

ASTRAZENECA PLC  
Form 6-K  
April 24, 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 April 2014

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

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AstraZeneca PLC  
FIRST QUARTER RESULTS 2014

London, 24 April 2014

Revenue up 3% at constant exchange rates (CER) in first quarter. Consolidation of full diabetes franchise contributed 2 percentage points of revenue growth. All growth platforms growing strongly.

- Brilinta sales \$99 million (+94% CER), diabetes \$347 million (+106% CER), respiratory \$1,271 million (+12% CER), Emerging Markets \$1,421 million (+11% CER) and Japan \$537 million (+13% CER).

Significant progress made towards achieving scientific leadership in core therapeutic areas.

- AZD9291 has been granted Breakthrough Therapy designation by the US FDA for the treatment of patients with metastatic, EGFR T790M mutation-positive, non-small cell lung cancer (NSCLC) whose NSCLC has progressed during treatment with an FDA-approved, EGFR tyrosine kinase inhibitor.

- Olaparib accepted for Priority Review by the US FDA in BRCA-mutated platinum-sensitive relapsed ovarian cancer.

- Phase III investment decisions made for MEDI4736, AZD9291, benralizumab and tralokinumab.

Integration of BMS part of diabetes alliance proceeding as planned. Strong launch of Farxiga in the US and continued success in Germany; Forxiga approved in Japan.

The Company maintains its financial guidance for 2014.

#### Financial Performance Highlights

Revenue for the quarter was \$6,416 million, up 3% at CER.

- The key growth platforms Brilinta, diabetes, respiratory, Emerging Markets and Japan delivered \$3.3 billion (+15% CER) of revenue in the first quarter. Emerging Markets grew by 11% at CER, with revenue in China increasing

- by 22% at CER.

Core EPS was \$1.17 for the quarter, an 11% decline at CER.

- Core EPS declined despite revenue growth, primarily due to investment in the Company's key growth platforms and rapidly progressing pipeline.

Reported EPS was \$0.40 for the quarter, a 40% decline at CER.

- Due to the loss on disposal of Alderley Park and the impact of the acquisition of the global diabetes alliance.

#### Other R&D Highlights

- Olaparib commenced Phase III trial in metastatic BRCAm breast cancer.
- Brodalumab commenced Phase III trial in psoriatic arthritis.
- Selumetinib commenced a registration trial in metastatic uveal melanoma.
- Bydureon Pen and orphan drug Myalept approved by the US FDA.
- Saxagliptin and dapagliflozin combination data submitted for presentation at American Diabetes Association meeting in June.

- Late stage pipeline now has 11 NMEs in Phase III or under regulatory review.

#### Financial Summary

Group	1st Quarter	Actual	CER
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	2014	%	%
	\$m		
Revenue	6,416	-	3
Core*			
Operating Profit	1,952	(16)	(11)
Earnings per Share	\$1.17	(17)	(11)
Reported			
Operating Profit	836	(40)	(31)
Earnings per Share	\$0.40	(51)	(40)

\* 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:

"The first quarter has seen continued momentum across the business and our revenue growth reflects the increasing contribution from the five growth platforms that showed strong performance.

"I am pleased with the significant progress we are making towards achieving scientific leadership in our core therapeutic areas. We have confirmed our decision to advance four programmes to Phase III in oncology and respiratory disease. The Breakthrough Therapy designation for AZD9291 in non-small cell lung cancer and the Priority Review granted for olaparib in ovarian cancer by the FDA act as a reminder of the distinctive science that AstraZeneca can bring to patients.

"We are investing in our rapidly progressing pipeline and the key platforms that are the backbone of our strategy to return to growth. To further concentrate organisational focus, we will continue to redeploy our resources in our core priorities and pursue opportunities that maximise the value of our pipeline and portfolio."

#### Research and Development Update

A comprehensive update of the AstraZeneca R&D pipeline is presented in conjunction with this Q1 2014 results announcement and is available on the Company's website.

The AstraZeneca pipeline continues to grow and now includes 104 projects, of which 90 are in the clinical phase of development. During Q1 2014, across the portfolio, 4 projects were approved and 7 projects have successfully progressed to their next phase (including 1 project entering first human testing).

In conjunction with the Full Year 2013 results, the Company announced that it anticipates 4 to 5 additional new molecular entity (NME) Phase III starts in 2014. The late stage pipeline now includes 11 NMEs in Phase III or under regulatory review. Myalept (metreleptin) gained regulatory approval from the US FDA in the first quarter.

A decision has been taken to initiate the first Phase III study in the Company's broad portfolio of immune-mediated therapies for cancer (IMT-C). The Phase III PACIFIC study will investigate the efficacy of MEDI4736, an anti-PD-L1 monoclonal antibody (MAB), as a sequential therapy following chemoradiation in patients with locally advanced, unresectable NSCLC and is anticipated to randomise the first patient imminently. The Phase III programme follows the evaluation of clinical activity and safety profile in the Company's Phase I programme, which will be presented at the American Society of Clinical Oncology (ASCO) conference in Chicago, 30 May - 3 June 2014.

On 16 April 2014, AZD9291 was granted Breakthrough Therapy designation by the US FDA, for the treatment of patients with metastatic, epidermal growth factor receptor (EGFR) T790M mutation-positive NSCLC, whose NSCLC

has progressed during treatment with an FDA-approved, EGFR tyrosine kinase inhibitor (TKI).

The Breakthrough Therapy designation for AZD9291 was granted by the US FDA on the basis of early clinical data from a Phase I study in patients with advanced/metastatic EGFR mutation-positive NSCLC whose disease had progressed following treatment with an EGFR TKI, including T790M mutation-positive tumours. This data will be presented at the 2014 ASCO annual congress.

In addition to the updates above, other significant pipeline developments since the Full Year 2013 results announcement include:

#### Further Phase III investment decisions

Since the Full Year 2013 results update on 6 February 2014, the Company has taken decisions to progress AZD9291 (NSCLC), benralizumab (COPD) and tralokinumab (severe asthma) into Phase III. The decisions to progress to Phase III were based on Phase I data for AZD9291 and Phase II data sets for benralizumab and tralokinumab, which will be presented at scientific congresses in Q2 2014.

#### Olaparib

The US FDA has granted Priority Review for olaparib, an oral poly ADP-ribose polymerase (PARP) inhibitor that exploits DNA repair pathway deficiencies to preferentially kill cancer cells. Olaparib is being reviewed for the treatment of ovarian cancer patients who have a BRCA mutation (BRCAm) and whose cancer has relapsed following a complete or partial response to platinum-based chemotherapy. Patients with the BRCA mutation are being identified through a companion diagnostic test.

