# AstraZeneca PLC THIRD QUARTER AND NINE MONTHS RESULTS 2009

London, 29 October 2009

## Third quarter revenue increased by 10 percent at constant exchange rates (CER) to \$8,200 million.

- -US sales of *Toprol-XL*, benefiting from withdrawal of generic products, accounted for 3 percent of global revenue growth at CER.
- -US sales of Novel Influenza A (H1N1) vaccine totalled \$152 million in the third quarter, accounting for 2 percent of global revenue growth at CER.
- -Emerging Markets revenue was up 15 percent at CER; on track for double-digit growth for the full year.

Core operating profit in the third quarter increased by 29 percent at CER to \$3,609 million on revenue growth and operational efficiencies.

Core EPS in the third quarter increased by 27 percent at CER to \$1.68.

#### Reported EPS in the third quarter increased by 22 percent at CER to \$1.46.

-Agreement in principle reached with the US Attorney's Office in Philadelphia to resolve its investigations related to *Seroquel* sales and marketing practices. This accounts for \$520 million of the \$538 million provisions taken in the first nine months, \$108 million of which taken in third guarter (see Note 4).

Strong cash flows have reduced net debt by \$3,981 million since 31 December 2008.

# Pipeline developments include:

- -New diabetes treatment ONGLYZA<sup>™</sup> approved in the US and the European Union.
- -Brilinta submitted for regulatory approval in the European Union; on track for US submission in the fourth quarter.
- -New late stage development collaborations announced with Forest Laboratories and Nektar Therapeutics.
- -Regulatory submissions for *Zactima* have been withdrawn, based upon an updated analysis that demonstrated no overall survival advantage when added to chemotherapy.

Core EPS target for the full year increased to range of \$6.20 to \$6.40.

# Financial Summary

Group	3 <sup>rd</sup> Quarter 2009 <u>\$m</u>	3 <sup>rd</sup> Quarter 2008 \$m	Actual <u>%</u>	CER <u>%</u>	9 Months 2009 <u>\$m</u>	9 Months 2008 <u>\$m</u>	Actual <u>%</u>	CER <u>%</u>
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Revenue	8,200	7,775	+5	+10	23,859	23,408	+2	+8
Reported								
Operating Profit	3,204	2,522	+27	+25	9,218	7,252	+27	+27
Profit before Tax	3,032	2,443	+24	+23	8,643	6,865	+26	+26
Earnings per Share	\$1.46	\$1.20	+23	+22	\$4.12	\$3.34	+24	+23
Core*								
Operating Profit	3,609	2,771	+30	+29	10,577	8,273	+28	+29
Profit before Tax	3,437	2,692	+28	+27	10,002	7,886	+27	+27
Earnings per Share	\$1.68	\$1.32	+28	+27	\$4.90	\$3.85	+27	+28

<sup>\*</sup> Core financial measures are supplemental non-GAAP measures which management believe enhances understanding of the Company's performance; it is upon these measures that financial guidance for 2009 is based. See page 10 for a definition of Core financial measures and pages 10 and 11 for a reconciliation of Core to Reported financial measures.

**David Brennan, Chief Executive Officer, said**: "Our strong business performance is driven by good operating execution bolstered by revenue upsides from *Toprol-XL* and H1N1 vaccine sales. All these factors are reflected in our results for the first nine months and our increased Core EPS target for the full year. Since the half year we have made progress on the pipeline with the approval of ONGLYZA<sup>TM</sup>, the European submission for *Brilinta* and new external collaborations, tempered by the disappointing news on *Zactima*."

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

### **Third Quarter**

Revenue in the third quarter increased by 10 percent at CER, but was up 5 percent on an actual basis as a result of the negative impact of exchange rate movements. Revenue benefited from strong growth of the *Toprol-XL* franchise in the US as a result of the market withdrawal by two generic competitors and from revenues from US government orders for vaccine for Novel Influenza A (H1N1); adjusting for these factors, global revenue increased by 5 percent. US revenue was up 14 percent (3 percent excluding *Toprol-XL* and H1N1 vaccine sales). Revenue in the Rest of World was also up 7 percent. Revenue in Established Markets was up 4 percent. Emerging Markets revenue growth was 15 percent. Double-digit revenue growth in Emerging Markets is anticipated for the full year.

Core operating profit in the third quarter was up 29 percent to \$3,609 million. The increase was chiefly the result of higher revenue; the added contribution from gross margin and lower R&D expenditures was partially offset by higher SG&A expense and slightly lower other income. Reported operating profit increased by 25 percent to \$3,204 million; this growth rate was slightly below the growth in Core operating profit, reflecting provisions totalling \$108 million with respect to various federal and state investigations and civil litigation matters relating to drug marketing and pricing practices taken in the third quarter 2009 and impairment charges relating to revised estimates of the potential value of licenses for the proprietary reverse genetics vaccine technology acquired with MedImmune.

