

ASTRAZENECA PLC  
Form 6-K  
April 25, 2013

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 April 2013

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

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AstraZeneca PLC

FIRST QUARTER RESULTS 2013

London, 25 April 2013

Revenue for the first quarter was \$6,385 million, down 12 percent at constant exchange rates (CER).

-Losses of exclusivity for Seroquel IR and Atacand in many markets, and for Crestor in Canada, were the key drivers for the revenue decline.

-Growth for Symbicort, Brilinta, Iressa and the inclusion of the Amylin diabetes products delivered more than \$250 million of revenue growth at CER in the quarter.

-Emerging Markets revenue increased by 9 percent at CER in the quarter.

Core operating profit was down 21 percent at CER to \$2,324 million in the first quarter.

-Core operating profit decline was driven by lower revenue and lower Core other income, partially offset by Core operating costs (combined R&D and SG&A) that were 4 percent lower at CER than last year.

Core EPS was \$1.41, down 21 percent at CER compared to the first quarter last year.

-Core EPS declined in line with Core operating profit, as a higher tax rate this year was broadly offset by a lower number of shares outstanding and lower net finance expense.

Reported EPS was down 31 percent at CER to \$0.81.

The Company continues to expect a mid-to-high single digit decline in revenue at CER and a Core EPS decline that is significantly larger than the decline in revenue for the full year.

Continued investment in distinctive science in core therapy areas through collaborations with Karolinska Institutet, Moderna Therapeutics, BIND Therapeutics and the acquisition of Alphacore Pharma.

Financial Summary

Group	1st Quarter 2013 \$m	1st Quarter 2012** \$m	Actual %	CER %
Revenue Reported	6,385	7,349	-13	-12

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Operating Profit	1,397	2,160	-35	-30
Profit before Tax	1,304	2,035	-36	-31
Earnings per Share	\$0.81	\$1.27	-36	-31
Core*				
Operating Profit	2,324	3,106	-25	-21
Profit before Tax	2,231	2,981	-25	-22
Earnings per Share	\$1.41	\$1.87	-25	-21

\* Core financial measures are supplemental non-GAAP measures which management believe enhance understanding of the Company's performance; it is upon these measures that financial guidance for 2013 is based. See page 2 for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.

\*\* 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 these first quarter results 2013. 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.

Pascal Soriot, Chief Executive Officer, commenting on the results, said: "As anticipated, the first quarter performance reflects the loss of exclusivity for several large products. We remain focused on our strategic priorities of returning to growth and achieving scientific leadership. Brilinta, the diabetes franchise, Emerging Markets, Japan and our Respiratory products have all made good progress and we continued to invest in distinctive science that will advance our knowledge of disease physiology and help to identify new drug targets."

## 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. 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.

### First Quarter

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

	Reported	Intangible	Intangible	Legal	Core	Restated	Actual	CER
	2013	Restructuring	Amortisation	Provisions	2013	Core	%	%
			Impairments	& Other		2012		
Revenue	6,385	-	-	-	6,385	7,349	(13)	(12)
Cost of Sales	(1,266)	12	118	-	(1,136)	(1,286)		
Gross Profit	5,119	12	118	-	5,249	6,063	(13)	(11)
% sales	80.2%				82.2%	82.5%	-0.3	+0.9
Distribution	(77)	-	-	-	(77)	(76)	1	1

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% sales	1.2%					1.2%	1.0%	-0.2	-0.2
R&D	(1,259)	291	5	-	-	(963)	(1,027)	(6)	(7)
% sales	19.7%					15.1%	13.9%	-1.2	-0.9
SG&A	(2,518)	240	223	-	-	(2,055)	(2,121)	(3)	(2)
% sales	39.5%					32.2%	28.9%	-3.3	-3.2
Other Income	132	-	38	-	-	170	267	(36)	(36)
% sales	2.1%					2.7%	3.6%	-0.9	-1.0
Operating Profit	1,397	543	384*	-	-	2,324	3,106	(25)	(21)
% sales	21.9%					36.4%	42.3%	-5.9	-4.4
Net Finance Expense	(93)	-	-	-	-	(93)	(125)		
Profit before Tax	1,304	543	384	-	-	2,231	2,981	(25)	(22)
Taxation	(292)	(121)	(63)*	-	-	(476)	(584)		
Profit after Tax	1,012	422	321	-	-	1,755	2,397	(27)	(23)
Non-controlling									
Interests	(1)	-	-	-	-	(1)	(2)		
Net Profit	1,011	422	321	-	-	1,754	2,395	(27)	(23)
Weighted Avg. Shares	1,248	1,248	1,248	1,248	1,248	1,248	1,281		
Earnings per Share	0.81	0.34	0.26	-	-	1.41	1.87	(25)	(21)

\* Intangible amortisation includes Merck related amortisation, of which \$100 million carries no tax adjustment.

Revenue in the first quarter was down 12 percent at CER and declined by 13 percent on an actual basis as a result of the negative impact of exchange rate movements, chiefly the weakening of the Japanese yen versus the US dollar, which reduced reported revenue in Japan by 13 percent. The impact from losses of exclusivity amounted to more than \$1 billion in the quarter, with Seroquel IR and Atacand in many markets, and Crestor in Canada accounting for more than 90 percent of this impact.

US revenues were down 16 percent. Generic competition for Seroquel IR commenced at the end of March last year. Although Seroquel IR revenues in the first quarter last year were reduced by the recognition of a \$223 million returns reserve against US trade inventories, Seroquel IR revenues in the first quarter of 2013 were still down 99 percent compared to last year. Excluding Seroquel IR, revenues in the US were up 3 percent, driven by the inclusion of the Amylin diabetes products and growth for Symbicort, Brilinta and the Onglyza franchise. The negative impact of US healthcare reform on first quarter revenue and costs was \$223 million.

Revenue in the Rest of World (ROW) was down 9 percent. Revenue in Europe for reporting purposes now combines Western Europe with revenue from many markets that were formerly reported in Emerging Rest of World. Revenue in Europe was down 16 percent, chiefly on the loss of exclusivity for Seroquel IR and erosion to Seroquel XR from adverse patent rulings in some markets coupled with "at risk" launches for generics, as well as loss of exclusivity for Atacand and Nexium. Revenue in Established ROW was down 17 percent, largely due to loss of exclusivity for Crestor in Canada and pricing pressures on Crestor in Australia, partially offset by a 5 percent revenue increase in Japan. Revenue in Emerging Markets (excluding those markets that are now included within Europe) was up 9 percent, largely driven by a 21 percent increase in China.

Core gross profit in the first quarter declined by 11 percent, slightly less than the decline in revenue. Core gross margin as a percentage of revenue was 82.2 percent in the quarter, up 0.9 percentage points, as an unfavourable mix effect was more than offset by a lower Core Merck expense as a result of the capitalisation of intangible assets following amendments to the Second Option made in 2012.

Expenditures in Core SG&A were down 2 percent. Benefits from restructuring programmes and overall lower selling and marketing expenses in developed markets more than offset selective investments in support of Emerging Markets,

Brilinta and the inclusion of the Company's share of selling costs for Byetta, Bydureon and Symlin. The excise fee imposed by the enactment of US healthcare reform measures amounted to 2.6 percent of Core SG&A expense in the quarter.

Core other income of \$170 million was down 36 percent, largely due to lower royalties from Zomig and the fact that 2012 benefited from a number of one-off gains.

