

# AstraZeneca PLC

## THIRD QUARTER AND NINE MONTHS RESULTS 2010

London, 28 October 2010

**Revenue for the third quarter declined by 2 percent at constant exchange rates (CER) to \$7,898 million.**

-Strong double-digit sales growth at CER for *Crestor*, *Symbicort* and *Seroquel XR*.

-Revenue in markets outside the US increased by 7 percent at CER, including a 14 percent increase in Emerging Markets.

-As expected, revenue in the US was affected by generic competition for *Arimidex*, *Pulmicort Respules* and *Toprol-XL*, as well as the absence of H1N1 pandemic influenza vaccine revenue that benefited the third quarter 2009. US revenue was down 13 percent at CER in the third quarter.

**Core operating profit in the third quarter was down 10 percent at CER to \$3,231 million.**

-With the impact from lower revenue being largely mitigated by operating efficiencies and higher other income, the decline in Core operating profit is chiefly the result of a net \$285 million adverse movement in gross margin – an intangible asset impairment charge this quarter set against a favourable provision release last year.

**Core EPS in the third quarter was down 10 percent at CER to \$1.50.**

**Reported EPS in the third quarter was down 26 percent at CER to \$1.08.**

-Restructuring costs and legal provisions were higher compared with the third quarter last year, with the largest impact arising from legal provisions totalling \$473 million in the third quarter 2010 which are related to ongoing product liability litigation for *Seroquel* (see Note 5).

**Net cash distributions to shareholders for the nine months increased to \$4,658 million through dividend payments of \$3,361 million and net share repurchases of \$1,297 million.**

**Core EPS target for the full year narrowed to the range of \$6.50 to \$6.65.**

### Financial Summary

<u>Group</u>	<u>3<sup>rd</sup> Quarter 2010 \$m</u>	<u>3<sup>rd</sup> Quarter 2009 \$m</u>	<u>Actual %</u>	<u>CER %</u>	<u>9 Months 2010 \$m</u>	<u>9 Months 2009 \$m</u>	<u>Actual %</u>	<u>CER %</u>
Revenue	7,898	8,200	-4	-2	24,652	23,859	+3	+2
<b>Reported</b>								
Operating Profit	2,406	3,204	-25	-24	9,083	9,218	-1	-3
Profit before Tax	2,258	3,032	-26	-26	8,694	8,643	+1	-2
Earnings per Share	\$1.08	\$1.46	-26	-26	\$4.45	\$4.12	+8	+6
<b>Core*</b>								
Operating Profit	3,231	3,609	-10	-10	10,738	10,577	+2	-
Profit before Tax	3,083	3,437	-10	-10	10,349	10,002	+3	+2
Earnings per Share	\$1.50	\$1.68	-11	-10	\$5.32	\$4.90	+9	+7

\* Core financial measures are supplemental non-GAAP measures which management believe enhance understanding of the Company's performance; it is upon these measures that financial guidance for 2010 is based. See pages 11 and 12 for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.

**David Brennan, Chief Executive Officer, said:** "We remain firmly on track to achieve our full year financial targets. The third quarter performance featured double-digit revenue growth in Emerging Markets. Revenue also increased in Western Europe and Established Rest of World. As expected, the impact of generic competition on several products and the absence of pandemic flu vaccine revenue led to a challenging quarter in the US."

### Third Quarter

Revenue in the third quarter was down 2 percent at CER and declined by 4 percent on an actual basis as a result of the negative impact of exchange rate movements. Revenue in markets outside the US increased by 7 percent, including a 14 percent increase in Emerging Markets. Revenue in Western Europe was up 3 percent. Revenue in Established Rest of World was up 5 percent, chiefly on good growth in Canada. As expected, revenue in the US was affected by generic competition for *Arimidex*, *Pulmicort Respules* and *Toprol-XL*, as well as the absence of H1N1 pandemic influenza vaccine revenue that benefited the third quarter 2009. US revenue was down 13 percent in the third quarter.

Core operating profit in the third quarter was \$3,231 million, down 10 percent. With the impact from the decline in revenue in the quarter being largely mitigated by operating efficiencies and higher other income, the decline in Core operating profit was chiefly due to a net \$285 million adverse movement in gross margin. Core gross margin this quarter was adversely affected by a \$128 million charge for impairment of intangible assets related to the decision to discontinue further development of lesogaberan (AZD3355), an investigational compound for GERD. In contrast, the third quarter 2009 benefited from the release of a provision with respect to the resolution of an issue related to a third party supply contract.

Reported operating profit declined by 24 percent, a larger decline than for Core operating profit; adjustments to Core operating profit were \$420 million higher than the third quarter last year, the result of higher restructuring costs and legal provisions. The third quarter 2010 includes legal provisions totalling \$473 million related to ongoing product liability litigation for *Seroquel*. Of the \$473 million, \$203 million relates to the agreements in principle that have already been reached to date to resolve more than 18,250 claims. The balance of \$270 million is an additional reserve, which is the aggregate of estimates for settlement costs of outstanding US claims that have not yet been resolved and are still subject to mediation and the anticipated future defence costs associated with resolving all or substantially all of such remaining claims (see Note 5).

Core earnings per share in the third quarter were \$1.50 compared with \$1.68 in the third quarter 2009, a 10 percent decline at CER, broadly in line with the trend for Core operating profit. Reported earnings per share in the third quarter were down 26 percent to \$1.08, as a result of the same restructuring costs and legal provisions that affected reported operating profit.

