

# AstraZeneca PLC

## FIRST QUARTER RESULTS 2009

London, 30 April 2009

**Sales for the first quarter increased by 7 percent at constant exchange rates (CER) to \$7,701 million.**

- Crestor sales increased by 35 percent at CER.
- Emerging Markets sales increased by 15 percent at CER.
- Benefit to US sales of *Toprol-XL* from withdrawal of some generic competitors.

**Core operating profit increased by 19 percent at CER to \$3,362 million.**

- Core operating margin improved on sales growth, operational efficiencies, higher other income from disposals and currency benefit.

**Core EPS increased by 20 percent at CER to \$1.58.**

**Reported EPS increased by 39 percent at CER to \$1.48.**

- Reported EPS growth rate affected by higher intangible impairment and restructuring costs last year.

**Progress on previously announced restructuring programmes on track.**

**Strong cash performance; after payment of the second interim dividend of \$2,103 million, net debt was reduced by a further \$321 million since 31 December.**

**Core EPS guidance confirmed; Core EPS target remains \$5.15 to \$5.45.**

**On 23 April, the European CHMP recommended approval of *Iressa*.**

- Recommendation is for adults with locally advanced or metastatic non-small cell lung cancer with activating mutations of EGFR-TK, in all lines of therapy.

### Financial Summary

<u>Group</u>	1 <sup>st</sup> Quarter 2009 \$m	1 <sup>st</sup> Quarter 2008 \$m	Actual %	CER %
Revenue	7,701	7,677	-	+7
<b>Reported</b>				
Operating Profit	3,163	2,257	+40	+37
Profit before Tax	3,003	2,143	+40	+36
Earnings per Share	\$1.48	\$1.03**	+44	+39
<b>Core*</b>				
Operating Profit	3,362	2,765	+22	+19
Profit before Tax	3,202	2,651	+21	+17
Earnings per Share	\$1.58	\$1.28	+24	+20

\* Core financial measures are supplemental non-GAAP measures which management believe useful to understanding the Company's performance; it is upon these measures that financial guidance for 2009 is based. See page 8 for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.

\*\* Included in Reported EPS for Q1 2008 is a (\$0.12) charge for impairment of intangible assets related to *Ethylol*, a product acquired with *MedImmune*, arising from an "at risk" launch of a generic product by *Sun Pharmaceutical Industries, Ltd.*, prior to the conclusion of ongoing patent litigation.

**David Brennan, Chief Executive Officer, said:** "Our business has proved to be resilient in the first quarter, the result of excellent execution in driving growth in key product franchises and in all regions, whilst delivering improvements in operating efficiency. Our full year target for Core EPS remains unchanged, reflecting our continued caution about the 2009 outlook for the pharmaceutical sector in the context of global economic conditions."

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

Sales in the first quarter increased by 7 percent at CER, but were unchanged on an as reported basis as a result of the negative impact of exchange rate movements. Sales in the US were up 7 percent compared with the first quarter 2008 which was affected by higher levels of destocking. Sales in the US also benefited from increased *Toprol-XL* franchise sales as two generic competitors withdrew their products from the market. Excluding *Toprol-XL*, US sales increased by 3 percent. Group sales in the Rest of World were up 7 percent. Sales in Established Markets were up 4 percent. Strong sales growth continued in Emerging Markets; the 15 percent increase in these markets accounted for more than half of Rest of World sales growth.

Core operating profit in the first quarter was up 19 percent to \$3,362 million, as a result of sales growth and operational efficiencies together with higher other income related to proceeds from the agreement returning Abraxane® co-promotion rights to Abraxis BioScience LLC. Reported operating profit increased by 37 percent to \$3,163 million, chiefly as a result of the *Ethylol* impairment charge and somewhat higher restructuring costs taken in the first quarter of 2008.

Core earnings per share in the first quarter were \$1.58 compared with \$1.28 in the first quarter 2008, a 20 percent increase at CER. Reported earnings per share in the first quarter were \$1.48, up 39 percent compared with the first quarter 2008, in line with the previously identified factors affecting reported operating profit growth.

### Research and Development Update

A comprehensive update of the AstraZeneca R&D pipeline was presented in conjunction with the Full Year 2008 results and the pipeline table remains available on the Company's website, [www.astrazeneca.com](http://www.astrazeneca.com), under information for investors.

Developments since the last update include:

#### ***Symbicort***

On 27 February, AstraZeneca announced that the US Food and Drug Administration (FDA) has approved *Symbicort* for the twice daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

On 6 April, AstraZeneca announced the Company has received a Complete Response Letter (CRL) from the US Food and Drug Administration (FDA) for *Symbicort* pressurised metered dose inhaler (pMDI) for the long-term maintenance treatment of asthma in paediatric patients ages 6-11 years. The FDA stated that AstraZeneca did not provide adequate data to establish the appropriate dose or doses of the individual components of *Symbicort* – budesonide and formoterol – and to establish how the individual components contribute to the combination product, in paediatric patients ages 6-11 years. AstraZeneca is evaluating the CRL and will provide a response to the Agency in due course.

#### **ONGLYZA™**

On 1 April, AstraZeneca and Bristol-Myers Squibb announced that the FDA's Endocrinologic and Metabolic Drugs Advisory Committee determined (by a vote of 10 to 2) that the data supporting the new drug application for ONGLYZA™ (saxagliptin) for the treatment of adults with type 2 diabetes were sufficient to rule out unacceptable cardiovascular risk relative to comparators in the programme.

The Advisory Committee unanimously recommended that the sponsors perform a post-marketing trial to confirm the cardiovascular profile of ONGLYZA™. AstraZeneca and Bristol-Myers Squibb are working on a series of Phase IIIb and IV studies, including a large, controlled, randomised post-marketing trial, to further characterise the long-term clinical effectiveness as well as the cardiovascular profile of ONGLYZA™. The companies will now work with the FDA to finalise the post-marketing trial design.

The new drug application for ONGLYZA™ was submitted to the FDA on 30 June 2008.

On 23 April, AstraZeneca and Bristol-Myers Squibb reported that the FDA has determined it needs additional time to complete the review of the New Drug Application (NDA) for ONGLYZA™ for the treatment of type 2 diabetes. Accordingly, the FDA has extended the Prescription Drug User Fee Act (PDUFA) date from 30 April 2009 to 30 July 2009. The companies continue to work closely with the FDA to support the review of ONGLYZA™.

### ***Seroquel XR***

On 8 April 2009, the FDA Psychopharmacologic Drugs Advisory Committee (PDAC) conducted a review of the safety and efficacy of supplemental new drug applications (sNDA) for *Seroquel XR* proposed for the treatment of major depressive disorder (MDD) and generalised anxiety disorder (GAD).

The FDA frequently convenes advisory committee meetings to obtain independent expert guidance and recommendations on clinical matters. While the FDA is not required to follow this guidance, the agency usually takes the advice into account when rendering its final decisions on pending applications and other public health matters.

The Advisory Committee concluded:

- *Seroquel XR* was shown to be effective in MDD as both monotherapy and adjunctive therapy, and shown to be effective in GAD as monotherapy.
- *Seroquel XR* was shown to be acceptably safe as an adjunctive treatment for MDD.
- *Seroquel XR* was not shown to be acceptably safe as a monotherapy for broad treatment for MDD.
- The committee was undecided as to whether *Seroquel XR* was shown to be acceptably safe in certain instances as a monotherapy treatment for MDD.
- *Seroquel XR* was not shown to be acceptably safe as a monotherapy for the treatment of GAD.