Core earnings per share in the third quarter were \$1.68 compared with \$1.32 in the third quarter 2008, a 27 percent increase at CER, broadly in line with the growth in Core operating profit in the quarter. Reported earnings per share in the third quarter were up 22 percent to \$1.46, after charging the legal provisions as well as the intangible impairment.

#### Nine Months

Revenue for the nine months increased by 8 percent at CER, but was up 2 percent on an actual basis as a result of the negative impact of exchange rate movements. Global revenue growth was 5 percent excluding US *Toprol-XL* and H1N1 vaccine sales. Revenue in the US was up 11 percent (4 percent excluding *Toprol-XL* and H1N1 vaccine sales). Revenue in the Rest of World was up 6 percent. Revenue in Established Markets was up 4 percent. Revenue in Emerging Markets increased by 13 percent.

Core operating profit increased by 29 percent to \$10,577 million as a result of revenue growth, operating efficiencies and higher other income compared with the nine months of 2008. Reported operating profit was \$9,218 million, an increase of 27 percent, broadly comparable to the growth in Core operating profit, as the negative impact of \$538 million in legal provisions taken in the second and third quarters of 2009 was somewhat offset by the *Ethyol* impairment that was charged in the first quarter 2008.

Core earnings per share for the nine months were \$4.90, an increase of 28 percent, in line with the growth in Core operating profit. Reported EPS increased by 23 percent to \$4.12, reflecting the effects of the legal provisions and the *Ethyol* impairment noted above. The other adjustments from Core to Reported EPS (restructuring costs and MedImmune and Merck amortisation) were broadly similar for both periods.

## Research and Development Update

A comprehensive update of the AstraZeneca R&D pipeline was presented in conjunction with the Half Year 2009 results announcement on 30 July, and the pipeline table remains available on the Company's website, <a href="https://www.astrazeneca.com">www.astrazeneca.com</a>, under information for investors.

Continued progress has been made on strengthening the pipeline since the Half Year 2009 update, including significant regulatory approvals and two new licensing collaborations:

#### ONGLYZA™

On 31 July 2009, AstraZeneca and Bristol-Myers Squibb announced that the US Food and Drug Administration (FDA) approved ONGLYZA<sup>TM</sup> (saxagliptin) for the treatment of type 2 diabetes mellitus in adults.

On 5 October 2009, the companies announced that the European Commission granted marketing authorisation for ONGLYZA<sup>TM</sup> in the 27 countries of the European Union, for the indication of adult patients with type 2 diabetes mellitus to improve glycaemic control in combination with metformin, a sulphonylurea, or a thiazolidinedione.

#### Ceftaroline

On 12 August 2009, AstraZeneca and Forest Laboratories announced a definitive collaboration agreement to co-develop and commercialise ceftaroline in all major markets outside the United States, Canada and Japan. Ceftaroline is Forest's late stage, next generation cephalosporin being investigated for the treatment of complicated skin and skin structure infections (cSSSI) and community-acquired bacterial pneumonia (CABP). Ceftaroline demonstrates bactericidal activity against a broad range of pathogens commonly implicated in cSSSI and CABP, including methicillin-resistant Staphylococcus aureus (MRSA) and multi-drug resistant Streptococcus pneumoniae (MDRSP).

Forest expects to file a New Drug Application (NDA) in the US by the end of 2009 with AstraZeneca filing a Marketing Authorisation Application (MAA) in Europe by the end of 2010.

#### NKTR-118 and NKTR-119

On 24 September 2009, AstraZeneca and Nektar Therapeutics announced an exclusive worldwide license agreement for two drug development programmes: NKTR-118, a late stage investigational product being evaluated for the treatment of opioid-induced constipation, and the NKTR-119 programme, an early stage programme that is intended to deliver products for the treatment of pain without constipation side effects. Both programmes were developed by Nektar, utilising their proprietary small molecule advanced polymer conjugate technology platform.

Under the terms of the agreement, AstraZeneca will assume responsibility for the continued development of both programmes, including the initiation of late stage clinical activities for NKTR-118. AstraZeneca expects completion of the design of the phase III programme in the near term, and anticipates filing the drug with regulators in 2013.

Other significant pipeline developments include:

#### Zactima

On 28 October 2009, AstraZeneca announced that it has withdrawn the regulatory submissions for the use of *Zactima* (vandetanib) 100mg in combination with chemotherapy in patients with advanced non-small cell lung cancer (NSCLC) from the US FDA and the European Medicines Agency (EMEA). The applications were submitted to regulatory agencies in June 2009.

The decision to withdraw this submission was based on an updated analysis that demonstrated no overall survival advantage when vandetanib was added to chemotherapy as well as preliminary feedback from regulatory agencies that the current package with progression-free survival (PFS) as the primary endpoint may not be sufficient for approval.

Phase III clinical trial results demonstrate that vandetanib is clinically active when used in combination with chemotherapy. AstraZeneca will complete the ongoing Phase III trial programme which will give a more complete view of vandetanib efficacy in different clinical settings. Results from the ZEPHYR (300mg monotherapy study in patients with advanced NSCLC who have previously received an EGFR inhibitor) and ZETA (300mg monotherapy in advanced medullary thyroid cancer) studies are expected in late 2009 or early 2010.