### Nine Months

Revenue for the nine months increased by 2 percent at CER, but was up 3 percent on an actual basis as a result of the positive impact of exchange rate movements. Revenue outside the US was up 8 percent, with more than half of this growth generated in Emerging Markets, where revenue was up 16 percent. Revenue in Western Europe was up 4 percent. Revenue in Established Rest of World increased by 7 percent. Revenue in the US was down 5 percent, driven largely by the factors that impacted performance in the third quarter.

Core operating profit was \$10,738 million for the nine months, unchanged at CER. The positive impact from higher revenue combined with lower expenditures in Research and Development were largely offset by lower other income and the unfavourable comparison for gross margin cited in the third quarter commentary. Reported operating profit was down 3 percent.

Core earnings per share for the nine months were \$5.32, an increase of 7 percent, which largely reflects the benefit from the net adjustments to tax provisions (\$0.13) in the first quarter 2010 and lower net finance expense. Reported earnings per share were up 6 percent to \$4.45.

### Enhancing Productivity

Good progress continues on the previously announced business reshaping programmes. In the third quarter, \$212 million in restructuring costs were charged, bringing the total for the nine months to \$777 million.

The first phase of the productivity programme is now largely complete. Since programme inception, the Company is on track to achieve \$2.4 billion in annual benefits by the end of 2010. The second phase is to be completed over the 2010-14 time frame, with the realisation of a further \$1.9 billion in annual benefits expected by the end of 2014. Restructuring charges of \$2.0 billion are anticipated between 2010 and 2013, with approximately 60 percent to be taken in 2010, and most of the remainder by 2011. The 2010 phasing of costs and benefits to date remains broadly in line with these estimates.

## Dividends and Share Repurchases

To date, the Company has now completed net share repurchases of \$1,297 million towards its target of \$2 billion in net share repurchases in 2010. The Group has repurchased 36.1 million shares for a total of \$1,742 million in the first nine months, whilst 10.7 million shares were issued in consideration of share option exercises for a total of \$445 million. The total number of shares in issue at 30 September 2010 was 1,425 million.

## Research and Development Update

A comprehensive update of the AstraZeneca R&D pipeline was presented in conjunction with the Half Year 2010 results announcement, and remains available on the Company's website, [www.astrazeneca.com](http://www.astrazeneca.com), under information for investors.

Significant pipeline developments since the half year update include:

### ***Brilinta/Brilique***

On 24 September, AstraZeneca announced that the Committee for Medicinal Products for Human Use (CHMP) in Europe issued a positive opinion on the marketing authorisation application for *Brilique* (ticagrelor) for the prevention of atherothrombotic events in adult patients with Acute Coronary Syndromes (ACS). The positive opinion by the Committee is now referred for a final decision by the European Commission. The European Commission, which makes the decision whether to approve a new drug candidate for use in the European Union, typically renders its decision within a few months of the CHMP issuing its opinion.

On 15 September, the Company announced that the US Food and Drug Administration (FDA) has extended the time to complete its review of the New Drug Application (NDA) for *Brilinta* (ticagrelor). Accordingly, the FDA extended the Prescription Drug User Fee Act (PDUFA) date from 16 September 2010 to 16 December 2010. AstraZeneca will continue to work closely with the FDA to support the review of the ticagrelor NDA.

On 1 October 2010, AstraZeneca announced the initiation of a large, international, clinical outcomes study for ticagrelor in collaboration with the Brigham and Women's Hospital-based Thrombolysis in Myocardial Infarction (TIMI) Study Group. The PEGASUS-TIMI 54 study is scheduled to begin patient enrolment during the fourth quarter 2010.

Current treatment guidelines for ACS patients recommend dual antiplatelet therapy for up to twelve months post-event, followed by longer-term treatment with aspirin alone.

The PEGASUS-TIMI 54 study will examine the long-term efficacy and safety of ticagrelor in patients who have sustained a heart attack from one to three years prior to enrolment. Such individuals are at substantially increased risk for another cardiovascular event. The study aims to determine in this group of patients if treatment with ticagrelor and aspirin will further reduce the risk of subsequent cardiovascular events compared to aspirin alone.

### ***Vimovo***

On 11 October, AstraZeneca and POZEN Inc. announced that *Vimovo* (naproxen/esomeprazole magnesium) 500/20mg modified-release tablets has cleared an important regulatory milestone by receiving positive agreement for approval in 23 countries across the European Union (EU). This follows all 22 Concerned Member States agreeing with the assessment of the Netherlands Health Authority, acting as the Reference Member State for the Decentralised Procedure. It also results in a harmonised Summary of Product Characteristics. The Member States will now pursue pricing and reimbursement and national approvals.

*Vimovo*, co-developed by POZEN Inc. and AstraZeneca, is indicated in Europe for the symptomatic treatment of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis in patients who are at risk for developing non-steroidal anti-inflammatory drug (NSAID)-associated gastric and/or duodenal ulcers and where treatment with lower doses of naproxen or of other NSAIDs is not considered sufficient.

### **Lesogaberan (AZD3355)**

Based on a review of phase II dose finding study results with the reflux inhibitor lesogaberan (AZD3355), a GABA<sub>B</sub> agonist under investigation for the treatment of gastroesophageal reflux disease, AstraZeneca has decided to terminate development of this compound.

Lesogaberan was one of the pipeline assets covered by the Merck exit arrangements (see Note 6). As a result of the termination of further development, the intangible asset associated with this project has been impaired, resulting in a \$128 million charge to cost of sales in the third quarter.

## **Zibotentan**

On 27 September, AstraZeneca announced that a study evaluating zibotentan for the treatment of men with metastatic castration resistant prostate cancer (CRPC) did not show a significant improvement in the primary endpoint of overall survival.