The US FDA grants Priority Review to medicines that, if approved, would deliver significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. The Priority Review status means that the US FDA intends to take action on the olaparib application within six months (compared to ten months under standard review). The Prescription Drug User Fee Act (PDUFA) date for the US FDA is 3 October 2014. The US FDA advisory committee meeting is scheduled for 25 June 2014.

Olaparib has the potential to be the first PARP inhibitor available for patients with BRCAm platinum-sensitive relapsed ovarian cancer.

AstraZeneca has also randomised first patient in the Phase III clinical development programme for olaparib in BRCAm breast cancer. The first of three studies to randomise patients is the OLaparib in ADvanced BRCAm (OLympiAD) study. OLYmpiAD is an open label, randomised, controlled, global and multi-centre Phase III study that will assess the efficacy and safety of single agent olaparib versus standard of care, based on physician's choice, in metastatic breast cancer patients with gBRCAm. A total of 310 patients will be randomised in 2:1 ratio to receive either olaparib (300mg twice daily) or physician's choice of capecitabine, vinorelbine or eribulin - continually to disease progression. The primary endpoint of the study is progression free survival.

AstraZeneca plans to initiate two additional studies in the breast cancer development programme during 2014, in BRCAm neoadjuvant breast cancer and BRCAm adjuvant breast cancer and anticipates first regulatory filing in breast cancer in the US and EU in 2016.

#### Brodalumab

Amgen and AstraZeneca have initiated two Phase III studies of brodalumab in psoriatic arthritis, AMVISION-1 and AMVISION-2, which together will provide detailed information on the impact of brodalumab on clinical signs and symptoms and its ability to prevent joint damage in psoriatic arthritis. Brodalumab is a novel human monoclonal

antibody that binds to and blocks signalling of the interleukin-17 (IL-17) receptor. In addition to psoriatic arthritis (Phase III), brodalumab is currently being investigated for the treatment of moderate-to-severe plaque psoriasis (Phase III) and asthma (Phase II).

In April 2012, Amgen and AstraZeneca formed a collaboration to jointly develop and commercialise five monoclonal antibodies from Amgen's clinical inflammation portfolio.

#### Selumetinib

In Q1 2014, a Phase II study with registrational intent evaluating selumetinib in combination with chemotherapy in patients with metastatic uveal melanoma was initiated. Selumetinib is a MEK inhibitor that has been shown to be clinically active and tolerated in clinical studies evaluating a range of solid tumours as monotherapy and in combination with chemotherapy standards of care. As of April 2014, three Phase III/registrational studies are investigating selumetinib in 2nd line KRAS mutation NSCLC, differentiated thyroid cancer and metastatic uveal melanoma.

AstraZeneca acquired exclusive worldwide rights to selumetinib from Array BioPharma in 2003.

#### Forxiga

On 24 March 2014, AstraZeneca announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) approved Forxiga (dapagliflozin) in 5mg and 10mg tablets, as a once-daily oral treatment for type 2 diabetes. Forxiga 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. The Forxiga application was submitted to the MHLW by Bristol-Myers Squibb K.K.

AstraZeneca and Ono Pharmaceutical entered into an agreement to co-promote Forxiga on 3 December 2013.

In addition, the Company has successfully completed the first combination study of dapagliflozin and saxagliptin, as a dual add on to metformin in patients with HbA1c > 8%, and will present the results as a late breaker at the American Diabetes Association conference to be held in San Francisco, 13-17 June 2014.

#### Bydureon Dual Chamber Pen

On 3 March 2014, AstraZeneca announced that the US FDA has approved the Bydureon Dual Chamber Pen (exenatide extended-release for injectable suspension) 2mg as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes. Bydureon was the first once-weekly medicine for adults with type 2 diabetes.

The Bydureon Dual Chamber Pen is a pre-filled, single-use pen injector, eliminating the need for the patient to transfer the medication between a vial and syringe during the self-injection process. It contains the same formulation and dose as the original Bydureon single-dose tray, providing the same continuous release of exenatide. Launch is planned for the second half of 2014.

#### Myalept

On 25 February 2014, the US FDA approved orphan drug Myalept (metreleptin for injection), which is indicated as an adjunct to diet as replacement therapy for the treatment of complications of leptin deficiency in patients with congenital or acquired generalised lipodystrophy. Myalept, a recombinant analogue of human leptin, is the first and only treatment approved by the US FDA for these patients.

#### Naloxegol

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 peripherally acting mu opioid receptor antagonist class of therapies for the treatment of opioid-induced constipation. Naloxegol will be included as part of the US FDA AADPAC discussion, tentatively scheduled for 11-12 June 2014. The PDUFA date for naloxegol is 16 September 2014.

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

American Thoracic Society (ATS) meeting, 16 - 21 May 2014

On 21 March 2014, ATS posted accepted abstracts, including Phase IIb abstracts evaluating safety and efficacy results for benralizumab, an anti-IL-5R MAb, and tralokinumab, an anti-IL-13 MAb, suggesting that these agents may provide useful therapeutic options for patients with severe, uncontrolled asthma. Benralizumab data will be confirmed in an ongoing Phase III programme currently underway and tralokinumab is anticipated to move into Phase III development in 2014. Phase IIa data for benralizumab in COPD will also be presented at ATS, and benralizumab is expected to move into Phase III development for COPD in 2014.

AstraZeneca will host a briefing for analysts and investors during the ATS conference, to be held in San Diego on 20 May 2014.

American Society of Clinical Oncology (ASCO) meeting, 30 May - 3 June 2014

On 21 April 2014, ASCO announced acceptance of numerous scientific abstracts for compounds across AstraZeneca's oncology pipeline, including the monotherapy studies for MEDI4736 and AZD9291.

AstraZeneca will host a briefing for analysts and investors during the ASCO conference, to be held in Chicago on 2 June 2014.

Business Development and Corporate Transactions

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Delisting of AstraZeneca Pharma India Limited

On 1 March 2014, AstraZeneca proposed to make a voluntary delisting offer to the public shareholders of AstraZeneca Pharma India Limited in accordance with the Securities and Exchange Board of India (Delisting of Equity Shares) Regulations 2009, as amended, with a view to delist its equity shares from BSE Limited, National Stock Exchange of India Limited and Bangalore Stock Exchange Limited, being the stock exchanges on which the equity shares of AstraZeneca Pharma India Limited are currently listed. AstraZeneca holds 75.00% of the total paid-up share capital of AstraZeneca Pharma India Limited.

University of Cambridge collaboration

On 12 March 2014, MedImmune announced a three-year oncology research collaboration with the University of Cambridge. This partnership aims to advance cancer research by using imaging technologies to measure key biologic changes within growing tumours.