### Brilinta

On 26 October 2009, the MAA for *Brilinta* was submitted to the EMEA and the Company awaits validation of the application. The US NDA is on track for submission, as planned, for the fourth quarter.

On 30 August 2009, AstraZeneca announced results from the Phase III head to head trial, PLATO (A Study of **Plat**elet Inhibition and Patient **O**utcomes), which demonstrate that ticagrelor (*Brilinta*) achieved greater efficacy in the primary endpoint, reduction of cardiovascular events (CV death, MI, stroke) over clopidogrel (Plavix®/Iscover®), without an increase in major bleeding. This efficacy endpoint was driven by a statistically significant reduction in both CV death and heart attacks (myocardial infarction) with no difference in stroke. Ticagrelor is the first investigational antiplatelet that has demonstrated a reduction in CV death versus clopidogrel in patients with acute coronary syndromes (ACS).

The PLATO trial design prospectively identified 66 subgroups including 33 efficacy and 33 safety. The findings from 62 of the 66 subgroups were consistent with the results in the overall study population.

Given the large number of subgroups evaluated, the four inconsistent findings may have been due to chance. One of the four subgroups showed a difference in efficacy results between patients in North America and those enrolled elsewhere. Alongside explanation by the play of chance, this raised questions of whether geographic differences between populations of patients or practice patterns influenced the effects of the randomised treatments. While no definitive explanation has been found to date, further analyses suggest a possible association between aspirin dose and the primary efficacy results, such that reduced efficacy was observed with ticagrelor and increasing aspirin doses. The Company and the PLATO investigators are continuing to explore these and other hypotheses, as well as other follow-on analyses of the PLATO trial data set, and plan to publish in due course.

Further scientific exchange of *Brilinta* data is planned, with eight presentations being accepted at the American Heart Association (AHA) Scientific Sessions in November. These presentations include:

- A Late-Breaker clinical trial presentation for the STEMI ACS cohort in PLATO
- First presentation of the ONSET/OFFSET Phase II study, investigating the speed of onset and offset of antiplatelet effect of ticagrelor versus clopidogrel.
- First presentation of the RESPOND Phase II study, comparing antiplatelet response of patients with ticagrelor versus clopidogrel.

Further Brilinta data from these studies will be published throughout 2010.

### Seroquel/Seroquel XR

On 29 September 2009, AstraZeneca announced that *Seroquel XR* and *Seroquel* have been approved under the European Mutual Recognition Procedure for the prevention of recurrence of bipolar disorder in patients whose manic, mixed or depressive episode has responded to quetiapine treatment.

Following this new indication, *Seroquel* and *Seroquel XR* are the only agents approved in the European Union to treat all phases of bipolar disorder – acute depressive episodes, acute manic episodes and maintenance treatment to prevent recurrence of any mood event in bipolar disorder.

#### Novel Influenza A (H1N1) Vaccine

On 15 September 2009, the Company received approval from the US FDA for its live attenuated influenza vaccine (LAIV) against the Novel Influenza A (H1N1) virus. The vaccine is indicated for the active immunisation of individuals 2-49 years of age against influenza caused by pandemic (H1N1) 2009 virus.

The US government has placed orders for approximately 40 million doses of LAIV for the H1N1 strain to date, with a total cumulative contract value of approximately \$453 million. Enough bulk vaccine to fill all orders placed by the US government has been manufactured. Distribution at the direction of public health authorities has already begun.

### Crestor

On 16 October 2009, the Company announced the US FDA approved *Crestor* for use in paediatric patients ages 10-17 with heterozygous familial hypercholesterolemia (HeFH) when diet therapy fails to reduce elevated cholesterol. HeFH, a genetic disease, is characterised by high LDL cholesterol (the "bad" cholesterol) and increased risk of early cardiovascular disease.

The FDA decision was based on a supplemental NDA submitted by AstraZeneca, which included data from the PLUTO (<u>P</u>aediatric <u>L</u>ipid-red<u>U</u>ction <u>T</u>rial of r<u>O</u>suvastatin) study. PLUTO was designed to evaluate the efficacy and safety of *Crestor* in children aged 10-17 with HeFH.

The completion and submission of the PLUTO study satisfied AstraZeneca's commitment to the FDA to conduct a study evaluating the impact of *Crestor* on this paediatric population, which resulted in the grant, in July 2009, of an additional six-month period of exclusivity to market *Crestor* for its approved cholesterol and atherosclerosis indications until July 2016.

Regulatory applications to amend the *Crestor* label to incorporate outcomes data from the JUPITER study are now under review by regulatory authorities in the US and in Europe. The Company has been informed that the US sNDA will be discussed at a meeting of the US FDA Endocrinologic and Metabolic Drugs Advisory Committee scheduled for 15 December 2009.