Study 14 was a randomised, placebo controlled phase III study which evaluated zibotentan 10mg added to standard of care treatment in 594 patients with metastatic CRPC. The safety and tolerability profile of zibotentan in this trial was in line with previous studies.

Based on this study result, AstraZeneca plans no regulatory submissions for zibotentan at this time. The zibotentan ENTHUSE trial programme includes two other ongoing studies with zibotentan in different CRPC settings. The full results of study 14 will be published in 2011.

## **Vandetanib**

On 23 September, AstraZeneca announced that the US FDA and the European Medicines Agency (EMA) have accepted regulatory submissions for review of the investigational drug vandetanib in the treatment of patients with advanced medullary thyroid cancer (MTC). The FDA also granted priority review status for the NDA and set a PDUFA action date of 7 January 2011. The Oncologic Drugs Advisory Committee of the FDA is scheduled to discuss the NDA at its meeting on 2 December 2010.

The submissions are supported by the results from the ZETA study evaluating the safety and efficacy of vandetanib compared to placebo in patients with advanced MTC. MTC accounts for 5 percent of all thyroid cancers. The American Cancer Society estimates that more than 44,000 new cases of thyroid cancer will be diagnosed in the United States in 2010. Across Europe the incidence is over 50,000 cases per year.

AstraZeneca is consulting with regulatory authorities on a proposed trade name for vandetanib.

## **Dapagliflozin**

Dapagliflozin, an investigational compound, is a first-in-class sodium-glucose cotransporter-2 (SGLT2) inhibitor and is currently in Phase III trials under joint development by AstraZeneca and Bristol-Myers Squibb as a once-daily oral therapy for the treatment of adult patients with type 2 diabetes. SGLT2 inhibitors, which act independently of insulin mechanisms, facilitate the excretion of glucose and associated calories in the urine, thereby lowering blood glucose levels.

In September 2010, at the European Association for the Study of Diabetes meeting in Stockholm, AstraZeneca and Bristol-Myers Squibb presented data from two Phase III studies of dapagliflozin. Data from a 24-week study demonstrate that dapagliflozin improved glycosylated hemoglobin levels (HbA1c) when added to glimepiride in adults with type 2 diabetes, compared to glimepiride alone. Data from a 52-week study demonstrate that dapagliflozin plus metformin was similar to glipizide plus metformin in improving HbA1c in adults with type 2 diabetes. In addition, the data demonstrated that dapagliflozin plus metformin reduced total body weight, compared to increases in body weight reported with glipizide, and reduced the number of patients reporting one or more hypoglycemic events.

A planned analysis of cardiovascular (CV) event data from the phase III dapagliflozin development programme, mandated by the new FDA guidelines, was recently completed. Based on this analysis, the Companies believe the data meet the guidance set forth by the FDA regarding assessment of CV risk and thus are deemed sufficient to support a filing. Therefore, the Companies continue to progress the global development plan and are targeting US and EU regulatory filings by the end of 2010/early 2011.

## **ONGLYZA™ fixed dose combination with metformin**

In August 2010, the Marketing Authorisation Application for a fixed dose combination of ONGLYZA™ plus metformin immediate release tablets as a treatment for adults with type 2 diabetes was validated by the European Medicines Agency.

In March 2010, AstraZeneca and Bristol-Myers Squibb announced that the US FDA has accepted for review an NDA for an investigational fixed dose combination of ONGLYZA™ plus metformin HCl extended-release tablets. The PDUFA date for the review is 29 October 2010.

## ***Seroquel XR***

On 11 September, AstraZeneca announced that the European Commission has issued a positive decision for the approval of once-daily *Seroquel XR* (quetiapine fumarate) Extended Release Tablets as an add-on treatment of major depressive episodes in patients with Major Depressive Disorder (MDD) who have had sub-optimal response to antidepressant monotherapy.

This decision follows a positive recommendation by the European Union CHMP in April of this year. AstraZeneca has secured approval in the 17 member states that took part in the original Mutual Recognition Procedure. For other member states timelines will vary.

The Company has withdrawn the mutual recognition procedure application for *Seroquel XR* for generalised anxiety disorder.

## **Motavizumab**

On 30 August, AstraZeneca announced that MedImmune, its biologics unit, has received a second complete response letter (CRL) on motavizumab from the US FDA. Based on the preliminary assessment of the CRL, it contains the following requirements that the Company should address to advance the motavizumab registration:

- The FDA has requested evidence from an additional clinical trial that supports a satisfactory risk/benefit profile in the population(s) for which the prophylaxis indication is being requested.

The Company continues to believe in the clinical benefit of motavizumab, and will conduct a complete review of the CRL, continue ongoing constructive dialogue with the FDA as well as make a decision regarding next steps in due course.

As previously disclosed, the Group holds intangible assets of \$445 million relating specifically to motavizumab, which may be subject to impairment following completion of the Group's analysis of the CRL. Any impairment would be excluded from Core earnings.

## ***Fluenz***

On 22 October, AstraZeneca announced that the European Union CHMP issued a positive opinion on the marketing authorisation application for *Fluenz* Influenza Vaccine (Live Attenuated, Nasal) its nasally administered live attenuated influenza vaccine (LAIV) for prevention of seasonal influenza. The CHMP issued its opinion for marketing this product in Europe for children 24 months to less than 18 years of age.

The Committee's positive opinion is now referred for a final decision by the European Commission, which typically renders its decision on whether to approve a new drug candidate for use in the European Union within a few months of the CHMP issuing its opinion.

## **Fostamatinib**

On 29 September 2010, the Company announced the enrollment of the first patient in the Phase III clinical development programme for fostamatinib, a novel oral Syk inhibitor. The Phase III programme, called OSKIRA (Oral Syk Inhibition in Rheumatoid Arthritis), is designed to investigate fostamatinib as a treatment for rheumatoid arthritis (RA) in patients with an inadequate response to disease modifying anti-rheumatic drugs (DMARDs), including methotrexate (MTX).