Core Pre-R&D operating profit was down 18 percent to \$3,287 million. Core Pre-R&D operating margin was 51.5 percent of revenue, 3.5 percentage points lower than last year, on higher Core SG&A expense as a percentage of revenue and lower Core other income, partially offset by a higher Core gross margin.

Core R&D expense was down 7 percent in the first quarter. Savings from restructuring programmes and lower clinical trial costs related to the winding down of Phase III trials (such as for fostamatinib and naloxegol) provided more than enough headroom to fund increased spending on new in-licensed, acquired or partnered projects.

Core operating profit was down 21 percent to \$2,324 million. Core operating margin was down 4.4 percentage points to 36.4 percent of revenue, the result of the decline in Core Pre-R&D operating margin combined with higher R&D expense as a percentage of revenue.

Core earnings per share were down 21 percent to \$1.41, in line with the decline in Core operating profit, as the benefits from a lower number of shares outstanding and lower net finance expense were broadly offset by the higher tax rate compared to the first quarter last year.

Reported operating profit was down 30 percent to \$1,397 million. Reported EPS was down 31 percent to \$0.81. Adjustments to Core financial measures were of a similar magnitude to those in the first quarter 2012, but when applied to a lower baseline Core operating profit in 2013, they result in declines in Reported operating profit and EPS that are significantly higher than the percentage declines for their respective Core measures.

#### Enhancing Productivity

In March 2013, a new set of restructuring initiatives were announced, including R&D site footprint changes to align with globally recognised bioscience clusters and further restructuring of SG&A activities. We have combined these new initiatives with the headcount changes (and associated costs and benefits) that remain to be enacted from the Phase 3 restructuring programme announced in February 2012, to create one integrated Phase 4 programme for tracking purposes.

This combined programme of changes will result in the elimination of approximately 5,050 roles and the relocation of 2,500 positions.

The combined programme will result in an estimated \$2.3 billion in restructuring charges, of which \$1.7 billion are expected to be cash costs. Approximately \$1.3 billion of restructuring costs are expected to be taken in 2013. The balance of the remainder will be split broadly evenly between 2014 and 2015, with a small residual charge in 2016.

This Phase 4 restructuring is expected to deliver benefits of \$800 million per annum by the end of 2016, half of which should be realised by the end of 2014.

Restructuring charges of \$543 million were taken in the first quarter 2013.

#### Finance Income and Expense

Net finance expense was \$93 million for the quarter, versus \$125 million in 2012. Net exchange gains, lower interest charges on long-term debt and reduced net finance cost on the Group's pension schemes contributed to the decrease.

#### Taxation

The Reported tax rate for the first quarter was 22.4 percent compared with 20.0 percent for the same period last year. The Group's Reported tax rate for 2013 is still anticipated to be around 23 percent.

#### Cash Flow

Cash generated from operating activities was \$2,198 million in the quarter to 31 March 2013, compared with \$1,540 million in the same period of 2012. Lower tax and interest payments partially offset the lower operating profit in 2013, whilst a one-off pension fund contribution drove higher outflows in the prior year.

Net cash outflows from investing activities were \$364 million in the quarter compared with a net inflow of \$593 million in the first quarter of 2012. Net cash outflows on externalisation activities were \$300 million compared with \$80 million in the comparative period of 2012, which also included a \$651 million inflow from the maturity of short-term investments.

Net cash distributions to shareholders were \$2,154 million, through the second interim dividend from 2012 of \$2,296 million partially offset by proceeds from the issue of shares of \$142 million.

#### Debt and Capital Structure

At 31 March 2013, outstanding gross debt (interest-bearing loans and borrowings) was \$10,209 million (31 December 2012: \$10,310 million). Of the gross debt outstanding at 31 March 2013, \$889 million is due within one year (31 December 2012: \$901 million).

Net debt of \$1,769 million has increased by \$400 million during the quarter as a result of the net cash outflow as described in the cash flow section above.

#### Shares in Issue

In the first quarter of 2013 2.9 million shares were issued in respect of share option exercises for a consideration of \$111 million.

The total number of shares in issue at 31 March 2013 was 1,250 million.

#### Future Prospects

As expected, the impact from the loss of exclusivity for several brands has affected performance in the first quarter. Whilst this impact will be felt throughout the year, comparisons with prior year periods should improve as the 12 month anniversaries for generic competition for Seroquel IR in many markets, and for Crestor in Canada are reached. Consequently, for the full year the Company continues to anticipate a mid-to-high single digit decline in revenue on a constant currency basis.

Productivity and efficiency programmes will continue to deliver their target levels of savings, providing the headroom to invest behind key growth platforms and progress the pipeline. Core operating costs (combined Core R&D and SG&A expense) in the first quarter were 4 percent lower than last year, but this is largely a matter of phasing. For the full year, we continue to anticipate that Core operating costs will be held to a slight increase compared with 2012 on a constant currency basis.

With a revenue and cost profile in line with guidance, the Company continues to expect Core EPS to decline at a rate that is significantly higher than the decline in revenue in 2013.

Financial guidance for 2013 has been based on January 2013 average exchange rates for our principal currencies, and actual first quarter results were broadly in line with this currency assumption. This guidance takes no account of the likelihood that average exchange rates for the remainder of 2013 may differ materially from the rates upon which our financial guidance is based. An estimate of the sales and earnings sensitivity to movements of our major currencies versus the US dollar was provided in conjunction with the Full Year 2012 results announcement, and can be found on the AstraZeneca website, [www.astrazeneca.com/investors](http://www.astrazeneca.com/investors).

## Research and Development Update

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A comprehensive update of the AstraZeneca R&D pipeline was presented in conjunction with the Full Year 2012 results and the pipeline table remains available on the Company's website, [www.astrazeneca.com](http://www.astrazeneca.com), under information for investors.

Considerable further detail on the pipeline and the Company's strategy to achieve scientific leadership was presented to investors in a briefing held on 21 March 2013. Among the highlights:

The Company announced plans to locate more of the Company's scientists close to globally recognised bioscience clusters, making it easier to access world-class talent and opportunities for collaboration and partnerships.

Research and Development efforts will be more focused. In large and small molecule R&D, scientific efforts and the weight of investment, including business development, will be concentrated on three core therapeutic areas: Respiratory, Inflammation & Autoimmunity; Cardiovascular & Metabolic Disease; and Oncology.

Six projects, three each in Respiratory, Inflammation & Autoimmunity and in Oncology, have been selected for accelerated development efforts. The Company anticipates approximately 5 to 7 Phase III programme starts from a cohort of 12 new molecular entity projects that have decision milestones before the end of 2014.

Important business development agreements since the Full Year 2012 results announcement include:

### Development agreement with Moderna Therapeutics

On 21 March 2013, the Company announced an exclusive agreement with Moderna Therapeutics to discover, develop and commercialise pioneering messenger RNA Therapeutics for the treatment of serious cardiovascular, metabolic and renal diseases as well as cancer. Messenger RNA Therapeutics are an entirely new treatment approach that enables the body to produce therapeutic protein *in vivo*, opening up new treatment options for a wide range of diseases that cannot be addressed today using existing technologies.

Under the terms of the agreement, AstraZeneca will make an upfront payment of \$240 million. AstraZeneca will have exclusive access to select any target of its choice in cardiometabolic diseases, as well as selected targets in oncology, over a period of up to five years for subsequent development of messenger RNA. In addition, Moderna is entitled to an additional \$180 million for the achievement of three technical milestones.