## **Symbicort**

On 16 October 2009, AstraZeneca announced that *Symbicort Turbuhaler* has been approved by Japan's Ministry of Health, Labour and Welfare (MHLW) for the maintenance treatment of bronchial asthma in patients aged 16 and over when a combination therapy of an inhaled steroid and a long-acting beta-2 agonist is necessary.

AstraZeneca and Astellas Pharma Inc. signed an agreement to co-promote *Symbicort Turbuhaler* in August 2009. The product will be manufactured and developed by AstraZeneca and distributed and sold by Astellas, while promotion will be jointly carried out by both companies.

#### Vimovo

On 16 October 2009, AstraZeneca and POZEN Inc. announced that AstraZeneca had submitted an MAA in the European Union via the Decentralised Procedure (DCP) for *Vimovo* (naproxen/esomeprazole magnesium, formerly known as PN 400) tablets, a product under investigation for the treatment of the signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis in patients who are at risk of developing NSAID-associated ulcers.

In June 2009, POZEN submitted an NDA to the US FDA for *Vimovo*. The NDA was accepted on 31 August 2009, and is currently under review.

## **Enhancing Productivity**

Good progress continues on the previously announced business reshaping programmes. In the third quarter, \$112 million in restructuring costs were charged, bringing the total charges for the nine months to \$374 million.

All programmes remain on track to deliver the expected benefits of \$2.1 billion per annum by 2010, with a further \$0.4 billion by 2013.

#### **Future Prospects**

Business performance in the context of tough global economic conditions has been better than we anticipated which, together with good operating execution and some unexpected revenue upsides (including *Toprol-XL* and delayed generic entry of *Casodex* in the US), combined to drive our strong performance in the first half. As expected, this trend has continued in the third quarter, including an uplift from initial sales of H1N1 influenza vaccine. The outlook for the remainder of the year has been boosted by several factors: the approval of an additional generic competitor for *Toprol-XL* for less than the full range of dosage strengths; additional orders for H1N1 influenza vaccine at the top of our estimate (at a production schedule which results in most of the revenue recognition in 2009); and the release of a provision within Cost of Sales that further benefited gross margin.

The Company now anticipates sales growth in the range of mid to high single-digits at CER for the full year. Core EPS is now anticipated in the range of \$6.20 to \$6.40.

This target takes no account of the likelihood that average exchange rates for the remainder of 2009 may differ materially from the January 2009 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 2008 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

*Nexium Losec/Prilosec* Total

Third C	Quarter	CER %	Nine N	CER %	
2009	2008		2009	2008	
\$m	\$m		\$m	\$m	
1,243	1,315	-1	3,681	3,876	+1
240	249	-3	696	791	-9
1,517	1,589	-1	4,458	4,733	-1

- In the US, *Nexium* sales in the third quarter were \$689 million, down 12 percent compared with the third quarter last year. Dispensed retail tablet volume decreased by around 1 percent. Average realised selling prices for *Nexium* were around 13 percent lower in the quarter, and around 9 percent for the year to date, in line with expectations for a high single-digit price decline for the full year.
- Nexium sales in the US for the nine months were down 7 percent to \$2,118 million.
- Nexium sales in other markets in the third quarter were up 13 percent to \$554 million. Sales in Western Europe
  were up 11 percent. Sales in Emerging Markets were up 30 percent, including 55 percent growth in China.
- Nexium sales in other markets were up 11 percent for the nine months to \$1,563 million.
- *Prilosec* sales in the US were down 54 percent in the third quarter and were down 64 percent for the nine months, as a result of the entry of generic competition to the 40mg dosage form in the second half of 2008.
- Sales of *Losec* in the Rest of World were up 6 percent in the third quarter, on good growth in Japan (up 15 percent) and China (up 33 percent). *Losec* sales in the Rest of World were up 2 percent for the nine months.

# Cardiovascular

Crestor Seloken /Toprol-XL Atacand Plendil Zestril ONGLYZA™<sup>\*</sup> Total

Third C	Quarter	CER %	Nine N	/lonths	CER %
2009	2008		2009	2008	
\$m	\$m		\$m	\$m	
1,147	922	+30	3,245	2,610	+32
414	204	+110	1,119	600	+32 +95
370	386	+5	1,049	1,120	+6
60	65	-5	181	201	-5
47	60	-15	141	184	-15
9	-	n/m	9	-	n/m
2,191	1,782	+29	6,149	5,160	+28

- ONGLYZA<sup>TM</sup> is recorded as "Alliance Revenue". This does not represent ex-factory sales, but rather AstraZeneca share of the gross profit from its collaboration with Bristol-Myers Squibb on this product.
- In the US, *Crestor* sales in the third quarter were up 25 percent to \$523 million. *Crestor* total prescriptions increased by 25 percent, compared with 6 percent for the statin market overall. *Crestor* share of total prescriptions continued to increase, reaching 11 percent in September 2009.
- US sales for Crestor for the nine months increased by 30 percent to \$1,548 million.
- Crestor sales in the Rest of World were up 34 percent to \$624 million in the third quarter. Crestor volume growth continues to run well ahead of the statin market growth in both Established and Emerging Markets. There was strong growth in Western Europe (up 26 percent), Canada (up 28 percent), Japan (up 43 percent) and Australia (up 64 percent). Sales in Emerging Markets were up 41 percent.
- Crestor sales in the Rest of World were up 34 percent to \$1,697 million for the nine months.