The Company looks forward to having further discussions with the FDA regarding both sNDAs.

### ***Crestor***

In April, AstraZeneca submitted an sNDA to the FDA to amend the *Crestor* label to reflect the significant reductions in cardiovascular events demonstrated in the landmark JUPITER clinical trial. Regulatory submissions in Europe are planned for later this quarter.

### ***Iressa***

On 23 April, the Company announced that the Committee for Medicinal Products for Human Use (CHMP), the scientific advisory committee of the European Medicines Agency (EMA), has issued a positive opinion supporting approval of the targeted oral anti-cancer drug, *Iressa*.

The CHMP has recommended the approval of *Iressa* for adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of EGFR-TK (epidermal growth factor receptor-tyrosine kinase), in all lines of therapy.

AstraZeneca will be required to conduct a Follow-up Measure Study, to generate further data in a Caucasian NSCLC patient population. AstraZeneca is in a discussion with CHMP to finalise the study design and endpoints.

The CHMP positive opinion is now referred for final action to the European Commission, which grants marketing approval in the European Union.

### **Enhancing Productivity**

In the first quarter, \$72 million in restructuring and synergy costs were charged to the accounts in relation to previously announced business reshaping programmes which, when fully implemented, are expected to deliver benefits of \$2.1 billion per annum by the end of 2010, with a further \$0.4 billion by 2013.

All programmes remain on track for costs incurred and benefits achieved.

## Future Prospects

The strong first quarter sales performance reflects determined execution of our plans combined with the favourable impact in the US related to the *Toprol-XL* market.

Global economic conditions remain difficult. Management believes that continued caution is warranted when assessing the potential impact of these conditions on the pharmaceutical sector and AstraZeneca. For the full year, the Company confirms that its guidance for Core EPS remains in the range of \$5.15 to \$5.45. Actual performance within this range is dependent on the extent of the impact of the downward pressures from the global economy.

This Core EPS guidance has been based on January 2009 average exchange rates for our principal currencies, and actual first quarter results were broadly in line with this currency assumption. The target takes no account of the likelihood that average exchange rates for the remainder of 2009 may differ materially from the rates upon which our earnings guidance is based. An estimate of the sales and earnings sensitivity to movements of our major currencies versus the US dollar was provided in conjunction with the Full Year 2008 results announcement, and can be found on the AstraZeneca website.

## Sales

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

### Gastrointestinal

	First Quarter		CER %
	2009 \$m	2008 \$m	
<i>Nexium</i>	1,192	1,238	+2
<i>Losec/ Prilosec</i>	211	252	-15
Total	1,427	1,510	-

- In the US, *Nexium* sales in the first quarter were \$705 million, down 4 percent compared with first quarter last year. Dispensed retail tablet volume increased by 3.6 percent; average realised selling prices were around 9 percent lower.
- *Nexium* sales in other markets were up 12 percent to \$487 million. Sales in Western Europe increased by 8 percent despite the 35 percent decline in Germany. Sales in Emerging Markets were up 19 percent, including good growth in China.
- *Prilosec* sales in the US were down 62 percent in the first quarter following generic entry of the 40mg dosage form in the second half of 2008.
- *Losec* sales in other markets were down 4 percent, although sales were up 14 percent in Emerging Markets.

### Cardiovascular

	First Quarter		CER %
	2009 \$m	2008 \$m	
<i>Crestor</i>	969	772	+35
<i>Seloken/ Toprol-XL</i>	288	190	+59
<i>Atacand</i>	323	346	+6
<i>Plendil</i>	61	66	-5
<i>Zestril</i>	47	59	-14
Total	1,810	1,571	+24

- In the US, *Crestor* sales in the first quarter were \$478 million, a 35 percent increase over last year. *Crestor* total prescriptions increased by 24 percent, more than 4 times the market growth rate of 5 percent. *Crestor* remains the only branded statin to gain market share; *Crestor* share of total prescriptions in the US reached 10.3 percent in March 2009.
- *Crestor* sales in Rest of World were up 34 percent to \$491 million. *Crestor* year-to-date volume growth was 4 times the market growth rate. Sales in Canada were up 26 percent. Sales in Established Markets grew by 34 percent. There was strong growth in Western Europe (up 22 percent), where *Crestor* volume share is over 20 percent in France and Italy. Sales in Australia were up 96 percent, and sales in Japan grew by 61 percent. Sales in Emerging Markets increased by 41 percent. *Crestor* has become the market leading statin by value and volume in Mexico.
- US sales of the *Toprol-XL* product range, which includes sales of the authorised generic, increased by 175 percent to \$176 million. This increase is the result of the withdrawal of two generic products from the market. It is difficult to ascertain as to when or if these products will return to the market or when potential new entrants will be approved. AstraZeneca is making every effort to increase the supply of *Toprol-XL* and the authorised generic to meet patient needs.
- Sales of *Seloken* in other markets in the first quarter were up 1 percent. The 14 percent growth in Emerging Markets more than offset the 26 percent decline in Western Europe.
- US sales for *Atacand* were down 2 percent in the quarter. Sales in the Rest of World were up 7 percent on broadly equal contribution for Established and Emerging markets.

Respiratory and Inflammation

	First Quarter		CER %
	2009 \$m	2008 \$m	
<i>Symbicort</i>	515	471	+24
<i>Pulmicort</i>	292	411	-26
<i>Rhinocort</i>	64	80	-15
<i>Oxis</i>	12	17	-12
<i>Accolate</i>	16	18	-6
Total	935	1,040	-1

- *Symbicort* sales in the US were \$99 million, a 125 percent increase over the first quarter last year, fuelled by continued growth in asthma and the launch of the COPD indication. *Symbicort* share of new prescriptions for fixed combination products increased to 12.8 percent in March 2009, paced by a market share of patients new to combination therapy that is now over 20 percent.
- *Symbicort* sales in other markets in the first quarter were \$416 million, 13 percent ahead of last year. Sales in Western Europe were up 12 percent. Emerging Market sales were up 19 percent in the quarter.
- US sales for *Pulmicort* were down 37 percent to \$173 million. *Pulmicort Respules* sales were down 42 percent. The dispensed prescription share attributable to the Teva generic product was 52 percent in the quarter, which is lower than expected. As a result, the impact on *Pulmicort Respules* sales will likely persist through the second quarter.
- Sales of *Pulmicort* in the Rest of World were down 3 percent in the quarter, to \$119 million.

Oncology

	First Quarter		CER %
	2009 \$m	2008 \$m	
<i>Arimidex</i>	463	430	+14
<i>Casodex</i>	236	316	-27
<i>Zoladex</i>	232	255	-
<i>Iressa</i>	68	58	+10
<i>Faslodex</i>	59	56	+14
<i>Nolvadex</i>	20	18	+6
<i>Ethyol</i>	4	14	-71
Total	1,083	1,165	-3

- In the US, sales of *Arimidex* were up 20 percent in the first quarter to \$219 million. Total prescriptions for *Arimidex* were down 3 percent, in line with the market decline of around 2 percent.
- *Arimidex* sales in other markets were up 10 percent to \$244 million. Sales in Western Europe were up 10 percent, whilst sales in Emerging Markets increased by 21 percent.
- *Casodex* sales in the US were down 18 percent in the first quarter to \$54 million. Total prescriptions were down 5 percent, and there was some destocking in anticipation of generic entry following loss of market exclusivity in April.
- *Casodex* sales in the Rest of World were down 29 percent to \$182 million. Sales in Western Europe declined by 58 percent as a result of the generic competition that began in the third quarter of last year.
- *Iressa* sales were up 10 percent to \$68 million. Sales in China were up 42 percent and sales in Japan increased by 12 percent over last year.
- *Faslodex* sales were up 4 percent in the US and were up 23 percent in the Rest of World.