Through this agreement, AstraZeneca has the option to select up to 40 drug products for clinical development and Moderna will be entitled to development and commercial milestone payments as well as royalties on drug sales ranging from high single digits to low double digits for each product. AstraZeneca will lead the preclinical, clinical development and commercialisation of therapeutics resulting from the agreement and Moderna will be responsible for

designing and manufacturing the messenger RNA against selected targets.

#### Collaboration with Karolinska Institutet

On 21 March 2013, AstraZeneca and the Swedish medical university Karolinska Institutet announced their intention to create an Integrated Translational Research Centre for cardiovascular and metabolic disease and regenerative medicine located at Karolinska Institutet's site in Stockholm, Sweden. The Centre will be set up to conduct preclinical and clinical studies aimed at advancing the understanding of cardiovascular and metabolic disease pathophysiology and assessing new drug targets for AstraZeneca's two biotech units, AstraZeneca Innovative Medicines and Early Development (iMed) and MedImmune.

Building on the organisations' longstanding collaboration, the Centre will initially run for a period of five years and will be made up of between 20 and 30 scientists, including a number of AstraZeneca scientists. In addition, AstraZeneca will contribute up to \$20 million per annum, and Karolinska Institutet will contribute expertise and facilities. The Centre is expected to be operational by mid-2013.

#### AlphaCore Pharma

On 3 April 2013, the Company announced its acquisition of AlphaCore Pharma, a biotechnology company focused on the development of ACP-501, a recombinant human lecithin-cholesterol acyltransferase (LCAT) enzyme.

LCAT, an enzyme in the bloodstream, is a key component in the reverse cholesterol transport (RCT) system, which is thought to play a major role in driving the removal of cholesterol from the body and may be critical in the management of high-density lipoprotein (HDL) cholesterol levels. The LCAT enzyme could also play a role in a rare, hereditary disorder called familial LCAT deficiency (FLD) in which the LCAT enzyme is absent.

Cardiovascular and metabolic disease is a core therapy area for AstraZeneca's small and large molecule research.

In 2012, results from a Phase I clinical trial of ACP-501 met the primary safety and tolerability endpoints. No serious adverse events were reported. ACP-501 also met the study's secondary endpoints by rapidly and substantially elevating HDL cholesterol. The data from this study support ongoing clinical development of ACP-501.

Pipeline developments since the Full Year 2012 results update include:

#### Fostamatinib

On 5 April 2013, top-line results were announced for OSKIRA-1, a Phase III study to assess the efficacy and safety of fostamatinib, the first oral spleen tyrosine kinase (SYK) inhibitor in development for rheumatoid arthritis (RA). OSKIRA-1 had two primary endpoints: assessing signs and symptoms of RA as measured by ACR20 response rates, and an X-ray endpoint known as mTSS (modified Total Sharp Score).

OSKIRA-1 randomised 923 patients who had experienced an inadequate response to methotrexate (MTX) and, over a 24 week period, evaluated the effectiveness of two dosing regimens of fostamatinib (100 mg twice daily or fostamatinib 100 mg twice daily for four weeks followed by 150 mg once daily) in combination with MTX versus placebo in combination with MTX. Patients on fostamatinib remained on treatment in OSKIRA-1 for 12 months.

In the OSKIRA-1 study, fostamatinib achieved a statistically significant improvement in ACR20 response rate at 24 weeks in both the 100 mg twice daily group and the group that received 100 mg twice daily for four weeks followed by 150 mg once daily (49%,  $p < 0.001$  and 44%,  $p = 0.006$  respectively) compared to placebo (34%). Fostamatinib did not demonstrate a statistically significant difference in mTSS compared to placebo at 24 weeks for either dose ( $p = 0.252$  and  $p = 0.170$ , respectively).



The safety and tolerability findings for fostamatinib observed in the OSKIRA-1 study were generally consistent with those previously reported for the TASKi Phase II programme. The most commonly reported adverse events were typical of those seen in earlier studies, including hypertension, diarrhoea, nausea, headache and nasopharyngitis (common cold).

These top-line results provide important information on the efficacy and safety of fostamatinib and demonstrate that the compound has an effect on the signs and symptoms of rheumatoid arthritis. The Company will await the results of the remaining Phase III studies, OSKIRA-2 and OSKIRA-3, expected in the second quarter of 2013, to further evaluate and characterise the profile of fostamatinib as a potential treatment for rheumatoid arthritis.

#### Naloxegol

On 26 February 2013, AstraZeneca announced high-level results from KODIAC-08, an open-label, randomised, 52-week, long-term safety trial of naloxegol versus usual care (UC) in patients with non-cancer related pain and opioid-induced constipation (OIC). UC was defined as the investigator's choice of an existing laxative treatment regimen for OIC. This is the fourth trial in the naloxegol Phase III development programme, and was designed to evaluate the long-term safety and adverse event (AE) profile of naloxegol in patients taking 25 mg once daily, as compared to UC.

In the trial, a total of 534 patients received naloxegol once daily for up to 52 weeks, while 270 patients received UC for OIC during the same treatment period. The most commonly reported AEs occurring more frequently on naloxegol than on usual care included abdominal pain, diarrhoea, nausea and headache. The trial reported no imbalances in serious adverse events (SAEs). In addition, there were a low number of major adverse cardiovascular events (MACE), as adjudicated by an independent external committee, and there was no imbalance of these events across naloxegol and UC arms.

There were no increases from baseline levels in mean daily pain scores or mean total daily opioid dose in either the naloxegol or the UC arm. Additionally, there were no reports of opioid withdrawal AEs which could be attributed to naloxegol. A full assessment of the safety and tolerability findings is ongoing.

These high-level results are similar to the safety results seen in the Phase III studies previously reported. The core Phase III programme has now been completed. Plans for naloxegol will be finalised over the coming months, incorporating the outcome of ongoing pre-NDA discussions with the US FDA.

The core Phase III KODIAC programme for naloxegol is comprised of four clinical trials, designed to investigate the safety and efficacy of naloxegol for the treatment of OIC in patients with non-cancer related pain. Three trials reported high level results in November 2012, including KODIAC-04, -05 and -07. KODIAC-04 and -05 were pivotal 12-week efficacy and safety trials, while KODIAC-07 was a 12-week safety extension of KODIAC-04.

Full results from KODIAC-04 and -05 will be presented at Digestive Disease Week (DDW), 18 to 21 May 2013. Full results from KODIAC-07, along with KODIAC-08, will be presented at a scientific meeting later in 2013.

#### Revenue

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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 areas is shown in Note 5.