- US sales of the *Toprol-XL* product range, which includes sales of the authorised generic, increased by 307 percent in the third quarter to \$293 million. Total prescriptions for the franchise increased by 118 percent. Price changes and additional pipeline filling of the authorised generic as full supply was restored accounted for the balance of the sales growth. In the third quarter, Watson entered the market with a generic metoprolol succinate product, although their initial approval was confined to the 25mg and 50mg dosage strengths. The Watson product accounted for around 6 percent of total prescriptions for metoprolol succinate in September 2009. The two original generic competitor products remain off the US market, and it remains difficult to ascertain when or if these products will return to the market or when potential new entrants may be approved.
- Toprol-XL franchise sales in the US for the nine months were up 271 percent to \$767 million.
- Sales of Seloken in other markets were up 2 percent in both the third quarter and for the nine months on doubledigit growth in Emerging Markets.
- US sales of *Atacand* were up 4 percent in the third quarter and down 1 percent for the nine months. *Atacand* sales in Rest of World were up 5 percent in the third quarter and 7 percent for the year to date.
- Alliance revenue from the ONGLYZA<sup>™</sup> collaboration with Bristol-Myers Squibb was \$9 million in the third quarter, reflecting AstraZeneca's share of launch stocking sales in the US following US FDA approval on 31 July 2009.

Respiratory and Inflammation

	Third G	Quarter	CER %	Nine N	CER %	
	2009	2009 2008		2009 2008		
	\$m	\$m		\$m	\$m	
Symbicort	562	501	+22	1,628	1,490	+23
Pulmicort	320	304	+8	923	1,098	-12
Rhinocort	63	72	-7	199	244	-13
Oxis	16	18	-	44	56	-5
Accolate	17	18	-	49	55	-7
Total	1,009	951	+13	2,941	3,069	+5

- Symbicort sales in the US were \$125 million in the third quarter, a 95 percent increase over last year. The launch of the COPD indication as well as continued market penetration in asthma is fuelling this growth. Symbicort share of new prescriptions for fixed combination products increased to 16.6 percent in September 2009, up 2.7 percentage points in the quarter; market share of patients new to combination therapy is now 26.3 percent.
- US sales of Symbicort for the nine months were \$335 million, an increase of 103 percent.
- Symbicort sales in other markets in the third quarter were \$437 million, 11 percent ahead of the third quarter last year. Sales in Western Europe were up 8 percent. Emerging Markets sales were up 22 percent in the quarter.
- Symbicort sales in the Rest of World for the nine months were up 13 percent to \$1,293 million.
- US sales of *Pulmicort* in the third quarter were up 6 percent to \$207 million. The generic budesonide for inhalation suspension (BIS) product shipped by Teva at the end of 2008 continued to be drawn down in the market during the quarter, although it would appear that supply will persist into the fourth quarter, ahead of Teva's launch of its generic product, under licence from AstraZeneca, on 15 December 2009. *Pulmicort Respules* share of dispensed BIS prescriptions increased to 73 percent in the third quarter, up from 62 percent in quarter two.
- US sales of *Pulmicort* for the nine months were down 20 percent to \$574 million.
- Sales of *Pulmicort* in the Rest of World for the nine months were up 3 percent to \$349 million.

#### Oncology

Arimidex Casodex Zoladex Iressa Faslodex Nolvadex Ethyol Total

Third	Quarter	CER %	Nine N	/lonths	CER %
2009	2008	]	2009	2008	
\$n	n \$m		\$m	\$m	
470	486	+2	1,422	1,406	+7
174	300	-43	655	974	-32
282	2 295	+1	786	860	-
75	67	+7	218	192	+9
6	7 67	+7	190	188	+10
22	2 20	+5	64	62	+2
	2 3	-33	11	23	+2 -52
1,099	1,256	-10	3,349	3,759	-6

- In the US, sales of *Arimidex* were up 11 percent in the third quarter to \$215 million. Total prescriptions for *Arimidex* were down 2.5 percent, slightly greater than the 1.4 percent decline in the market for hormonal treatments for breast cancer.
- US sales of *Arimidex* for the nine months were up 14 percent to \$658 million.
- Arimidex sales in other markets were down 5 percent in the third quarter. For the nine months, sales were up 3 percent.
- Casodex sales in the US in the third quarter were down 80 percent to \$14 million following FDA approval of 8 generic bicalutamide products in July. Casodex sales in the US for the nine months were down 40 percent to \$130 million.
- Casodex sales in the Rest of World in the third quarter were down 31 percent to \$160 million as a result of generic competition in Western Europe, where sales were down 57 percent. For the nine months, sales in the Rest of World were down 30 percent to \$525 million.
- *Iressa* sales increased by 9 percent to \$218 million for the nine months, including \$4 million of sales in Western Europe following EU regulatory approval in July. There were double-digit sales increases in Japan and in China for the nine months.
- Faslodex sales for the nine months increased by 4 percent in the US and grew by 15 percent in the Rest of World.

