative impact of exchange rate movements. The revenue decline was driven by a loss of exclusivity on several brands. US revenue was down 9 percent; revenue in the Rest of World was down 4 percent.

Core gross margin was 82.0 percent, 0.5 percentage points lower than last year.

Core R&D expense for the year was up 1 percent, as a result of absorbing higher costs from business development projects as well as investment in the growing late stage pipeline.

Expenditures in Core SG&A were 7 percent higher than last year, as a result of increased investment in support of growth platforms, an effect which is magnified by relatively low levels of expenditure in 2012. The excise fee imposed by the enactment of US healthcare reform measures amounted to 2.7 percent of Core SG&A expense in 2013.

Core other income for the year was down 30 percent, reflecting the income from the sale of OTC rights for Nexium in 2012.

Core operating profit for the year was down 22 percent to \$8,390 million. Core operating margin was 32.6 percent of revenue, down 6.9 percentage points.

Core earnings per share were \$5.05, down 23 percent compared with last year and broadly in line with the decline in Core operating profit.

<sup>\*\*</sup> Legal Provisions & Other includes \$14 million which carries no tax adjustment.

Reported operating profit for the year was down 51 percent to \$3,712 million. Reported EPS was down 55 percent to \$2.04. The larger declines compared with the respective Core financial measures are mainly the result of the \$1,758 million impairment of intangible assets related to Bydureon, as well as the full year amortisation related to the Merck second option.

# Expansion of Phase 4 Restructuring Programme

In March 2013 the Company described how transforming the way it works is crucial to delivering its strategy. The Company committed to dramatically simplifying its organisation and processes, while creating an innovative environment, including through co-location on a more focused footprint. AstraZeneca continues to drive productivity improvements across the organisation, removing complexity and creating additional headroom to invest in growing its business and ensuring returns to its shareholders.

As previously announced, the Company combined the restructuring announced on 21 March 2013 with a previously announced programme to create a combined Phase 4 programme that entails an estimated global headcount reduction of about 5,050 over the 2013-2016 period. The combined programme of changes was estimated to incur \$2.3 billion in one-time restructuring charges to the P&L, of which \$1.7 billion are expected to be cash costs. In 2013, the Company continued to implement the Phase 4 programme with speed, incurring costs of \$1.4 billion and delivering approximately \$400 million of annualised benefits. The overall programme remains on track to deliver the approximately \$800 million anticipated annual benefits by the end of 2016. Total costs for this programme are now anticipated to be approximately \$200 million higher at \$2.5 billion.

These restructuring initiatives have been expanded in order to create further headroom to invest behind the pipeline and key growth platforms. Additional activities include a transformation of the IT organisation and infrastructure, the exit of R&D activities in Bangalore, India, and the exit from branded generics in certain Emerging Markets to further reduce costs and increase flexibility. When completed, the expansion of the restructuring programme will deliver a further \$300 million in annual benefits by the end of 2016, bringing total anticipated annualised benefits of the Phase 4 programme to \$1.1 billion. Total incremental programme costs from these new initiatives, included in non-Core restructuring costs, are estimated to be \$700 million, of which \$600 million is cash, bringing the total anticipated cost of our Phase 4 programme to \$3.2 billion. As already announced internally, the expansion of the programme is estimated to impact approximately 550 positions, bringing the total global headcount reduction under the Phase 4 programme to around 5,600 over the 2013-2016 period.

Final estimates for programme costs, benefits and headcount impact in all functions are subject to completion of the requisite consultation processes in the various areas many of which have already commenced. Our priority as we undertake these restructuring initiatives is to work with our affected employees on the proposed changes, acting in accordance with relevant local consultation requirements and labour laws.

# Finance Income and Expense

Net finance expense was \$124 million for the fourth quarter 2013, versus \$128 million in 2012. For the full year, net finance expense was \$445 million, versus \$502 million for the same period of 2012. Interest payable on defined benefit pension scheme liabilities fell by \$14 million for the full year, and there were fair value gains of \$5 million recorded on long-term bonds in 2013, versus \$10 million losses in 2012. Interest on long-term bonds for the full year was \$16 million lower than the comparative period in 2012.

### **Taxation**

The Reported tax rate for the year was 21.3 percent compared with 18.0 percent for 2012. The Reported tax rate for the quarter was 27.3 percent compared with 17.2 percent for the same period last year. The Reported tax rate for the year ended 31 December 2012 benefited from a \$230 million adjustment to deferred tax balances following

substantive enactment of a reduction in the Swedish corporation tax rate from 26.3 percent to 22.0 percent, and a \$240 million adjustment in respect of prior periods following the settlement of a transfer pricing matter. Excluding these benefits, the Reported tax rate for 2012 would have been 24.1 percent.

### Cash Flow

Cash generated from operating activities was \$7,400 million in the year to 31 December 2013, compared with \$6,948 million in 2012. Lower tax and interest payments partially offset the lower operating profit in 2013, after adjusting for impairments and non-cash costs, whilst working capital movements and a one-off pension fund contribution drove higher outflows in the prior year.

Net cash outflows from investing activities were \$2,889 million, compared with \$1,859 million in 2012. While intangible asset purchases were \$2,631 million lower in 2013, this was more than offset by lower inflows from the maturity of short-term investments, which benefited investing cash flows by \$3,619 million in the prior year.

Net cash distributions to shareholders were \$2,979 million, through dividends of \$3,461 million partially offset by proceeds from the issue of shares of \$482 million.

### Debt and Capital Structure

At 31 December 2013, outstanding gross debt (interest-bearing loans and borrowings) was \$10,376 million (31 December 2012: \$10,310 million). Of the gross debt outstanding at 31 December 2013, \$1,788 million is due within one year (31 December 2012: \$901 million).

At 1 January 2013, the Company had net debt of \$1,369 million. At 31 December 2013, the Company had net funds of \$39 million. The movement during the year is as a result of the net cash inflow as described in the cash flow section above.

### Dividends and share repurchases

The Board has recommended a second interim dividend of \$1.90 (116.8 pence, 12.41 SEK) to be paid on 24 March 2014. This brings the full year dividend to \$2.80 (176.0 pence, 18.33 SEK).

This dividend is consistent with the progressive dividend policy, by which the Board intends to maintain or grow the dividend each year.

The Board regularly reviews its distribution policy and its overall financial strategy to continue to strike a balance between the interests of the business, our financial creditors and our shareholders. The Board continues to target a strong, investment grade credit rating. Having regard for business investment, funding the progressive dividend policy and meeting our debt service obligations, the Board currently believes it is appropriate to continue the suspension of the buyback which was announced in October 2012.

During 2013, 10.4 million shares were issued in respect of share schemes for a consideration of \$451 million.

The total number of shares in issue at 31 December 2013 was 1,257 million.

# **Future Prospects**

The Company provides the following financial guidance, which supersedes all previous guidance and planning assumptions:

- It expects a low-to-mid single digit percentage decline in revenue at CER for 2014.
- In percentage terms, Core EPS for 2014 is expected to decline in the teens at CER.
  - The Company expects revenues in 2017 will be broadly in line with 2013.

The above guidance assumes Nexium US generic launch at the end of May 2014.

This guidance has been based on January 2014 average exchange rates for our principal currencies. The target takes no account of the likelihood that average exchange rates for the remainder of 2014 may differ materially from the rates upon which our earnings guidance is based. An estimate of the sales and earnings sensitivity to movements of our major currencies versus the US dollar has been provided with these results and can be found on the AstraZeneca website, www.astrazeneca.com/investors.

### Research and Development Update

A comprehensive update of the AstraZeneca R&D pipeline is presented in conjunction with this Full Year 2013 results announcement, and is available on the Company's website. In the future, AstraZeneca will update its R&D pipeline on a quarterly basis, a change from current bi-annual updates.

At the Investor Day on 21 March 2013, the Company outlined its strategy to achieve scientific leadership, including focusing its R&D efforts on distinctive science in three core therapeutic areas: Respiratory, Inflammation & Autoimmunity; Cardiovascular & Metabolic Disease; and Oncology. The AstraZeneca pipeline has subsequently undergone a significant transformation and now includes 99 projects, of which 85 are in the clinical phase of development and 14 are either approved, launched or filed. During 2013, across the portfolio, 33 projects have successfully progressed to their next phase (including 14 projects entering first human testing) and 15 projects have been withdrawn.

2013 was a very productive year for the R&D function as the Company prioritised and, in several cases, accelerated late-stage development of projects in those disease areas with the greatest potential to meet patient need. As a result, the late stage pipeline has grown faster than expected and now includes 11 new molecular entities in Phase III or under regulatory review, a near-doubling since the start of 2013. Consequently, the Company has achieved its 2016 target volume for the Phase III pipeline approximately 3 years ahead of schedule.

The strengthening of the R&D pipeline was fuelled by acquisitions of Pearl Therapeutics and Omthera Pharmaceuticals, and in-licensing of an investigational compound from FibroGen for renal disease. At the Company's Investor Day in March 2013, 4 projects (benralizumab, olaparib, moxetumomab pasudotox and selumetinib) were identified for potential Phase III starts in 2013 and all 4 have now successfully progressed to late-stage development.

A number of early-stage projects have presented first clinical data in patients and are rapidly progressing towards registration trials. Notable projects include: MEDI4736, an anti-PD-L1 monoclonal antibody (mAb), in patients with solid tumours, and AZD9291, a third generation irreversible epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI), in advanced EGFR mutation-positive (M+) non-small-cell lung cancer (NSCLC) patients. Both are anticipated to initiate Phase III trials in 2014. Consequently, the Company has identified 19 projects for potential Phase III starts in 2014-2015.

Selected pipeline developments since the third quarter 2013 update include:

Immune-mediated therapies for cancer (IMT-C)

The Company's IMT-C pipeline has grown rapidly. Several combination trials have been initiated. Two studies exploring the combination of tremelimumab, the anti-CTLA-4 monoclonal antibody (mAb), and MEDI4736 (anti-PD-L1 mAb) are evaluating safety and efficacy across multiple tumour types, as well as a combination study with MEDI4736 plus dabrafenib/trametinib in melanoma (GSK collaboration). Another Phase I studyis exploring the combination of Iressa and tremelimumab in advanced EGFR M+ NSCLC. Additional combination studies are planned to start in 2014. The Company also initiated a Phase I, first-in-human dose-escalation study of MEDI0680/AMP-514, the anti-PD-1 mAb acquired by the Amplimmune acquisition, in adult subjects with solid tumours. Furthermore, a randomized Phase II study is exploring tremelimumab in patients with unresectable pleural or peritoneal malignant mesothelioma.

### Farxiga

On 8 January 2014, AstraZeneca and its partner, Bristol-Myers Squibb (BMS), announced that the US Food and Drug Administration (FDA) approved Farxiga (dapagliflozin) tablets for the treatment of adult patients with type 2 diabetes. Farxiga is a selective and reversible inhibitor of sodium-glucose co-transporter 2 (SGLT2) that works independently of insulin to help remove excess glucose from the body. Farxiga was approved under the trade name Forxiga in the EU in November 2012.

### Xigduo

On 22 January 2014, AstraZeneca and its partner, BMS, announced that Xigduo (dapagliflozin and metformin hydrochloride) had been approved in the EU for type 2 diabetes. Xigduo combines dapagliflozin, a selective and reversible inhibitor of SGLT2, with metformin hydrochloride, two anti-hyperglycaemic products with complementary mechanisms of action to improve glycaemic control, in a twice-daily tablet. This is the first regulatory approval for a fixed-dose combination of an SGLT2 inhibitor and metformin.

In the fourth quarter 2013, AstraZeneca and its partner, BMS, submitted a New Drug Application (NDA) to the US FDA for Xigduo (dapagliflozin and metformin hydrochloride extended release) fixed-dose combination for the treatment of patients with type 2 diabetes, in a once-daily tablet.

### Fluenz Tetra

On 6 December 2013, AstraZeneca announced that the European Commission (EC) had approved Fluenz Tetra for the prevention of seasonal influenza in children. Fluenz Tetra is a nasally administered four-strain live attenuated influenza vaccine for the prevention of influenza in children and adolescents from 24 months up to 18 years of age. The EC approval makes Fluenz Tetra the first and only intra-nasal four-strain influenza vaccine available in Europe.

### Metreleptin

On 11 December 2013, the US FDA's Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) recommended the investigational medicine metreleptin for the treatment of paediatric and adult patients with generalised lipodystrophy. The EMDAC did not recommend metreleptin in patients with partial lipodystrophy. The FDA is not bound by the EMDAC's recommendation but will take it into consideration when reviewing the Biologics License Application for metreleptin. The prescription-drug user fee act (PDUFA) goal date for metreleptin is 24 February 2014.

### Bydureon Dual Chamber Pen

In the fourth quarter 2013, AstraZeneca and its partner, BMS, submitted a Type 2 Variation to the European Medicines Agency (EMA) for Bydureon Dual Chamber Pen for treatment of patients with type 2 diabetes.

### Naloxegol

On 19 November 2013, the Company announced that the US FDA acknowledged receipt of the NDA for its investigational drug naloxegol, an oral peripherally-acting, mu-opioid receptor antagonist (PAMORA), which has been studied in opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, a common side effect of prescription opioid pain medicines.