The OSKIRA clinical trial programme will include three pivotal Phase III studies assessing the efficacy and tolerability of fostamatinib: two 12-month studies examining the effect of fostamatinib on patients responding inadequately to DMARDs including MTX, and a six-month study assessing the effect of fostamatinib on patients who have previously responded inadequately to anti-TNF therapy. The fostamatinib programme will also include long-term safety extension studies involving more than 2,000 of the patients recruited during the course of the Phase II and III programmes.

## Future Prospects

As expected, the third quarter presented some challenging revenue and Core Earnings comparisons compared with the third quarter last year. The continued good revenue growth in markets outside the US was more than offset by a US performance that included the anticipated adverse impact of generic competition in the US and the absence of H1N1 pandemic flu vaccine revenues. Gross margin also reflected the adverse impact from the intangible impairment in the third quarter this year, compared with the provision release that benefited gross margin in the third quarter 2009.

The Company still expects demanding revenue and Core EPS comparisons to carry into the fourth quarter. Nevertheless, based on the year to date performance and the outlook for the rest of the year, revenue for the full year is now likely to be broadly unchanged in constant currency terms compared with full year 2009. Based on the January 2010 average exchange rates for our principal currencies, the target for Core EPS for the full year is in the range of \$6.50 to \$6.65, a narrowing of the previous \$6.35 to \$6.65 guidance range.

This target takes no account of the likelihood that average exchange rates for the remainder of 2010 may differ materially from the January 2010 average 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 2009 results announcement, and can be found on the AstraZeneca web site.

## Revenue

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

### Gastrointestinal

	Third Quarter		CER %	Nine Months		CER %
	2010 \$m	2009 \$m		2010 \$m	2009 \$m	
<i>Nexium</i>	1,242	1,243	+2	3,738	3,681	-
<i>Losec/Prilosec</i>	233	240	-4	743	696	+3
Total	1,512	1,517	+1	4,588	4,458	+1

- In the US, *Nexium* sales in the third quarter were \$682 million, down 1 percent compared with the third quarter last year. Dispensed retail tablet volume declined by around 4 percent, although *Nexium* market share of dispensed units is down only 0.3 percentage points in September 2010 compared with December 2009. Average realised selling prices for *Nexium* were around 4 percent higher than the third quarter last year.
- Nexium* sales in the US for the nine months were down 4 percent to \$2,030 million.
- Nexium* sales in other markets in the third quarter were up 5 percent to \$560 million. Sales in Emerging Markets increased by 16 percent, including 47 percent growth in China. Sales in Established Rest of World were up 5 percent, on 19 percent growth in Canada. Sales in Western Europe were up 1 percent. In Germany, several generic esomeprazole products were launched during September and October 2010. On 15 October 2010, AstraZeneca filed requests for preliminary injunctions to restrain the companies from marketing and selling these products in Germany.
- Nexium* sales in other markets were up 7 percent for the nine months to \$1,708 million.
- Prilosec* sales in the US were down 56 percent in the third quarter and were down 24 percent for the nine months. Sales for the nine months in the US were \$38 million.
- Sales of *Losec* in the Rest of World were unchanged at CER in the third quarter at \$225 million. Sales in China were up 23 percent. *Losec* sales in the Rest of World were up 5 percent for the nine months to \$705 million.

### Cardiovascular

	Third Quarter		CER %	Nine Months		CER %
	2010 \$m	2009 \$m		2010 \$m	2009 \$m	
<i>Crestor</i>	1,374	1,147	+20	4,104	3,245	+23
<i>Seloken/Toprol-XL</i>	273	414	-34	957	1,119	-16
<i>Atacand</i>	359	370	+1	1,108	1,049	+4
<i>Plendil</i>	63	60	+5	192	181	+4
<i>Zestril</i>	35	47	-21	117	141	-17
ONGLYZA <sup>™</sup>	19	9	+111	37	9	n/m
Total	2,249	2,191	+4	6,916	6,149	+10

- In the US, *Crestor* sales in the third quarter were up 20 percent to \$626 million. *Crestor* total prescriptions increased by 12 percent, nearly five times the statin market growth. *Crestor* share of total prescriptions continued to increase, reaching 12 percent in September 2010. *Crestor* dynamic share (new and switch patients) is now 15.4 percent, second only to generic simvastatin.
- US sales for *Crestor* for the nine months increased by 22 percent to \$1,888 million.
- Crestor* sales in Rest of World were up 21 percent to \$748 million in the third quarter on volume growth that is well ahead of the statin market. Sales in Western Europe were up 16 percent on good growth in France and Italy and a strong launch uptake in Spain. Sales in Established ROW were up 25 percent on strong growth in Canada, Japan and Australia. Sales in Emerging Markets were up 23 percent.
- Crestor* sales in the Rest of World were up 25 percent to \$2,216 million for the nine months.
- US sales of the *Toprol-XL* product range, which includes sales of the authorised generic, declined by 49 percent in the third quarter to \$149 million. Total prescriptions for the franchise were down 33 percent, reflecting the additional competition from the launch of the 100mg and 200mg dosage forms by Watson in early May and from the launch of the Wockhardt generic in August. Ex-factory volume was also lower compared with the third quarter

last year, which included pipeline filling for the authorised generic that followed a return to full supply. It remains difficult to ascertain when additional generic entrants may be approved in the US market.