## **Neuroscience**

Seroquel Zomig Total

	Third C	Quarter	CER %	Nine N	/lonths	CER %
Ī	2009	2008		2009	2008	
	\$m	\$m		\$m	\$m	
Ī	1,231	1,130	+12	3,605	3,292	+14
	111	115	+1	319	336	+1
Ī	1,578	1,476	+11	4,601	4,342	+11

- In the US, Seroquel sales were up 14 percent to \$851 million in the third quarter. Total prescriptions for the Seroquel franchise increased by 2.4 percent in the third quarter, with all of the growth attributable to the Seroquel XR formulation. Market share for the Seroquel franchise was a market-leading 31.3 percent in September 2009 (up 12 basis points in the quarter), of which 3.0 percentage points were for Seroquel XR, which was up 62 basis points. Seroquel XR accounted for 9.5 percent of total prescriptions for the franchise in September 2009.
- US sales of Seroquel for the nine months were \$2,544 million, 16 percent ahead of last year.
- Seroquel sales in the Rest of World were \$380 million in the third quarter, a 9 percent increase despite the 73 percent decline in Canada due to generic competition. Sales in Western Europe were up 17 percent. Sales in Emerging Markets were up 15 percent.
- For the nine months, Seroquel sales in the Rest of World increased by 9 percent to \$1,061 million.

#### Infection and Other

Synagis Merrem FluMist H1N1 pandemic vaccine Total

Third (	Quarter	CER %	Nine N	CER %	
2009	2009 2008		2009	2008	
\$m	\$m		\$m	\$m	
82	124	-34	681	724	-6
221	241	-	636	680	+6
92	71	+30	94	71	+32
152	-	n/m	152	-	n/m
582	494	+22	1,676	1,646	+7

- In the US, sales of *Synagis* for the nine months were down 4 percent to \$519 million, the majority of which were recorded during the RSV season in the first quarter. Outside the US, *Synagis* sales were down 10 percent to \$162 million, related to the timing of shipments to Abbott, our international distributor for *Synagis*.
- FluMist sales in the third quarter were \$92 million, an increase of 30 percent compared to the third quarter last year.
- The US government has placed orders for approximately 40 million doses of LAIV against Novel Influenza A
   (H1N1) with a total cumulative contract value of approximately \$453 million. Sales of \$152 million were recorded
   in the third quarter, with most of the balance of the contract value expected to be realised in the fourth quarter of
   2009. This project has been funded in whole or in part with Federal funds from HHS/ASPR/BARDA, under
   Contract No. HHS01002009000021.

#### Geographic Sales

North America US Established ROW\* Emerging ROW

	Third C	Quarter	CER %	Nine N	Nine Months					
	2009 2008		2009 2008		2009 2008			2009	2008	
	\$m	\$m		\$m	\$m					
	3,959	3,519	+13	11,693	10,705	+10				
	3,659	3,199	+14	10,831	9,726	+11				
	3,094	3,140	+4	8,979	9,453	+4				
	1,147	1,116	+15	3,187	3,250	+13				

- \* Established ROW comprises Western Europe (including France, UK, Germany, Italy, Sweden, and others), Japan, Australia and New Zealand.
- In the US, revenue was up 14 percent in the third quarter. In addition to the revenue upsides from *Toprol-XL* and H1N1 influenza vaccine sales, *Crestor, Seroquel* and *Symbicort* were also drivers of revenue growth in the quarter, more than offsetting the declines in *Nexium, Casodex* and *Prilosec*. Adjusting for *Toprol-XL* and H1N1 vaccine sales, US revenue growth was 3 percent in the quarter.
- Revenue in the Established Rest of World segment was up 4 percent in the third quarter. Revenue in Western Europe was up 3 percent, as growth for *Crestor*, *Seroquel*, *Nexium* and *Symbicort* more than offset generic erosion on *Casodex*. Revenue in Japan was up 9 percent, chiefly on sales growth for *Crestor* and *Seroquel*. *Crestor* accounted for all of the 8 percent revenue increase in Australia.
- Revenue in Emerging Markets was up 15 percent in the third quarter. Revenue in China was up 26 percent in the quarter. The Company continues to anticipate double-digit revenue growth in Emerging Markets for the full year.

# **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. 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. More detail on the nature of each of these adjustments is given in our Annual Report and Form 20-F Information 2008. During the second quarter, the Group enhanced its methodology for calculating growth rates in constant currency terms. The constant exchange growth rates (CER) disclosed for the third quarter and the nine months have been calculated using the updated methodology.