AstraZeneca has been informed that the US FDA Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) is planning to review safety data as it relates to the PAMORA class of therapies for the treatment of OIC. Naloxegol will be included as part of the FDA AADPAC discussion, at a date still to be determined.

Naloxegol is part of an exclusive worldwide license agreement between AstraZeneca and Nektar Therapeutics.

### Lesinurad

On 13 December 2013, the Company announced top-line results from LIGHT, a Phase III study investigating the potential of lesinurad as a monotherapy in the small population of gout patients who are intolerant to, or otherwise cannot take, one or both xanthine oxidase inhibitors allopurinol and febuxostat. Lesinurad is an investigational agent being studied as a selective uric acid re-absorption inhibitor (SURI) that inhibits the URAT1 transporter, normalising uric acid excretion and reducing serum uric acid (sUA).

In the trial, lesinurad met the primary endpoint with a statistically significant (p<0.0001) higher proportion of patients meeting the sUA goal of <6.0 mg/dL at six months compared with those patients treated with placebo.

Patients in the LIGHT study treated with lesinurad monotherapy were more likely to experience serum creatinine elevations and renal adverse events, including serious events, compared to patients on placebo. Other commonly reported adverse events in patients treated with lesinurad monotherapy were diarrhoea, nausea and constipation.

The other Phase III trials in the lesinurad programme are investigating lesinurad in combination with allopurinol in patients not reaching target sUA levels on allopurinol alone (CLEAR1 and CLEAR2) and as a combination therapy with febuxostat in patients with tophaceous gout (CRYSTAL). The results of these studies are expected in mid 2014, and regulatory submissions in the US (NDA) and EU (MAA) are expected in the second half of 2014.

### Zinforo

In November 2013, the Asia Community Acquired Pneumonia (CAP) Phase III study was completed and the study demonstrated a favourable efficacy and comparable tolerability profile for Zinforo (ceftaroline fosamil) 600mg twice daily compared to ceftriaxone 2g once daily in patients in Asia with CAP. The purpose of this Phase III, randomised, double-blind, active comparator trial was to confirm the effectiveness and tolerability profile of Zinforo in adult patients with CAP in the Asian region.

Full results of the study will be presented at an upcoming scientific congress.

In 2009, Forest Laboratories, Inc. granted AstraZeneca exclusive worldwide commercial rights and co-exclusive development rights for ceftaroline fosamil, excluding the US, Canada and Japan.

**Business Development Transactions** 

Acquisition of BMS share of global diabetes alliance assets

On 1 February 2014, AstraZeneca completed the acquisition of BMS's share of global diabetes alliance assets. The deal, which is accounted for as a business combination, comprises an initial consideration of \$2.7 billion on completion, \$1.4 billion in regulatory, launch and sales-related payments, and various sales-related royalty payments up until 2025. In addition, AstraZeneca may make payments up to \$225 million when certain assets are subsequently transferred. See Note 9 for further details.

Upon completion of the transaction, AstraZeneca assumed ownership of intellectual property and global rights for the development, manufacture and commercialisation of the diabetes business, which includes Onglyza (saxagliptin), Kombiglyze XR (saxagliptin and metformin HCl extended release), Komboglyze (saxagliptin and metformin HCl), Farxiga (marketed as Forxiga outside the US), Byetta (exenatide), Bydureon (exenatide extended-release for injectable suspension), metreleptin and Symlin (pramlintide acetate).

The transaction consolidates worldwide ownership of the diabetes business within AstraZeneca, leveraging its primary and specialty care capabilities and its geographical reach, especially in Emerging Markets. The agreement reinforces AstraZeneca's long-term commitment to patients with diabetes, a core strategic area and an important platform for returning AstraZeneca to growth.

### Immunocore

On 8 January 2014, AstraZeneca announced an oncology research collaboration and licensing agreement with Immunocore Limited, a privately-held, UK-based biotechnology company.

Both companies will research and develop novel cancer therapies using Immunocore's Immune Mobilising Monoclonal T-Cell Receptor Against Cancer (ImmTAC) technology.

This platform of biological medicines exploits the power of the body's own immune system to find and kill diseased cells. ImmTACs direct a patient's T cells to specifically destroy only the cancerous cells, avoiding damage to healthy cells.

Under the terms of the agreement, Immunocore and MedImmune, AstraZeneca's biologics arm, will work together to generate ImmTACs against selected cancer targets. AstraZeneca and MedImmune will have the right to further develop and commercialise ImmTAC products to add to their immune-mediated cancer therapy portfolio. The agreement comprises an upfront payment of \$20 million per programme, up to \$300 million in development and commercial milestone payments for each target programme and significant tiered royalties if the programmes are successful.

### Revenue

All narrative in this section refers to growth rates at constant exchange rates (CER) unless otherwise indicated.

A full analysis of the Group's revenue by product and geographic area is shown in Notes 11 and 12.

Fourth Qu	ıarter		Full Y	ear	
2013	2012	CER	2013	2012	CER
\$m	\$m	%	\$m	\$m	%

Cardiovascular

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Crestor	1,463	1,622	(8)	5,622	6,253	(8)
Onglyza	93	88	6	378	323	17
Byetta	54	47	17	206	74	181
Bydureon	49	26	88	151	37	308
Forxiga	3	-	n/m	10	-	n/m
Brilinta/Brilique	92	38	139	283	89	216
Atacand	134	202	(33)	611	1,009	(39)
Seloken/Toprol-XL	170	256	(32)	750	918	(18)
Gastrointestinal						
Nexium	991	1,047	(3)	3,872	3,944	_
Losec/Prilosec	122	156	(18)	486	710	(28)
Respiratory & Inflammation						
Symbicort	976	891	11	3,483	3,194	10
Pulmicort	245	242	3	867	866	1
Oncology						
Zoladex	247	271	1	996	1,093	_
Arimidex	86	122	(23)	351	543	(30)
Casodex	95	112	(4)	376	454	(7)
Iressa	158	160	5	647	611	11
Faslodex	182	175	6	681	654	6
Neuroscience						
Seroquel	372	476	(22)	1,682	2,803	(39)
Seroquel IR	35	94	(64)	345	1,294	(72)
Seroquel XR	337	382	(12)	1,337	1,509	(12)
Zomig	35	39	(5)	134	182	(23)
Vimovo	24	18	39	91	65	42
Infection and other						
Synagis	515	503	2	1,060	1,038	2
Merrem	77	106	(25)	293	396	(24)
FluMist/Fluenz	50	32	56	245	181	35

### Cardiovascular

- In the US, Crestor sales in the fourth quarter were \$779 million, down 10 percent, on a 7 percent decline in total prescriptions combined with some impact from lower stocking and slightly lower realised net price. Crestor share of total prescriptions at 10.6 percent has been resilient in a competitive generic market. Crestor sales for the full year in the US were down 8 percent to \$2,912 million.
- · Crestor sales in the Rest of World in the fourth quarter were down 6 percent to \$684 million, reflecting the loss of exclusivity in Australia and Canada. Excluding these markets, ROW sales were up by 2 percent, driven by growth in China. Crestor sales in the Rest of World for the full year were down 9 percent to \$2,710 million.

Alliance revenue from the Onglyza collaboration with Bristol-Myers Squibb was up 6 percent in the fourth quarter to \$93 million, with all growth coming in markets outside the US, where revenue was up 20 percent to \$30 million. US revenue was flat at \$63 million, with favourable price realisation fully offsetting a share decline largely driven by a less favourable formulary position.

- Market share of total prescriptions in the US for the Onglyza franchise in the DPP4 market was 15.8 percent in December, down 2 points this year primarily related to formulary position, with little impact realised from the launch of new entrants. AstraZeneca's share of worldwide alliance revenue for the full year was \$378 million, up 17 percent.
- Alliance revenue for Forxiga was \$3 million in the quarter and \$10 million for the full year, all in Europe, where there has been good physician acceptance since approval in November 2012, but a challenging reimbursement climate to navigate.
- The Company's share of Byetta and Bydureon revenues was \$103 million in the fourth quarter; comprised of \$76 million in the US and \$27 million in ROW. There were no revenues recorded in ROW in 2012 as the alliance only assumed responsibility for promotion outside the US in April 2013. In the US, total prescriptions for Bydureon were up 49 percent over the fourth quarter 2012 and total prescriptions for Byetta down 35 percent resulting in a 9 percent decline for the exenatide franchise over the same period. However, the quarter-over-quarter total prescription volume decline stopped in the fourth quarter on improved new-to-brand share for Bydureon. The Company's share of worldwide revenue for the exenatide products was \$357 million for the full year.
- Global sales of Brilinta/Brilique were \$92 million in the fourth quarter, up from \$75 million in the third quarter 2013. More than half of the sales were in Europe where fourth quarter sales have more than doubled since last year. Performance in Canada, Australia and the Emerging Markets is also contributing to brand revenue growth, representing more than 18 percent of sales in the quarter. Worldwide sales for Brilinta/Brilique were \$283 million for the full year.
- US sales of Brilinta in the fourth quarter were \$24 million, 33 percent above the third quarter 2013. Dispensed demand growth of 17 percent was in line with sales growth when the impact of reserve adjustments posted in the third quarter is excluded. Total prescription share for Brilinta in the US was 1.85 percent in December, growing more than a full share point in the year. This growth was driven by new to brand share of 6.8 percent, growth of which was accelerating before the announcement of a Civil Investigative Demand related to the PLATO trial. The Company is fully cooperating with the inquiry and is confident in the integrity of the PLATO study. Full year sales of Brilinta in the US were \$73 million.
- · US sales of Atacand were down 69 percent in the fourth quarter to \$10 million, as both forms of the brand now have generic competition. Sales for the full year were down 52 percent to \$72 million.
- Atacand sales in other markets were down 26 percent to \$124 million in the fourth quarter, largely
  due to the loss of exclusivity in developed markets and slight decrease in Emerging Markets. Sales
  in ROW for the full year were \$539 million, down 36 percent.
- US sales of the Toprol-XL product range, which includes sales of the authorised generic, decreased by 81 percent in the fourth quarter to \$19 million, driven by lower prescription volume and lower net realised price following the launch of a fourth generic late in 2012. The decline in the quarter was exacerbated by a favourable returns adjustment in the prior year. Sales for the full year in the US were down 59 percent to \$131 million.

• Sales of Seloken in other markets in the fourth quarter were down 3 percent to \$151 million. Sales for the full year were up 5 percent to \$619 million.

### Gastrointestinal

- In the US, Nexium sales in the fourth quarter were \$545 million, down 9 percent compared with the fourth quarter last year. Dispensed retail tablet volume declined by around 11 percent. Nexium sales in the US for the full year were down 7 percent to \$2,123 million.
- As a result of various patent litigation settlements, several generic companies were granted a license to enter the US market with their proposed ANDA versions of generic esomeprazole on 27 May 2014, subject to regulatory approval, or earlier, in certain circumstances. In line with the Company's standard practice, a returns reserve will be taken against the estimated trade inventories of Nexium at the time of the first generic launch. The Company will also move the brand to demand based accounting, wherein revenue will be recognised based on demand sales, indicated by dispensed prescription demand, rather than ex-factory shipments. Therefore, Nexium revenue in 2014 will reflect this accounting treatment, the loss of market share to generic substitution, and the impact of channel destocking as trade inventories contract to adjust to the declining sales trend.
- Nexium sales in other markets in the fourth quarter increased by 5 percent to \$446 million. Sales in Europe were down 12 percent, largely the result of generic competition. Sales in Established Rest of World were up 30 percent, driven by a doubling of sales in Japan. Sales in Emerging Markets decreased by 5 percent, as growth in China of 29 percent was more than offset by declines in other markets. Nexium sales in other markets were up 10 percent for the full year to \$1,749 million.
- · Losec sales in markets outside the US were down 20 percent in the fourth quarter to \$115 million, largely on lower sales in Japan. Global sales for the full year were down 28 percent to \$486 million.

### Respiratory and Inflammation

- Symbicort sales in the fourth quarter in the US were \$350 million, a 28 percent increase over the fourth quarter last year. Total prescriptions for Symbicort were up 17 percent in the relatively flat market for fixed combination products. Symbicort share of total prescriptions for fixed combination products reached 26.2 percent in December 2013, up 3.9 percentage points since December 2012. Market share of patients new to brand was 35.3 percent in December, up 6.8 points from December 2012, with current weekly share of 41.1 percent reflecting the effect of 2014 formulary changes in the fixed combination market. Symbicort sales in the US for the full year were up 23 percent to \$1,233 million.
- Symbicort sales in ROW in the fourth quarter were \$626 million, up 3 percent, on 21 percent growth in Emerging Markets, driven by China, up 122 percent. Reported sales decline of 5 percent in Japan reflects the phasing of shipments to our marketing partner; in market demand is up 22 percent. Market share in Japan is up 3.8 percentage points since the beginning of the year. Sales in other established markets were broadly flat. Symbicort sales in the Rest of World for the full year were up 4 percent to \$2,250 million.
- · US sales of Pulmicort were up 5 percent in the fourth quarter to \$59 million. Sales for the full year were down 4 percent to \$224 million.