Neuroscience

	First Quarter		CER %
	2009 \$m	2008 \$m	
<i>Seroquel</i>	1,125	1,050	+11
<i>Zomig</i>	101	107	+1
Total	1,432	1,378	+9

- In the US, *Seroquel* sales were up 14 percent to \$800 million. With the indications for bipolar depression and bipolar mania now launched for *Seroquel XR*, the market-leading 31.5 percent share of total prescriptions for antipsychotics for *Seroquel* franchise was broadly unchanged in the quarter. Total prescriptions increased by 3 percent, with more than 80 percent of this increase attributable to *Seroquel XR*.
- *Seroquel* sales in the Rest of World were up 6 percent despite the 68 percent decline in Canada due to generic competition, on the strength of a 19 percent increase in Western Europe.
- *Zomig* sales in the US were down 2 percent to \$43 million. Sales in the Rest of World were up 3 percent to \$58 million.

Infection and Other

	First Quarter		CER %
	2009 \$m	2008 \$m	
<i>Synagis</i>	545	519	+5
<i>Merrem</i>	202	213	+8
<i>FluMist</i>	2	-	n/a
Total	792	787	+5

- Sales of *Synagis* were up 5 percent to \$545 million. Sales in the US were \$471 million, a 3 percent increase. Sales in the Rest of World increased by 17 percent to \$74 million.

Geographic Sales

	First Quarter		CER %
	2009 \$m	2008 \$m	
North America	3,891	3,723	+6
US	3,624	3,401	+7
Established ROW*	2,834	2,973	+4
Emerging ROW	976	981	+15

\*Established ROW comprises Western Europe (including France, UK, Germany, Italy, Sweden, and others), Japan, Australia and New Zealand.

- In the US, sales were up 7 percent. Excluding *Toprol-XL*, sales increased by 3 percent. Estimated underlying demand growth was below reported sales growth as a result of higher levels of destocking in the prior year quarter. *Crestor* and *Symbicort* were the key drivers of underlying demand growth in the quarter, more than offsetting the sales declines for *Pulmicort Respules* and *Nexium*.
- Sales in the Established Rest of World segment were up 4 percent. Sales in Western Europe were up 2 percent, as growth for *Crestor*, *Seroquel* and *Symbicort* more than offset the decline in *Casodex* sales resulting from generic competition. Sales in Japan were up 10 percent chiefly on sales growth for *Crestor* and the oncology franchise. *Crestor* was the primary driver of the 14 percent increase in sales in Australia.
- Sales in Emerging Markets were up 15 percent. More than one-third of the increase is attributable to *Crestor* and *Nexium*; the balance achieved across a broad range of product franchises. Sales in Emerging Europe were up 16 percent. Sales in China increased by 35 percent in the quarter.

## 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. These measures are non-GAAP measures which management believe useful to understanding the Group's performance. The Core financial measure is adjusted to exclude certain items, such as charges and provisions related to restructuring and synergy programmes, amortisation and the impairment of the significant intangibles arising from corporate acquisitions and those related to our current and future exit arrangements with Merck in the US, and other specified items.

### First Quarter

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

	Reported 2009	Restructuring and synergy costs	MedImmune Amortisation	Intangible Impairment	Merck Amortisation	Core 2009	Core 2008	Actual %	CER %
<b>Sales</b>	<b>7,701</b>	-	-	-	-	<b>7,701</b>	<b>7,677</b>	-	<b>7</b>
Cost of Sales	(1,383)	31	-	-	-	(1,352)	(1,470)		
<b>Gross Margin</b>	<b>6,318</b>	<b>31</b>	-	-	-	<b>6,349</b>	<b>6,207</b>	<b>2</b>	<b>8</b>
% sales	82.0%					82.4%	80.9%	+1.5	+0.9
Distribution	(64)	-	-	-	-	(64)	(66)	(3)	16
% sales	0.8%					0.8%	0.9%	+0.1	-0.1
R&D	(980)	-	-	-	-	(980)	(1,182)	(17)	-
% sales	12.7%					12.7%	15.4%	+2.7	+1.0
SG&A	(2,376)	41	76	-	23	(2,236)	(2,345)	(5)	5
% sales	30.9%					29.1%	30.6%	+1.5	+0.5
Other income	265	-	28	-	-	293	151	94	111
% sales	3.4%					3.8%	2.0%	+1.8	+1.9
<b>Operating Profit</b>	<b>3,163</b>	<b>72</b>	<b>104</b>	-	<b>23</b>	<b>3,362</b>	<b>2,765</b>	<b>22</b>	<b>19</b>
% sales	41.0%					43.6%	36.0%	+7.6	+4.2
Net finance expense	(160)	-	-	-	-	(160)	(114)		
<b>Profit before Tax</b>	<b>3,003</b>	<b>72</b>	<b>104</b>	-	<b>23</b>	<b>3,202</b>	<b>2,651</b>	<b>21</b>	<b>17</b>
Taxation	(859)	(21)	(30)	-	-	(910)	(782)		
<b>Profit after Tax</b>	<b>2,144</b>	<b>51</b>	<b>74</b>	-	<b>23</b>	<b>2,292</b>	<b>1,869</b>	<b>23</b>	<b>19</b>
Minority Interests	2	-	-	-	-	2	(2)		
<b>Net Profit</b>	<b>2,146</b>	<b>51</b>	<b>74</b>	-	<b>23</b>	<b>2,294</b>	<b>1,867</b>	<b>23</b>	<b>19</b>
Weighted Average Shares	1,447	1,447	1,447	1,447	1,447	1,447	1,457		
<b>Earnings per Share</b>	<b>1.48</b>	<b>0.03</b>	<b>0.05</b>	-	<b>0.02</b>	<b>1.58</b>	<b>1.28</b>	<b>24</b>	<b>20</b>

Sales were unchanged on a reported basis and grew by 7 percent on a constant currency basis. Currency movements resulted in a negative impact of 7 percent.

Core gross margin of 82.4 percent in the first quarter was 0.9 percentage points higher than last year in constant currency terms. Lower payments to Merck (0.7 percentage points) and continued efficiency gains and mix factors (1.1 percentage points) were partially offset by higher royalty payments (0.9 percentage points).

Core R&D expenditure was \$980 million in the first quarter, unchanged from last year in constant currency terms as increased costs associated with the growing number of later stage pipeline projects were offset by continued R&D productivity improvements.

Core SG&A costs of \$2,236 million were 5 percent higher than the first quarter of 2008 as a result of continued investment in Emerging Markets and the phasing of certain costs within G&A, partially offset by operational efficiencies.

Core other income of \$293 million was \$142 million higher than the first quarter of 2008, chiefly as a result of the Abraxane® disposal.

Core operating profit was \$3,362 million, an increase of 19 percent at CER, up 22 percent on an as reported basis. Currency movements increased Core operating profit by 3 percent. In comparison with last year, the dollar was 15 percent stronger against the euro (reducing sales and costs), 33 percent stronger against the Swedish krona (reducing costs), and 38 percent stronger against sterling (reducing costs). On a constant currency basis, Core operating margin increased by 4.2 percentage points to 43.6 percent of sales, as a result of sales growth, efficiencies in gross margin, SG&A and R&D, as well as the Abraxane® disposal within other income.