MD Anderson collaboration

On 13 March 2014, MedImmune announced a three-year translational and clinical research collaboration with The University of Texas MD Anderson Cancer Center to study therapies that unleash patients' immune systems to attack

their cancers through MD Anderson's Moon Shots Program. MD Anderson's Moon Shots Program is an ambitious effort to dramatically reduce cancer deaths by targeting eight cancers with the support of several new research platforms that provide infrastructure, expertise and technology.

#### Acquisition of AstraZeneca K.K. (Japan) minority

On 26 March 2014, the Company announced the completion of the purchase of Sumitomo Chemical's remaining shares in AstraZeneca K.K., a shareholding that related to a historic relationship between Sumitomo and ICI in Japan.

The purchase was valued at \$102 million and gives AstraZeneca ownership of the entire shareholding of AstraZeneca K.K.

#### AstraZeneca and Medical Research Council (MRC) strategic collaboration

On 31 March 2014, AstraZeneca and MRC announced a groundbreaking collaboration aimed at better understanding the mechanisms of human disease. The collaboration will see the creation of a joint research facility at AstraZeneca's new R&D centre in Cambridge in the UK. The AstraZeneca MRC UK Centre for Lead Discovery will sit within the new AstraZeneca site at the Cambridge Biomedical Campus, due to be completed in 2016. It will see world class MRC-supported researchers working side by side with scientists in AstraZeneca's high throughput screening group, identifying new methods to better understand a range of diseases and potential treatment options.

#### 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:

- amortisation and impairment of intangibles, including impairment reversals but excluding any charges relating to IT assets
- charges and provisions related to our global restructuring programmes (this will include such charges that relate to the impact of our global restructuring programmes on our capitalised IT assets)
- other specified items, principally comprising legal settlements and acquisition-related costs, which include fair value adjustments and the imputed finance charge relating to contingent consideration

More detail on the nature of these measures is given on page 76 of our Annual Report and Form 20-F Information 2013.

#### First Quarter

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

Reported	Restructuring	Intangible	Acquisition	Other	Core	Core	Actual	CER
2014	2014	Amortisation	of BMS	2014	2014	2013	%	%
		&	share of					
		Impairments	diabetes					

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alliance  
(See note  
4)

Revenue	6,416	-	-	-	-	6,416	6,385	-	3
Cost of Sales	(1,453)	11	125	124	-	(1,193)	(1,136)		
Gross Profit	4,963	11	125	124	-	5,223	5,249	-	2
% sales	77.3%					81.4%	82.2%	-0.8	-0.7
Distribution	(72)	-	-	-	-	(72)	(77)	(6)	(4)
% sales	1.1%					1.1%	1.2%	+0.1	+0.1
R&D	(1,200)	85	17	-	-	(1,098)	(963)	14	13
% sales	18.7%					17.1%	15.1%	-2.0	-1.5
SG&A	(2,726)	91	197	74	47	(2,317)	(2,055)	13	14
% sales	42.5%					36.1%	32.2%	-3.9	-3.6
Other (Expense)/Income	(129)	292	53	-	-	216	170	27	29
% sales	2.0%					3.3%	2.7%	+0.6	+0.7
Operating Profit	836	479	392*	198	47	1,952	2,324	(16)	(11)
% sales	13.0%					30.4%	36.4%	-6.0	-5.0
Net Finance Expense	(198)	-	-	63**	9**	(126)	(93)		
Profit before Tax	638	479	392	261	56	1,826	2,231	(18)	(13)
Taxation	(132)	(99)	(61)*	(51)	(10)	(353)	(476)		
Profit after Tax	506	380	331	210	46	1,473	1,755	(16)	(11)
Non-controlling Interests	(2)	-	-	-	-	(2)	(1)		
Net Profit	504	380	331	210	46	1,471	1,754	(16)	(11)
Weighted Avg. Shares	1,260	1,260	1,260	1,260	1,260	1,260	1,248		
Earnings per Share	0.40	0.30	0.26	0.17	0.04	1.17	1.41	(17)	(11)

\* Intangible Amortisation & Impairments includes Merck related amortisation, of which \$97 million carries no tax adjustment.

\*\* Contains certain items that carry no tax adjustment.

Revenue in the first quarter was up 3 percent at CER and was broadly flat 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. Major patent expiries have now largely annualised but the impact from losses of exclusivity amounted to nearly \$150 million in the quarter, with the authorised generic for Toprol-XL in the US and Crestor in Australia among the major drivers.

US revenues were up 3 percent. Crestor grew by 8 percent in the quarter, driven by prior year rebate adjustments. Diabetes revenues were boosted by the consolidation of the full franchise as well as progress in Bydureon's market share. The launch of Farxiga is proceeding strongly and the share penetration is the best of all oral anti-diabetic launches since the launch of sitagliptin.

Revenue in the Rest of World (ROW) was up 3 percent. Revenue in Europe was down 4 percent, chiefly on the continuing impact of loss of exclusivity for Seroquel IR, Atacand and Nexium and erosion to Seroquel XR from adverse patent rulings in some markets coupled with "at risk" launches for generics. Revenue in Established ROW was up 2 percent, with the generic competition for Crestor in Australia more than offset by a 13 percent revenue increase in Japan. Revenue in Emerging Markets was up 11 percent, with a 22 percent increase in China being the major driver.

Core gross profit in the first quarter increased by 2 percent, slightly less than the increase in revenue. Core gross margin was 81.4 percent, down 0.7 percentage points, as an unfavourable mix effect and the impact of including the



costs associated with diabetes brands previously accounted for as alliance revenue more than offset the benefit of a lower Crestor royalty.

Core R&D expense was up 13 percent in the first quarter. Our pipeline is growing strongly in quantity and quality, and projects are progressing rapidly, resulting in the need to invest to sustain our portfolio.

Expenditures in Core SG&A were up 14 percent. This increase was driven by the inclusion of 100 percent of the costs associated with the diabetes portfolio, the launch of Farxiga in the US and continued investment in Emerging Markets, particularly China. 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.

The growth in Core R&D and Core SG&A also reflects a low 2013 base. Core SG&A in the first quarter of 2013 decreased by 2 percent in comparison with the prior year and Core R&D was down 7 percent in the first quarter of 2013 compared with the same period in 2012.

Core other income of \$216 million was up 29 percent. This quarter included a one-off milestone receipt, which accounted for about 70 percent of the growth.

Core operating profit was down 11 percent to \$1,952 million. Core operating margin was down 5.0 percentage points to 30.4 percent of revenue, as a result of the increased investment in R&D and the growth platforms.

Core earnings per share were down 11 percent to \$1.17, in line with the decline in Core operating profit, as the impact of a higher number of shares outstanding and higher net finance expense were broadly offset by the lower tax rate compared to the first quarter last year.