Pulmicort sales in the Rest of World were up 2 percent in the fourth quarter to \$186 million, largely
on a 28 percent increase in China. Full year sales of Pulmicort in China were \$243 million, a growth
of 21 percent. Rest of World sales for Pulmicort for the full year were \$643 million, 3 percent higher
than last year.

### Oncology

- Arimidex sales for the full year were down 30 percent worldwide to \$351 million, as a result of loss
  of exclusivity. Sales in Japan, which account for 38 percent of global revenue, were down 28
  percent for the full year. US Sales now represent less than 2 percent of total revenue.
- · Global Casodex sales for the full year were down 7 percent to \$376 million. Sales in Japan, which account for 57 percent of global revenue, were down 10 percent for the full year.
- Iressa sales in the fourth quarter were up 5 percent to \$158 million. Sales in Japan were flat for the quarter, but were up 7 percent for the year and represent 29 percent of global sales of the brand. Sales in Emerging Markets were up 11 percent in the fourth quarter, driven by a 10 percent increase in China, which now represents 20 percent of global sales for the year. Worldwide sales of Iressa for the full year increased by 11 percent to \$647 million.
- · Global Faslodex sales were up 6 percent for the fourth quarter and full year. Worldwide sales for the year of \$681 million were driven by steady growth in the US of 5 percent to \$324 million, along with strong growth in ROW markets, such as Japan (up 24 percent) and Latin America (up 26 percent).

### Neuroscience

- · In the US, sales of Seroquel IR for the full year were -\$17 million, as unfavourable adjustments taken for the Medicaid liability and the estimated trade inventory reserve more than offset current year revenue.
- · Sales of Seroquel XR in the US were down 9 percent to \$194 million in the fourth quarter. Total prescription volume was down 6 percent. Seroquel XR share of total prescriptions has shown recent signs of stabilising at 4.2 percent, stemming the decline following the launch of quetiapine IR generics at the end of March 2012. US sales of Seroquel XR for the full year were down 8 percent to \$743 million.
- Sales of Seroquel IR in the Rest of World were down 50 percent to \$54 million in the fourth quarter, driven by partner ordering patterns in Japan in conjunction with a price concession on trade inventory posted in the quarter. Sales in the Rest of World for Seroquel IR for the full year were down 36 percent to \$362 million.
- Sales of Seroquel XR in the Rest of World were down 17 percent to \$143 million in the fourth quarter. Sales in established markets (Europe and Established ROW) were down 23 percent, as growth in France was more than offset by declines in several markets following the patent invalidation actions and at risk launch in some EU markets. Sales in Emerging Markets were up 21 percent in the quarter. Seroquel XR sales in the Rest of World for the full year were \$594 million, down 15 percent.

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Sales of Vimovo in the fourth quarter were \$24 million, comprised of \$3 million in the US and \$21 million in the Rest of the World. The Company divested its rights to Vimovo in the US in November 2013. Global sales for the full year were \$91 million.

### Infection and Other

- Synagis sales in the US were down 1 percent to \$300 million in the fourth quarter. Outside the US,
   Synagis sales were up 8 percent to \$215 million. Global full year sales were up 2 percent to \$1,060 million
- · Sales of Merrem for the full year were down 24 percent to \$293 million, as a result of generic competition in many markets.
- Sales of FluMist/Fluenz in the fourth quarter were \$50 million, of which \$22 million were in the US and \$23 million in the UK. Global full year sales were up 35 percent to \$245 million, driven by good reception for the launch of FluMist Quadrivalent/Fluenz in the US with sales of \$199 million and effective implementation of vaccination policy programs in the UK with sales of \$38 million.

### Regional Revenue

	Fourth Quarter				Full Y	ear		
	2013	2012	% Chan	ge	2013	2012	% Chang	e
	\$m	\$m	Actual	CER	\$m	\$m	Actual	CER
US	2,634	2,823	(7)	(7)	9,691	10,655	(9)	(9)
Europe1	1,822	1,790	2	(2)	6,658	7,143	(7)	(9)
Established ROW2	1,023	1,347	(24)	(10)	3,973	5,080	(22)	(10)
Japan	668	860	(22)	(4)	2,485	2,904	(14)	4
Canada	161	209	(23)	(19)	637	1,090	(42)	(40)
Other Established								
ROW	194	278	(30)	(23)	851	1,086	(22)	(18)
Emerging Markets3	1,365	1,322	3	6	5,389	5,095	6	8
China	477	384	24	21	1,840	1,512	22	19
Total	6,844	7,282	(6)	(4)	25,711	27,973	(8)	(6)

1Europe comprises Western Europe and many markets that were formerly reported in Emerging Rest of World. 2Established ROW comprises Canada, Japan, Australia and New Zealand.

3Emerging Markets comprises all of the remaining Rest of World markets, including Brazil, China, India, Mexico, Russia, and Turkey.

- · In the US, revenue was down 7 percent in the fourth quarter, largely driven by generic competition on Atacand and the Toprol-XL franchise. There was strong revenue growth for Symbicort and Brilinta; however this was offset by continued decline of Nexium volume. Nexium and Crestor were also unfavourably impacted by an adjustment to the Medicare Coverage Gap liability.
- Revenue in Europe was down 2 percent in the fourth quarter. Revenue increases for Brilique and Synagis across most markets and Fluenz in the UK could not offset declines related to generic competition on several brands including Seroquel, Atacand, Nexium and Merrem.

Revenue in Established ROW was down 10 percent in the fourth quarter, with more than half of the decline driven by generic competition for Crestor and Atacand in Australia and Seroquel XR, Nexium and Crestor in Canada. Revenue in Japan was down 4 percent, as growth of Nexium was more than offset by declines of Losec and Seroquel IR.

• Revenue in Emerging Markets was up 6 percent in the fourth quarter, driven by 21 percent growth in China on strong sales of Crestor, Pulmicort and Nexium. Revenue increased by 17 percent in South Korea. Emerging Markets growth in the quarter was impacted by inventory adjustments in Mexico. Excluding these adjustments, growth in Emerging Markets was 8 percent in the quarter.