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	First Quarter		CER %
	2013 \$m	2012 \$m	
<b>Cardiovascular</b>			
Crestor	1,323	1,500	-11
Onglyza	90	72	+27
Byetta	42	-	n/m
Bydureon	27	-	n/m
Forxiga	1	-	n/m
Brilinta/Brilique	51	9	n/m
Atacand	168	317	-47
Seloken /Toprol-XL	224	224	-
<b>Gastrointestinal</b>			
Nexium	940	953	-1
Losec/Prilosec	125	170	-23
<b>Respiratory &amp; Inflammation</b>			
Symbicort	826	723	+14
Pulmicort	233	227	+3
<b>Oncology</b>			
Zoladex	240	273	-8
Arimidex	92	144	-33
Casodex	92	113	-13
Iressa	168	143	+20
Faslodex	157	151	+5
<b>Neuroscience</b>			
Seroquel	449	1,138	-60
Seroquel IR	127	754	-82
Seroquel XR	322	384	-16
Vimovo	20	16	+25
<b>Infection and other</b>			
Synagis	404	384	+5
Merrem	68	100	-31
FluMist	5	2	+150

**Cardiovascular**

- In the US, Crestor sales in the first quarter were \$652 million, down 4 percent. Total prescriptions for statin products in the US increased by 1 percent in the first quarter. Crestor total prescriptions were down 7 percent. Excluding the adjustment in Medicare coverage gap discounts made in the first quarter last year, average realised selling prices were slightly lower in the quarter.
- Crestor sales in the Rest of World were down 16 percent to \$671 million, reflecting the loss of exclusivity in Canada in April 2012 arising from settlements of patent litigation. Sales in Canada were down 90 percent in the quarter; excluding Canada, sales in the Rest of World were up 5

percent. In addition to the decline in Canada, pricing pressure in Australia also contributed to the 41 percent decline in Established Rest of World; sales in Japan increased 27 percent in the quarter. Sales in Europe were down 2 percent. Sales in Emerging Markets were up 16 percent, with China accounting for more than 60 percent of the increase.

- Alliance revenue from the Onglyza collaboration with Bristol-Myers Squibb was up 27 percent in the first quarter to \$90 million, of which \$64 million was in the US and \$26 million in other markets. Total prescriptions for the Onglyza franchise in the US were up 9 percent compared with the first quarter last year; share of total prescriptions was 16.1 percent in March 2013, down 1.7 percentage points since December 2012, reflecting a decline in preferred reimbursement positions on some managed care formularies.
- Sales of Forxiga were \$1 million in the first quarter, reflecting the fact that the launch rollout in Europe is in its very early stages following approval in November 2012.
- The Company's share of Byetta and Bydureon revenues in the US was \$69 million. There were no revenues in the first quarter last year. Total prescriptions for the exenatide franchise were up 6 percent compared to the first quarter last year. The Alliance assumes responsibility for promotion in Rest of World markets from April 2013 onwards.
- Sales of Brilinta/Brilique were \$51 million in the first quarter. Sales in Europe were \$30 million, nearly one-third of European sales were in Germany, where Brilique is the number two oral antiplatelet molecule by volume share in both the retail and the hospital settings.
- Brilinta sales in the US in the first quarter were \$15 million. There were no sales in the first quarter last year, as launch stocks were still being drawn down. Total prescriptions for Brilinta in the US in the first quarter 2013 were 29 percent higher than the fourth quarter 2012. The weekly average number of retail patients newly starting Brilinta at the end of March was around 30 percent higher than the number starting at the end of December 2012.
- US sales of Atacand were down 33 percent in the quarter, to \$27 million. Generic competition for the diuretic combination product followed the loss of exclusivity in December 2012. Atacand sales in other markets were down 49 percent to \$141 million, reflecting loss of exclusivity in many markets.
- US sales of the Toprol-XL product range, which includes sales of the authorised generic, were down 23 percent to \$56 million, largely the result of market share loss following the introduction of a fourth competitor in September 2012. Sales of Seloken in other markets were up 12 percent to \$168 million, largely on growth in China.

#### Gastrointestinal

- In the US, Nexium sales in the first quarter were \$523 million, down 2 percent compared with the first quarter last year. Dispensed retail tablet volume declined by 8 percent. A change in mix (declining volumes in low margin Medicaid business) continues to create an increase in average realised selling prices, although this mix effect will diminish in the second half of the year.
- Nexium sales in other markets were up 1 percent to \$417 million. Sales in Europe were down 29 percent, reflecting the continued effects of generic competition. Sales in Established Rest of World were up 12 percent on a continued strong performance in Japan, partially offset by the

impact of generic competition in Canada. Sales in Emerging Markets were up 17 percent, with sales in China up 50 percent in the quarter.

- Losec sales in markets outside the US were down 24 percent in the first quarter to \$118 million, largely on lower sales in Japan.

#### Respiratory and Inflammation

- Symbicort sales in the US were \$287 million in the first quarter, a 32 percent increase over last year. Total prescriptions for Symbicort were up 15 percent compared to a 3 percent increase in the market for fixed combination products. Symbicort share of total prescriptions for fixed combination products reached 23.3 percent in March 2013, up 1 percentage point since December 2012. Market share of patients newly starting combination therapy is 29.1 percent, up 1.4 percentage points since December.
- Symbicort sales in other markets in the first quarter were \$539 million, up 7 percent. Sales in Europe were up 4 percent. Sales in Established Rest of World were up 21 percent on growth in Japan, Australia and New Zealand. Sales in Emerging Markets were up 9 percent.
- US sales of Pulmicort were up 11 percent to \$62 million. Pulmicort sales in the Rest of World were up 1 percent to \$171 million, as growth in Emerging Markets more than offset declines in Europe.

#### Oncology

- Arimidex sales were \$92 million in the first quarter. Sales in markets outside the US were \$89 million, down 31 percent as sales continue to decline as a result of loss of exclusivity.
- Sales for Casodex, all of which were outside the US, were down 13 percent to \$92 million, largely on a 15 percent decline in Japan, which accounts for nearly 60 percent of worldwide revenue.
- Iressa sales in the first quarter were up 20 percent to \$168 million. Emerging Markets accounted for more than half of the increase, including a 37 percent increase in China. Sales in Japan were up 11 percent. Sales in Europe were up 15 percent.
- Faslodex sales in the US were up 1 percent to \$73 million. Sales in the Rest of World were up 8 percent to \$84 million, chiefly on growth in Japan.

#### Neuroscience

- In the US, sales of Seroquel IR were down 99 percent to \$7 million in the first quarter. Sales of \$542 million in the first quarter last year were reduced by a returns reserve of \$223 million taken against the estimated trade inventories following the launch of quetiapine IR generics at the end of March.
- Sales of Seroquel XR in the US were \$170 million, down 15 percent. Total prescriptions were down 12 percent, and there was more trade destocking in this quarter compared to the first quarter last year.

- Sales of Seroquel IR in the Rest of World were down 41 percent to \$120 million in the quarter, primarily due to a 75 percent decline in Europe. Sales in Established Rest of World were down 18 percent, despite an 11 percent increase in Japan. Sales in Emerging Markets were up 24 percent.
- Sales of Seroquel XR in the Rest of World were down 17 percent to \$152 million, as a result of generic competition (including some "at risk" launches) in Europe, where sales were down 28 percent; Germany accounted for more than half of the European sales decline. Sales in Emerging Markets were up 26 percent.

#### Infection and Other

- Sales of Synagis in the US were \$313 million in the first quarter, a 3 percent increase. A favourable mix effect on price and favourable adjustments to Medicaid provisions more than offset lower volumes resulting from continuing efforts to control utilisation by payers. Outside the US, Synagis sales were up 11 percent to \$91 million.
- Sales of Merrem were down 31 percent to \$68 million as a result of generic competition in many markets.

#### Regional Revenue

	First Quarter		% Change	
	2013 \$m	2012 \$m	Actual	CER
US	2,445	2,920	-16	-16
Europe <sup>1</sup>	1,660	1,954	-15	-16
Established ROW <sup>2</sup>	950	1,238	-23	-17
Japan	549	598	-8	+5
Canada	170	377	-55	-55
Other Established ROW	231	263	-12	-12
Emerging Markets <sup>3</sup>	1,330	1,237	+8	+9
China	465	380	+22	+21
Total	6,385	7,349	-13	-12

<sup>1</sup>Europe comprises Western Europe and many markets that were formerly reported in Emerging Rest of World.