Core earnings per share in the first quarter were \$1.58, up 20 percent at CER, as the increase in Core operating profit and the lower tax rate was partially offset by higher net finance expense. Core earnings per share on an as reported basis, including a currency benefit of 4 percent, increased by 24 percent.

Reported operating profit was up 37 percent at CER at \$3,163 million, reflecting lower restructuring and synergy costs and the *Ethyol* impairment charge (\$257 million) in the first quarter of 2008. Reported earnings per share were \$1.48.

### **Finance Income and Expense**

Net finance expense was \$160 million for the quarter, versus \$114 million in 2008. The key drivers were the reversal of the fair value gain as described below, reduced interest received due to lower interest rates, a higher net interest expense on pension obligations, partially offset by reduced interest payable on lower debt balances.

Net finance expense included a net fair value loss of \$21 million for the quarter (\$44 million gain in Q1 2008) as credit spreads have reduced since the year end. As outlined in the full year 2008 results, a net fair value gain of \$130 million was recorded in 2008 mainly relating to two long-term bonds. These bonds are swapped to floating interest rates and accounted for using the fair value option under IFRS. Under this accounting treatment both the bonds and the related interest rate swaps are measured at fair value, with changes in fair value reported in the Income Statement. The fair value of each instrument reflects changes in market interest rates, which broadly offset, but the fair value of these bonds also reflects changes in credit spreads. The Company anticipates that the 2008 gain will reverse further in 2009 if credit spreads continue to reduce.

### **Taxation**

The effective tax rate for the quarter was 28.6 percent compared with 29.8 percent for the same period last year. The full year tax rate for 2009 is currently anticipated to be around 29.5 percent.

### **Cash Flow**

Cash generated from operating activities was \$2,227 million in the quarter, compared with \$2,391 million in the corresponding quarter in 2008. Cash generated from operations increased by \$190 million driven by strong underlying performance, although this was more than offset by a phasing related increase in tax payments of \$325 million.

Net cash inflows from investing activities were \$74 million in the quarter compared with outflows of \$2,937 million in the corresponding quarter in 2008. The movement of \$3,011 million is due primarily to the payment of \$2,630 million to Merck as part of the partial retirement in 2008, the proceeds from the disposal of the Abraxane® co-promotion rights of \$269 million in the quarter and a movement in the net cash flow from short-term investments and fixed deposits of \$99 million.

Cash distributions to shareholders were \$2,103 million through payment of the second interim dividend from 2008.

A series of option-based currency hedges have been executed to protect the current year free cash flow from adverse exchange rate movements. The nature of these hedges is such that they will only provide protection if there is an extreme movement in exchange rates from current levels. The cost of executing these hedges along with changes in fair value are recorded in earnings and as such may introduce some earnings volatility during the year. This volatility is not expected to be significant unless there is an extreme adverse movement in exchange rates, in which case the hedges are likely to result in a gain.

### **Debt and Capital Structure**

As at 31 March 2009, outstanding gross debt (including loans, short-term borrowings and overdrafts) was \$11,634 million (31 December 2008: \$11,848 million). Of this debt, \$1,628 million is due within one year (31 December 2008: \$993 million), which we currently anticipate repaying from current cash balances of \$4,441 million and business cash flows, without the need to refinance. Outstanding net debt of \$6,853 million has decreased by \$321 million since 31 December 2008.

## Share Repurchases

As announced in 2008, the Group's share repurchase programme has been suspended. As a result, during the first quarter, no shares were re-purchased. In the quarter, 0.2 million shares were issued in consideration of share option exercises for a total of \$6 million.

The total number of shares in issue at 31 March 2009 was 1,448 million.

## Calendar

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30 April 2009	Annual General Meeting
30 July 2009	Announcement of second quarter and half year 2009 results
29 October 2009	Announcement of third quarter and nine months 2009 results

David Brennan  
Chief Executive Officer

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## Condensed Consolidated Statement of Comprehensive Income

For the <b>quarter</b> ended 31 March	2009 \$m	2008 \$m
<b>Revenue</b>	7,701	7,677
Cost of sales	(1,383)	(1,502)
<b>Gross profit</b>	6,318	6,175
Distribution costs	(64)	(66)
Research and development	(980)	(1,236)
Selling, general and administrative costs	(2,376)	(2,737)
Other operating income and expense	265	121
<b>Operating profit</b>	3,163	2,257
Finance income	113	258
Finance expense	(273)	(372)
<b>Profit before tax</b>	3,003	2,143
Taxation	(859)	(638)
<b>Profit for the period</b>	2,144	1,505
<b>Other comprehensive income:</b>		
Foreign exchange arising on consolidation	(231)	287
Foreign exchange differences on borrowings forming net investment hedges	129	(167)
Net available for sale losses taken to equity	(11)	(14)
Actuarial (loss)/gain for the period	(570)	290
Income tax relating to components of other comprehensive income	125	(26)
Other comprehensive income for the period, net of tax	(558)	370
<b>Total comprehensive income for the period</b>	1,586	1,875
<b>Profit/(loss) attributable to:</b>		
Owners of the parent	2,146	1,503
Non-controlling interests	(2)	2
	2,144	1,505
<b>Total comprehensive income attributable to:</b>		
Owners of the parent	1,588	1,865
Non-controlling interests	(2)	10
	1,586	1,875
Basic earnings per \$0.25 Ordinary Share	\$1.48	\$1.03
Diluted earnings per \$0.25 Ordinary Share	\$1.48	\$1.03
Weighted average number of Ordinary Shares in issue (millions)	1,447	1,457
Diluted average number of Ordinary Shares in issue (millions)	1,448	1,457

# Condensed Consolidated Statement of Financial Position

	As at 31 Mar 2009 \$m	As at 31 Dec 2008 \$m	As at 31 Mar 2008 \$m
<b>ASSETS</b>			
<b>Non-current assets</b>			
Property, plant and equipment	6,820	7,043	8,486
Goodwill	9,855	9,874	9,906
Intangible assets	12,040	12,323	13,778
Derivative financial instruments	416	449	239
Other investments	149	156	197
Deferred tax assets	1,383	1,236	1,400
	<u>30,663</u>	<u>31,081</u>	<u>34,006</u>
<b>Current assets</b>			
Inventories	1,702	1,636	2,169
Trade and other receivables	7,126	7,261	7,054
Derivative financial instruments	-	-	36
Other investments	49	105	55
Income tax receivable	2,534	2,581	2,218
Cash and cash equivalents	4,441	4,286	2,920
	<u>15,852</u>	<u>15,869</u>	<u>14,452</u>
<b>Total assets</b>	<u>46,515</u>	<u>46,950</u>	<u>48,458</u>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Interest bearing loans and borrowings	(1,628)	(993)	(3,886)
Trade and other payables	(7,150)	(7,178)	(7,194)
Derivative financial instruments	(125)	(95)	-
Provisions	(479)	(600)	(531)
Income tax payable	(4,667)	(4,549)	(4,071)
	<u>(14,049)</u>	<u>(13,415)</u>	<u>(15,682)</u>
<b>Non-current liabilities</b>			
Interest bearing loans and borrowings	(10,006)	(10,855)	(11,116)
Derivative financial instruments	-	(71)	-
Deferred tax liabilities	(3,110)	(3,126)	(4,322)
Retirement benefit obligations	(3,174)	(2,732)	(1,755)
Provisions	(514)	(542)	(490)
Other payables	(133)	(149)	(226)
	<u>(16,937)</u>	<u>(17,475)</u>	<u>(17,909)</u>
<b>Total liabilities</b>	<u>(30,986)</u>	<u>(30,890)</u>	<u>(33,591)</u>
<b>Net assets</b>	<u>15,529</u>	<u>16,060</u>	<u>14,867</u>
<b>EQUITY</b>			
<b>Capital and reserves attributable to equity holders of the Company</b>			
Share capital	362	362	364
Share premium account	2,052	2,046	1,889
Other reserves	1,947	1,932	1,882
Retained earnings	11,022	11,572	10,585
	<u>15,383</u>	<u>15,912</u>	<u>14,720</u>
<b>Non-controlling interests</b>	146	148	147
<b>Total equity</b>	<u>15,529</u>	<u>16,060</u>	<u>14,867</u>