# Condensed Consolidated Statement of Comprehensive Income

Restated   Restated   Revenue   Restated   Revenue   R	r		
For the year ended 31 December         \$m         \$m           Revenue         25,711         27,973           Cost of sales         (5,261)         (5,393)           Gross profit         20,450         22,580           Distribution costs         (306)         (320)           Research and development expense **         (4,821)         (5,243)           Selling, general and administrative costs **         (12,206)         (9,839)           Other operating income and expense         595         970           Other operating profit         3,712         8,148           Finance income         50         42           Finance expense         (495)         (544)           Profit before tax         3,267         7,646           Taxation         (696)         (1,376)           Profit for the period         2,571         6,270           Other comprehensive income         1         6,270           Items that will not be reclassified to profit or loss         (82)         (65)           Remeasurement of the defined benefit pension liability         8         (13)           Tax on items that may be reclassified subsequently to profit or loss         (82)         (65)           Foreign exchange arising on consolidation			Restated*
Revenue         25,711         27,973           Cost of sales         (5,261)         (5,393)           Gross profit         20,450         22,580           Distribution costs         (306)         (3206)           Research and development expense **         (4,821)         (5,243)           Selling, general and administrative costs **         (12,206)         (9,839)           Other operating income and expense         595         970           Operating profit         3,712         8,148           Finance income         50         42           Finance expense         (495)         (544)           Profit before tax         3,267         7,646           Taxation         (696)         (1,376)           Profit for the period         2,571         6,270           Other comprehensive income         Items that will not be reclassified to profit or loss         8         (13)           Remeasurement of the defined benefit pension liability         8         (13)           Tax on items that will not be reclassified to profit or loss         (82)         (65)           Foreign exchange arising on consolidation         (166)         106           Foreign exchange differences on borrowings designated in net investment hedges         11			
Cost of sales         (5,261)         (5,393)           Gross profit         20,450         22,580           Distribution costs         (306)         (320)           Research and development expense **         (4,821)         (5,243)           Selling, general and administrative costs **         (12,206)         (9,839)           Other operating income and expense         595         970           Operating profit         3,712         8,148           Finance income         50         42           Finance expense         (495)         (544)           Profit before tax         3,267         7,646           Taxation         (696)         (1,376)           Profit for the period         2,571         6,270           Other comprehensive income         Items that will not be reclassified to profit or loss         82         (65)           Remeasurement of the defined benefit pension liability         8         (13)           Tax on items that will not be reclassified to profit or loss         (82)         (65)           Foreign exchange arising on consolidation         (166)         106           Foreign exchange arising on consolidation         (58)         (46)           Foreign exchange differences on borrowings designated in net investment hedges </td <td>•</td> <td></td> <td></td>	•		
Gross profit         20,450         22,580           Distribution costs         (306)         (320)           Research and development expense **         (4,821)         (5,243)           Selling, general and administrative costs **         (12,206)         (9,839)           Other operating income and expense         595         970           Operating profit         3,712         8,148           Finance income         50         42           Finance expense         (495)         (544)           Profit before tax         3,267         7,646           Taxation         (696)         (1,376)           Profit for the period         2,571         6,270           Other comprehensive income           Items that will not be reclassified to profit or loss         8         (13)           Remeasurement of the defined benefit pension liability         8         (13)           Tax on items that will not be reclassified to profit or loss         (82)         (65)           Foreign exchange arising on consolidation         (166)         106           Foreign exchange arising on consolidation         (166)         106           Foreign exchange differences on borrowings designated in net investment hedges         111         76		•	
Distribution costs         (306)         (320)           Research and development expense **         (4,821)         (5,243)           Selling, general and administrative costs **         (12,206)         (9,839)           Other operating income and expense         595         970           Operating profit         3,712         8,148           Finance income         50         42           Finance expense         (495)         (544)           Profit before tax         3,267         7,646           Taxation         (696)         (1,376)           Profit for the period         2,571         6,270           Other comprehensive income         8         (13)           Items that will not be reclassified to profit or loss         (82)         (65)           Remeasurement of the defined benefit pension liability         8         (13)           Tax on items that will not be reclassified to profit or loss         (82)         (65)           Foreign exchange arising on consolidation         (166)         106           Foreign exchange arising on consolidation         (166)         106           Foreign exchange differences on borrowings designated in net investment hedges         11         76           Fair value movements on derivatives designated in net invest			
Research and development expense **         (4,821)         (5,243)           Selling, general and administrative costs **         (12,206)         (9,839)           Other operating income and expense         595         970           Operating profit         3,712         8,148           Finance income         50         42           Finance expense         (495)         (544)           Profit before tax         3,267         7,646           Taxation         (696)         (1,376)           Profit for the period         2,571         6,270           Other comprehensive income           Items that will not be reclassified to profit or loss         (82)         (65)           Remeasurement of the defined benefit pension liability         8         (13)           Tax on items that will not be reclassified to profit or loss         (82)         (65)           Items that may be reclassified subsequently to profit or loss         (82)         (65)           Foreign exchange arising on consolidation         (166)         106           Foreign exchange differences on borrowings designated in net investment hedges         (58)         (46)           Fair value movements on derivatives designated in net investment hedges         111         76           Amortisation of l		20,450	22,580
Selling, general and administrative costs **         (12,206)         (9,839)           Other operating income and expense         595         970           Operating profit         3,712         8,148           Finance income         50         42           Finance expense         (495)         (544)           Profit before tax         3,267         7,646           Taxation         (696)         (1,376)           Profit for the period         2,571         6,270           Other comprehensive income           Items that will not be reclassified to profit or loss         (82)         (65)           Remeasurement of the defined benefit pension liability         8         (13)           Tax on items that will not be reclassified to profit or loss         (82)         (65)           Foreign exchange arising on consolidation         (166)         106           Foreign exchange arising on consolidation         (166)         106           Foreign exchange differences on borrowings designated in net investment hedges         111         76           Fair value movements on derivatives designated in net investment hedges         111         76           Amortisation of loss on cash flow hedge         1         1           Net available for sale gains taken to equity <td>Distribution costs</td> <td></td> <td>(320)</td>	Distribution costs		(320)
Other operating income and expense         595         970           Operating profit         3,712         8,148           Finance income         50         42           Finance expense         (495)         (544)           Profit before tax         3,267         7,646           Taxation         (696)         (1,376)           Profit for the period         2,571         6,270           Other comprehensive income         3,267         7,646           Items that will not be reclassified to profit or loss         8         (13)           Remeasurement of the defined benefit pension liability         8         (13)           Tax on items that will not be reclassified to profit or loss         (82)         (65)           Items that may be reclassified subsequently to profit or loss         (82)         (65)           Foreign exchange arising on consolidation         (166)         106           Foreign exchange differences on borrowings designated in net investment hedges         11         76           Fair value movements on derivatives designated in net investment hedges         11         1           Fair value movements on derivatives designated in net investment hedges         11         1           Fair value movements on derivatives designated in net investment hedges         11		(4,821)	(5,243)
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Finance income 50 42 Finance expense (495) (544) Profit before tax 3,267 7,646 Taxation (696) (1,376) Profit for the period 2,571 6,270  Other comprehensive income Items that will not be reclassified to profit or loss Remeasurement of the defined benefit pension liability 8 (13) Tax on items that will not be reclassified to profit or loss (82) (65) (74) (78)  Items that may be reclassified subsequently to profit or loss Foreign exchange arising on consolidation (166) 106 Foreign exchange differences on borrowings designated in net investment hedges Fair value movements on derivatives designated in net investment hedges 11 76 Amortisation of loss on cash flow hedge 1 1 1 Net available for sale gains taken to equity 69 72 Tax on items that may be reclassified subsequently to profit or loss (39) 213 Other comprehensive income for the period, net of tax (113) 135 Total comprehensive income for the period	Other operating income and expense	595	970
Finance expense (495) (544) Profit before tax 3,267 7,646 Taxation (696) (1,376) Profit for the period 2,571 6,270  Other comprehensive income Items that will not be reclassified to profit or loss Remeasurement of the defined benefit pension liability 8 (13) Tax on items that will not be reclassified to profit or loss (82) (65) Tax on items that will not be reclassified to profit or loss (82) (65) Tax on items that may be reclassified subsequently to profit or loss Foreign exchange arising on consolidation (166) 106 Foreign exchange differences on borrowings designated in net investment hedges Fair value movements on derivatives designated in net investment hedges Fair value movements on cash flow hedge 1 1 Net available for sale gains taken to equity 69 72 Tax on items that may be reclassified subsequently to profit or loss (39) 213 Other comprehensive income for the period, net of tax (113) 135 Total comprehensive income for the period	Operating profit	3,712	8,148
Profit before tax  Taxation  (696)  (1,376)  Profit for the period  Other comprehensive income Items that will not be reclassified to profit or loss Remeasurement of the defined benefit pension liability  Tax on items that will not be reclassified to profit or loss  Remeasurement of the defined benefit pension liability  Tax on items that will not be reclassified to profit or loss  Foreign exchange arising on consolidation  Foreign exchange differences on borrowings designated in net investment hedges  Fair value movements on derivatives designated in net investment hedges  Fair value movements on cash flow hedge  Amortisation of loss on cash flow hedge  Net available for sale gains taken to equity  Tax on items that may be reclassified subsequently to profit or loss  4  4  4  Capping and the defined benefit pension liability  Remeasurement of the defined benefit pension liability  Remeasurement of the defined benefit pension liability  8  (13)  (166)  (166)  (166)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (106)  (	Finance income	50	42
Taxation (696) (1,376) Profit for the period 2,571 6,270  Other comprehensive income Items that will not be reclassified to profit or loss Remeasurement of the defined benefit pension liability 8 (13) Tax on items that will not be reclassified to profit or loss (82) (65) (74) (78)  Items that may be reclassified subsequently to profit or loss Foreign exchange arising on consolidation (166) 106 Foreign exchange differences on borrowings designated in net investment hedges Fair value movements on derivatives designated in net investment hedges Fair value movements on derivatives designated in net investment hedges 11 76 Amortisation of loss on cash flow hedge 1 1 1 Net available for sale gains taken to equity 69 72 Tax on items that may be reclassified subsequently to profit or loss 4 4 A 4 Other comprehensive income for the period, net of tax (113) 135 Total comprehensive income for the period 2,458 6,405	Finance expense	(495)	(544)
Profit for the period 2,571 6,270  Other comprehensive income  Items that will not be reclassified to profit or loss  Remeasurement of the defined benefit pension liability 8 (13)  Tax on items that will not be reclassified to profit or loss (82) (65)  (74) (78)  Items that may be reclassified subsequently to profit or loss  Foreign exchange arising on consolidation (166) 106  Foreign exchange differences on borrowings designated in net investment hedges  Fair value movements on derivatives designated in net investment hedges 11 76  Amortisation of loss on cash flow hedge 1 1 1  Net available for sale gains taken to equity 69 72  Tax on items that may be reclassified subsequently to profit or loss 4 4  4 4  Other comprehensive income for the period, net of tax (113) 135  Total comprehensive income for the period  Profit attributable to:	Profit before tax	3,267	7,646
Other comprehensive income Items that will not be reclassified to profit or loss Remeasurement of the defined benefit pension liability  Tax on items that will not be reclassified to profit or loss  (82) (65) (74) (78)  Items that may be reclassified subsequently to profit or loss Foreign exchange arising on consolidation  Foreign exchange differences on borrowings designated in net investment hedges Fair value movements on derivatives designated in net investment hedges  Fair value movements on derivatives designated in net investment hedges  Amortisation of loss on cash flow hedge  1 1  Net available for sale gains taken to equity 69 72  Tax on items that may be reclassified subsequently to profit or loss 4 4 4 6 (39) 213  Other comprehensive income for the period, net of tax (113) 135  Total comprehensive income for the period	Taxation	(696)	(1,376)
Other comprehensive income Items that will not be reclassified to profit or loss Remeasurement of the defined benefit pension liability  Tax on items that will not be reclassified to profit or loss  (82) (65) (74) (78)  Items that may be reclassified subsequently to profit or loss Foreign exchange arising on consolidation  Foreign exchange differences on borrowings designated in net investment hedges Fair value movements on derivatives designated in net investment hedges  Fair value movements on derivatives designated in net investment hedges  Amortisation of loss on cash flow hedge  1 1  Net available for sale gains taken to equity 69 72  Tax on items that may be reclassified subsequently to profit or loss 4 4 4 6 (39) 213  Other comprehensive income for the period, net of tax (113) 135  Total comprehensive income for the period	Profit for the period	2,571	6,270
Items that will not be reclassified to profit or loss Remeasurement of the defined benefit pension liability  Tax on items that will not be reclassified to profit or loss  (82) (65) (74) (78)  Items that may be reclassified subsequently to profit or loss Foreign exchange arising on consolidation  Foreign exchange differences on borrowings designated in net investment hedges  Fair value movements on derivatives designated in net investment hedges  Fair value movements on cash flow hedge  Amortisation of loss on cash flow hedge  Net available for sale gains taken to equity  Fax on items that may be reclassified subsequently to profit or loss  4  4  Cother comprehensive income for the period, net of tax  Total comprehensive income for the period  Profit attributable to:			
Remeasurement of the defined benefit pension liability  Tax on items that will not be reclassified to profit or loss  (82) (65) (74) (78)  Items that may be reclassified subsequently to profit or loss  Foreign exchange arising on consolidation  Foreign exchange differences on borrowings designated in net investment hedges  Fair value movements on derivatives designated in net investment hedges  Fair value movements on cash flow hedge  Amortisation of loss on cash flow hedge  Net available for sale gains taken to equity  Fax on items that may be reclassified subsequently to profit or loss  (39) 213  Other comprehensive income for the period, net of tax  Total comprehensive income for the period  Profit attributable to:	Other comprehensive income		
Tax on items that will not be reclassified to profit or loss  (82) (65) (74) (78)  Items that may be reclassified subsequently to profit or loss  Foreign exchange arising on consolidation  Foreign exchange differences on borrowings designated in net investment hedges  Fair value movements on derivatives designated in net investment hedges  Fair value movements on cash flow hedge  Amortisation of loss on cash flow hedge  Net available for sale gains taken to equity  Fax on items that may be reclassified subsequently to profit or loss  4  4  4  Cother comprehensive income for the period, net of tax  Total comprehensive income for the period  Profit attributable to:	Items that will not be reclassified to profit or loss		
Items that may be reclassified subsequently to profit or loss  Foreign exchange arising on consolidation (166) 106  Foreign exchange differences on borrowings designated in net investment hedges  Fair value movements on derivatives designated in net investment hedges 111 76  Amortisation of loss on cash flow hedge 1 1  Net available for sale gains taken to equity 69 72  Tax on items that may be reclassified subsequently to profit or loss 4 4  Cother comprehensive income for the period, net of tax (113) 135  Total comprehensive income for the period 2,458 6,405  Profit attributable to:	Remeasurement of the defined benefit pension liability	8	(13)
Items that may be reclassified subsequently to profit or loss  Foreign exchange arising on consolidation (166) 106  Foreign exchange differences on borrowings designated in net investment hedges  Fair value movements on derivatives designated in net investment hedges 111 76  Amortisation of loss on cash flow hedge 1 1  Net available for sale gains taken to equity 69 72  Tax on items that may be reclassified subsequently to profit or loss 4 4  Cother comprehensive income for the period, net of tax (113) 135  Total comprehensive income for the period 2,458 6,405  Profit attributable to:	Tax on items that will not be reclassified to profit or loss	(82)	(65)
Foreign exchange arising on consolidation  Foreign exchange differences on borrowings designated in net investment hedges  Fair value movements on derivatives designated in net investment hedges  Fair value movements on cash flow hedge  Amortisation of loss on cash flow hedge  Net available for sale gains taken to equity  Tax on items that may be reclassified subsequently to profit or loss  4  4  Cother comprehensive income for the period, net of tax  Total comprehensive income for the period  Profit attributable to:	•	(74)	(78)
Foreign exchange arising on consolidation  Foreign exchange differences on borrowings designated in net investment hedges  Fair value movements on derivatives designated in net investment hedges  Fair value movements on cash flow hedge  Amortisation of loss on cash flow hedge  Net available for sale gains taken to equity  Tax on items that may be reclassified subsequently to profit or loss  4  4  Cother comprehensive income for the period, net of tax  Total comprehensive income for the period  Profit attributable to:	Items that may be reclassified subsequently to profit or loss		
Foreign exchange differences on borrowings designated in net investment hedges  Fair value movements on derivatives designated in net investment hedges  Amortisation of loss on cash flow hedge  Net available for sale gains taken to equity  Tax on items that may be reclassified subsequently to profit or loss  (39)  Other comprehensive income for the period, net of tax  Total comprehensive income for the period  Profit attributable to:		(166)	106
investment hedges Fair value movements on derivatives designated in net investment hedges Amortisation of loss on cash flow hedge Net available for sale gains taken to equity 69 72 Tax on items that may be reclassified subsequently to profit or loss 4 4 4 0 39) 213 Other comprehensive income for the period, net of tax Total comprehensive income for the period Profit attributable to:		(50)	(46)
Fair value movements on derivatives designated in net investment hedges  Amortisation of loss on cash flow hedge  Net available for sale gains taken to equity  Tax on items that may be reclassified subsequently to profit or loss  4  4  4  Other comprehensive income for the period, net of tax  Total comprehensive income for the period  Profit attributable to:		(58)	(46)
Amortisation of loss on cash flow hedge  Net available for sale gains taken to equity  Tax on items that may be reclassified subsequently to profit or loss  4  4  Other comprehensive income for the period, net of tax  Total comprehensive income for the period  Profit attributable to:		111	76
Net available for sale gains taken to equity  Tax on items that may be reclassified subsequently to profit or loss  4 4 4 Other comprehensive income for the period, net of tax  Total comprehensive income for the period  Profit attributable to:		1	1
Tax on items that may be reclassified subsequently to profit or loss  4 4 (39) 213  Other comprehensive income for the period, net of tax (113) 135  Total comprehensive income for the period  Profit attributable to:		69	72
Other comprehensive income for the period, net of tax Total comprehensive income for the period  Profit attributable to:  (39) 213 (113) 135 2,458 6,405		4	4
Other comprehensive income for the period, net of tax Total comprehensive income for the period  2,458  Profit attributable to:		(39)	213
Total comprehensive income for the period 2,458 6,405  Profit attributable to:	Other comprehensive income for the period, net of tax	` '	135
Profit attributable to:		` ′	
		,	-,
	Profit attributable to:		
		2.556	6.240
Non-controlling interests 15 30	•	•	•
2,571 6,270			

Total comprehensive income attributable to: Owners of the parent 2,470 6,395 Non-controlling interests (12)10 2,458 6,405 Basic earnings per \$0.25 Ordinary Share \$2.04 \$4.95 Diluted earnings per \$0.25 Ordinary Share \$2.04 \$4.94 Weighted average number of Ordinary Shares in issue (millions) 1,252 1,261 Diluted weighted average number of Ordinary Shares in issue (millions) 1,254 1,264

# Condensed Consolidated Statement of Comprehensive Income

•		Restated*
	2013	2012
For the quarter ended 31 December	\$m	\$m
Revenue	6,844	7,282
Cost of sales	(1,440)	(1,398)
Gross profit	5,404	5,884
Distribution costs	(72)	(79)
Research and development expense **	(1,429)	(1,320)
Selling, general and administrative costs **	(4,642)	(2,669)
Other operating income and expense	148	148
Operating (loss)/profit	(591)	1,964
Finance income	13	15
Finance expense	(137)	(143)
(Loss)/profit before tax	(715)	1,836
Taxation	195	(316)
(Loss)/profit for the period	(520)	1,520
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	247	145
Tax on items that will not be reclassified to profit or loss	(44)	(47)
	203	98
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(26)	(109)
Foreign exchange differences on borrowings designated in net investment hedges	(35)	(21)
Fair value movements on derivatives designated in net investment hedges	51	76
Net available for sale gains taken to equity	10	33
Tax on items that may be reclassified subsequently to profit or loss	3	1

<sup>\*</sup> Restatement relates to the adoption of IAS 19 (2011), see Note 1.

<sup>\*\*</sup> In 2013, the Company recognised intangible asset impairments related to Bydureon of \$138 million in research and development expense and \$1,620 million in selling, general and administrative costs.