Reported operating profit was down 31 percent to \$836 million. Reported EPS was down 40 percent to \$0.40. Reported operating profit in the quarter was reduced by the loss on disposal of the previously disclosed sale of the Company's R&D site at Alderley Park and the impact of the acquisition of BMS's share of the global diabetes alliance.

#### Finance Income and Expense

Core net finance expense was \$126 million for the first quarter, versus \$93 million in the same period of 2013. The increase is principally due to exchange movements and the effect of discounting a long-term liability. Since this liability does not relate to a business combination, under our definition for Core financial measures the charge is not excluded from the Core result. In the first quarter of 2014, Reported net finance expense includes a charge of \$72 million relating to the discount unwind on contingent consideration creditors recognised on business combinations, principally relating to the acquisition of BMS's share of the global diabetes alliance.

#### Taxation

The Reported tax rate for the first quarter was 20.7 percent compared with 22.4 percent for the same period last year.

#### Cash Flow

Cash generated from operating activities was \$1,187 million in the three months to 31 March 2014. Net cash outflows from investing activities were \$3,777 million in the first quarter of 2014, compared with \$364 million in the prior year. Cash outflows as a result of the acquisition of BMS's share of the global diabetes alliance, in the first quarter of 2014, was the principal reason for the increase.

Net cash distributions to shareholders were \$2,228 million, through dividends of \$2,425 million partially offset by proceeds from the issue of shares of \$197 million.

## Debt and Capital Structure

At 31 March 2014, outstanding gross debt (interest-bearing loans and borrowings) was \$10,340 million (31 December 2013: \$10,376 million). Of the gross debt outstanding at 31 March 2014, \$2,787 million is due within one year (31 December 2013: \$1,788 million).

The Company's net debt position at 31 March 2014 was \$4,833 million.

## Shares in Issue

In the quarter, 4.1 million shares were issued in respect of share option exercises for a consideration of \$197 million.

The total number of shares in issue at 31 March 2014 was 1,261 million.

## Future Prospects

The Company maintains its guidance for 2014:

- 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.

This guidance is predicated on the launch of generic Nexium in the US at the end of May 2014.

## 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 areas is shown in Note 7.

	First Quarter		
	2014	2013	CER
	\$m	\$m	%
Cardiovascular and Metabolic disease			
Crestor	1,332	1,323	2
Seloken/Toprol-XL	193	224	(11)
Onglyza	162	90	81
Atacand	122	168	(25)
Brilinta/Brilique	99	51	94
Byetta	78	42	86
Bydureon	80	27	196
Oncology			
Zoladex	221	240	(3)
Iressa	169	168	5
Faslodex	172	157	11
Arimidex	78	92	(11)
Casodex	83	92	(2)

Respiratory, Inflammation and  
Autoimmunity

Symbicort	928	826	13
Pulmicort	263	233	13

Infection, Neuroscience and  
Gastrointestinal

Nexium	930	940	2
Synagis	328	404	(19)
Seroquel XR	292	322	(9)
Seroquel IR	66	127	(46)
Losec/Prilosec	110	125	(10)

## Cardiovascular and Metabolic disease

- In the US, Crestor sales in the first quarter were \$705 million, up 8 percent. Total prescriptions for statin products in the US decreased by 1 percent in the first quarter. Crestor total prescriptions were down 6 percent. Favourable net price realisation in the first quarter was driven by prior year rebate adjustments.
- Crestor sales in the Rest of World were down 4 percent to \$627 million, reflecting the impact of generic competition in Australia. In addition to the decline in Australia, Canada also contributed to the 10 percent decline in Established Rest of World. Sales in Japan increased by 15 percent in the quarter and sales in Emerging Markets were up 13 percent, with China growing by 90 percent.
- US sales of the Toprol-XL product range, which includes sales of the authorised generic, were down 57 percent to \$24 million, largely the result of market share loss following additional generic entrants. Seloken sales in other markets were up 5 percent to \$169 million.
- Onglyza revenue was up 81 percent in the first quarter to \$162 million, of which \$106 million was in the US and \$56 million in other markets. AstraZeneca completed the acquisition of BMS's share of the global diabetes alliance on 1 February 2014 and began reflecting 100 percent ownership at that point. Total prescriptions for the Onglyza franchise in the US were down 3 percent compared with the first quarter last year; share of total prescriptions was 15.8 percent in March 2014, down 0.5 percentage points since December 2013. Average realised selling prices were lower in the quarter.
- US sales of Atacand were down 59 percent in the quarter to \$11 million. Generic competition for the diuretic combination product followed the loss of exclusivity in December 2012. Atacand sales in other markets were down 19 percent to \$111 million, reflecting loss of exclusivity in many markets.
- Sales of Brilinta/Brilique were \$99 million in the first quarter. More than half of the sales were in Europe, where first quarter sales have increased by 70 percent compared with the first quarter of 2013. Performance in Canada, Australia and Emerging Markets is also contributing to brand revenue growth.
- Brilinta sales in the US in the first quarter were \$28 million. Total prescriptions for Brilinta in the US in the first quarter of 2014 were 11 percent higher than the fourth quarter of 2013. New to brand share is now 6.8 percent, growth of 0.7 percentage points in the quarter.
- Byetta and Bydureon revenues in the US were \$121 million, and \$37 million in ROW. No revenue was recorded in ROW in Q1 2013 as the alliance only assumed responsibility for promotion outside the US in April 2013. Bydureon share of total prescriptions in the US was 19.6 percent in March 2014, up 2.4 percentage points since December 2013 largely due to favourable formulary position.

## Oncology

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Iressa sales in the first quarter were up 5 percent to \$169 million. There was continued growth in Japan following first line approval, with sales up 23 percent.

- Faslodex sales in the US were up 4 percent to \$76 million. Sales in the Rest of World were up 18 percent to \$96 million, chiefly on growth in Europe.
- Arimidex sales were \$78 million in the first quarter. Sales in markets outside the US were \$73 million, down 13 percent as sales continue to decline as a result of loss of exclusivity.

### Respiratory, Inflammation and Autoimmunity

- Symbicort sales in the US were \$344 million in the first quarter, a 20 percent increase over last year. Total prescriptions for Symbicort were up 27 percent, compared to a stable market for fixed combination products. Symbicort share of total prescriptions for fixed combination products reached 29.8 percent in March 2013, up 3.5 percentage points since December 2013, accelerated by favourable formulary position. Strong demand was partially offset by higher inventory destocking in the quarter; price was broadly flat.
- Symbicort sales in other markets in the first quarter were \$584 million, up 10 percent. Sales in Europe were down 3 percent. Sales in Established Rest of World were up 57 percent on growth in Japan, Australia and New Zealand. Sales in Emerging Markets were up 24 percent.
- US sales of Pulmicort were down 16 percent to \$52 million. Pulmicort sales in the Rest of World were up 24 percent to \$211 million, with China now comprising more than half.