<sup>2</sup>Established ROW comprises Canada, Japan, Australia and New Zealand.

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

- In the US, revenue was down 16 percent in the first quarter, largely due to the loss of exclusivity for Seroquel IR. Excluding Seroquel IR, revenue was up 3 percent. Inclusion of the Amylin diabetes products provided \$78 million of incremental revenue, with growth from Symbicort, Brilinta and the Onglyza franchise also contributing.
- In the first quarter, revenue in Europe was down 16 percent, chiefly due to the loss of exclusivity for Seroquel IR, launches of Seroquel XR generics in some markets (particularly Germany) and the continuing impact from loss of exclusivity for Atacand and Nexium. With effect from the first

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quarter 2013, the Company has adopted a new revenue reporting framework for Europe. This combines Western Europe with revenue from many markets that were formerly reported in Emerging Rest of World. Eight quarters of revenue history reflecting the new regional boundaries has been provided on the AstraZeneca website, [www.astrazeneca.com/investors](http://www.astrazeneca.com/investors).

- Revenue in Established ROW was down 17 percent in the quarter, chiefly due to the loss of exclusivity for Crestor in Canada and pricing pressures on Crestor in Australia. Sales in Japan were up 5 percent, on good growth for Nexium, Crestor and Symbicort.
- Revenue in Emerging Markets (excluding those now reported in Europe) was up 9 percent in the quarter, largely the result of a 21 percent increase in China. Growth drivers included Crestor, Seloken, Nexium and Iressa.

Condensed Consolidated Statement of Comprehensive Income

	2013	Restated 2012
	\$m	\$m
For the quarter ended 31 March		
Revenue	6,385	7,349
Cost of sales	(1,266)	(1,375)
Gross profit	5,119	5,974
Distribution costs	(77)	(76)
Research and development expense	(1,259)	(1,530)
Selling, general and administrative costs	(2,518)	(2,461)
Other operating income and expense	132	253
Operating profit	1,397	2,160
Finance income	22	7
Finance expense	(115)	(132)
Profit before tax	1,304	2,035
Taxation	(292)	(408)
Profit for the period	1,012	1,627
Other comprehensive income		
Items that will not be reclassified to profit or loss:		
Actuarial (loss)/gain for the period	(60)	92
Tax on items that will not be reclassified to profit or loss	14	(54)
Total items that will not be reclassified to profit or loss	(46)	38
Items that may be reclassified subsequently to profit or loss:		
Foreign exchange arising on consolidation	(319)	121
Foreign exchange differences on borrowings designated in net investment hedges	64	(50)
Fair value movements on derivatives designated in net investment hedges	58	-
Net available for sale gains taken to equity	51	18
Tax on items that may be reclassified subsequently to profit or loss	8	5
Total items that may be reclassified subsequently to profit or loss	(138)	94

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Other comprehensive income for the period, net of tax	(184)	132
Total comprehensive income for the period	828	1,759
Profit attributable to:		
Owners of the parent	1,011	1,625
Non-controlling interests	1	2
	1,012	1,627
Total comprehensive income attributable to:		
Owners of the parent	845	1,767
Non-controlling interests	(17)	(8)
	828	1,759
Basic earnings per \$0.25 Ordinary Share	\$0.81	\$1.27
Diluted earnings per \$0.25 Ordinary Share	\$0.81	\$1.27
Weighted average number of Ordinary Shares in issue (millions)	1,248	1,281
Diluted weighted average number of Ordinary Shares in issue (millions)	1,250	1,285

Condensed Consolidated Statement of Financial Position

	At 31	Restated	Restated
	Mar	At 31	At 31
	2013	Dec	Mar
	\$m	2012	2012
		\$m	\$m
<b>ASSETS</b>			
Non-current assets			
Property, plant and equipment	5,882	6,089	6,335
Goodwill	9,881	9,898	9,871
Intangible assets	16,051	16,448	11,027
Derivative financial instruments	416	389	326
Other investments	212	199	204
Other receivables	325	352	-
Deferred tax assets	1,218	1,111	1,440
	33,985	34,486	29,203
Current assets			
Inventories	2,039	2,061	2,040
Trade and other receivables	7,520	7,629	8,511
Other investments	795	823	3,637
Derivative financial instruments	-	31	31
Income tax receivable	756	803	1,009
Cash and cash equivalents	7,234	7,701	6,332
	18,344	19,048	21,560

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Total assets	52,329	53,534	50,763
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Interest-bearing loans and borrowings	(889)	(901)	(2,006)
Trade and other payables	(9,465)	(9,221)	(8,945)
Derivative financial instruments	(5)	(3)	-
Provisions	(685)	(916)	(1,683)
Income tax payable	(2,818)	(2,862)	(3,166)
	(13,862)	(13,903)	(15,800)
<b>Non-current liabilities</b>			
Interest-bearing loans and borrowings	(9,320)	(9,409)	(7,377)
Deferred tax liabilities	(2,657)	(2,576)	(2,671)
Retirement benefit obligations	(2,287)	(2,271)	(2,197)
Provisions	(822)	(428)	(496)
Other payables	(893)	(1,001)	(507)
	(15,979)	(15,685)	(13,248)
Total liabilities	(29,841)	(29,588)	(29,048)
Net assets	22,488	23,946	21,715
<b>EQUITY</b>			
<b>Capital and reserves attributable to equity holders of the Company</b>			
Share capital	313	312	318
Share premium account	3,645	3,504	3,220
Other reserves	1,966	1,960	1,952
Retained earnings	16,368	17,955	16,020
	22,292	23,731	21,510
Non-controlling interests	196	215	205
Total equity	22,488	23,946	21,715

Condensed Consolidated Statement of Cash Flows

	2013	Restated 2012
	\$m	\$m
For the quarter ended 31 March		
Cash flows from operating activities		
Profit before tax	1,304	2,035
Finance income and expense	93	125
Depreciation, amortisation and impairment	651	499
Decrease in working capital and short-term provisions	290	364
Non-cash and other movements	387	(484)
Cash generated from operations	2,725	2,539
Interest paid	(218)	(248)
Tax paid	(309)	(751)
Net cash inflow from operating activities	2,198	1,540
Cash flows from investing activities		



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Movement in short-term investments and fixed deposits	22	651
Purchase of property, plant and equipment	(114)	(122)
Disposal of property, plant and equipment	9	125
Purchase of intangible assets	(300)	(80)
Purchase of non-current asset investments	(4)	(2)
Interest received	26	41
Payments made by subsidiaries to non-controlling interests	(3)	(20)
Net cash (outflow)/inflow from investing activities	(364)	593
Net cash inflow before financing activities	1,834	2,133
Cash flows from financing activities		
Proceeds from issue of share capital	142	143
Repurchase of shares for cancellation	-	(1,055)
Dividends paid	(2,296)	(2,505)
Hedge contracts relating to dividend payments	(72)	13
Repayment of obligations under finance leases	(6)	-
Movement in short-term borrowings	-	(34)
Net cash outflow from financing activities	(2,232)	(3,438)
Net decrease in cash and cash equivalents in the period	(398)	(1,305)
Cash and cash equivalents at the beginning of the period	7,596	7,434
Exchange rate effects	(52)	14
Cash and cash equivalents at the end of the period	7,146	6,143
Cash and cash equivalents consists of:		
Cash and cash equivalents	7,234	6,332
Overdrafts	(88)	(189)
	7,146	6,143