	3	(20)
Other comprehensive income for the period, net of tax	206	78
Total comprehensive income for the period	(314)	1,598
(Loss)/profit attributable to:		
Owners of the parent	(524)	1,507
Non-controlling interests	4	13
	(520)	1,520
Total comprehensive income attributable to:		
Owners of the parent	(315)	1,603
Non-controlling interests	1	(5)
	(314)	1,598
Basic (loss)/earnings per \$0.25 Ordinary Share	(\$0.42)	\$1.21
Diluted (loss)/earnings per \$0.25 Ordinary Share	(\$0.42)	\$1.21
Weighted average number of Ordinary Shares in issue (millions)	1,254	1,246
Diluted weighted average number of Ordinary Shares in issue (millions)	1,256	1,248

<sup>\*</sup> Restatement relates to the adoption of IAS 19 (2011), see Note 1.

# Condensed Consolidated Statement of Financial Position

ASSETS	At 31 Dec 2013 \$m	Restated* At 31 Dec 2012 \$m
Non-current assets		
Property, plant and equipment	5,818	6,089
Goodwill	9,981	9,898
Intangible assets	16,047	16,448
Derivative financial instruments	365	389
Other investments	281	199
Other receivables	1,867	352
Deferred tax assets	1,205	1,111
	35,564	34,486
Current assets		
Inventories	1,909	2,061
Trade and other receivables	7,879	7,629
Other investments	796	823
Derivative financial instruments	40	31
Income tax receivable	494	803

<sup>\*\*</sup> In 2013, the Company recognised intangible asset impairments related to Bydureon of \$138 million in research and development expense and \$1,620 million in selling, general and administrative costs.

•		
Cash and cash equivalents	9,217	7,701
	20,335	19,048
Total assets	55,899	53,534
LIABILITIES		
Current liabilities		
Interest-bearing loans and borrowings	(1,788)	(901)
Trade and other payables	(10,362)	(9,221)
Derivative financial instruments	(2)	(3)
Provisions	(823)	(916)
Income tax payable	(3,076)	(2,862)
	(16,051)	(13,903)
Non-current liabilities		
Interest-bearing loans and borrowings	(8,588)	(9,409)
Derivative financial instruments	(1)	-
Deferred tax liabilities	(2,827)	(2,576)
Retirement benefit obligations	(2,261)	(2,271)
Provisions	(566)	(428)
Other payables	(2,352)	(1,001)
	(16,595)	(15,685)
Total liabilities	(32,646)	(29,588)
Net assets	23,253	23,946
EQUITY		
Capital and reserves attributable to equity holders of the Company		
Share capital	315	312
Share premium account	3,983	3,504
Other reserves	1,966	1,960
Retained earnings	16,960	17,955
	23,224	23,731
Non-controlling interests	29	215
Total equity	23,253	23,946
* Restatement relates to the adoption of IAS 19 (2011), see Note 1.	,	ŕ
1		
Condensed Consolidated Statement of Cash Flows		
		Restated*
	2013	2012
For the year ended 31 December	\$m	\$m
Cash flows from operating activities		
Profit before tax	3,267	7,646
Finance income and expense	445	502
Depreciation, amortisation and impairment	4,583	2,518
Decrease/(increase) in working capital and short-term provisions	166	(706)
Non-cash and other movements	258	(424)
Cash generated from operations	8,719	9,536
Interest paid	(475)	(545)
Tax paid	(844)	(2,043)
Net cash inflow from operating activities	7,400	6,948
Cash flows from investing activities	,,100	0,210
Movement in short-term investments and fixed deposits	130	3,619
Purchase of property, plant and equipment	(742)	(672)
1 arenase of property, plant and equipment	(172)	(072)

Disposal of property, plant and againment	69	199
Disposal of property, plant and equipment Purchase of intangible assets	(1,316)	(3,947)
	(1,310)	(3,947)
Disposal of intangible assets		(46)
Purchase of non-current asset investments	(91)	(46)
Disposal of non-current asset investments	38	43
Acquisitions of business operations	(1,158)	(1,187)
Dividends received	-	1.7
Interest received	114	145
Payments made by subsidiaries to non-controlling interests	(10)	(20)
Payments received by subsidiaries from non-controlling interests	42	-
Net cash outflow from investing activities	(2,889)	(1,859)
Net cash inflow before financing activities	4,511	5,089
Cash flows from financing activities		
Proceeds from issue of share capital	482	429
Repurchase of shares	-	(2,635)
Issue of loans	-	1,980
Repayment of loans	-	(1,750)
Dividends paid	(3,461)	(3,665)
Hedge contracts relating to dividend payments	(36)	48
Repayment of obligations under finance leases	(27)	(17)
Movement in short-term borrowings	(5)	687
Net cash outflow from financing activities	(3,047)	(4,923)
Net increase in cash and cash equivalents in the period	1,464	166
Cash and cash equivalents at the beginning of the period	7,596	7,434
Exchange rate effects	(65)	(4)
Cash and cash equivalents at the end of the period	8,995	7,596
Cash and cash equivalents consists of:	- ,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Cash and cash equivalents	9,217	7,701
Overdrafts	(222)	(105)
O TOTAL DESCRIPTION OF THE PROPERTY OF THE PRO	8,995	7,596
	0,773	1,500

 $<sup>\</sup>ensuremath{^{*}}$  Restatement relates to the adoption of IAS 19 (2011), see Note 1.

# Condensed Consolidated Statement of Changes in Equity

		Share				Non-	
	Share	premium	Other	Retained		controlling	Total
	capital	account	reserves*	earnings	Total	interests	equity
	\$m	\$m	\$m	\$m	\$m	\$m	\$m
At 1 Jan 2012**	323	3,078	1,951	17,888	23,240	226	23,466
Profit for the period**	-	-	-	6,240	6,240	30	6,270
Other comprehensive income**	-	-	-	155	155	(20)	135
Transfer to other reserves	-	-	(5)	5	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,619)	(3,619)	-	(3,619)

Issue of Ordinary Shares	3	426	-	-	429	-	429
Repurchase of Ordinary Shares	(14)	-	14	(2,635)	(2,635)	-	(2,635)
Share-based payments Transfer from	-	-	-	(79)	(79)	-	(79)
non-controlling interests to payables	-	-	-	-	-	(10)	(10)
Dividend paid to non-controlling interests	-	-	-	-	-	(11)	(11)
Net movement	(11)	426	9	67	491	(11)	480
At 31 Dec 2012**	312	3,504	1,960	17,955	23,731	215	23,946
		Share				Non-	
	Share	premium	Other	Retained		controlling	Total
	capital	account	reserves*	earnings	Total	interests	equity
	\$m	\$m	\$m	\$m	\$m	\$m	\$m
At 1 Jan 2013**	312	3,504	1,960	17,955	23,731	215	23,946
Profit for the period	_	_	-	2,556	2,556	15	2,571
Other comprehensive income	-	-	-	(86)	(86)	(27)	(113)
Transfer to other reserves Transactions with owners:	-	-	6	(6)	-	-	-
Divdends	_	_	_	(3,499)	(3,499)	_	(3,499)
Issue of Ordinary Shares	3	479	_	-	482	_	482
Share-based payments Transfer from	-	-	-	(57)	(57)	-	(57)
non-controlling interests to payables	-	-	-	-	-	(6)	(6)
Dividend paid to non-controlling interests	-	-	-	-	-	(3)	(3)
Net acquisition of non-controlling interests	-	-	-	97	97	(165)	(68)
Net movement	3	479	6	(995)	(507)	(186)	(693)
At 31 Dec 2013	315	3,983	1,966	16,960	23,224	29	23,253

<sup>\*</sup> Other reserves includes the capital redemption reserve and the merger reserve.

### Notes to the Interim Financial Statements

### 1 BASIS OF PREPARATION AND ACCOUNTING POLICIES

The preliminary announcement for the year ended 31 December 2013 has been prepared in accordance with International Financial Reporting Standards (IFRSs) as adopted by the European Union (EU) and as issued by the International Accounting Standards Board (IASB). There have been no significant changes in accounting policies from those set out in AstraZeneca PLC's Annual Report and Form 20-F Information 2012.

<sup>\*\*</sup> Restated on adoption of IAS 19 (2011), see Note 1.

With effect from 1 January 2013, the Group adopted the amendments to IAS 19 Employee Benefits. Under IAS 19 (2011), the Group determines net interest on the net retirement benefit obligation by applying the discount rate used to measure the retirement benefit obligations at the beginning of the annual period. Consequently, the net charge to 'finance expense' now comprises interest cost on the defined benefit obligation and interest income on plan assets. Previously, the Group determined interest income on plan assets based on their long-term rate of expected return and recorded as 'finance income'. As a result of applying the discount rate as detailed above, the prior period net finance expense has been restated to reflect a \$72 million increase with an equal and opposite decrease recognised in other comprehensive income. The Group's net assets have reduced by \$6 million on adoption of the amendments, as previously unrecognised past service costs, which were previously recognised over the remaining service life of the employees, are recognised retrospectively in retained earnings.

The Group has also adopted the amendments to IAS 1 Presentation of Items in Other Comprehensive Income issued in 2011, resulting in a change to the presentation of items within other comprehensive income. In addition, effective 1 January 2013, the Group has adopted IFRS 10 Consolidated Financial Statements, IFRS 11 Joint Arrangements, IFRS 12 Disclosure of Interests in Other Entities and IFRS 13 Fair Value Measurement, along with consequential amendments to IAS 27 Separate Financial Statements and IAS 28 Investments in Associates and Joint Ventures, and amendments to IFRS 7 Financial Instruments: Disclosures on offsetting financial assets and liabilities, none of which have had an impact on the Group's net results, net assets or disclosures, other than additional information on financial instruments included in Note 9, arising from the adoption of IFRS 13.

The information contained in Note 10 updates the disclosures concerning legal proceedings and contingent liabilities in the Group's Annual Report and Form 20-F Information 2012.

The Group has considerable financial resources available. As at 31 December 2013, the Group has \$10.4 billion in financial resources (cash balances of \$9.2 billion and undrawn committed bank facilities of \$3.0 billion which are available until April 2018, with only \$1.8 billion of debt due within one year). The Group's revenues are largely derived from sales of products which are covered by patents which provide a relatively high level of resilience and predictability to cash inflows, although our revenue is expected to continue to be significantly impacted by the expiry of patents over the medium term. In addition, recent government price interventions in response to budgetary constraints are expected to continue to adversely affect revenues in many of our mature markets. However, we anticipate new revenue streams from both recently launched medicines and products in development, and the Group has a wide diversity of customers and suppliers across different geographic areas. Consequently, the Directors believe that, overall, the Group is well placed to manage its business risks successfully despite the current uncertain economic outlook.

On the basis of the above paragraph and after making enquiries, the Directors have a reasonable expectation that the Company and the Group have adequate resources to continue in operational existence for the foreseeable future. Accordingly, the preliminary announcement has been prepared on a going concern basis.

The financial information included in the preliminary announcement does not constitute statutory accounts of the Group for the years ended 31 December 2013 and 2012 but is derived from those accounts. Statutory accounts for 2012 have been delivered to the registrar of companies and those for 2013 will be delivered in due course. Those accounts have been reported on by the Group's auditors; their reports were (i) unqualified, (ii) did not include a reference to any matters to which the auditors drew attention by way of emphasis without qualifying their report, and (iii) did not contain a statement under section 498(2) or (3) of the Companies Act 2006.

# 2 NET FUNDS

The table below provides an analysis of net funds and a reconciliation of net cash flow to the movement in net funds.

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	At 1				At 31
	Jan	Cash	Non-cash	Exchange	Dec
	2013	Flow	Movements	Movements	2013
	\$m	\$m	\$m	\$m	\$m
Loans due after one year	(9,347)	-	888	(57)	(8,516)
Finance leases due after one year	(62)	-	(10)	-	(72)
Total long term debt	(9,409)	-	878	(57)	(8,588)
Current instalments of loans	-	-	(766)	-	(766)
Current instalments of finance	(22)	27	(35)	_	(30)
leases			` '		. ,
Total current debt	(22)	27	(801)	-	(796)
Othersian	922	(120)	0.0	1.5	706
Other investments - current	823	(130)	88	15	796
Net derivative financial	417	36	(51)	-	402
instruments  Cash and cash aquivalents	7,701	1,578		(62)	9,217
Cash and cash equivalents	•	•	-	` '	•
Overdrafts	(105)	(114)	-	(3)	(222)
Short-term borrowings	(774)	5	-	(1)	(770)
	8,062	1,375	37	(51)	9,423
Net (debt)/funds	(1,369)	1,402	114	(108)	39

Non-cash movements in the period include fair value adjustments under IAS 39.