#### **Third Quarter**

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

	Reported 2009	Restructuring and Synergy Costs	Merck & MedImmune Amortisation	Intangible Impairments	Legal Provisions	Core 2009	Core 2008	Actual %	CER %
Revenue	8,200	-	-	-		8,200	7,775	5	10
Cost of Sales	(1,263)	24	-	-	_	(1,239)	(1,457)		
Gross Profit	6,937	24	-	-		6,961	6,318	10	14
% sales	84.6%					84.9%	81.3%	+3.6	+2.7
Distribution	(73)	-	-	-	-	(73)	(79)	(7)	4
% sales	0.9%					0.9%	1.0%	+0.1	+0.1
R&D	(1,056)	6	-	1	-	(1,049)	(1,261)	(17)	(9)
% sales	12.9%					12.8%	16.2%	+3.4	+2.8
SG&A	(2,663)	82	100	-	108	(2,373)	(2,369)	-	7
% sales	32.5%					28.9%	30.5%	+1.6	+0.9
Other Income	59	-	24	60	-	143	162	(11)	(13)
% sales	0.7%					1.7%	2.1%	-0.4	-0.4
Operating Profit	3,204	112	124	61	108	3,609	2,771	30	29
% sales	39.0%					44.0%	35.7%	+8.3	+6.1
Net Finance Expense	(172)	-	-	-	-	(172)	(79)		
Profit before Tax	3,032	112	124	61	108	3,437	2,692	28	27
Taxation	(911)	(33)	(30)	(19)	_	(993)	(770)		
Profit after Tax	2,121	79	94	42	108	2,444	1,922	27	27
Minority Interests	(6)	-	-	-	_	(6)	(8)		
Net Profit	2,115	79	94	42	108	2,438	1,914	27	27
Weighted Average Shares	1,449	1,449	1,449	1,449	1,449	1,449	1,452		
Earnings per Share	1.46	0.05	0.07	0.03	0.07	1.68	1.32	28	27

Revenue grew by 10 percent in the third quarter to \$8,200 million.

Core gross margin of 84.9 percent in the third quarter was 2.7 percentage points higher than last year. Lower payments to Merck (0.7 percentage points), the release of a provision with respect to the resolution of an issue related to a third party supply contract (1.8 percentage points) and continued efficiency gains and mix factors (0.9 percentage points) were partially offset by higher royalty payments (0.7 percentage points).

Core R&D expenditure was \$1,049 million in the third quarter, 9 percent lower than last year, as increased investment in biologics was more than offset by continued productivity initiatives, lower charges relating to intangible asset impairments and lower project costs resulting from several late stage development projects completing their Phase III programmes and progressing to pre-registration.

Core SG&A costs of \$2,373 million in the third quarter were 7 percent higher than last year, as continued investment in Emerging Markets, an increase in marketing spend for the influenza vaccine franchise and in support of current and planned small molecule product launches and increased legal expenses were only partially offset by operational efficiencies.

Core other income of \$143 million was \$19 million lower than the third quarter of 2008, chiefly on expected lower one-time gains.

Core operating profit was \$3,609 million, an increase of 29 percent at CER, up 30 percent on an actual basis. In comparison with last year against the dollar, the euro was 5 percent weaker (reducing sales and costs), the Swedish krona was 14 percent weaker (reducing costs) and sterling was 13 percent weaker (reducing costs).

Core operating margin increased by 6.1 percentage points to 44.0 percent of revenue as result of leveraging sales growth with cost efficiencies and lower R&D spend.

Core earnings per share in the third quarter were \$1.68, up 27 percent, as the increase in core operating profit was partially offset by higher net finance expense.

Reported operating profit was up 25 percent to \$3,204 million. Reported earnings per share were \$1.46 up 22 percent.

#### **Nine Months**

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

	Reported 2009	Restructuring and Synergy Costs	Merck & MedImmune Amortisation	Intangible Impairments	Legal Provisions	Core 2009	Core 2008	Actual %	CER %
Revenue	23,859	-	-	-		23,859	23,408	2	8
Cost of Sales	(4,110)	139	-	-	-	(3,971)	(4,358)		
Gross Profit	19,749	139	-	-	-	19,888	19,050	4	10
% sales	82.8%					83.4%	81.4%	+2.0	+1.5
Distribution	(207)	-	-	-	-	(207)	(220)	(6)	10
% sales	0.9%					0.9%	0.9%	-	-
R&D	(3,095)	30	-	1	-	(3,064)	(3,708)	(17)	(4)
% sales	13.0%					12.9%	15.8%	+2.9	+1.9
SG&A	(7,867)	205	299	-	538	(6,825)	(7,370)	(7)	1
% sales	33.0%					28.6%	31.5%	+2.9	+2.2
Other Income	638	-	87	60	-	785	521	51	56
% sales	2.7%					3.3%	2.2%	+1.1	+1.0
Operating Profit	9,218	374	386	61	538	10,577	8,273	28	29
% sales	38.6%					44.3%	35.4%	+8.9	+6.6
Net Finance Expense	(575)	-	-	-	_	(575)	(387)		
Profit before Tax	8,643	374	386	61	538	10,002	7,886	27	27
Taxation	(2,661)	(115)	(97)	(19)	_	(2,892)	(2,271)		
Profit after Tax	5,982	259	289	42	538	7,110	5,615	27	27
Minority Interests	(14)	-	-	-	_	(14)	(18)		
Net Profit	5,968	259	289	42	538	7,096	5,597	27	27
Weighted Average Shares	1,448	1,448	1,448	1,448	1,448	1,448	1,455		
Earnings per Share	4.12	0.18	0.20	0.03	0.37	4.90	3.85	27	28

Revenue grew by 8 percent in the first nine months to \$23,859 million.