- *Toprol-XL* franchise sales in the US for the nine months were down 26 percent to \$571 million.
- Sales of *Seloken* in other markets were up 3 percent in the third quarter and increased 6 percent for the nine months. Sales in Emerging Markets increased by 8 percent in the third quarter, and were up 14 percent for the nine months.
- US sales for *Atacand* were down 26 percent in the third quarter to \$52 million, and were down 16 percent for the nine months.
- *Atacand* sales in Rest of World were up 7 percent in the third quarter to \$307 million. For the year to date, those sales increased by 8 percent, chiefly on growth in Emerging Markets, where sales were up 21 percent for the nine months.
- Alliance revenue from the ONGLYZA™ collaboration with Bristol-Myers Squibb totalled \$19 million in the third quarter and \$37 million for the nine months. Alliance revenue in the US was \$16 million in the third quarter. ONGLYZA™ share of total prescriptions in the US DPP4 market reached 9.1 percent in the week ending 15 October. ONGLYZA™ share of patients newly starting DPP4 treatment was 24.5 percent.

### Respiratory and Inflammation

	Third Quarter		CER %	Nine Months		CER %
	2010	2009		2010	2009	
	\$m	\$m		\$m	\$m	
<i>Symbicort</i>	640	562	+19	2,005	1,628	+22
<i>Pulmicort</i>	180	320	-43	639	923	-32
<i>Rhinocort</i>	55	63	-13	175	199	-14
<i>Oxis</i>	15	16	-	48	44	+7
<i>Accolate</i>	17	17	-	50	49	-
Total	936	1,009	-4	3,013	2,941	+1

- *Symbicort* sales in the US were \$175 million in the third quarter, a 40 percent increase over last year. *Symbicort* share of new prescriptions for fixed combination products increased to 19.3 percent in September 2010, up another 0.4 percentage points since the beginning of the quarter. Market share of patients new to combination therapy is 26 percent.
- US sales of *Symbicort* for the nine months were \$529 million, an increase of 58 percent.
- *Symbicort* sales in other markets in the third quarter were \$465 million, 13 percent ahead of the third quarter last year. Sales in Established Rest of World increased by 56 percent, reflecting the launch in Japan where volume share is now over 20 percent. Sales in Emerging Markets were up 26 percent. Sales in Western Europe were up 4 percent.
- *Symbicort* sales in the Rest of World were up 13 percent to \$1,476 million for the nine months.
- US sales for *Pulmicort* in the third quarter were down 71 percent to \$61 million, as a result of the launch of the Teva generic budesonide inhaled suspension (BIS) product in December 2009. *Pulmicort Respules* share of dispensed BIS prescriptions was 17 percent in the quarter.
- US sales of *Pulmicort* for the nine months were down 59 percent to \$237 million.
- Sales of *Pulmicort* in the Rest of World for the nine months were up 12 percent to \$402 million on a 36 percent increase in Emerging Markets.



## Oncology

	Third Quarter		CER %	Nine Months		CER %
	2010 \$m	2009 \$m		2010 \$m	2009 \$m	
<i>Arimidex</i>	284	476	-38	1,234	1,422	-14
<i>Casodex</i>	137	174	-23	431	655	-36
<i>Zoladex</i>	268	282	-5	813	786	-1
<i>Iressa</i>	102	75	+33	278	218	+24
<i>Faslodex</i>	84	67	+31	234	190	+24
<i>Nolvadex</i>	21	22	-9	64	64	-5
Total	899	1,099	-18	3,063	3,349	-10

- In the US, sales of *Arimidex* were down 80 percent in the third quarter to \$43 million following a number of generic approvals at the end of June 2010. Total prescriptions for *Arimidex* were down 81 percent in the quarter.
- US sales for *Arimidex* for the nine months were down 28 percent to \$472 million.
- *Arimidex* sales in other markets were down 4 percent in the third quarter to \$241 million. Under the terms of the European Union Paediatric Regulation, the Supplementary Protection Certificate (SPC) Extensions received in 12 applicable EU Member States (including France, Italy and the UK) have extended market exclusivity from August 2010 until February 2011. ROW sales for the nine months were \$762 million, down 2 percent.
- *Casodex* sales in the US in the third quarter were down 79 percent to \$3 million, as a result of generic competition that began in the third quarter last year. *Casodex* sales in the US for the nine months were down 89 percent to \$14 million.
- *Casodex* sales in the Rest of World in the third quarter were down 18 percent to \$134 million, chiefly on generic erosion in Western Europe and Japan. Sales for the nine months in Rest of World were down 23 percent to \$417 million.
- *Iressa* sales increased by 24 percent to \$278 million for the nine months, including \$29 million of sales in Western Europe. Sales in Japan were up 7 percent. Sales in Emerging Markets were up 19 percent, including a 22 percent increase in China.
- *Faslodex* sales for the nine months increased by 17 percent in the US to \$98 million and grew by 29 percent in the Rest of World to \$136 million.