## Condensed Consolidated Statement of Cash Flows

For the <b>quarter</b> ended 31 March	<b>2009</b> \$m	<b>2008</b> \$m
<b>Cash flows from operating activities</b>		
Profit before taxation	3,003	2,143
Finance income and expense	160	114
Depreciation, amortisation and impairment	385	702
Increase in working capital	(63)	(59)
Other non-cash movements	(295)	100
Cash generated from operations	3,190	3,000
Interest paid	(287)	(258)
Tax paid	(676)	(351)
<b>Net cash inflow from operating activities</b>	<b>2,227</b>	<b>2,391</b>
<b>Cash flows from investing activities</b>		
Movement in short term investments and fixed deposits	68	(31)
Purchase of property, plant and equipment	(190)	(249)
Disposal of property, plant and equipment	15	14
Purchase of intangible assets	(94)	(2,689)
Disposal of intangible assets	269	-
Purchase of non-current asset investments	(10)	(29)
Disposal of non-current asset investments	1	-
Interest received	24	61
Dividends paid by subsidiaries to minority interest	(9)	(14)
<b>Net cash inflow/(outflow) from investing activities</b>	<b>74</b>	<b>(2,937)</b>
<b>Net cash inflow/(outflow) before financing activities</b>	<b>2,301</b>	<b>(546)</b>
<b>Cash flows from financing activities</b>		
Proceeds from issue of share capital	6	1
Dividends paid	(2,103)	(2,007)
Movement in short term borrowings	(157)	(375)
<b>Net cash outflow from financing activities</b>	<b>(2,254)</b>	<b>(2,381)</b>
<b>Net increase/(decrease) in cash and cash equivalents in the period</b>	<b>47</b>	<b>(2,927)</b>
Cash and cash equivalents at the beginning of the period	4,123	5,727
Exchange rate effects	(25)	1
<b>Cash and cash equivalents at the end of the period</b>	<b>4,145</b>	<b>2,801</b>
<b>Cash and cash equivalents consists of:</b>		
Cash and cash equivalents	4,441	2,920
Overdrafts	(296)	(119)
	<b>4,145</b>	<b>2,801</b>

## Condensed Consolidated Statement of Changes in Equity

	Share capital \$m	Share premium account \$m	Other* reserves \$m	Retained earnings \$m	Total \$m	Non-controlling interests \$m	Total equity \$m
<b>At 1 January 2008</b>	364	1,888	1,902	10,624	14,778	137	14,915
Profit for the period	-	-	-	1,503	1,503	2	1,505
Other comprehensive income	-	-	-	362	362	8	370
Transfer to other reserve	-	-	(20)	20	-	-	-
<b>Transactions with owners:</b>							
Dividends	-	-	-	(1,967)	(1,967)	-	(1,967)
Issue of AstraZeneca PLC Ordinary shares	-	1	-	-	1	-	1
Share-based payments	-	-	-	43	43	-	43
<b>At 31 March 2008</b>	364	1,889	1,882	10,585	14,720	147	14,867
	Share capital \$m	Share premium account \$m	Other* reserves \$m	Retained earnings \$m	Total \$m	Non-controlling interests \$m	Total equity \$m
<b>At 1 January 2009</b>	362	2,046	1,932	11,572	15,912	148	16,060
Profit for the period	-	-	-	2,146	2,146	(2)	2,144
Other comprehensive income	-	-	-	(558)	(558)	-	(558)
Transfer to other reserve	-	-	15	(15)	-	-	-
<b>Transactions with owners:</b>							
Dividends	-	-	-	(2,171)	(2,171)	-	(2,171)
Issue of AstraZeneca PLC Ordinary shares	-	6	-	-	6	-	6
Share-based payments	-	-	-	48	48	-	48
<b>At 31 March 2009</b>	362	2,052	1,947	11,022	15,383	146	15,529

\* 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 2009 have been prepared in accordance with IAS34 *Interim Financial Reporting* as adopted by the European Union. Details of the accounting policies applied are those set out in AstraZeneca PLC's Annual Report and Form 20-F Information 2008.

During the year, the Group has applied IAS 1 *Presentation of Financial Statements (revised 2007)* which has introduced a number of terminology changes (including titles for the condensed primary statements) and has resulted in a number of changes in presentation and disclosure. The revised standard has had no impact on the reported results or financial position of the Group. In addition, the Group has adopted IFRS 2 *Amendment regarding Vesting Conditions and Cancellations*, IFRS 8 *Operating Segments*, IAS 23 *Borrowing Costs (revised 2007)* and Amendments to IAS 32 *Financial Instruments: Presentation* and IAS 1 *Presentation of Financial Statements*, none of which have had a significant effect on the reported results or financial position of the Group.

The Group has considerable financial resources available. The Group's revenues are largely derived from sales of products which are covered by patents and for which, historically at least, demand has been relatively unaffected by changes in the general economy. As a consequence, the Directors believe that the Group is well placed to manage its business risks successfully despite the current uncertain economic outlook and as such, the interim financial statements have been prepared on a Going Concern basis.

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 2008.

The comparative figures for the financial year ended 31 December 2008 are not the Company's statutory accounts for that financial year. Those accounts have been reported on by the Group's auditors and 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 237(2) or (3) of the Companies Act 1985.

## 2 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 2009 \$m	Cash flow \$m	Non-cash movements \$m	Exchange movements \$m	At 31 Mar 2009 \$m
Loans due after one year	(10,855)	-	714	135	(10,006)
Current instalments of loans	(650)	-	(703)	44	(1,309)
Total loans	(11,505)	-	11	179	(11,315)
Other investments - current	105	(68)	13	(1)	49
Net derivative financial instruments	283	-	8	-	291
Cash and cash equivalents	4,286	180	-	(25)	4,441
Overdrafts	(163)	(133)	-	-	(296)
Short term borrowings	(180)	157	-	-	(23)
	4,331	136	21	(26)	4,462
Net debt	(7,174)	136	32	153	(6,853)

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

## 3 RESTRUCTURING AND SYNERGY COSTS

Profit before tax for the quarter ended 31 March 2009 is stated after charging restructuring and synergy costs of \$72 million (\$117 million in 2008). These have been charged to the income statement as follows:

	1 <sup>st</sup> Quarter 2009 \$m	1 <sup>st</sup> Quarter 2008 \$m
Cost of sales	31	32
Research and development	-	54
Selling, general and administrative costs	41	31
Total	72	117

#### 4 LEGAL PROCEEDINGS AND CONTINGENT LIABILITIES

AstraZeneca is involved in various legal proceedings considered typical to its business, including litigation relating to product liability, commercial disputes, infringement of intellectual property rights, the validity of certain patents and anti-trust law. 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 2008.

Unless noted otherwise below or in the Annual Report and Form 20-F Information 2008, no provisions have been established in respect of the claims discussed below.