Core gross margin of 83.4 percent in the first nine months was 1.5 percentage points higher than last year. Lower payments to Merck (0.6 percentage points), the provision release in the third quarter (0.6 percentage points) and continued efficiency gains and mix factors (1.2 percentage points) were partially offset by higher royalty payments (0.9 percentage points).

Core R&D expenditure was \$3,064 million in the first nine months, 4 percent lower than last year, as increased investment in biologics was more than offset by the continued productivity initiatives and lower costs associated with late stage development projects that have progressed to pre-registration.

Core SG&A costs of \$6,825 million in the first nine months were 1 percent higher than last year, as continued investment in Emerging Markets and increased marketing investment for the influenza vaccine franchise and current and planned small molecule product launches, were largely offset by operational efficiencies across the business.

Core other income of \$785 million was \$264 million higher than the first nine months of 2008, chiefly as a result of the Abraxane® and Nordic OTC disposals in the first half of the year.

Core operating profit was \$10,577 million, an increase of 29 percent. Core operating margin increased by 6.6 percentage points to 44.3 percent of revenue, as a result of sales growth, efficiencies across the cost base, lower R&D spend and the disposals within other income.

Core earnings per share in the first nine months were \$4.90, an increase of 28 percent as the increase in core operating profit was partially offset by higher net finance expense.

Reported operating profit was up 27 percent to \$9,218 million. Reported earnings per share were \$4.12 up 23 percent.

#### **Finance Income and Expense**

Net finance expense was \$575 million for the nine months (\$172 million for the quarter), versus \$387 million in the corresponding nine month period in 2008 (\$79 million for the quarter). The key drivers were the continued 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 \$30 million for the quarter (\$49 million gain in Q3 2008) and \$130 million for the nine months (\$57 million gain in the corresponding nine month period in 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 2008 gain has now reversed fully in 2009 and, if credit spreads continue to reduce, further losses could be recorded.

#### **Taxation**

The effective tax rate for the third quarter is 30.0 percent (2008: 28.9 percent) and 30.8 percent for the first nine months (2008: 29.0 percent). Excluding the impact of the legal provisions (\$108 million for the third quarter and \$538 million for the first nine months), the effective tax rate for the third quarter would be 29.0 percent and 29.0 percent for the first nine months. For the full year, the tax rate, excluding the impact of the \$538 million legal provisions, is currently anticipated to be around 29.0 percent.

# **Cash Flow**

Cash generated from operating activities was \$7,657 million in the nine months to 30 September 2009, compared with \$5,951 million in the corresponding nine month period in 2008. The improvement of \$1,706 million is primarily driven by the increase in cash generated from operations of \$1,903 million, reflecting the strong underlying performance and improved working capital management, partially offset by higher tax payments of \$221 million.

Net cash outflows from investing activities were \$572 million in the nine months compared with \$3,424 million in the corresponding period in 2008. The movement of \$2,852 million is due primarily to the payment of \$2,630 million to Merck in 2008 as part of the partial retirement, and the proceeds from the disposal of the Abraxane® co-promotion rights of \$269 million received in 2009.

Cash distributions to shareholders were \$2,977 million through payment of the second interim dividend from 2008 and the first interim dividend for 2009.

# **Debt and Capital Structure**

During the quarter, the two–year \$650 million Floating Rate Note (issued in September 2007) was repaid on maturity. As at 30 September 2009, outstanding gross debt (including loans, short-term borrowings and overdrafts) was \$11,270 million (31 December 2008: \$11,848 million). Of this debt, \$980 million is due within one year (31 December 2008: \$993 million), which we currently anticipate repaying from current cash balances of \$7,794 million, without the need to refinance. Strong business cash flows have reduced net debt by \$3,981 million since 31 December 2008 to \$3,193 million.

# **Dividends and Share Repurchases**

As announced in 2008, the Group's share repurchase programme has been suspended. As a result, during the first nine months, no shares were re-purchased. In the nine months, 2.2 million shares were issued in consideration of share option exercises for a total of \$85 million.

The total number of shares in issue at 30 September 2009 was 1,450 million.

# Calendar

28 January 2010 Announcement of fourth quarter and full year 2009 results

Announcement of first quarter 2010 results 29 April 2010

29 April 2010 **Annual General Meeting** 

29 July 2010 Announcement of second quarter and half year 2010 results 28 October 2010 Announcement of third quarter and nine months 2010 results

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