## Neuroscience

	Third Quarter		CER %	Nine Months		CER %
	2010 \$m	2009 \$m		2010 \$m	2009 \$m	
<i>Seroquel</i>	1,303	1,231	+7	3,962	3,605	+9
<i>Seroquel IR</i>	1,024	1,039	-1	3,124	3,130	-1
<i>Seroquel XR</i>	279	192	+50	838	475	+76
<i>Zomig</i>	103	111	-5	318	319	-1
<i>Vimovo</i>	5	-	n/m	5	-	n/m
Total	1,644	1,578	+5	4,998	4,601	+8

- In the US, *Seroquel* franchise sales were up 10 percent to \$936 million in the third quarter. Total prescriptions for the *Seroquel* franchise increased by 0.6 percent in the third quarter. Total prescriptions for *Seroquel XR* increased by 73 percent, accounting for 15 percent of prescriptions for the franchise in the US. Market share for the *Seroquel* franchise was a market-leading 30.8 percent in September 2010 (down 17 basis points from June 2010).
- US sales for *Seroquel* for the nine months were \$2,814 million, 11 percent ahead of last year.
- *Seroquel* franchise sales in the Rest of World were \$367 million in the third quarter, a 1 percent increase. Sales of *Seroquel XR* increased by 35 percent, and now account for 33.5 percent of franchise sales outside the US. *Seroquel* franchise sales were down 4 percent in Established ROW, reflecting the phasing of shipments to our marketing partner in Japan partially offset by some growth in Canada now that generic erosion on the immediate release formulation has stabilised following loss of exclusivity in 2008. *Seroquel* franchise sales were up 10 percent in Emerging Markets. Franchise sales were unchanged in Western Europe.
- For the nine months, *Seroquel* sales in the Rest of World increased by 6 percent to \$1,148 million.

- *Vimovo* sales in the US were \$5 million in the third quarter, reflecting trade stocking ahead of sales force promotion that commenced in September 2010.

#### Infection and Other

	Third Quarter		CER %	Nine Months		CER %
	2010 \$m	2009 \$m		2010 \$m	2009 \$m	
<i>Synagis</i>	139	82	+70	641	681	-6
<i>Merrem</i>	204	221	-5	634	636	-3
<i>FluMist</i>	120	92	+30	123	94	+31
Non seasonal flu vaccine	-	152	n/m	39	152	-74
Total	493	582	-14	1,520	1,676	-10

- In the US, sales of *Synagis* for the nine months were down 29 percent to \$370 million, the majority of which were recorded during the RSV season in the first quarter, which was negatively impacted by the new guidelines published by the COID. Outside the US, *Synagis* sales were up 67 percent to \$271 million, reflecting timing differences in shipments to Abbott, our international distributor, rather than underlying sales trends.
- Sales of *FluMist* were \$120 million, a 30 percent increase over the third quarter last year.
- There was no revenue recorded in the third quarter for US government orders for Live Attenuated Influenza Vaccine (LAIV) against Novel Influenza A (H1N1). This strain has now been incorporated into the traditional seasonal influenza vaccine.

This project has been funded in whole or in part with Federal funds from HHS/ASPR/BARDA, under Contract No. HHS01002009000021.

#### Geographic Sales

	Third Quarter		CER %	Nine Months		CER %
	2010 \$m	2009 \$m		2010 \$m	2009 \$m	
US	3,179	3,659	-13	10,273	10,831	-5
Western Europe	2,150	2,286	+3	6,821	6,696	+4
Established ROW*	1,262	1,109	+5	3,701	3,146	+7
Emerging ROW	1,307	1,146	+14	3,857	3,186	+16

\* Established ROW comprises Canada, Japan, Australia and New Zealand.

- In the US, revenue was down 13 percent in the third quarter, as a result of generic competition for *Arimidex*, *Toprol-XL* and *Pulmicort Respules* as well as the absence of H1N1 pandemic influenza vaccine revenues that benefited the third quarter 2009. There was strong growth for *Crestor*, *Seroquel XR* and *Symbicort*.
- Revenue in Western Europe was up 3 percent in the third quarter, as good volume growth was partially offset by price reductions chiefly related to government interventions. Much of the volume growth was attributable to *Crestor*, *Seroquel XR* and *Symbicort*.
- Revenue in Established Rest of World was up 5 percent in the third quarter, largely the result of a 19 percent increase in Canada which was driven by *Crestor*. Revenue in Japan was up 1 percent, as good volume growth fuelled by *Crestor* and the *Symbicort* launch was largely offset by the impact of the biennial price reductions across the portfolio.
- Revenue in Emerging Rest of World was up 14 percent. Revenue in Emerging Europe was up 7 percent, as very strong volume growth was attenuated by price reductions, chiefly in Turkey. Revenue in China was up 27 percent on good growth for the PPI franchise, oncology and cardiovascular products. Revenue in Other Emerging ROW was up 17 percent, driven by *Atacand*, *Nexium* and *Crestor*.

## 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, 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 businesses and the key business drivers thereto. Core financial measures are adjusted to exclude certain items, such as charges and provisions related to our global restructuring and synergy programmes, amortisation and impairment of the significant intangibles relating to our acquisition of MedImmune Inc. in 2007 and our current and future exit arrangements with Merck in the US, and other specified items. More detail on the nature of these measures is given on page 37 of our Annual Report and Form 20-F Information 2009.