### 3 RESTRUCTURING COSTS

Profit before tax for the year ended 31 December 2013 is stated after charging restructuring costs of \$1,421 million (\$385 million for the fourth quarter 2013). These have been charged to profit as follows:

	4th	4th	Full	
	Quarter	Quarter	Year	Full Year
	2013	2012	2013	2012
	\$m	\$m	\$m	\$m
Cost of sales	22	61	126	136
Research and development expense	84	94	490	791
Selling, general and administrative costs	279	243	805	631
Total	385	398	1,421	1,558

# 4 ACQUISITION OF PEARL THERAPEUTICS

On 27 June 2013, AstraZeneca completed the acquisition of Pearl Therapeutics, Inc. Pearl is based in Redwood City, California and is focused on the development of inhaled small-molecule therapeutics for respiratory disease. AstraZeneca acquired 100 percent of Pearl's shares for an upfront consideration of \$569 million. In addition, deferred consideration of up to \$450 million will become payable if specified development and regulatory milestones in respect

of any triple combination therapies and selected future products that AstraZeneca develops using Pearl's technology platform are achieved. Sales-related payments of up to a further \$140 million will become payable if pre-agreed cumulative sales thresholds are exceeded. Contingent consideration has been fair valued using decision tree analysis, with key inputs including the probability of success and consideration of potential delays.

In business acquisitions, any part of the cost that is not capable of being attributed in accounting terms to identifiable assets and liabilities acquired is recognised as goodwill. In the case of the acquisition of Pearl, this goodwill is underpinned by a number of elements, which individually cannot be quantified. Most significant among these is the synergistic benefit generated by acquiring Pearl's workforce, whose skills and knowhow are critical to the best and most efficient completion of the ongoing development programmes.

Pearl's results have been consolidated into the Company's results from 27 June 2013. For the period from acquisition to 31 December 2013, Pearl had no revenues and its net loss was \$49 million.

For the year ended 31 December 2013, Pearl had no revenues and its net loss was \$81 million.

In the period since acquisition, AstraZeneca received new information regarding the future recoverability of Pearl's previously unrecognised tax losses. This new information indicates that the deferred tax assets acquired with Pearl are \$60 million. The relevant facts and circumstances that have been highlighted by the new information were in place at the date of acquisition and have not changed since that date. Therefore, the result of this new information has been reflected by adjusting the acquisition accounting entries, that were disclosed in the Company's half year results ended 30 June 2013, by increasing the fair value adjustment on deferred tax assets by \$30 million and correspondingly reducing the value of recognised goodwill by \$30 million. The revised acquisition entries are shown below.

		Fair value	
	Book value	adjustment	Fair value
	\$m	\$m	\$m
Non-current assets			
Intangible assets	-	985	985
Deferred tax assets	-	60	60
	-	1,045	1,045
Current assets	12	-	12
Current liabilities	(4)	-	(4)
Non-current liabilities			
Deferred tax liabilities	-	(379)	(379)
	-	(379)	(379)
Total assets acquired	8	666	674
Goodwill			44
Fair value of total consideration			718
Less: fair value of contingent			
consideration			(149)
Total upfront consideration			569
Less: cash and cash equivalents acquired			(4)
Net cash outflow			565

# 5 ACQUISITION OF OMTHERA PHARMACEUTICALS

On 18 July 2013, AstraZeneca completed the acquisition of Omthera Pharmaceuticals, Inc. Omthera is a specialty pharmaceutical company based in Princeton, New Jersey, focused on the development and commercialisation of new therapies for abnormal levels of lipids in the blood, referred to as dyslipidaemia. AstraZeneca acquired 100 percent of

Omthera's shares for an upfront consideration of \$323 million with up to \$120 million in future development and approval milestones. Contingent consideration has been fair valued using decision tree analysis, with key inputs including the probability of success and consideration of potential delays.

Omthera's results have been consolidated into the Company's results from 18 July 2013. For the period from acquisition to 31 December 2013, Omthera had no revenues and its net loss was \$10 million.

For the year ended 31 December 2013, Omthera had no revenues and its net loss was \$33 million.

		Fair value	
	Book value	adjustment	Fair value
	\$m	\$m	\$m
Non-current assets			
Intangible assets	-	526	526
Deferred tax assets	-	18	18
	-	544	544
Current assets	67	-	67
Current liabilities	(10)	-	(10)
Non-current liabilities			
Deferred tax liabilities	-	(216)	(216)
	-	(216)	(216)
Total assets acquired	57	328	385
Goodwill			-
Fair value of total consideration			385
Less: fair value of contingent			
consideration			(62)
Upfront consideration			323
Less: cash acquired			(63)
Cash outflow			260

### 6 ACQUISITION OF AMPLIMMUNE

On 4 October 2013, AstraZeneca completed the acquisition of Amplimmune, Inc, a privately-held, Maryland, US-based biologics company focused on developing novel therapeutics in cancer immunology. Under the terms of the agreement, AstraZeneca has acquired 100 percent of Amplimmune's shares for an initial consideration of \$225 million and deferred consideration of up to \$275 million based on reaching predetermined development milestones. Contingent consideration has been fair valued using decision tree analysis, with key inputs including the probability of success and consideration of potential delays.

The acquisition bolsters AstraZeneca's oncology pipeline by obtaining multiple early-stage assets for its immune-mediated cancer therapy (IMT-C) portfolio, including AMP-514, an anti-programmed cell death 1 (PD-1) monoclonal antibody (mAb). AMP-514 was in late-stage pre-clinical development with the aim of an investigational new drug (IND) filing before the end of 2013, which has now been achieved. Other Amplimmune assets include multiple preclinical molecules targeting the B7 pathways.

In business acquisitions, any part of the cost that is not capable of being attributed in accounting terms to identifiable assets and liabilities acquired is recognised as goodwill. In the case of the acquisition of Amplimmune, this goodwill is underpinned by a number of elements, which individually cannot be quantified but include Amplimmune's very early programmes of potential interest for oncology, immunology, infectious diseases as well as research tools and animal models.

Amplimmune's results have been consolidated into the Company's results from 4 October 2013. For the period from acquisition to 31 December 2013, Amplimmune had no revenues and its net loss was \$5 million.

For the year ended 31 December 2013, Amplimmune had no revenues and its net loss was \$27 million.

		Fair value	
	Book value	adjustment	Fair value
	\$m	\$m	\$m
Non-current assets			
Intangible assets	-	534	534
Property, plant and equipment	7	-	7
Deferred tax assets	-	14	14
	7	548	555
Current assets	17	-	17
Current liabilities	(8)	-	(8)
Non-current liabilities			
Deferred tax liabilities	-	(219)	(219)
	-	(219)	(219)
Total assets acquired	16	329	345
Goodwill			33
Fair value of total consideration			378
Less: fair value of contingent			
consideration			(153)
Total upfront consideration			225
Less: cash and cash equivalents acquired			(17)
Less: deferred upfront consideration			(75)
Net cash outflow			133

### 7 ACQUISITION OF SPIROGEN

On 15 October 2013, AstraZeneca completed the acquisition of Spirogen Sarl, a privately-held biotech company focused on antibody-drug conjugate technology for use in oncology. AstraZeneca acquired 100 percent of Spirogen's shares for an initial consideration of \$200 million and deferred consideration of up to \$240 million based on reaching predetermined development milestones. Existing out-licensing agreements and associated revenue streams are excluded from this acquisition. Contingent consideration has been fair valued using decision tree analysis, with key inputs including the probability of success and consideration of potential delays.

AstraZeneca has also entered into a collaboration agreement with ADC Therapeutics to jointly develop two of ADC Therapeutics' antibody-drug conjugate programmes in pre-clinical development. In addition, AstraZeneca has made an equity investment in ADC Therapeutics, which has an existing licensing agreement with Spirogen.

Spirogen's results have been consolidated into the Company's results from 15 October 2013. For the period from acquisition to 31 December 2013, Spirogen had no revenues and its net loss was immaterial.

For the year ended 31 December 2013, Spirogen had no revenues and its net loss was \$9 million.

Book value Fair value sm adjustment Fair value

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	\$m	\$m
1	370	371
1	-	1
2	370	372
-	(4)	(4)
-	(4)	(4)
2	366	368
		-
		368
		(168)
		200
		-
		200
	1 2	1 370 1 - 2 370 - (4) - (4)

# 8 ACQUISITION OF BMS SHARE OF GLOBAL DIABETES ALLIANCE ASSETS

On 1 February 2014, AstraZeneca completed the acquisition of BMS's interests in the companies' diabetes alliance. The acquisition provides AstraZeneca with 100% ownership of the intellectual property and global rights for the development, manufacture and commercialisation of the diabetes business, which includes Onglyza (saxagliptin), Kombiglyze XR (saxagliptin and metformin HCl extended release), Komboglyze (saxagliptin and metformin HCl), Farxiga (dapagliflozin, marketed as Forxiga outside the US), Byetta (exenatide), Bydureon (exenatide extended-release for injectable suspension), metreleptin and Symlin (pramlintide acetate).

The transaction consolidates worldwide ownership of the diabetes business within AstraZeneca leveraging its primary and specialty care capabilities and its geographical reach, especially in emerging markets. The transaction included the acquisition of 100% of the share capital of Amylin Pharmaceuticals, LLC, and the asset purchase of the additional intellectual property and global rights not already owned by AstraZeneca, for the development, manufacture and commercialisation of Onglyza, Kombiglyze XR, Komboglyze and Farxiga. In total, approximately 4,100 BMS employees are expected to transfer as part of the acquisition. This combination of intangible product rights and manufacturing assets with an established work force and their associated operating processes, principally those related to the global manufacturing and selling and marketing operations, requires that the acquisition is accounted for as a business combination in accordance with IFRS3 Business Combinations.

Upfront consideration for the acquisition of \$2.7 billion was paid on 1 February 2014, with further payments of up to \$1.4 billion being payable for future regulatory, launch and sales-related milestones. AstraZeneca has also agreed to pay various sales-related royalty payments up until 2025. The amount of royalties payable under the agreement is inherently uncertain and difficult to predict, given the direct link to future sales and the range of outcomes cannot be reliably estimated. The maximum amount payable in each year is with reference to net sales. AstraZeneca may also make payments up to \$225 million when certain additional assets are subsequently transferred. Contingent consideration has been fair valued using decision tree analysis, with key inputs including the probability of success and consideration of potential delays. In accordance with IFRS3, the fair value of contingent consideration, including future royalties, is recognised immediately as a liability.

In addition to the acquired interests, AstraZeneca has entered into certain agreements with BMS to maintain the manufacturing and supply chain of the full portfolio of diabetes products. BMS will also continue to deliver specified clinical trials in line with the ongoing clinical trial plan, with an agreed number of R&D and manufacturing employees dedicated to diabetes remaining with BMS to progress the diabetes portfolio and support the transition for these areas.

These arrangements will be carried out over future periods and future payments by AstraZeneca to BMS in relation to these arrangements will be expensed as incurred. No amounts have been recognised in the initial acquisition accounting in relation to these arrangements but have been separated, at fair value, from the business combination accounting in accordance with IFRS 3.

The terms of the agreement partially reflect settlement of the launch and sales-related milestones under the pre-existing Onglyza and Farxiga collaboration agreements, which have been terminated in relation to the acquisition. The expected value of those pre-existing milestones is \$0.3 billion and has been recognised as a separate component of consideration and excluded from the business combination accounting in accordance with IFRS 3. Separate intangible assets have been recognised.

Goodwill of \$1.6 billion is underpinned by a number of elements, which individually cannot be quantified. Most significant among these are the synergies AstraZeneca expect to be able to generate through more efficient manufacturing processes and the incremental value accessible through strategic and operational independence upon taking full control of the alliance.

The fair value of receivables acquired as part of the acquisition approximates the gross contractual amounts receivable. There are no significant amounts which are not expected to be collected.

The results from the additional acquired interests in the diabetes alliance will be consolidated into the Company's results from 1 February 2014.

Given the proximity of the completion of the transaction to the date that the Financial Statements were approved, the finalisation of the accounting entries for this transaction has yet to be completed. Our provisional assessment of the fair values of the assets and liabilities acquired, and of the fair value of the consideration payable, is detailed below. Our assessment will be completed in 2014.

	Fair value \$m
Non-current assets	ΨΠ
	5 760
Intangible assets	5,762
Property, plant and equipment	490
	6,252
Current assets	478
Current liabilities	(262)
Non-current liabilities	(130)
Total assets acquired	6,338
Goodwill	1,565
Fair value of total consideration	7,903
Less: fair value of contingent consideration	(5,205)
Total upfront consideration	2,698
Less: cash and cash equivalents acquired	-
Net cash outflow	2,698

### 9 FINANCIAL INSTRUMENTS

As detailed in our most recent annual financial statements, our principal financial instruments consist of derivative financial instruments, other investments, trade and other receivables, cash and cash equivalents, trade and other payables, and interest-bearing loans and borrowings. As indicated in Note 1, there have been no changes to the accounting policies, including fair value measurement, for financial instruments from those disclosed on pages 148

and 149 of the Company's Annual Report and Form 20-F Information 2012. In addition, there have been no changes of significance to the categorisation or fair value hierarchy of our financial instruments. Financial instruments measured at fair value include \$1,077 million of other investments, \$1,978 million of loans, and \$402 million of derivatives as at 31 December 2013. The total fair value of interest-bearing loans and borrowings at 31 December 2013, which have a carrying value of \$10,376 million in the Condensed Consolidated Statement of Financial Position, was \$11,156 million. As detailed in Notes 4 to 7, contingent consideration arising on the Company's acquisitions during the year has been fair valued under Level 3 fair value methodology. For all other financial instruments which are carried at amortised costs, amortised cost approximates to fair value.