##### **Crestor (rosuvastatin)**

###### *Patent litigation – US*

As previously disclosed, in January 2008 abbreviated new drug application-filers sued by AstraZeneca in the District of Delaware for infringement of the Patent No. RE37,314 (the '314 patent), responded to AstraZeneca's pleadings, some submitting jurisdictional motions seeking dismissals of parties and claims. In November 2008, the Court issued a magistrate's Report and Recommendation Regarding Motions to Dismiss deciding the defendants' various jurisdictional motions. In January 2009, the Court adopted the magistrate's recommendations.

In March 2009, Magistrate Judge Leonard Stark heard argument and reserved judgment in the Court's *Markman* Hearing in respect of claim construction of the '314 patent claims. Discovery proceeds under an amended schedule.

As previously disclosed, in October 2008, Teva Pharmaceuticals Industries Ltd. (Teva), filed a patent infringement lawsuit against AstraZeneca Pharmaceuticals LP, AstraZeneca PLC, AstraZeneca UK Limited and IPR Pharmaceuticals, Inc. in the Eastern District of Pennsylvania. In January 2009, AstraZeneca PLC and AstraZeneca UK Limited moved for dismissal on jurisdictional grounds. The Court administratively dismissed the motions without prejudice to allow time for discovery. In April 2009, AstraZeneca PLC and AstraZeneca UK Limited renewed those motions, which will proceed. In March 2009, AstraZeneca moved to transfer the case to the US District Court, District of Delaware. On 8 April 2009, AstraZeneca also moved to strike Teva's jury demand. Discovery is continuing.

###### *Patent litigation – Canada*

On 1 April 2009, AstraZeneca Canada Inc. received a Notice of Allegation from Cobalt Pharmaceuticals, Inc. (Cobalt) in respect of Canadian Patent Nos. 2,072,945 (the '945 patent) and 2,313,783 (the '783 patent) listed on the Patent Register in Canada for *Crestor*. Cobalt claims that the '945 patent is not infringed and invalid; and that the '783 patent is not infringed and invalid.

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

##### **Prilosec OTC (omeprazole magnesium)**

###### *Patent litigation*

As previously disclosed, in June 2007 Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Limited (together Dr. Reddy's) notified AstraZeneca that Dr. Reddy's had submitted an abbreviated new drug application (ANDA) seeking FDA approval to market a 20mg delayed release omeprazole magnesium product for the OTC market. In July 2007, AstraZeneca commenced patent infringement litigation against Dr. Reddy's in the Southern District of New York in response to Dr. Reddy's Paragraph IV certifications. In July 2008, Dr. Reddy's filed a motion for summary judgment of non-infringement of the patents-in-suit. In March 2009, the Court granted Dr. Reddy's motion for summary judgment of non-infringement of the patents-in-suit. AstraZeneca is considering options including appeal of the Court's summary judgment decision to the United States District Court for the Federal Circuit.

AstraZeneca has full confidence in, and will vigorously defend and enforce, its intellectual property protecting *Prilosec OTC*.

##### **Nexium (esomeprazole magnesium)**

###### *Sales and marketing practices*

As previously disclosed, AstraZeneca entities have been sued in various state and federal courts in the US in purported representative class actions involving the marketing of *Nexium*. In June 2008, AstraZeneca filed oppositions to the class certification motions filed in the California and Massachusetts cases, and also filed motions for summary judgment in California and Massachusetts. In March 2009, the California Court granted AstraZeneca's motions for summary judgment, ending the claims of all named plaintiffs. The Court also denied plaintiffs' motion for class certification. Oral argument on the Massachusetts motions is scheduled for 6 and 7 May 2009.

As previously disclosed, the US Court of Appeals for the 3rd Circuit had affirmed the dismissal of a similar case filed in Delaware Federal Court, and the plaintiffs had filed a petition for certiorari in the US Supreme Court. In March 2009, the US Supreme Court granted certiorari, vacated the 3rd Circuit decision and remanded the case back to the 3rd Circuit for reconsideration in light of the Supreme Court's pre-emption decision in *Wyeth v. Levine*. AstraZeneca expects a briefing schedule to be established within the next few months.

###### *Patent litigation*

As previously disclosed in December 2008, AstraZeneca received a Paragraph IV Certification notice-letter from Sandoz, Inc. (Sandoz) that Sandoz had submitted an ANDA for 20mg and 40mg esomeprazole magnesium delayed-release capsules alleging invalidity and/or non-infringement in respect of certain AstraZeneca US patents. In January 2009, AstraZeneca commenced patent infringement litigation in the District of New Jersey in response. No trial date has been set.



As previously disclosed, in May and June 2008, AstraZeneca received a complaint from IVAX Pharmaceuticals Inc. and IVAX Corporation (together IVAX) and a complaint from Dr. Reddy's for declaratory judgments of non-infringement and/or invalidity for patents that were not previously at issue in the ongoing infringement litigations. In August 2008, the Court dismissed the IVAX and Dr. Reddy's declaratory judgment actions as to certain patents and stayed the declaratory judgment actions as to remaining patents at issue. In January 2009, the Court vacated the August 2008 Orders that had dismissed and stayed the declaratory judgment actions. As a result, the IVAX and Dr. Reddy's declaratory judgment actions are proceeding. No trial date has been set.

As previously disclosed, in January 2006 AstraZeneca received a Paragraph IV Certification notice-letter from IVAX that IVAX had submitted an ANDA to the FDA for 20mg and 40mg esomeprazole magnesium delayed-release capsules. The ANDA contained Paragraph IV certifications of invalidity and/or non-infringement in respect of certain AstraZeneca US patents listed in the FDA Orange Book with reference to *Nexium*. In March 2006, AstraZeneca commenced wilful patent infringement litigation in the US District Court for the District of New Jersey against IVAX, its parent Teva Pharmaceuticals, and their affiliates. In December 2008, the Court granted AstraZeneca's motion to add Cipla, Ltd. as a defendant in the IVAX/Teva litigation. In January 2008, AstraZeneca commenced patent infringement litigation in the US District Court for the District of New Jersey against Dr. Reddy's in response to Dr. Reddy's Paragraph IV certifications regarding *Nexium*. In March 2009, the Court consolidated the IVAX/Teva, Cipla and Dr. Reddy's patent infringement litigations. The Court has indicated trial in the consolidated patent infringement litigation as soon as January 2010.

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

### ***Pulmicort Respules (budesonide inhalation suspension)***

#### *Patent litigation*

In March 2009, AstraZeneca filed a lawsuit in the US District Court for the District of New Jersey against Apotex, Inc. and Apotex Corp. (together Apotex) seeking a declaration of patent infringement. The lawsuit follows the FDA approval of an ANDA filed by Apotex and concerns Apotex's intent to market a generic version of AstraZeneca's *Pulmicort Respules* in the US prior to the expiration of AstraZeneca's patents. On 16 April, the Court issued a Temporary Restraining Order barring Apotex from launching its generic version of *Pulmicort Respules* until further order of the Court. On 27 April, the Court commenced a hearing to determine whether to continue the injunction.

AstraZeneca has full confidence in, and will vigorously defend and enforce, its intellectual property protecting *Pulmicort Respules*.

### ***Seroquel (quetiapine fumarate)***

#### *Sales and marketing practices*

In February 2009, the State of New Mexico filed a lawsuit against AstraZeneca, similar to the previously disclosed suits filed by Pennsylvania, Arkansas, Montana and South Carolina, which seek compensation for costs incurred by the state for the treatment of Medicaid and other public assistance beneficiaries who allegedly developed diabetes, hyperglycemia and other conditions as a result of using *Seroquel* without adequate warning. In addition, these lawsuits seek reimbursement of payments made by the state Medicaid programs for prescriptions that relate to so-called non-medically accepted indications of *Seroquel*.