Condensed Consolidated Statement of Changes in Equity

	Share capital	Share premium account	Other reserves*	Retained earnings	Total	Non-controlling interests	Total 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	-	-	-	1,625	1,625	2	1,627
Other comprehensive income	-	-	-	142	142	(10)	132
Transfer to other reserves	-	-	(5)	5	-	-	-
Transactions with owners:							
Dividends	-	-	-	(2,495)	(2,495)	-	(2,495)
Issue of Ordinary Shares	1	142	-	-	143	-	143

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Repurchase of Ordinary Shares	(6)	-	6	(1,055)	(1,055)	-	(1,055)
Share-based payments	-	-	-	(90)	(90)	-	(90)
Transfer from non-controlling interests to payables	-	-	-	-	-	(2)	(2)
Dividend paid to non-controlling interests	-	-	-	-	-	(11)	(11)
Net movement	(5)	142	1	(1,868)	(1,730)	(21)	(1,751)
At 31 Mar 2012	318	3,220	1,952	16,020	21,510	205	21,715

	Share capital \$m	Share premium account \$m	Other reserves* \$m	Retained earnings \$m	Total \$m	Non-controlling interests \$m	Total equity \$m
At 1 Jan 2013 (Restated)	312	3,504	1,960	17,955	23,731	215	23,946
Profit for the period	-	-	-	1,011	1,011	1	1,012
Other comprehensive income	-	-	-	(166)	(166)	(18)	(184)
Transfer to other reserves	-	-	6	(6)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(2,371)	(2,371)	-	(2,371)
Issue of Ordinary Shares	1	141	-	-	142	-	142
Share-based payments	-	-	-	(55)	(55)	-	(55)
Transfer from non-controlling interests to payables	-	-	-	-	-	1	1
Dividend paid to non-controlling interests	-	-	-	-	-	(3)	(3)
Net movement	1	141	6	(1,587)	(1,439)	(19)	(1,458)
At 31 Mar 2013	313	3,645	1,966	16,368	22,292	196	22,488

\* Other reserves includes the capital redemption reserve and the merger reserve.

Notes to the Interim Financial Statements

1 BASIS OF PREPARATION AND ACCOUNTING POLICIES

These unaudited condensed consolidated interim financial statements ("interim financial statements") for the quarter ended 31 March 2013 have been prepared in accordance with IAS 34 Interim Financial Reporting as adopted by the European Union and as issued by the International Accounting Standards Board. These interim financial statements have been prepared using the same accounting policies and methods of computation as followed in the most recent annual financial statements. Details of the accounting policies applied are those set out in AstraZeneca PLC's Annual Report and Form 20-F Information 2012.

With effect from 1 January 2013, the Group adopted the amendments to IAS 19 Employee Benefits, which were endorsed by the European Union in June 2012. The revised standard requires a presentational change to the income statement, with net interest expense on the net pension deficit being reported within 'finance expense' (previously expected return on pension assets was reported in 'finance income'). Results for the prior period have been restated accordingly. The amendments also result in a change to the methodology used in calculating the expected return on pension assets, now reported in finance expense. As a result, prior period finance expense has been restated to reflect an \$18 million increase. The Group's net assets have reduced by \$6 million on adoption of the amendments, as previously unrecognised past service costs 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.

The information contained in Note 4 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 March 2013, the Group has \$9.3 billion in financial resources (cash balances of \$7.2 billion and undrawn committed bank facilities of \$3.0 billion which are available until April 2017, with only \$0.9 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.

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 interim financial statements have been prepared on a going concern basis.

The comparative figures for the financial year ended 31 December 2012 are not the Company's statutory accounts for that financial year. Those accounts have been reported on by the Group's auditors and will be delivered to the registrar of companies. The report of the auditors was (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 RESTRUCTURING COSTS

Profit before tax for the quarter ended 31 March 2013 is stated after charging restructuring costs of \$543 million (\$702million for the first quarter 2012). These have been charged to profit as follows:

	1st Quarter 2013 \$m	1st Quarter 2012 \$m
Cost of sales	12	55
Research and development expense	291	445
Selling, general and administrative costs	240	202
Total	543	702

## 3 NET DEBT

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

	At 1 Jan 2013 \$m		Cash Flow \$m	Non-cash Mvmts \$m	Exchange Mvmts \$m	At 31 Mar 2013 \$m
Loans due after one year	(9,347)	-	-	31	64	(9,252)
Finance leases due after one year	(62)	-	-	(7)	1	(68)
Total long term debt	(9,409)	-	-	24	65	(9,320)
Current instalments of loans	-	-	-	-	-	-
Current instalments of finance leases	(22)	6	-	(10)	-	(26)
Total current debt	(22)	6	-	(10)	-	(26)
Other investments - current	823	(22)	-	42	(48)	795
Net derivative financial instruments	417	72	-	(78)	-	411
Cash and cash equivalents	7,701	(414)	-	-	(53)	7,234
Overdrafts	(105)	16	-	-	1	(88)
Short-term borrowings	(774)	-	-	-	(1)	(775)
	8,062	(348)	-	(36)	(101)	7,577
Net debt	(1,369)	(342)	-	(22)	(36)	(1,769)

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

#### 4 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 (the "2012 Disclosures"). Unless noted otherwise below or in the 2012 Disclosures, no provisions have been established in respect of the claims discussed below.

As discussed in the 2012 Disclosures, 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 2012 Disclosures and herein.

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

Matters disclosed in respect of the first quarter of 2013 and April 2013

##### Patent litigation

Atacand (candesartan cilexetil)

Patent proceedings in the US

In March 2013, AstraZeneca received a Paragraph IV Notice Letter (Notice) from Sandoz Inc. related to Atacand. AstraZeneca is considering the Notice.

Crestor (rosuvastatin calcium)

Patent proceedings in the US

As previously disclosed, in January 2013, defendants Aurobindo Pharma Limited, Teva Pharmaceuticals USA, Inc., Mylan Pharmaceuticals Inc., Sun Pharmaceutical Industries, LTD., and, separately, Apotex Corp., filed petitions for rehearing and rehearing en banc of aspects of the US Court of Appeals for the Federal Circuit's December 2012 decision in favour of AstraZeneca. In February and March 2013, the Court of Appeals denied the petitions. In April 2013, AstraZeneca and Apotex, Inc (the Canadian affiliate of Apotex Corp.) jointly requested the US District Court in Florida to enter a stipulated order dismissing the claims and counterclaims in the case against Apotex, Inc.

As previously disclosed, a December 2012 trial took place in the US District Court for the District of Delaware in which AstraZeneca contended that a §505(b)(2) New Drug Application for rosuvastatin zinc tablets infringes the substance patent for Crestor tablets. On 25 March 2013, the parties entered into a settlement agreement resolving the litigation, and the case has been dismissed by consent judgment. Under the agreement, Watson Laboratories, Inc. and Actavis, Inc (together, Watson), and EGIS Pharmaceuticals concede that the Crestor substance patent is valid, enforceable and would be infringed by Watson's rosuvastatin zinc product and its rosuvastatin calcium product. The settlement agreement permits Watson to begin selling its generic version of Crestor and its rosuvastatin zinc product

beginning 2 May 2016, at a fee to AstraZeneca of 39% of net sales of Watson's products until the end of paediatric exclusivity on 8 July 2016. The entry date could be earlier and the fees eliminated in certain circumstances.