### Infection, Neuroscience and Gastrointestinal

- In the US, Nexium sales in the first quarter were \$484 million, down 7 percent compared with the first quarter last year. Dispensed retail tablet volume declined by approximately 13 percent and realised net price is slightly lower. Declines were partially offset by sales related to third party clinical trial supply and other adjustments.
- Nexium sales in other markets were up 14 percent to \$446 million. Sales in Europe were down 1 percent, reflecting the continued effects of generic competition. Sales in Established Rest of World were up 34 percent on a continued strong performance in Japan, partially offset by the impact of generic competition in Canada. Sales in Emerging Markets were up 8 percent, with 40 percent growth in China partially offset by declining volume in Latin America.
- Sales of Synagis in the US were \$256 million in the first quarter, down 18 percent largely driven by a mix effect on price and favourable adjustments to Medicaid provisions in the prior year. Outside the US, Synagis sales were down 21 percent to \$72 million, attributable to timing of shipments to our marketing partner AbbVie.
- Sales of Seroquel XR in the US were \$166 million, down 2 percent. Total prescriptions were down 6 percent, offset by slightly higher realised net price.
- Sales of Seroquel XR in the Rest of World were down 16 percent to \$126 million, as a result of generic competition (including some "at risk" launches) in Europe. Sales in Established Rest of World were down 57 percent, as a result of generic competition in Canada. Sales in Emerging Markets were down 7 percent.
- Sales of Seroquel IR were down 46 percent in the quarter to \$66 million. More than half of this decline is attributable to Japan, as the partner built inventory in 2013 in anticipation of a manufacturing site change.
- Losec sales in markets outside the US were down 12 percent in the first quarter to \$102 million, largely on lower sales in Japan.

### Regional Revenue

First Quarter

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	2014	2013	% Change	
	\$m	\$m	Actual	CER
US	2,513	2,445	3	3
Europe	1,637	1,660	(1)	(4)
Established ROW <sup>1</sup>	845	950	(11)	2
Japan	537	549	(2)	13
Canada	139	170	(18)	(11)
Other Established	169	231	(27)	(15)
ROW				
Emerging Markets <sup>2</sup>	1,421	1,330	7	11
China	584	465	26	22
Total	6,416	6,385	-	3

<sup>1</sup>Established ROW comprises Canada, Japan, Australia and New Zealand.

<sup>2</sup>Emerging Markets comprises all remaining Rest of World markets, including Brazil, China, India, Mexico, Russia, and Turkey.

- In the US, revenue was up 3 percent in the first quarter, with declines in revenue from brands such as Nexium, Toprol-XL and Synagis offset by the growth platforms and the impact of completing the acquisition of BMS's share of the global diabetes alliance. The diabetes products provided \$103 million of incremental revenue, with growth from Symbicort, Brilinta and Crestor also contributing.
- In the first quarter, revenue in Europe was down 4 percent, due to continuing impact from loss of exclusivity on Seroquel IR, Seroquel XR in some markets, and Atacand, timing of partner purchases on Synagis and volume declines on Crestor. This is partially offset by favourable impact from the acquisition of BMS's share of the global diabetes alliance and 70 percent sales growth for Brilinta.
- Revenue in Established ROW was up 2 percent in the quarter, chiefly due to the growth of Nexium, Crestor and Symbicort in Japan. Nexium is now the number one proton pump inhibitor in Japan measured in value. Forxiga was approved in Japan during the quarter. There was generic competition on Crestor in Australia and on Nexium and Seroquel XR in Canada.
- Revenue in Emerging Markets was up 11 percent in the quarter, largely the result of a 22 percent increase in China. China now represents approximately 40 percent of the total Emerging Markets business, with growth driven by Pulmicort, Crestor, Nexium and Symbicort. Pulmicort sales in China increased by 60 percent in the quarter to \$107 million as the Company has been investing in nebulising centres.

Condensed Consolidated Statement of Comprehensive Income

	2014	2013
	\$m	\$m
For the quarter ended 31 March		
Revenue	6,416	6,385
Cost of sales	(1,453)	(1,266)
Gross profit	4,963	5,119
Distribution costs	(72)	(77)
Research and development expense	(1,200)	(1,259)
Selling, general and administrative costs	(2,726)	(2,518)
Other operating income and expense	(129)	132
Operating profit	836	1,397
Finance income	15	22
Finance expense	(213)	(115)
Profit before tax	638	1,304

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Taxation	(132)	(292)
Profit for the period	506	1,012
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(25)	(60)
Tax on items that will not be reclassified to profit or loss	6	14
	(19)	(46)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	55	(319)
Foreign exchange differences on borrowings designated in net investment hedges	(1)	64
Fair value movements on derivatives designated in net investment hedges	(9)	58
Net available for sale gains taken to equity	2	51
Tax on items that may be reclassified subsequently to profit or loss	(7)	8
	40	(138)
Other comprehensive income for the period, net of tax	21	(184)
Total comprehensive income for the period	527	828
Profit attributable to:		
Owners of the parent	504	1,011
Non-controlling interests	2	1
	506	1,012
Total comprehensive income attributable to:		
Owners of the parent	531	845
Non-controlling interests	(4)	(17)
	527	828
Basic earnings per \$0.25 Ordinary Share	\$0.40	\$0.81
Diluted earnings per \$0.25 Ordinary Share	\$0.40	\$0.81
Weighted average number of Ordinary Shares in issue (millions)	1,260	1,248
Diluted weighted average number of Ordinary Shares in issue (millions)	1,262	1,250

Condensed Consolidated Statement of Financial Position

	At 31 Mar 2014 \$m	At 31 Dec 2013 \$m	At 31 Mar 2013 \$m
<b>ASSETS</b>			
Non-current assets			
Property, plant and equipment	6,173	5,818	5,882
Goodwill	11,601	9,981	9,881
Intangible assets	21,532	16,047	16,051
Derivative financial instruments	352	365	416
Other investments	297	281	212
Other receivables	1,430	1,867	325
Deferred tax assets	1,463	1,205	1,218
	42,848	35,564	33,985