### Third Quarter

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

	Reported 2010	Restructuring	Merck & MedImmune Amortisation	Intangible Impairments	Legal Provisions	Core 2010	Core 2009	Actual %	CER %
<b>Revenue</b>	<b>7,898</b>	-	-	-	-	<b>7,898</b>	<b>8,200</b>	<b>(4)</b>	<b>(2)</b>
Cost of Sales	(1,524)	19	-	-	-	(1,505)	(1,239)		
<b>Gross Profit</b>	<b>6,374</b>	<b>19</b>	-	-	-	<b>6,393</b>	<b>6,961</b>	<b>(8)</b>	<b>(7)</b>
% sales	80.7%					80.9%	84.9%	-4.0	-4.2
Distribution	(82)	-	-	-	-	(82)	(73)	12	12
% sales	1.0%					1.0%	0.9%	-0.1	-0.1
R&D	(1,077)	91	-	-	-	(986)	(1,049)	(6)	(5)
% sales	13.6%					12.5%	12.8%	+0.3	+0.3
SG&A	(3,011)	102	115	-	478	(2,316)	(2,373)	(2)	(1)
% sales	38.1%					29.3%	28.9%	-0.4	-0.4
Other Income	202	-	20	-	-	222	143	54	56
% sales	2.5%					2.8%	1.7%	+1.1	+1.0
<b>Operating Profit</b>	<b>2,406</b>	<b>212</b>	<b>135</b>	-	<b>478</b>	<b>3,231</b>	<b>3,609</b>	<b>(10)</b>	<b>(10)</b>
% sales	30.5%					40.9%	44.0%	-3.1	-3.4
Net Finance Expense	(148)	-	-	-	-	(148)	(172)		
<b>Profit before Tax</b>	<b>2,258</b>	<b>212</b>	<b>135</b>	-	<b>478</b>	<b>3,083</b>	<b>3,437</b>	<b>(10)</b>	<b>(10)</b>
Taxation	(704)	(66)	(28)	-	(124)	(922)	(993)		
<b>Profit after Tax</b>	<b>1,554</b>	<b>146</b>	<b>107</b>	-	<b>354</b>	<b>2,161</b>	<b>2,444</b>	<b>(12)</b>	<b>(11)</b>
Non-controlling Interests	(6)	-	-	-	-	(6)	(6)		
<b>Net Profit</b>	<b>1,548</b>	<b>146</b>	<b>107</b>	-	<b>354</b>	<b>2,155</b>	<b>2,438</b>	<b>(12)</b>	<b>(11)</b>
Weighted Average Shares	1,437	1,437	1,437	1,437	1,437	1,437	1,449		
<b>Earnings per Share</b>	<b>1.08</b>	<b>0.10</b>	<b>0.08</b>	-	<b>0.24</b>	<b>1.50</b>	<b>1.68</b>	<b>(11)</b>	<b>(10)</b>

Revenue declined by 2 percent to \$7,898 million.

Core gross margin of 80.9% was 4.2 percentage points lower than last year. The charge for impairment of intangible assets related to lesogaberan (AZD3355) (1.6 percentage points) and the 2009 benefit from the release of a provision with respect to the resolution of an issue related to a third party supply contract (1.9 percentage points) were responsible for the majority of the decline. The remaining decline was as a result of higher royalty payments (0.9 percentage points) which were only partially offset by favourable mix and operating efficiencies (0.1 percentage points) and lower payments to Merck (0.1 percentage points).

Core SG&A costs of \$2,316 million were 1 percent lower than last year. Investments in Emerging Markets and recently launched brands were more than offset by operational efficiencies across Established Markets.

Core other income of \$222 million was \$79 million higher than last year including royalties received from sales of Teva's generic version of *Pulmicort Respules*.

Core Pre-R&D Operating Margin was 53.4 percent, down 3.7 percentage points, with higher other income more than offset by the lower gross margin described above.

Core R&D expenditure was \$986 million, 5 percent lower than last year, with continued investment in biologics being more than offset by reduced activity across the small molecule portfolio and efficiencies.

Core operating profit was \$3,231 million, down 10 percent. In comparison with last year against the dollar, the euro was 10 percent weaker (reducing sales and costs), the Swedish krona was unchanged (neutral to costs) and sterling was 6 percent weaker (reducing costs). Core operating margin decreased by 3.4 percentage points to 40.9 percent as a result of the negative impact on gross margin from an intangible asset impairment charge this quarter compared with the gross margin in the third quarter 2009, which included the release of a provision that benefited gross margin.

Core earnings per share in the third quarter were \$1.50, down 10 percent, in line with operating profit.

Reported operating profit was down 24 percent to \$2,406 million. Reported earnings per share were \$1.08 down 26 percent as a result of the factors affecting Core earnings per share, higher restructuring costs and legal provisions, with the largest impact arising from legal provisions totalling \$473 million in the third quarter 2010 which are related to ongoing product liability litigation for *Seroquel*.

## Nine Months

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

	Reported 2010	Restructuring	Merck & MedImmune Amortisation	Intangible Impairments	Legal Provisions	Core 2010	Core 2009	Actual %	CER %
<b>Revenue</b>	<b>24,652</b>	-	-	-	-	<b>24,652</b>	<b>23,859</b>	<b>3</b>	<b>2</b>
Cost of Sales	(4,630)	110	-	-	-	(4,520)	(3,971)		
<b>Gross Profit</b>	<b>20,022</b>	<b>110</b>	-	-	-	<b>20,132</b>	<b>19,888</b>	<b>1</b>	-
% sales	81.2%					81.7%	83.4%	-1.7	-1.8
Distribution	(248)	-	-	-	-	(248)	(207)	19	16
% sales	1.0%					1.0%	0.9%	-0.1	-0.1
R&D	(3,388)	463	-	-	-	(2,925)	(3,064)	(5)	(6)
% sales	13.7%					11.9%	12.9%	+1.0	+1.0
SG&A	(7,923)	204	327	-	493	(6,899)	(6,825)	1	-
% sales	32.1%					28.0%	28.6%	+0.6	+0.6
Other Income	620	-	58	-	-	678	785	(14)	(14)
% sales	2.5%					2.8%	3.3%	-0.5	-0.5
<b>Operating Profit</b>	<b>9,083</b>	<b>777</b>	<b>385</b>	-	<b>493</b>	<b>10,738</b>	<b>10,577</b>	<b>2</b>	-
% sales	36.9%					43.6%	44.3%	-0.7	-0.8
Net Finance Expense	(389)	-	-	-	-	(389)	(575)		
<b>Profit before Tax</b>	<b>8,694</b>	<b>777</b>	<b>385</b>	-	<b>493</b>	<b>10,349</b>	<b>10,002</b>	<b>3</b>	<b>2</b>
Taxation	(2,245)	(201)	(74)	-	(127)	(2,647)	(2,892)		
<b>Profit after Tax</b>	<b>6,449</b>	<b>576</b>	<b>311</b>	-	<b>366</b>	<b>7,702</b>	<b>7,110</b>	<b>8</b>	<b>6</b>
Non-controlling Interests	(17)	-	-	-	-	(17)	(14)		
<b>Net Profit</b>	<b>6,432</b>	<b>576</b>	<b>311</b>	-	<b>366</b>	<b>7,685</b>	<b>7,096</b>	<b>8</b>	<b>6</b>
Weighted Average Shares	1,445	1,445	1,445	1,445	1,445	1,445	1,448		
<b>Earnings per Share</b>	<b>4.45</b>	<b>0.40</b>	<b>0.22</b>	-	<b>0.25</b>	<b>5.32</b>	<b>4.90</b>	<b>9</b>	<b>7</b>