Patent proceedings outside the US

As previously disclosed, in Australia in 2011 AstraZeneca instituted proceedings against Apotex Pty Ltd asserting infringement of various formulation and method patents for Crestor. In January 2012, AstraZeneca instituted similar proceedings against Watson Pharma Pty Ltd. and Actavis Australia Pty Ltd. On 5 March 2013, the Federal Court of Australia held all three patents at issue invalid. AstraZeneca has appealed the decision.

Losec/Prilosec (omeprazole)

Patent proceedings outside the US

As previously reported, in May 2012, in Canada, the Federal Court found AstraZeneca liable to Apotex Inc. for section 8 damages arising from notice of compliance proceedings that had been finally dismissed in December 2003. In March 2013, AstraZeneca's appeal was dismissed.

Nexium (esomeprazole magnesium)

Patent proceedings in the US

In February 2013, AstraZeneca received a Paragraph IV notice letter from Watson Laboratories, Inc. (Watson), and in March 2013, AstraZeneca commenced a patent infringement action against Watson in the US District Court for the District of New Jersey regarding Watson's generic ANDA product.

Patent proceedings outside the US

In Canada, in March 2013, the Federal Court prohibited Ranbaxy Pharmaceuticals Canada Inc. from receiving a marketing authorisation for its esomeprazole magnesium product until June 2015.

As previously disclosed, in Australia in 2011, Ranbaxy Laboratories Ltd and Ranbaxy Australia Pty Ltd (together, Ranbaxy) filed an application for the 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). A trial was held during February and March 2013. AstraZeneca expects that a decision could be delivered on or before 1 May 2013.

Pulmicort Respules (budesonide inhalation suspension)

Patent proceedings in the US

On 1 April 2013, the US District Court for the District of New Jersey ruled that AstraZeneca's US Patent No. 6,598,603 is invalid and that the generic defendants involved in the litigation do not infringe a second patent, US Patent No. 7,524,834. AstraZeneca intends to appeal. On 2 April 2013, the Court granted AstraZeneca's motion and enjoined the generic defendants from entering the market until 12 April 2013 to allow AstraZeneca the opportunity to seek an injunction pending appeal in the Court of Appeals. AstraZeneca has filed a notice of appeal and a motion seeking an injunction pending appeal. On 10 April 2013, the Court of Appeals extended the injunction period until its ruling on AstraZeneca's motion.

Seroquel IR (quetiapine fumarate) and Seroquel XR (quetiapine fumarate)

Patent proceedings in the US

In February 2013, the US Court of Appeals for the Federal Circuit affirmed the March 2012 decision of the US District Court for the District of New Jersey that the Seroquel XR formulation patent is valid and infringed.

In February 2013, AstraZeneca settled its patent infringement action against Torrent Pharmaceuticals Limited and Torrent Pharma Inc. by granting a licence to the Seroquel XR product patent, effective 1 November 2016, or earlier, in certain circumstances.

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In April 2013, AstraZeneca settled its patent infringement action against Lupin Ltd. by granting a licence to the Seroquel XR product patent, effective 1 November 2016, or earlier, in certain circumstances.

### Patent proceedings outside the US

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 for its generic quetiapine fumarate product relating to Seroquel XR. Also in March 2013, AstraZeneca discontinued its application to prohibit the Canadian Minister of Health from issuing a Notice of Compliance to Sandoz Canada Inc. (Sandoz) for its generic quetiapine fumarate product relating to Seroquel XR. AstraZeneca previously filed a patent infringement action against Sandoz related to Seroquel XR.

Generic versions of Seroquel XR have been launched in Austria, Denmark, Germany, Italy, Portugal, UK, Romania and elsewhere. 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.

### US regulatory proceedings

As previously disclosed, the US District Court for the District of Columbia denied AstraZeneca's and granted the FDA's cross motions for summary judgment on the issue of exclusivity for Seroquel IR. On 21 March 2013, the US Court of Appeals for the District of Columbia Circuit heard oral argument on AstraZeneca's appeal of the District Court's ruling.

### Product liability litigation

#### Iressa (gefitinib)

Between 2004 and 2008, seven claims were filed against AstraZeneca in Japan in the Osaka and Tokyo District Courts alleging that Iressa caused a fatal incidence of interstitial lung disease in Japanese patients. As previously reported, in November 2011 and in May 2012, the Tokyo and Osaka High Courts reversed the District Courts' decisions and ruled that neither AstraZeneca, nor the Japanese Ministry of Health, Labour and Welfare (MHLW), had any liability for any of the claims. The plaintiffs appealed both decisions to the Japanese Supreme Court. On 12 April 2013, the Supreme Court issued decisions to reject appeals against AstraZeneca in all respects. Appeals against MHLW were also rejected by the Supreme Court.

#### Seroquel IR (quetiapine fumarate)

As previously disclosed, a putative class action was initiated in Ontario, Canada alleging that AstraZeneca failed to provide adequate warnings in connection with an alleged association between Seroquel IR and certain medical conditions. In February 2013, the Ontario Divisional Court dismissed the plaintiffs' appeal of a lower court decision denying class certification. In March 2013, the plaintiffs served notice of their motion to seek leave to appeal to the Court of Appeal for Ontario.

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 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. Legal proceedings were brought in the UK against two of the insurers in respect of policies with aggregate coverage limits of \$200 million; 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 intends to appeal the decision. AstraZeneca had not recognised an insurance receivable prior to this ruling.

### Commercial litigation

#### Nexium (esomeprazole magnesium)

As previously disclosed, AstraZeneca is a defendant in a class action lawsuit in the Massachusetts State Court based on allegations that AstraZeneca's promotion and advertising of Nexium to physicians, consumers and third party payers was unfair, unlawful and deceptive. In February 2013, the Massachusetts State Court granted the plaintiffs' unopposed motion for preliminary approval of the class settlement agreement. The final approval hearing is scheduled for 31 July 2013.

#### Toprol-XL (metoprolol succinate)

As previously disclosed, AstraZeneca was defending anti-trust claims in the US regarding the listing and enforcement of patents protecting Toprol-XL. In March 2013, the US District Court for the District of Delaware entered an Order and Final Judgment approving AstraZeneca's settlement agreement with the end-payers, for which a provision had been taken in 2012. There are no further pending claims.

#### Medco qui tam litigation (Schumann)

As previously disclosed, AstraZeneca had been named as a defendant in a lawsuit filed in Federal Court in Philadelphia under the qui tam (whistleblower) provisions of the federal and certain state False Claims Acts alleging overpayments by federal and state governments resulting from alleged false pricing information reported to the government and improper payments intended to influence the formulary status of Prilosec and Nexium to Medco and its customers. The action was initially filed in September 2003 but remained under seal until July 2009, at which time AstraZeneca was served with a copy of the amended complaint following the US government's decision not to intervene in the case. On 25 January 2013, the Court granted AstraZeneca's motion and dismissed the case with prejudice. In February 2013, the plaintiff filed a notice of appeal to the US Court of Appeals for the Third Circuit in regard to the lower court's decision to dismiss AstraZeneca from the litigation with prejudice.

#### Drug importation and anti-trust litigation

As previously disclosed, in August 2004, Californian retail pharmacy plaintiffs filed an action in the Superior Court of California alleging a conspiracy by AstraZeneca and other pharmaceutical manufacturer defendants to set the price of drugs sold in California at or above the Canadian sales price for those drugs and otherwise restrict the importation of pharmaceuticals into the US. In April 2013, following the denial by the California Supreme Court to hear an appeal of the lower courts' decisions in AstraZeneca's favour the plaintiffs filed a writ of certiorari to the US Supreme Court seeking an appeal.