### 10 LEGAL PROCEEDINGS AND CONTINGENT LIABILITIES

AstraZeneca is involved in various legal proceedings considered typical to its business, including litigation and investigations relating to product liability, commercial disputes, infringement of intellectual property rights, the validity of certain patents, anti-trust law and sales and marketing practices. The matters discussed below constitute the more significant developments since publication of the disclosures concerning legal proceedings in the Company's Annual Report and Form 20-F Information 2012 and the Interim Management Statement 2013 as part of the Company's Half-Yearly Financial Report for the six-month period to 30 June 2013 and the Third Quarter and Nine Months Results 2013 (together the "Disclosures"). Unless noted otherwise below or in the Disclosures, no provisions have been established in respect of the claims discussed below.

As discussed in the Company's Annual Report and Form 20-F Information 2012, for the majority of claims in which AstraZeneca is involved it is not possible to make a reasonable estimate of the expected financial effect, if any, that will result from ultimate resolution of the proceedings. In these cases, AstraZeneca discloses information with respect only to the nature and facts of the cases but no provision is made.

In cases that have been settled or adjudicated, or where quantifiable fines and penalties have been assessed and which are not subject to appeal, or where a loss is probable and we are able to make a reasonable estimate of the loss, we record the loss absorbed or make a provision for our best estimate of the expected loss.

The position could change over time and the estimates that we have made and upon which we have relied in calculating these provisions are inherently imprecise. There can, therefore, be no assurance that any losses that result from the outcome of any legal proceedings will not exceed the amount of the provisions that have been booked in the accounts. The major factors causing this uncertainty are described more fully in the Company's Annual Report and Form 20-F Information 2012 and herein.

AstraZeneca has full confidence in, and will vigorously defend and enforce, its intellectual property.

Matters disclosed in respect of the fourth quarter of 2013 and January 2014

Patent litigation

Nexium (esomeprazole magnesium)

Patent proceedings in the US

In October 2013, AstraZeneca received a Paragraph IV notice letter (Notice) from Kremers Urban Pharmaceuticals Inc. (Kremers) and a separate Notice from Aurobindo Pharma Ltd. (Aurobindo), relating to Nexium. In December 2013, in response to each Notice, AstraZeneca commenced patent infringement litigation in the US District Court for the District of New Jersey against Kremers and, separately, against Aurobindo.

As previously disclosed, in February 2011, AstraZeneca commenced patent infringement litigation in the District Court for the District of New Jersey (District Court) against Hanmi USA Inc. and affiliates (Hanmi) in response to

Hanmi's filing of an New Drug Application under §505(b)(2) to market esomeprazole strontium delayed-release capsules. In June 2013, AstraZeneca entered into a settlement agreement to expedite AstraZeneca's appeal of the District Court's December 2012 claim construction to the US Court of Appeals for the Federal Circuit (Court of Appeals). Under a District Court consent judgment, Hanmi conceded that AstraZeneca's two patents at issue are valid and enforceable. In December 2013, the Court of Appeals affirmed the District Court's claim construction, including that Hanmi's product would not infringe the patents at issue. In January 2014, AstraZeneca requested a rehearing in the Court of Appeals. AstraZeneca understands that Hanmi's §505(b)(2) esomeprazole strontium product is not AB-rated and is not subject to automatic substitution with Nexium.

### Patent proceedings outside the US

As previously disclosed, in Australia in 2011, Ranbaxy Laboratories Ltd and Ranbaxy Australia Pty Ltd (together, Ranbaxy) filed an application for revocation on the basis of invalidity of two Nexium patents (Australian patent No. 676337 and Australian Patent No. 695966) with the Federal Court of Australia. AstraZeneca cross-claimed for infringement of these patents and asserted infringement of a further Nexium patent (Australian Patent No. 695774). In May 2013, the Federal Court of Australia maintained the validity of each of the patents-in-suit and held that Ranbaxy infringed the 676337 and 695966 patents, but that the 695774 patent was not infringed. Ranbaxy appealed this decision and AstraZeneca cross-appealed. In November 2013, AstraZeneca and Ranbaxy entered into a settlement agreement. Under the terms of the agreement the appeal and cross-appeal were discontinued.

In Canada, patent infringement proceedings against Apotex Inc. continue. A trial was held from September to November 2013. The decision is under reserve.

In Canada, in October 2012, the Federal Court prohibited Pharmascience Inc. (PMS) from receiving a marketing authorisation for its esomeprazole magnesium product until May 2018. PMS appealed and the decision is under reserve.

In Canada, on 16 December 2013, AstraZeneca settled its previously disclosed notice of compliance proceeding with Ranbaxy Pharmaceuticals Canada Inc.

As previously disclosed, in the UK, in September 2010, AstraZeneca initiated patent infringement proceedings against Consilient Health Limited (Consilient) and Krka, d.d., Novo Mesto (Krka). Consilient and Krka had previously agreed not to launch their esomeprazole magnesium product pending the outcome of the patent infringement proceedings. Although this injunction was discharged in July 2011, AstraZeneca may remain liable for damages resulting from the injunction. In 2012, Consilient and Krka commenced damages proceedings. A damages inquiry hearing took place in December 2013 and a finding of fact was issued in January 2014. Damages will be awarded to Consilient and Krka in due course. A provision has been taken. The decision is under reserve.

While AstraZeneca continues to have confidence in the patents protecting Nexium and will continue to take appropriate legal action, additional generic launches and adverse court rulings are possible.

Prilosec (omeprazole capsules)

Patent proceedings in the US

As previously disclosed, AstraZeneca continues litigation to recover patent infringement damages against Apotex Corp. and Apotex Inc. (together, Apotex). On 11 December 2013, the US District Court for the Southern District of New York entered final judgment against Apotex for approximately \$104 million. Apotex has appealed the decision.

Pulmicort Respules (budesonide inhalation suspension)

Patent proceedings in the US

As previously disclosed, on 1 April 2013, the US District Court for the District of New Jersey (District Court) ruled that AstraZeneca's US patent no. 6,598,603 (the '603 patent) is invalid and that the generic defendants involved in the litigation do not infringe a second patent, US patent no. 7,524,834 (the '834 patent). AstraZeneca filed a notice of

appeal and on 24 May 2013, the US Court of Appeals for the Federal Circuit (Court of Appeals) enjoined the generic defendants from entering the market until its ruling on AstraZeneca's appeal. On 30 October 2013, the Court of Appeals reversed and remanded for further proceedings the District Court's decision that the generic defendants involved in the litigation do not infringe the '834 patent. However, the Court of Appeals upheld the District Court's decision that the '603 patent is invalid. On 18 December 2013, the District Court granted AstraZeneca's motion and temporarily enjoined the generic defendants from entering the market until resolution of AstraZeneca's motion for a preliminary injunction. On 19 December 2013, the Court of Appeals issued its mandate to the District Court.

Seroquel XR (quetiapine fumarate)

Patent proceedings outside the US

As previously disclosed, in March 2012, the UK High Court found the Seroquel XR formulation patent invalid. In April 2013, the Court of Appeal denied AstraZeneca's appeal. In December 2013, the Supreme Court decided not to hear an appeal of the Court of Appeal's decision.

As previously disclosed, in October 2013, in Spain, the Barcelona Court of Appeal reversed the July 2012 opinion by the Commercial Court in Barcelona and found the Seroquel XR formulation patent invalid. AstraZeneca has appealed the decision.

As previously disclosed, in March 2013, the Federal Court of Canada dismissed AstraZeneca's application to prohibit the Canadian Minister of Health from issuing a Notice of Compliance to Teva Canada Limited (Teva) for its generic quetiapine fumarate product relating to Seroquel XR. Teva has filed an action seeking section 8 damages arising from these proceedings.

In Portugal, there have been numerous challenges to the Seroquel XR formulation patent. There have been three arbitral panel decisions rendered in September, October and November 2013 respectively, all decided in AstraZeneca's favour. There are other similar proceedings pending in Portugal.

In Belgium, in December 2013, the Commercial Court of Antwerp found the Seroquel XR formulation patent invalid. AstraZeneca intends to appeal this decision.

Generic versions of Seroquel XR have been launched in Austria, Denmark, Germany, Italy, Portugal, Romania, UK and elsewhere in Europe. While AstraZeneca continues to have confidence in the patent protecting Seroquel XR and will continue to take appropriate legal action, additional generic launches and adverse court rulings are possible.

Vimovo (fixed dose combination of naproxen/esomeprazole)

Patent proceedings in the US

In January 2014, AstraZeneca and POZEN Inc. commenced patent infringement actions in the US District Court for the District of New Jersey against two additional ANDA challengers seeking approval to market a generic copy of Vimovo. Separately, four patent infringement actions regarding generic versions of Vimovo are pending in the same Court. No trial dates have been set.

Product liability litigation

### Byetta/Bydureon (exenatide)

Amylin Pharmaceuticals, LLC, a wholly owned subsidiary of AstraZeneca, is a defendant in 272 filed lawsuits in various federal and state courts in the US involving a total of 442 plaintiffs claiming physical injury from treatment with Byetta or Bydureon. The lawsuits allege multiple types of injuries including pancreatitis, pancreatic cancer, and thyroid cancer. A Multi-District Litigation has been established in the US District Court for the Southern District of California in regard to the alleged pancreatic cancer cases in federal courts. Further, a coordinated proceeding has been established in Los Angeles, California in regard to the various lawsuits in California state courts. A trial involving a single plaintiff alleging pancreatitis caused by Byetta is scheduled for 18 February 2014 in the California

state court coordinated proceeding.

### Nexium (esomeprazole magnesium)

As previously disclosed, AstraZeneca has been defending product liability lawsuits brought by approximately 1,900 plaintiffs, who allege that Nexium caused bone deterioration, loss of bone density and/or bone fractures. Approximately 1,700 of these plaintiffs' claims have been consolidated for pre-trial proceeding in the US District Court for the Central District of California through the Multi-District Litigation (MDL) process. In November 2013, the MDL court granted motions to dismiss the claims of 1,104 plaintiffs. In December 2013, 522 of the 1,104 dismissed plaintiffs collectively moved the MDL court to have their claims reinstated. AstraZeneca has opposed this motion, which remains pending. On 13 January 2014, the MDL court dismissed the claims of an additional 179 plaintiffs.

### Seroquel IR (quetiapine fumarate)

As previously disclosed, with regard to insurance coverage for the substantial legal defence costs and settlements that have been incurred in connection with the Seroquel IR product liability claims in the US related to alleged diabetes and/or other related alleged injuries (which now exceed the total amount of insurance coverage available), disputes continue with insurers about the availability of coverage under certain insurance policies. These policies have aggregate coverage limits of \$300 million.

AstraZeneca commenced legal proceedings in the UK against two of the insurers in respect of policies with aggregate coverage limits of \$200 million and in February 2013 the High Court issued a judgment on preliminary legal issues which ruled that AstraZeneca was not entitled to recover under those policies. AstraZeneca appealed the decision, but on 20 December 2013 the Court of Appeal issued a judgment which upheld the High Court's ruling.

An arbitration has commenced against another insurer in respect of a policy with a coverage limit of \$50 million.

AstraZeneca has not recognised an insurance receivable in respect of these legal actions.

### Commercial litigation

### Crestor qui tam litigation

As disclosed in the Government investigations section below, the US Attorney's Offices and all states, except for the State of Texas, have declined to intervene in the civil component of a previously disclosed investigation regarding Crestor. As a result, AstraZeneca has now been named as a defendant in a lawsuit filed in the US Federal Court in Wilmington, Delaware, under the qui tam (whistleblower) provisions of the federal False Claims Act and the Florida Whistleblower Act, alleging that AstraZeneca directed certain employees to promote Crestor off-label. AstraZeneca intends to vigorously defend this matter.

### Shionogi arbitration Crestor royalty calculation

As previously disclosed, in July 2012, Shionogi & Co. Ltd (Shionogi) initiated arbitration proceedings to resolve issues relating to the treatment of certain excise taxes and other specific items in the calculation of royalties on Crestor sales. On 26 December 2013, the parties announced the full resolution of the arbitration proceedings and the extension of the global license agreement for Crestor.

### Nexium consumer litigation (esomeprazole magnesium)

As previously disclosed, AstraZeneca is a defendant in a lawsuit in the Delaware Superior Court based on allegations that its promotion and advertising of Nexium to physicians, consumers and third party payers was unfair, unlawful and deceptive. This action has been stayed since 2005. On 17 December 2013, the Court denied AstraZeneca's motion to dismiss the matter for failure to prosecute. AstraZeneca anticipates that the stay of the case will be lifted in the first quarter of 2014.

### Nexium settlement anti-trust litigation

As previously disclosed, AstraZeneca is one of several defendants in a now consolidated, Multi-District Litigation proposed class action and individual lawsuits, alleging that AstraZeneca's settlements of certain patent litigation in the US relating to Nexium violated US anti-trust law and various state laws.

On 14 November 2013, the US District Court for the District of Massachusetts (District Court) granted the end-payers' motion for class certification, and on 11 December 2013, the Court granted the direct purchasers' motion for class certification. AstraZeneca and the other defendants have filed petitions for appellate review of both decisions.