#### *Product liability*

As previously disclosed, AstraZeneca Pharmaceuticals LP, either alone or in conjunction with one or more affiliates, has been sued in numerous individual personal injury actions involving *Seroquel*.

As of 13 April 2009, AstraZeneca was defending approximately 9,976 served or answered lawsuits involving approximately 16,198 plaintiff groups. To date, approximately 2,383 additional cases have been dismissed by order or agreement and approximately 1,500 of those cases have been dismissed with prejudice.

On 30 January 2009 and 6 February 2009, the federal judge presiding over the *Seroquel* Multi-District Litigation (MDL) in the District Court for the Middle District of Florida granted AstraZeneca's motions for summary judgment in the first two *Seroquel* product liability cases set for trial and dismissed those cases. The plaintiff in one of these cases filed a notice of appeal to the United States Court of Appeals for the Eleventh Circuit. The federal MDL court has stayed all remaining Florida cases pending a decision on that appeal and is currently evaluating the procedural posture of all non-Florida cases.

The first trial is scheduled to begin in Delaware state court on 29 June 2009. AstraZeneca expects that an additional two to four trials may be scheduled to commence in 2009. AstraZeneca is also aware of approximately 59 additional cases that have been filed but not yet served and has not determined how many additional cases, if any, may have been filed. Some of the cases also include claims against other pharmaceutical manufacturers such as Eli Lilly & Co., Janssen Pharmaceutica, Inc. and/or Bristol-Myers Squibb Company. AstraZeneca intends to litigate these cases on their individual merits and will defend against the cases vigorously.

#### *Patent litigation*

In December 2008, Teva announced that the US Food and Drug Administration (FDA) had tentatively approved its generic quetiapine tablets. In July 2008, the US District Court, District of New Jersey had granted AstraZeneca's motion for summary judgment of No Inequitable Conduct. Teva and Sandoz appealed to the Federal Circuit Court of Appeals. In December 2008, the parties completed briefing. A three-judge panel of the Federal Circuit Court of Appeals heard oral argument in March 2009. The Court reserved judgment. A decision is pending.

In February 2009, AstraZeneca received a second Paragraph IV Certification notice-letter from Sandoz advising that it had amended its ANDA seeking approval to market a generic version of 25mg *Seroquel* tablets before expiration of AstraZeneca's patents covering the product. The amended ANDA seeks approval to market 50mg, 100mg, 150mg, 200mg, 300mg and 400mg tablets. In March 2009, AstraZeneca filed a second lawsuit in US District Court, District of New Jersey against Sandoz alleging infringement of AstraZeneca's patent covering the active ingredient of *Seroquel* tablets. The filing of this additional lawsuit triggered a 30-month stay of FDA final approval for Sandoz's 50mg, 100mg, 150mg, 200mg, 300mg and 400mg ANDA products.

#### *Patent litigation - Seroquel XR*

AstraZeneca lists two patents in the FDA's Orange Book referencing *Seroquel XR*: US Patent No. 4,879,288 (the '288 patent) covering quetiapine fumarate, the active ingredient, and US Patent No. 5,948,437 (the '437 patent) covering extended-release formulations, processes and methods in respect of quetiapine fumarate.

In October and November 2008, AstraZeneca received a third and fourth Paragraph IV Certification notice-letter from Handa Pharmaceuticals (Handa) advising that it had submitted an ANDA seeking approval to market generic versions of 50mg and 150mg *Seroquel XR* tablets before expiration of AstraZeneca's patents covering the product. In October 2008, AstraZeneca filed a second lawsuit in District of New Jersey against Handa alleging infringement of AstraZeneca's patents covering the active ingredient and formulation of *Seroquel XR* 50mg tablets. In December 2008, AstraZeneca filed a third lawsuit against Handa alleging infringement of AstraZeneca's patents covering the active ingredient and formulation of *Seroquel XR* 150mg tablets. The filing of these additional lawsuits triggered 30-month stays of FDA final approval for Handa's 50mg and 150mg ANDA products.

For purposes of discovery, the three Handa actions and the previously disclosed Accord action have been consolidated under a common scheduling order. The consolidated matter proceeds.

In December 2008, AstraZeneca received a Paragraph IV Certification notice-letter from Biovail Laboratories International SRL (Biovail) stating that it had submitted an ANDA seeking approval to market generic versions of 200mg, 300mg and 400mg *Seroquel XR* tablets before the expiration of AstraZeneca's two listed patents covering *Seroquel XR* alleging non-infringement and invalidity in respect of AstraZeneca's patents. In January 2009, AstraZeneca filed a lawsuit in the District of New Jersey against Biovail alleging infringement of AstraZeneca's '288 and '437 patents covering *Seroquel XR* 200mg, 300mg and 400mg tablets. The filing of this lawsuit triggered a 30-month stay of FDA final approval for Biovail's ANDA products.

In January 2009, AstraZeneca received a second Paragraph IV Certification notice-letter from Accord advising that it had submitted an ANDA seeking approval to market a generic version of 150mg *Seroquel XR* tablets before expiration of AstraZeneca's '437 patent covering the product. In February 2009, AstraZeneca filed a second lawsuit in the District of New Jersey against Accord alleging infringement of AstraZeneca's patent covering the formulation of *Seroquel XR* 150mg tablets. The filing of this additional lawsuit triggered a 30-month stay of FDA final approval for Accord's 150mg ANDA product.

The three matters proceed in co-ordinated discovery. In April 2009, AstraZeneca moved to stay discovery respecting the '288 patent covering the active ingredient in *Seroquel XR*, pending the decision of the Federal Circuit Court of Appeals in the above described related case of *AstraZeneca v. Teva and Sandoz*, which pertains to ANDAs for *Seroquel*.

AstraZeneca has full confidence in, and will vigorously defend and enforce, its intellectual property protecting *Seroquel* and *Seroquel XR*.

#### **Atacand (candesartan cilexetil)**

##### *Patent litigation – Canada*

On 3 April 2009, AstraZeneca Canada Inc. received a Notice of Allegation from Sandoz Canada Inc. (Sandoz) in respect of Canadian Patent Nos. 2,040,955 (the '955 patent) and 2,083,305 (the '305 patent) listed on the Patent Register in Canada for *Atacand*. Sandoz has confirmed that it will await the expiry of the '955 patent, but alleges that the '305 patent is not infringed and is not properly listed on the Patent Register.

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

#### **Pain pump litigation**

As previously disclosed, starting in February 2008, AstraZeneca LP, AstraZeneca Pharmaceuticals LP, Zeneca Holdings Inc., and/or AstraZeneca PLC have been named as defendants and served in approximately 51 lawsuits, involving approximately 58 plaintiffs, filed in various US jurisdictions, alleging injuries caused by third-party pain pumps. The complaints in these cases generally allege that the use of *Marcaine*, *Sensorcaine*, *Xylocaine* and/or *Naropin*, with or without epinephrine, in pain pumps that were implanted into patients in connection with arthroscopic surgery, caused chondrolysis. Other named defendants in these cases are other manufacturers and distributors of *bupivacaine* and *lidocaine* and other pain medications, pain pump manufacturers, and in some cases the surgeons. To date, 38 plaintiffs have dismissed their cases against the AstraZeneca defendants while the case was in preliminary stages, and a 39th plaintiff's case was involuntarily terminated when the court granted AstraZeneca's motion to dismiss. The AstraZeneca defendants have filed a motion to dismiss in one additional case. In addition, two active plaintiffs have voluntarily dismissed AstraZeneca PLC but have maintained their suits against other AstraZeneca defendants.