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Current assets			
Inventories	2,163	1,909	2,039
Trade and other receivables	8,579	7,879	7,520
Other investments	777	796	795
Derivative financial instruments	8	40	-
Income tax receivable	636	494	756
Cash and cash equivalents	4,379	9,217	7,234
	16,542	20,335	18,344
Total assets	59,390	55,899	52,329
LIABILITIES			
Current liabilities			
Interest-bearing loans and borrowings	(2,787)	(1,788)	(889)
Trade and other payables	(10,626)	(10,362)	(9,465)
Derivative financial instruments	(8)	(2)	(5)
Provisions	(776)	(823)	(685)
Income tax payable	(3,316)	(3,076)	(2,818)
	(17,513)	(16,051)	(13,862)
Non-current liabilities			
Interest-bearing loans and borrowings	(7,553)	(8,588)	(9,320)
Derivative financial instruments	(1)	(1)	-
Deferred tax liabilities	(2,760)	(2,827)	(2,657)
Retirement benefit obligations	(2,357)	(2,261)	(2,287)
Provisions	(586)	(566)	(822)
Other payables	(7,143)	(2,352)	(893)
	(20,400)	(16,595)	(15,979)
Total liabilities	(37,913)	(32,646)	(29,841)
Net assets	21,477	23,253	22,488
EQUITY			
Capital and reserves attributable to equity holders of the Company			
Share capital	316	315	313
Share premium account	4,179	3,983	3,645
Other reserves	1,967	1,966	1,966
Retained earnings	14,992	16,960	16,368
	21,454	23,224	22,292
Non-controlling interests	23	29	196
Total equity	21,477	23,253	22,488

Condensed Consolidated Statement of Cash Flows

	2014	2013
For the quarter ended 31 March	\$m	\$m
Cash flows from operating activities		
Profit before tax	638	1,304
Finance income and expense	198	93
Depreciation, amortisation and impairment	712	651
Decrease in working capital and short-term provisions	30	290
Non-cash and other movements	207	387
Cash generated from operations	1,785	2,725
Interest paid	(231)	(218)
Tax paid	(367)	(309)
Net cash inflow from operating activities	1,187	2,198

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Cash flows from investing activities		
Movement in short-term investments and fixed deposits	36	22
Purchase of property, plant and equipment	(183)	(114)
Disposal of property, plant and equipment	57	9
Purchase of intangible assets	(545)	(300)
Purchase of non-current asset investments	(2)	(4)
Acquisitions of business operations	(3,068)	-
Interest received	30	26
Payments made by subsidiaries to non-controlling interests	(102)	(3)
Net cash outflow from investing activities	(3,777)	(364)
Net cash (outflow)/inflow before financing activities	(2,590)	1,834
Cash flows from financing activities		
Proceeds from issue of share capital	197	142
Dividends paid	(2,425)	(2,296)
Hedge contracts relating to dividend payments	25	(72)
Repayment of obligations under finance leases	(9)	(6)
Net cash outflow from financing activities	(2,212)	(2,232)
Net decrease in cash and cash equivalents in the period	(4,802)	(398)
Cash and cash equivalents at the beginning of the period	8,995	7,596
Exchange rate effects	(5)	(52)
Cash and cash equivalents at the end of the period	4,188	7,146
Cash and cash equivalents consists of:		
Cash and cash equivalents	4,379	7,234
Overdrafts	(191)	(88)
	4,188	7,146

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 2013	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)



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At 31 Mar 2013	313	3,645	1,966	16,368	22,292	196	22,488
	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 2014	315	3,983	1,966	16,960	23,224	29	23,253
Profit for the period	-	-	-	504	504	2	506
Other comprehensive income	-	-	-	27	27	(6)	21
Transfer to other reserves	-	-	1	(1)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(2,395)	(2,395)	-	(2,395)
Issue of Ordinary Shares	1	196	-	-	197	-	197
Share-based payments	-	-	-	(103)	(103)	-	(103)
Transfer from non-controlling interests to payables	-	-	-	-	-	(2)	(2)
Net movement	1	196	1	(1,968)	(1,770)	(6)	(1,776)
At 31 Mar 2014	316	4,179	1,967	14,992	21,454	23	21,477

\* 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 2014 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 2013. There have been no significant new or revised accounting standards applied in the quarter ended 31 March 2014.

The information contained in Note 6 updates the disclosures concerning legal proceedings and contingent liabilities in the Group's Annual Report and Form 20-F Information 2013.

The Group has considerable financial resources available. As at 31 March 2014, the Group had \$4.6 billion in financial resources (cash balances of \$4.4 billion and undrawn committed bank facilities of \$3.0 billion that are available

until April 2017, with \$2.8 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

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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.

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

The comparative figures for the financial year ended 31 December 2013 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 2014 is stated after charging restructuring costs of \$479 million (\$543million for the first quarter 2013). These have been charged to profit as follows:

	1st Quarter 2014 \$m	1st Quarter 2013 \$m
Cost of sales	11	12
Research and development expense	85	291
Selling, general and administrative costs	91	240
Other operating income and expense	292	-
Total	479	543

### 3 NET DEBT

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

	At 1 Jan 2014 \$m	Cash Flow \$m	Non-cash Mvmts \$m	Exchange Mvmts \$m	At 31 Mar 2014 \$m
Loans due after one year	(8,516)	-	1,034	(4)	(7,486)
Finance leases due after one year	(72)	-	6	(1)	(67)
Total long term debt	(8,588)	-	1,040	(5)	(7,553)
Current instalments of loans	(766)	-	(1,025)	4	(1,787)
Current instalments of finance leases	(30)	9	(18)	-	(39)
Total current debt	(796)	9	(1,043)	4	(1,826)
Other investments - current	796	(36)	10	7	777
Net derivative financial instruments	402	(25)	(26)	-	351
Cash and cash equivalents	9,217	(4,833)	-	(5)	4,379
Overdrafts	(222)	31	-	-	(191)

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Short-term borrowings	(770)	-	-	-	(770)
	9,423	(4,863)	(16)	2	4,546
Net funds/(debt)	39	(4,854)	(19)	1	(4,833)

Non-cash movements in the period include movement of loans from long term to current and fair value adjustments under IAS 39.

#### 4 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), Xigduo (dapagliflozin and metformin HCl), Byetta (exenatide), Bydureon (exenatide extended release for injectable suspension), Myalept (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 4,200 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 IFRS 3 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 IFRS 3, 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

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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 have been consolidated into the Company's results from 1 February 2014.

	Fair value
	\$m
Non-current assets	
Intangible assets	5,746
Property, plant and equipment	478
	6,224
Current assets	519
Current liabilities	(311)
Non-current liabilities	(99)
Total assets acquired	6,333
Goodwill	1,619
Fair value of total consideration	7,952
Less: fair value of contingent consideration	(5,249)
Total upfront consideration	2,703
Less: cash and cash equivalents acquired	-
Net cash outflow	2,703

Future contingent consideration has been recognised initially at fair value and subsequently revalued to fair value at each balance sheet date. Changes in fair value can arise as a result of a number of factors, including external news flow and internal re-forecasts, which may affect the likelihood of specific milestones becoming payable or the expected quantum of future royalty payments. These changes, which are potentially volatile and material, are included within selling, general and administrative costs. They are excluded from the Group's Core results.