#### Government Investigations

##### Department of Justice/Attorney General of Texas investigation - Nexium (esomeprazole magnesium)

As previously disclosed, AstraZeneca received a subpoena from the Department of Justice and a Civil Investigative Demand issued by the Attorney General of Texas in connection with an investigation of the possible submission of false or otherwise improper pricing information for certain formulations of Nexium to the Centers for Medicare and Medicaid Services. In March 2013, the federal case was dismissed with prejudice as to the relator, with the consent of the government, and without prejudice to the US government. In addition, the state case has been dismissed with prejudice as to the relator and without prejudice to the State of Texas.

##### Good Manufacturing Practices Subpoena

On 28 March 2013, AstraZeneca received a subpoena duces tecum from the US Attorney's Office in Boston, Massachusetts seeking documents and records related to manufacturing, quality or good manufacturing practices at its Macclesfield facility in the UK. AstraZeneca is coordinating its response to the subpoena and intends to cooperate with the inquiry.



## 5 FIRST QUARTER PRODUCT REVENUE ANALYSIS

	World		US		Europe		Established ROW		Emerging Markets	
	Q1	CER	Q1	CER	Q1	CER	Q1	CER	Q1	CER
	2013 \$m	%	2013 \$m	%	2013 \$m	%	2013 \$m	%	2013 \$m	%
Cardiovascular:										
Crestor	1,323	(11)	652	(4)	316	(2)	199	(41)	156	16
Atacand	168	(47)	27	(33)	61	(66)	23	(41)	57	(2)
Seloken/Toprol-XL	224	-	56	(23)	32	(6)	6	(25)	130	20
Onglyza	90	27	64	19	13	18	5	150	8	100
Plendil	66	(11)	-	(100)	5	(29)	2	(33)	59	(6)
Tenormin	46	(14)	2	(33)	13	-	19	(16)	12	(20)
Brilinta/Brilique	51	n/m	15	n/m	30	n/m	2	n/m	4	n/m
Byetta	42	n/m	42	n/m	-	-	-	-	-	-
Bydureon	27	n/m	27	n/m	-	-	-	-	-	-
Forxiga	1	n/m	-	-	1	n/m	-	-	-	-
Others	82	(4)	11	n/m	42	(5)	5	(38)	24	(23)
Total Cardiovascular	2,120	(8)	896	5	513	(17)	261	(38)	450	8
Gastrointestinal:										
Nexium	940	(1)	523	(2)	93	(29)	130	12	194	17
Losec/Prilosec	125	(23)	7	(13)	34	(23)	41	(36)	43	(4)
Others	53	4	41	8	11	(8)	1	-	-	-
Total Gastrointestinal	1,118	(4)	571	(2)	138	(26)	172	(6)	237	13
Respiratory:										
Symbicort	826	14	287	32	384	4	83	21	72	9
Pulmicort	233	3	62	11	53	(5)	26	-	92	5
Others	81	(11)	14	(26)	31	(9)	6	(14)	30	(3)
Total Respiratory	1,140	10	363	24	468	2	115	13	194	5
Oncology:										
Zoladex	240	(8)	6	-	66	(8)	90	(6)	78	(11)
Iressa	168	20	-	-	45	15	47	15	76	28
Faslodex	157	5	73	1	54	(2)	14	60	16	6
Arimidex	92	(33)	3	(57)	25	(40)	39	(35)	25	(7)
Casodex	92	(13)	-	-	14	(18)	55	(15)	23	(4)
Others	34	33	7	17	6	50	14	23	7	75
Total Oncology	783	(5)	89	(2)	210	(8)	259	(8)	225	3
Neuroscience:										
Seroquel XR	322	(16)	170	(15)	101	(28)	23	-	28	26
Seroquel IR	127	(82)	7	(99)	29	(75)	41	(18)	50	24
Local Anaesthetics	125	(5)	-	-	53	(10)	43	(2)	29	4
Vimovo	20	25	6	(33)	7	75	4	33	3	n/m
Others	113	(9)	8	60	30	(38)	25	(13)	50	16
Total Neuroscience	707	(49)	191	(75)	220	(40)	136	(9)	160	20
Infection & Other:										
Synagis	404	5	313	3	91	11	-	-	-	-
Merrem	68	(31)	(2)	n/m	15	(38)	2	(75)	53	(8)
FluMist	5	150	5	150	-	-	-	-	-	-

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Others	40	150	19	n/m	5	33	5	-	11	140
Total Infection & Other	517	3	335	6	111	1	7	(46)	64	3
Aptium Oncology	-	(100)	-	(100)	-	-	-	-	-	-
Total	6,385	(12)	2,445	(16)	1,660	(16)	950	(17)	1,330	9

Shareholder Information

ANNOUNCEMENTS AND MEETINGS

Annual General Meeting	25 April 2013
Announcement of second quarter and half year 2013 results	1 August 2013
Announcement of third quarter and nine months 2013 results	31 October 2013

DIVIDENDS

Future dividends will normally be paid as follows:

First interim	Announced in July and paid in September
Second interim	Announced in January and paid in March

TRADEMARKS

Trademarks of the AstraZeneca group of companies and of companies other than AstraZeneca appear throughout this document in italics. AstraZeneca, the AstraZeneca logotype and the AstraZeneca symbol are all trademarks of the AstraZeneca group of companies. Trademarks of companies other than AstraZeneca that appear in this document include: Onglyza and Forxiga, trademarks of Bristol-Myers Squibb Company; Byetta, Bydureon and Symlin, trademarks of Amylin Pharmaceuticals, LLC and AstraZeneca Pharmaceuticals LP; and messenger RNA Therapeutics, a trademark of Moderna Therapeutics, Inc.

ADDRESSES FOR CORRESPONDENCE

Registrar and Transfer Office	US Depository	Registered Office	Swedish Central Securities Depository
Equiniti Limited	JP Morgan Chase & Co	2 Kingdom Street	Euroclear Sweden AB
Aspect House	PO Box 64504	London	PO Box 191
Spencer Road	St Paul	W2 6BD	SE-101 23 Stockholm
Lancing	MN 55164-0504	UK	Sweden
West Sussex	US		
BN99 6DA			
UK			
Tel (freephone in UK): 0800 389 1580	Tel (toll free in US): 888 697 8018	Tel: +44 (0)20 7604 8000	Tel: +46 (0)8 402 9000

Tel (outside UK):      Tel (outside US):  
+44 (0)121 415 7033    +1 (651) 453 2128

CONTACT INFORMATION

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Media Enquiries:	Esra Erkal-Paler (London)	+44 20 7604 8030
Vanessa Rhodes (London)	+44 20 7604 8037	
Tony Jewell (Wilmington)	+1 302 885 4594	
Jacob Lund (Södertälje)	+46 8 553 260 20	

Analyst/Investor Enquiries:	James Ward-Lilley (London)	+44 20 7604 8122
Karl Hård (London)	+44 20 7604 8123	
Ed Seage (US)	+1 302 886 4065	
Colleen Proctor (US)	+1 302 886 1842	

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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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 interim financial statements contain 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 interim financial statements 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: 25 April 2013

By: /s/ Adrian Kemp

Name: Adrian Kemp

Title: Company Secretary