Rights to market *Sensorcaine*, *Xylocaine* and *Naropin* in the US were sold to Abraxis Bioscience Inc. (Abraxis) in June 2006 but many of these lawsuits may be a retained liability under the terms of the Asset Purchase Agreement with Abraxis. To date, AstraZeneca has tendered approximately fifteen of the claims to Abraxis, twelve of which have been dismissed as described outlined above.

It was previously reported that plaintiffs moved to consolidate the federal pain pump cases under the Multi-District Litigation (MDL) process. The Judicial Panel on MDL denied that motion in August 2008. Accordingly, the cases will continue as individual lawsuits.

AstraZeneca intends to vigorously defend these cases.

**Tax**

As previously disclosed, AstraZeneca and Her Majesty's Revenue & Customs (HMRC) have made a joint referral to the UK Court in respect of transfer pricing between our UK and one of our overseas operations for the years 1996 to date as there continues to be a material difference between the Group's and HMRC's positions. An additional referral in respect of controlled foreign company aspects of the same case was made during 2008. Absent a negotiated settlement, litigation is set to commence in 2010. Management continues to believe that AstraZeneca's positions on all its transfer pricing audits and disputes are robust and that AstraZeneca is adequately provided.

## 5 FIRST QUARTER TERRITORIAL SALES ANALYSIS

	1 <sup>st</sup> Quarter 2009 \$m	1 <sup>st</sup> Quarter 2008 \$m	% Growth	
			Actual	Constant Currency
US	3,624	3,401	7	7
Canada	267	322	(17)	2
North America	3,891	3,723	5	6
Western Europe**	2,176	2,405	(10)	2
Japan	497	378	31	10
Other Established ROW	161	190	(15)	14
Established ROW*	2,834	2,973	(5)	4
Emerging Europe	264	287	(8)	16
China	190	133	43	35
Emerging Asia Pacific	184	204	(10)	7
Other Emerging ROW	338	357	(5)	12
Emerging ROW	976	981	(1)	15
Total Sales	7,701	7,677	-	7

\* Established ROW comprises Western Europe (including France, UK, Germany, Italy, Sweden and others), Japan, Australia and New Zealand.

\*\* For the first quarter 2009, Western Europe sales growth excluding Synagis would be -10 percent on an actual basis and 2 percent on a constant currency basis.

## 6 FIRST QUARTER PRODUCT SALES ANALYSIS

	World				US	
	1 <sup>st</sup> Quarter 2009 \$m	1 <sup>st</sup> Quarter 2008 \$m	Actual Growth %	Constant Currency Growth %	1 <sup>st</sup> Quarter 2009 \$m	Actual Growth %
Gastrointestinal:						
<i>Nexium</i>	1,192	1,238	(4)	2	705	(4)
<i>Losec/Prilosec</i>	211	252	(16)	(15)	18	(62)
Others	24	20	20	30	12	100
Total Gastrointestinal	1,427	1,510	(5)	-	735	(7)
Cardiovascular:						
<i>Crestor</i>	969	772	26	35	478	35
<i>Seloken/Toprol-XL</i>	288	190	52	59	176	175
<i>Atacand</i>	323	346	(7)	6	61	(2)
<i>Tenormin</i>	66	70	(6)	(6)	4	(20)
<i>Zestril</i>	47	59	(20)	(14)	4	-
<i>Plendil</i>	61	66	(8)	(5)	3	(50)
Others	56	68	(18)	(7)	-	(100)
Total Cardiovascular	1,810	1,571	15	24	726	47
Respiratory:						
<i>Symbicort</i>	515	471	9	24	99	125
<i>Pulmicort</i>	292	411	(29)	(26)	173	(37)
<i>Rhinocort</i>	64	80	(20)	(15)	37	(24)
<i>Oxis</i>	12	17	(29)	(12)	-	-
<i>Accolate</i>	16	18	(11)	(6)	12	-
Others	36	43	(16)	(2)	-	-
Total Respiratory	935	1,040	(10)	(1)	321	(16)
Oncology:						
<i>Arimidex</i>	463	430	8	14	219	20
<i>Casodex</i>	236	316	(25)	(27)	54	(18)
<i>Zoladex</i>	232	255	(9)	-	11	(31)
<i>Iressa</i>	68	58	17	10	1	(50)
<i>Ethyol</i>	4	14	(71)	(71)	4	(71)
Others	80	92	(13)	(9)	26	(35)
Total Oncology	1,083	1,165	(7)	(3)	315	(2)
Neuroscience:						
<i>Seroquel</i>	1,125	1,050	7	11	800	14
Local anaesthetics	132	138	(4)	7	8	-
<i>Zomig</i>	101	107	(6)	1	43	(2)
<i>Diprivan</i>	64	68	(6)	(1)	10	(9)
Others	10	15	(33)	(20)	1	(67)
Total Neuroscience	1,432	1,378	4	9	862	12
Infection and Other:						
<i>Synagis</i>	545	519	5	5	471	3
<i>Merrem</i>	202	213	(5)	8	46	-
<i>FluMist</i>	2	-	n/a	n/a	2	n/a
Other Products	43	55	(22)	(15)	21	(28)
Total Infection and Other	792	787	1	5	540	2
Aptium Oncology	105	98	7	7	105	7
Astra Tech	117	128	(9)	3	20	5
Total	7,701	7,677	-	7	3,624	7

# Shareholder Information

## ANNOUNCEMENTS AND MEETINGS

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Annual General Meeting	30 April 2009
Announcement of second quarter and half year 2009 results	30 July 2009
Announcement of third quarter and nine months 2009 results	29 October 2009

## DIVIDENDS

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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

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## ADDRESSES FOR CORRESPONDENCE

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<b>Registrar and Transfer Office</b>	<b>US Depository</b>	<b>Registered Office</b>	<b>Swedish Central Securities Depository</b>
The AstraZeneca Registrar Equiniti Limited Aspect House Spencer Road Lancing West Sussex BN99 6DA UK	JP Morgan Chase & Co PO Box 64504 St Paul MN 55164-0504 US	15 Stanhope Gate London W1K 1LN UK	Euroclear Sweden AB PO Box 7822 SE-103 97 Stockholm Sweden
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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: These 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 at the date of preparation of these 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. These forward-looking statements are subject to numerous risks and uncertainties. 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 risk of expiration or early loss of patents (including patents covering competing products), marketing exclusivity or trademarks; the risk of patent litigation; failure to obtain patent protection; the impact of fluctuations in exchange rates; our debt-funding arrangements; bad debts; the adverse impact of a sustained economic downturn; risks relating to owning and operating a biologics and vaccines business; competition; price controls and price reductions; taxation; the risk of substantial product liability claims; the performance of new products; environmental/occupational health and safety liabilities; the development of our business in emerging markets; product counterfeiting; the risk of adverse outcome of litigation and/or government investigations and risk of insufficient insurance coverage; the difficulties of obtaining and maintaining regulatory approvals for new products; the risk of failure to observe continuing regulatory oversight; the risk that R&D will not yield new products that achieve commercial success; the risk that acquisitions and strategic alliances formed as part of our externalisation strategy may be unsuccessful; the risk of reliance on third parties for supplies of materials and services; the risk of failure to manage a crisis; the risk of delay to new product launches; information technology and outsourcing; risks relating to productivity initiatives and reputation.