The fair value of contingent consideration is also affected over time by the unwinding effect of discounting. This effect gives a charge to finance income and expense which reduces over time as the liability reduces. As a direct result of a material business acquisition, this effect is excluded from the Group's Core results.

In the period between acquisition and 31 March 2014, the effect of discounting increased the contingent consideration liability by \$62 million and there were no revaluations to fair value.

In addition, inventory acquired at completion has been recorded at fair value, which is higher than manufacturing cost. The adjustment to increase the inventory to fair value is held in inventory until product is sold, at which time it is released to profit as a cost of sale. This results in a lower gross margin in the first turn of inventory and, since this arises as a direct result of a material business acquisition, this effect is excluded from the Group's Core results. The charge to cost of sales in the first quarter was \$124 million and represents the significant majority of the total adjustment to the fair value of inventory.

## 5 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. There have been no significant changes to the accounting policies, including fair value measurement, for financial instruments from those disclosed on page 139 of the Company's Annual Report and Form 20-F Information 2013. 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 \$1,074 million of other investments, \$1,969 million of loans, and \$351 million of derivatives as at 31 March 2014. The total fair value of interest-bearing loans and borrowings at 31 March 2014, which have a carrying value of \$10,340 million in the Condensed Consolidated Statement of Financial Position, was \$11,336 million. As detailed in Note 4, contingent consideration arising on the Company's acquisition 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.

## 6 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 2013 (the 2013 Disclosures). Unless noted otherwise below or in the 2013 Disclosures, no provisions have been established in respect of the claims discussed below.

As discussed in the 2013 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 2013 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 2014 and April 2014

### Patent litigation

Crestor (rosuvastatin calcium)

Patent proceedings outside the US

On 1 April 2014, Shionogi & Co. Ltd, the licensor of the Crestor patent, received confirmation of a request for trial for patent invalidation in the Japanese Patent Office. The request was initiated by Teva Pharma Japan Inc. and relates to the substance patent.

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On 17 April 2014, AstraZeneca received a writ of summons from Resolution Chemicals Ltd. (Resolution) challenging the validity of Supplementary Protection Certificate 300125 for Crestor in the Netherlands. Resolution also seeks a declaration of non-infringement of its rosuvastatin zinc product that it intends to market in the Netherlands.

### Epanova

#### Patent proceedings in the US

In March 2014, AstraZeneca received a complaint from Amarin Pharmaceuticals Ireland Ltd. alleging that AstraZeneca's proposed Epanova product (for the treatment of patients with severe hypertriglyceridaemia) infringes US Patent No. 8,663,662. On 18 September 2013, AstraZeneca announced that the FDA had accepted for review a New Drug Application for Epanova and the Prescription Drug User Fee Act goal date for the FDA is 5 May 2014.

### Pulmicort Respules (budesonide inhalation suspension)

#### Patent proceedings in the US

As previously disclosed, in December 2013, the US District Court for the District of New Jersey 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 1 April 2014, the Court entered an order scheduling oral argument on AstraZeneca's motion for a preliminary injunction for 9 May 2014.

### Faslodex (fulvestrant)

#### Patent proceedings in the US

In April 2014, Sandoz Inc. sent notice that it had submitted an Abbreviated New Drug Application (ANDA) for fulvestrant injection, 250mg/5ml containing a Paragraph IV Certification alleging that patents listed in the FDA Orange Book with reference to Faslodex are invalid, unenforceable and/or will not be infringed by the Sandoz product as described in its ANDA. The challenged patents are US Patent Nos. 6,774,122; 7,456,160; 8,329,680 and 8,466,139.

#### Patent proceedings outside the US

As previously disclosed, in Europe, in 2008, the Opposition Division of the European Patent Office (EPO) maintained a Faslodex formulation patent, EP 1250138, following an opposition against the grant of this patent by Gedeon Richter Plc, which appealed this decision. The Board of Appeal of the EPO called the parties to oral proceedings in March 2014 and decided to remit the case back to the Opposition Division for further consideration.

### Nexium (esomeprazole magnesium)

#### Patent proceedings outside the US

As previously disclosed, in the UK, in 2010, AstraZeneca initiated patent infringement proceedings against Consilient Health Limited and Krka, d.d. Novo Mesto (Consilient/Krka). During previous proceedings, Consilient/Krka agreed not to launch their esomeprazole magnesium product. This injunction was discharged in July 2011. In March 2014, in damages proceedings initiated by Consilient/Krka, the High Court awarded Consilient/Krka £27.4 million in damages. AstraZeneca is considering its legal options including seeking leave to appeal. A provision has been taken.

### Onglyza (saxagliptin)

#### Patent proceedings in the US

In April 2014, multiple generic companies sent notices that they had submitted Abbreviated New Drug Applications (ANDAs) for saxagliptin hydrochloride 2.5 mg and 5 mg tablets containing Paragraph IV Certifications alleging that US Patent No. 7,951,400 and/or RE44,186, listed in the FDA Orange Book with reference to Onglyza, are invalid, unenforceable and/or will not be infringed by the products as described in the ANDAs.

### Seroquel XR (quetiapine fumarate)

#### Patent proceedings outside the US

As previously disclosed, in Germany, Ratiopharm GmbH, CT Arzneimittel GmbH and AbZ Pharma GmbH are seeking damages relating to the preliminary injunction issued in April 2012 that prevented generic Seroquel XR sales by those entities. The injunction was subsequently lifted following the November 2012 Federal Patent Court (the

Federal Court) decision that held that the Seroquel XR patent was invalid. AstraZeneca has appealed the Federal Court's decision.

In Romania, in March 2014, AstraZeneca settled patent litigation with Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals S.R.L.

#### Product liability litigation

##### Byetta/Bydureon (exenatide)

As previously disclosed, Amylin Pharmaceuticals, LLC, a wholly owned subsidiary of AstraZeneca, and/or AstraZeneca are among multiple defendants in various lawsuits filed in federal and state courts in the US involving approximately 409 plaintiffs claiming physical injury from treatment with Byetta and/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. AstraZeneca and certain defendants recently reached an agreement to settle 84 cases pending in the California state court proceeding, including a matter that was scheduled for trial in February 2014.

##### Nexium (esomeprazole magnesium)

As previously disclosed, in December 2013, 522 already dismissed plaintiffs collectively moved the federal Multi-District Litigation court (the MDL Court) to have their claims reinstated, and AstraZeneca opposed that motion. In March 2014, more than 440 of the 522 plaintiffs seeking reinstatement failed to satisfy certain court-imposed conditions for reinstatement, and their claims are in the process of being dismissed with prejudice. AstraZeneca has withdrawn its opposition to more than 50 of the 522 plaintiffs' requests for reinstatement after they satisfied certain court-imposed conditions, and those plaintiffs' claims will be reinstated. The remaining of the 522 plaintiffs' requests for reinstatement remain outstanding and in dispute. In addition, in February 2014, the MDL Court dismissed the claims of an additional 62 plaintiffs.