On 27 November 2013, the Court denied AstraZeneca and Ranbaxy Pharmaceuticals, Inc., Ranbaxy Inc., and Ranbaxy Laboratories Ltd's (together, Ranbaxy) motion for summary judgment on the grounds that the plaintiffs' claims with respect to the 2008 settlement agreement are barred by the four year statute of limitations. On 4 December 2013, the Court denied AstraZeneca and Ranbaxy's motion for reconsideration of that decision. AstraZeneca has filed a petition seeking appellate review of this decision in the context of a review of the class certification rulings.

On 10 December 2013, AstraZeneca and the other defendants filed numerous motions for summary judgment and motions challenging expert witnesses. Plaintiffs filed numerous motions challenging expert witnesses proposed by the defendants. On 30 December 2013, the Court issued an oral ruling striking certain experts, subject to reconsideration prior to, or at, trial. In January 2014, the Court issued an oral ruling striking additional plaintiff expert witnesses, and oral and written orders denying certain of the summary judgment motions. Several summary judgment motions remain under consideration. A trial on certain factual issues in this matter is currently scheduled to commence in March 2014.

# Government investigations

### Serbia

As previously disclosed, in August 2011, AstraZeneca's Representative Office in Belgrade, Serbia (the Representative Office) was served with a criminal indictment alleging that local employees of AstraZeneca and several other pharmaceutical companies made allegedly improper payments to physicians at the Institute of Oncology and Radiology of Serbia. In December 2013, the Representative Office reached an agreement with the Serbian prosecutor, pursuant to which the prosecutor dismissed the indictment. A provision has been taken.

### Other US Attorney's Offices investigations

As previously disclosed, the US Attorney's Offices in Alabama, Delaware and Texas along with the US Department of Justice are conducting investigations related to sales and marketing activities involving Crestor and Seroquel. In January 2014, AstraZeneca was advised that the Department of Justice and all of the states, except for the State of Texas, intend to file a notice of non-intervention in the federal case with regard to Seroquel.

With regard to the Crestor investigation, the US Attorney's Offices and all states, except for the State of Texas, have declined to intervene in the civil component of the investigation. Additional components of the investigation by the Department of Justice, as well as an investigation by the Texas Office of Attorney General, continue.

### 11 FULL YEAR PRODUCT REVENUE ANALYSIS

						Establ	ished	Emer	ging
Wor	ld	US	S	Eur	ope	RO	W	Mar	kets
FY	CER	FY	CER	FY	CER	FY	CER	FY	CER
2013	%	2013	%	2013	%	2013	%	2013	%

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	\$m		\$m		\$m		\$m		\$m	
Cardiovascular:			·		,		·		·	
Crestor	5,622	(8)	2,912	(8)	1,225	(3)	807	(27)	678	17
Atacand	611	(39)	72	(52)	225	(52)	71	(49)	243	(1)
Seloken/Toprol-XL	750	(18)	131	(59)	130	(5)	24	(7)	465	8
Onglyza	378	17	265	12	56	12	20	54	37	61
Plendil	260	2	_	(100)	21	(17)	10	(17)	229	7
Tenormin	197	(7)	15	50	51	(6)	77	(13)	54	(7)
Brilinta/Brilique	283	216	73	284	163	179	17	n/m	30	210
Byetta	206	181	152	105	36	n/m	11	n/m	7	n/m
Bydureon	151	308	131	254	17	n/m	1	n/m	2	n/m
Forxiga	10	n/m	_		10	n/m	_	_	_	-
Others	362	4	50	100	164	(5)	25	(15)	123	2
Total										
Cardiovascular	8,830	(6)	3,801	(6)	2,098	(6)	1,063	(25)	1,868	11
Gastrointestinal:										
Nexium	3,872	_	2,123	(7)	360	(21)	597	41	792	8
Losec/Prilosec	486	(28)	30	-	131	(33)	165	(39)	160	(9)
Others	231	16	178	23	43	(5)	7	-	3	-
Total										
Gastrointestinal	4,589	(3)	2,331	(5)	534	(24)	769	9	955	5
Respiratory:										
Symbicort	3,483	10	1,233	23	1,502	1	423	7	325	17
Pulmicort	867	10	224	(4)	171	(13)	112	2	360	13
Others	327	(8)	58	(11)	115	(13)	33	(15)	121	13
Total Respiratory	4,677	7	1,515	16	1,788	(2)	568	4	806	13
Oncology:	1,077	,	1,515	10	1,700	(2)	300	-	000	13
Zoladex	996	_	23	(4)	252	(8)	372	(4)	349	10
Iressa	647	11	-	-	177	11	202	9	268	14
Faslodex	681	6	324	5	221	(2)	62	21	74	29
Arimidex	351	(30)	6	(71)	93	(34)	154	(35)	98	(6)
Casodex	376	(7)	5	(267)	53	(13)	225	(10)	93	(4)
Others	142	15	25	(207)	29	53	60	14	28	4
Total Oncology	3,193	(2)	383	2	825	(6)	1,075	(7)	910	9
Neuroscience:	3,193	(2)	363	2	623	(0)	1,075	(7)	910	7
Seroquel XR	1,337	(12)	743	(8)	416	(19)	71	(25)	107	12
Seroquel IR	345	(72)	(17)	n/m	105	(57)	106	(40)	151	(3)
Local Anaesthetics	510			-	206	(5)	182	(1)	122	2
Vimovo	91	(2) 42	20		32	41	20	50	19	400
Others	452		33	(20) 18	113	(25)	20 97	(16)	209	3
Total Neuroscience		(9)	33 779	(50)	872				608	6
Infection & Other:	2,735	(29)	119	(30)	012	(24)	476	(19)	008	U
	1.060	2	617	1	443	4				
Synagis	1,060			(71)			-	(72)	220	(0)
Merrem	293	(24)	11	(71)	49	(42)	5	(72)	228	(8)
FluMist/Fluenz	245	35	199 55	14	42	n/m	4	33 55	1 /	(100)
Others	89	(5)	55	(5)	7	(63)	13	55	14	(17)
Total Infection &	1,687	(1)	882	-	541	3	22	(19)	242	(9)
Other				(100)				. ,		. ,
Aptium Oncology	- 25 711	(100)	0.601	(100)	6 (50	- (0)	2 072	(10)	- - 200	- 0
Total	25,711	(6)	9,691	(9)	6,658	(9)	3,973	(10)	5,389	8

# 12 FOURTH QUARTER PRODUCT REVENUE ANALYSIS

	Would		HC		Eumana		Established DOW		Emerging Markets	
	World		US		Europe		Established ROW			
	Q4	CED	Q4	CED	Q4	CED	Q4	CED	Q4	CED
	2013	CER	2013	CER	2013	CER	2013	CER	2013	CER
C 1' 1	\$m	%	\$m	%	\$m	%	\$m	%	\$m	%
Cardiovascular:	1 460	(0)	770	(10)	211	(2)	20.4	(10)	1.60	1.4
Crestor	1,463	(8)	779	(10)	311	(3)	204	(19)	169	14
Atacand	134	(33)	10	(69)	54	(29)	13	(58)	57	(6)
Seloken/Toprol-XL	170	(32)	19	(81)	33	(9)	7	29	111	(3)
Onglyza	93	6	63	-	15	-	6	50	9	50
Plendil	66	3	-	-	6	(17)	3	<u>-</u>	57	6
Tenormin	46	(9)	3	50	13	(7)	19	(21)	11	9
Brilinta/Brilique	92	139	24	167	51	113	6	250	11	175
Byetta	54	17	36	(23)	11	n/m	4	n/m	3	n/m
Bydureon	49	88	40	54	6	n/m	1	n/m	2	n/m
Forxiga	3	n/m	-	-	3	n/m	-	-	-	-
Others	92	(4)	15	15	39	(12)	6	(40)	32	10
Total	2,262	(8)	989	(14)	542	1	269	(18)	462	8
Cardiovascular	2,202	(6)	202	(14)	342	1	209	(10)	402	O
Gastrointestinal:										
Nexium	991	(3)	545	(9)	92	(12)	165	30	189	(5)
Losec/Prilosec	122	(18)	7	40	35	3	41	(36)	39	(7)
Others	55	2	42	14	10	(17)	2	-	1	(100)
Total	1 160	(5)	504	(7)	127	(0)	200	7	220	(6)
Gastrointestinal	1,168	(5)	594	(7)	137	(9)	208	7	229	(6)
Respiratory:										
Symbicort	976	11	350	28	395	-	129	(1)	102	21
Pulmicort	245	3	59	5	44	(16)	34	5	108	10
Others	85	(12)	16	(11)	28	(13)	9	(23)	32	(6)
Total Respiratory	1,306	7	425	22	467	(3)	172	(1)	242	12
Oncology:	•					. ,		. ,		
Zoladex	247	1	5	_	60	(13)	96	(5)	86	23
Iressa	158	5	_	_	45	2	53	2	60	11
Faslodex	182	6	87	5	58	(4)	17	10	20	40
Arimidex	86	(23)	4	_	22	(19)	38	(33)	22	_
Casodex	95	(4)	2	_	13	(7)	57	(6)	23	_
Others	40	19	7	17	9	50	18	22	6	(14)
Total Oncology	808	-	105	7	207	(6)	279	(7)	217	15
Neuroscience:	000		100	,	207	(0)	2,,,	(,)	21,	10
Seroquel XR	337	(12)	194	(9)	104	(15)	11	(56)	28	21
Seroquel IR	35	(64)	(19)	n/m	24	(31)	(2)	n/m	32	3
Local Anaesthetics	132	(1)	(1)	11/111	53	(2)	49	4	30	(6)
Vimovo	24	39	3	(50)	9	14	6	40	6	(0)
Others	114		9	29	27		24		54	2
Total Neuroscience	642	(4)	9 187			(7)	2 <del>4</del> 88	(17)		2 8
	042	(14)	10/	(13)	217	(13)	00	(38)	150	ō
Infection & Other:	£15	2	200	(1)	215	Ō				
Synagis	515	2	300	(1)	215	8	-	-	-	-

Merrem	77	(25)	2	(89)	11	(39)	-	(100)	64	-
FluMist/Fluenz	50	56	22	(24)	26	n/m	2	100	-	(100)
Others	16	(28)	10	(47)	-	-	5	n/m	1	(70)
Total Infection & Other	658	-	334	(10)	252	14	7	n/m	65	(10)
Aptium Oncology	-	(100)	-	(100)	-	-	-	-	-	-
Total	6,844	(4)	2,634	(7)	1,822	(2)	1,023	(10)	1,365	6

### **Shareholder Information**

### ANNOUNCEMENTS AND MEETINGS

Announcement of first quarter 2014 results
Annual General Meeting
Announcement of second quarter and half year 2014 results
Announcement of third quarter and nine months 2014 results

24 April 2014 24 April 2014 31 July 2014 6 November 2014

### **DIVIDENDS**

The record date for the first interim dividend, payable on 16 September 2013, was 16 August 2013. Shares traded ex-dividend from 14 August 2013.

The record date for the second interim dividend for 2013, payable on 24 March 2014, will be 21 February 2014. Shares will trade ex-dividend from 19 February 2014.

Future dividends will normally be paid as follows:

First interim Announced with second quarter and half year results and

paid in September

Second interim Announced with fourth quarter and full year results and paid

in March

### **TRADEMARKS**

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**US** Depositary Transfer Office Equiniti Limited

JP Morgan Chase

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

In order, among other things, to utilise the 'safe harbour' provisions of the US Private Securities Litigation Reform Act 1995, we are providing the following cautionary statement: The preliminary announcement contains certain forward-looking statements with respect to the operations, performance and financial condition of the Group. Although we believe our expectations are based on reasonable assumptions, any forward-looking statements, by their very nature, involve risks and uncertainties and may be influenced by factors that could cause actual outcomes and results to be materially different from those predicted. The forward-looking statements reflect knowledge and information available at the date of preparation of the preliminary announcement and AstraZeneca undertakes no obligation to update these forward-looking statements. We identify the forward-looking statements by using the words 'anticipates', 'believes', 'expects', 'intends' and similar expressions in such statements. Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond our control, include, among other things: the loss or expiration of patents, marketing exclusivity or trademarks, or the risk of failure to obtain patent protection; the risk of substantial adverse litigation/government investigation claims and insufficient insurance coverage; exchange rate fluctuations; the risk that R&D will not yield new products that achieve commercial success; the risk that strategic alliances and acquisitions will be unsuccessful; the impact of competition, price controls and price reductions; taxation risks; the risk of substantial product liability claims; the impact of any delays in the manufacturing, distribution and sale of any of our products; the impact of any failure by third parties to supply materials or services; the risk of failure to manage a crisis; the risk of delay to new

product launches; the difficulties of obtaining and maintaining regulatory approvals for products; the risk of failure to observe ongoing regulatory oversight; the risk that new products do not perform as we expect; the risk of environmental liabilities; the risks associated with conducting business in emerging markets; the risk of reputational damage; the risk of product counterfeiting; the risk of failure to successfully implement planned cost reduction measures through productivity initiatives and restructuring programmes; the risk that regulatory approval processes for biosimilars could have an adverse effect on future commercial prospects; the impact of failing to attract and retain key personnel and to successfully engage with our employees; and the impact of increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation.

### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 06 February 2014 By: /s/ Adrian Kemp

Name: Adrian Kemp Title: Company Secretary