Revenue grew by 2 percent to \$24,652 million.

Core gross margin of 81.7 percent was 1.8 percentage points lower than last year. The third quarter intangible impairment (0.5 percentage points), the 2009 benefit from the release of a provision with respect to the resolution of an issue related to a third party supply contract (0.7 percentage points), higher royalty payments (0.4 percentage points) and regional and product mix factors (0.4 percentage points) were only partially offset by lower payments to Merck (0.2 percentage points).

Core SG&A costs of \$6,899 million were flat at CER compared with last year. Investments in Emerging Markets and recently launched brands together with higher legal costs were mostly offset by operational efficiencies across Established Markets.

Core other income of \$678 million was \$107 million lower than last year chiefly as a result of the prior year Nordic OTC and Abraxane® disposal gains only being partially offset by royalties received from sales of Teva's generic version of *Pulmicort Respules*.

Core Pre-R&D Operating Margin was 55.5 percent, down 1.8 percentage points, with the lower gross margin and lower disposals within other income only partially offset by the leverage from revenue growth and efficiencies within SG&A.

Core R&D expenditure was \$2,925 million, 6 percent lower than last year, as the increased investment in biologics was more than offset by lower intangible impairments and project costs and efficiencies. The lower project costs reflect several late stage projects completing their trials.

Core operating profit was \$10,738 million, flat at CER. Core operating margin declined by 0.8 percentage points to 43.6 percent as a result of lower R&D expenditure and operational efficiencies which were more than offset by the third quarter items within gross margin.

Core earnings per share in the first nine months were \$5.32, up 7 percent, with operating performance boosted by

lower net finance expense and a lower effective tax rate largely due to the first quarter net adjustments to tax provisions (\$0.13).

Reported operating profit was down 3 percent to \$9,083 million. Reported earnings per share were \$4.45, up 6 percent, as a result of the factors affecting Core earnings per share partially offset by higher restructuring costs.

### **Finance Income and Expense**

Net finance expense was \$389 million for the year to September, versus \$575 million in 2009 (\$148 million for the quarter, versus \$172 million for the third quarter of 2009). Fair value gains of \$6 million were recorded on the long-term bonds in the year to September, versus fair value losses of \$130 million for the first nine months of 2009 (\$2 million loss for the quarter versus \$30 million loss for quarter three 2009). In addition to this, there is reduced interest payable on lower debt balances, and slightly increased returns from higher cash and cash equivalent balances.

### **Taxation**

The effective tax rate for the third quarter is 31.2 percent (2009 30.0 percent) and 25.8 percent for the first nine months (2009 30.8 percent). As previously disclosed, the effective tax rate has benefited from an adjustment in respect of prior periods following the announcement in February that AstraZeneca had settled a long-running transfer pricing issue and certain other outstanding UK tax matters with the UK Tax Authorities. The effect of this settlement and developments in other transfer pricing matters resulted in a net benefit to earnings of \$194 million which was reported in the first quarter. For the full year, the Company anticipates the tax rate to be around 27 percent.

### **Cash Flow**

Cash generated from operating activities was \$7,120 million for the nine months to 30 September 2010, compared with \$7,657 million in the corresponding period of 2009. The reduction of \$537 million is primarily driven by legal settlement payments relating to *Seroquel* sales and marketing practices and Average Wholesale Price litigation in the US of \$645 million, partially offset by a stronger underlying performance.

Net cash outflows from investing activities were \$1,888 million in the nine months compared with \$572 million in 2009. The increase of \$1,316 million is due primarily to higher net payments on externalisation activities of \$1,472 million (including the Merck First Option payment of \$647 million).

Net cash distributions to shareholders increased to \$4,658 million (from \$2,892 million in 2009) through dividend payments of \$3,361 million and net share repurchases of \$1,297 million.

## Debt and Capital Structure

As at 30 September 2010, gross debt (including loans, short-term borrowings and overdrafts) was \$10,607 million (31 December 2009: \$11,063 million). The reduction in gross debt of \$456 million during the first nine months of the year was principally due to the repayment on maturity of the Euro 500 million 18-month bond issued in July 2008, partially offset by an increase in short-term borrowings and overdrafts. Of the gross debt at 30 September 2010, \$1,376 million is due within one year (31 December 2009: \$1,926 million). Net funds of \$1,307 million have increased by \$772 million since 31 December 2009 as a result of the net cash inflow during the nine months to 30 September 2010 as described above.

## Calendar

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27 January 2011	Announcement of fourth quarter and full year 2010 results
28 April 2011	Announcement of first quarter 2011 results
28 April 2011	Annual General Meeting
28 July 2011	Announcement of second quarter and half year 2011 results
27 October 2011	Announcement of third quarter and nine months 2011 results

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