#### Commercial litigation

##### Average Wholesale Price (AWP) Litigation

As previously disclosed, AstraZeneca and other pharmaceutical manufacturers were named as defendants in litigation involving allegations that, by causing the publication of allegedly inflated wholesale list prices, defendants caused entities to overpay for prescription drugs. In March 2014, AstraZeneca reached a settlement with the State of Utah and in April 2014, AstraZeneca reached a settlement in principle with the State of Wisconsin. With these settlements, AstraZeneca has brought the AWP litigation to a conclusion.

##### Crestor qui tam litigation

As previously disclosed, the US Attorney's Offices and all US states, except for the State of Texas, have declined to intervene in the civil component of a previously disclosed investigation regarding Crestor. Partly as a result thereof, AstraZeneca was served with two additional lawsuits filed in the US District Court for the District of Delaware under the qui tam (whistleblower) provisions of the federal False Claims Act and related state statutes, alleging that AstraZeneca directed certain employees to promote Crestor off-label and provided unlawful remuneration to physicians in connection with the promotion of Crestor. AstraZeneca intends to vigorously defend these matters.

##### Nexium settlement anti-trust litigation

As previously disclosed, AstraZeneca is one of several defendants in a 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 12 February 2014, the US District Court for the District of Massachusetts (the Court) issued an order granting three motions for summary judgment in full, granting two in

part, denying one as premature, and denying five.

In particular, the Court held that AstraZeneca's settlement agreements with Teva and Dr. Reddy's Laboratories did not include "large, unjustified reverse payments" that would raise anti-trust concerns. The Court granted the motion as to the Ranbaxy agreement because plaintiffs could not establish that the agreement delayed generic entry beyond any delay caused by Ranbaxy's manufacturing and approval issues. The Court denied the motion seeking judgment on the allegation of a conspiracy among all defendants.

The Court initially indefinitely postponed the trial and administratively closed the case pending the issuance of written decisions. On 17 April 2014, the Court granted the plaintiffs' motion for reconsideration of the motion directed to the Teva agreement and decided that there was sufficient evidence to proceed to trial on the question of whether the Teva settlement raised anti-trust concerns. The Court scheduled an October 2014 trial on the plaintiffs' claims that remain in the case. The Court's decisions are subject to further motions, including additional motions for reconsideration, and appeal.

Separately, AstraZeneca was notified that indirect purchaser plaintiffs who opted out of the Massachusetts class action intend to file complaints in the Pennsylvania Court of Common Pleas.

#### Government investigations

##### Medco New Jersey subpoena

In April 2014, AstraZeneca was served with a subpoena from the New Jersey Attorney General's Office seeking certain documents relating to the price of Nexium and/or its business relationships with Medco Health Solutions, Inc. and Express Scripts Holding Company.

#### 7 FIRST QUARTER PRODUCT REVENUE ANALYSIS

	World		US		Europe		Established ROW		Emerging Markets	
	Q1	CER	Q1	CER	Q1	CER	Q1	CER	Q1	CER
	2014	%	2014	%	2014	%	2014	%	2014	%
	\$m		\$m		\$m		\$m		\$m	
Cardiovascular and Metabolic disease:										
Crestor	1,332	2	705	8	301	(8)	156	(10)	170	13
Seloken/Toprol-XL	193	(11)	24	(57)	31	(3)	5	(17)	133	8
Onglyza	162	81	106	66	26	92	11	140	19	150
Atacand	122	(25)	11	(59)	49	(21)	11	(48)	51	(5)
Brilinta/Brilique	99	94	28	87	52	70	6	250	13	225
Byetta	78	86	52	24	17	n/m	5	n/m	4	n/m
Bydureon	80	196	69	156	9	n/m	1	n/m	1	n/m
Plendil	69	3	-	-	5	-	2	-	62	3
Tenormin	39	(11)	2	-	12	(8)	13	(21)	12	-
Others	94	12	19	73	44	-	5	-	26	8
Total Cardiovascular and Metabolic disease	2,268	8	1,016	13	546	4	215	(7)	491	13
Oncology:										
Zoladex	221	(3)	6	-	58	(15)	75	(4)	82	10
Iressa	169	5	-	-	43	(7)	50	21	76	1
Faslodex	172	11	76	4	63	13	15	21	18	31
Arimidex	78	(11)	5	67	21	(20)	27	(21)	25	4



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Casodex	83	(2)	1	n/m	11	(21)	43	(11)	28	26
Others	31	(3)	6	(14)	8	33	9	(29)	8	29
Total Oncology	754	1	94	6	204	(6)	219	(3)	237	10
Respiratory, Inflammation and Autoimmunity:										
Symbicort	928	13	344	20	386	(3)	115	57	83	24
Pulmicort	263	13	52	(16)	46	(15)	25	12	140	49
Others	80	(1)	12	(14)	28	(10)	6	-	34	13
Total Respiratory, Inflammation and Autoimmunity	1,271	12	408	12	460	(4)	146	43	257	34
Infection, Neuroscience and Gastrointestinal:										
Nexium	930	2	484	(7)	94	(1)	151	34	201	8
Synagis	328	(19)	256	(18)	72	(21)	-	-	-	-
Seroquel XR	292	(9)	166	(2)	93	(10)	9	(57)	24	(7)
Seroquel IR	66	(46)	7	-	24	(21)	7	(80)	28	(40)
Local Anaesthetics	122	2	-	-	53	(2)	40	7	29	3
Losec/Prilosec	110	(10)	8	14	34	(3)	26	(29)	42	(2)
Merrem	65	-	4	n/m	9	(40)	1	(50)	51	2
FluMist/Fluenz	7	40	5	-	-	-	2	n/m	-	-
Others	203	(2)	65	(12)	48	(17)	29	11	61	17
Total Infection, Neuroscience and Gastrointestinal	2,123	(7)	995	(9)	427	(11)	265	(2)	436	1
Total	6,416	3	2,513	3	1,637	(4)	845	2	1,421	11

Shareholder Information

ANNOUNCEMENTS AND MEETINGS

Annual General Meeting	24 April 2014
Announcement of second quarter and half year 2014 results	31 July 2014
Announcement of third quarter and nine months 2014 results	6 November 2014

DIVIDENDS

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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### ADDRESSES FOR CORRESPONDENCE

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### CONTACT INFORMATION

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### 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 failure of information technology and cybercrime; 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: 24 April 2014

By: /s/ Adrian Kemp  
Name: Adrian Kemp  
Title: Company Secretary