

ASTRAZENECA PLC  
Form 6-K  
February 06, 2009  
FORM 6-K

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of  
the Securities Exchange Act of 1934

For January 2009

Commission File Number: 001-11960

AstraZeneca PLC

15 Stanhope Gate, London W1K 1LN, England

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): \_\_\_\_\_

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes  No

If "Yes" is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-\_\_\_\_\_

---

AstraZeneca PLC

INDEX TO EXHIBITS

1. Press release entitled, “Transparency Directive Voting Rights and Capital”, dated 5 January 2009.
  2. Press release entitled, “Director’s Dealing: Pledge of Shares”, dated 22 January 2009.
  3. Press release entitled, “AstraZeneca Fourth Quarter and Full Year Results 2008”, dated 28 January 2009.
  4. Press release entitled, “AstraZeneca’s partner, Pozen informed by FDA that Gastric Ulcers are valid primary endpoint in PN 400 trials”, dated 29 January 2009.
  5. Press release entitled, “AstraZeneca provides updated currency sensitivity assumptions as part of 2009 guidance”, dated 29 January 2009.
  6. Press release entitled, “AstraZeneca PLC Fourth Quarter and Full Year Results 2008” (front half), dated 29 January 2009.
  7. Press release entitled, “AstraZeneca PLC Fourth Quarter and Full Year Results 2008 Condensed Consolidated Income Statement” (back half), dated 29 January 2009.
  8. Press release entitled, “Transparency Directive Voting Rights and Capital”, dated 30 January 2009.
-

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 5 February 2009

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

---

Item 1

Transparency Directive  
Voting Rights and Capital

The following notification is made in accordance with the UK Financial Services Authority Disclosure and Transparency Rule 5.6.1. On 31 December 2008 the issued share capital of AstraZeneca PLC with voting rights is 1,447,481,548 ordinary shares of US\$0.25. No shares are held in Treasury. Therefore, the total number of voting rights in AstraZeneca PLC is 1,447,481,548.

The above figure for the total number of voting rights may be used by shareholders as the denominator for the calculations by which they will determine if they are required to notify their interest in, or a change to their interest in, AstraZeneca PLC under the FSA's Disclosure and Transparency Rules.

A C N Kemp  
Company Secretary  
5 January 2009

---

Item 2

DIRECTOR'S DEALING: PLEDGE OF SHARES

Following recent clarification by the Financial Services Authority, in accordance with Disclosure and Transparency Rule 3.1.2, AstraZeneca PLC (the "Company") announces that it has received notification from Marcus Wallenberg, a Non-Executive Director of the Company, that he has pledged 60,028 shares in the Company owned by him as security against personal loans.

A C N Kemp  
Company Secretary  
22 January 2009

---

Item 3

AstraZeneca Fourth Quarter and Full Year Results 2008

On Thursday, 29 January 2009, AstraZeneca will release fourth quarter and full year results for 2008 at 11:00GMT.

An analyst presentation covering the results will be held at 13:30GMT and can be joined, live, via teleconference on the following numbers:

UK: 0800 012 1327

Sweden: 0200 110 487

US: 1 866 804 8688

International: +44 (0)844 8000 810

Passcode: "AstraZeneca Analyst Conference"

These numbers, and details of the replay facility (available until 17:00GMT Friday, 13 February 2009) are available on the Investors section of the AstraZeneca website ([www.astrazeneca.com](http://www.astrazeneca.com)).

A live webcast of the presentation will also be available on this site.

---

Item 4

ASTRAZENECA'S PARTNER, POZEN INFORMED BY FDA THAT GASTRIC ULCERS ARE VALID PRIMARY ENDPOINT IN PN 400 TRIALS

POZEN Inc., AstraZeneca's co-development partner for the investigational compound PN 400, has been informed that the US Food and Drug Administration (FDA) has completed its internal discussions and that there is no change to the previous agreements that gastric ulcer incidence is an acceptable primary endpoint for the PN 400 Phase III clinical programmes.

In October, the FDA had announced that they were conducting an internal review on the acceptability of gastric ulcers as a primary endpoint in clinical studies.

PN 400 is a fixed dose combination of enteric-coated naproxen with immediate release esomeprazole 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 gastric ulcers. The two pivotal ulcer risk reduction studies have completed and met their primary endpoints. In both studies, patients taking PN 400 experienced significantly fewer endoscopically confirmed gastric ulcers compared to subjects receiving enteric-coated naproxen during the six-month treatment period. Two additional Phase III studies are still ongoing.

Upon completion of the entire PN400 Phase III clinical programme, AstraZeneca will make a final determination regarding regulatory filing. A regulatory submission for PN400 in the US is currently planned for mid 2009.

About PN 400

PN 400 is an investigational compound under co-development by AstraZeneca and POZEN, Inc. that combines the pain reliever naproxen (a non-steroidal anti-inflammatory drug, or NSAID) with esomeprazole – a proton pump inhibitor (PPI), for the treatment of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis in patients who are at risk of developing gastric ulcers.

About AstraZeneca

AstraZeneca is a major international healthcare business engaged in research, development, manufacturing and marketing of prescription pharmaceuticals and supplier for healthcare services. AstraZeneca is one of the world's leading pharmaceutical companies with healthcare sales of US \$29.55 billion and is a leader in gastrointestinal, cardiovascular, neuroscience, respiratory, oncology and infection product sales. AstraZeneca is listed in the Dow Jones Sustainability Index (Global) as well as the FTSE4Good Index. For more Information visit [www.astrazeneca.com](http://www.astrazeneca.com)

Media Enquiries UK:

Chris Sampson +44 20 7304 5130 (24 hours)

Neil McCrae +44 207 304 5045 (24 hours)

Sarah Lindgreen +44 20 7304 5033 (24 hours)

Media Enquiries US:

Michele.Pelkowski

+1 302 885 4055

---

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Investor Enquiries UK:

Jonathan Hunt	+44 207 304 5087	mob: +44 7775 704032
Karl Hard	+44 207 304 5322	mob: +44 7789 654364

Investor Enquiries US:

Ed Seage	+1 302 886 4065	mob: +1 302 373 1361
Jorgen Winroth	+1 212 579 0506	mob: +1 917 612 4043

29 January 2009

- ENDS -

---

Item 5

AstraZeneca provides updated currency sensitivity assumptions as part of 2009 guidance

Today, in conjunction with reporting full year 2008 earnings, AstraZeneca gave earnings guidance for 2009. The guidance utilised the average daily exchange rates for January 2009 (to 28th Jan) for its principal functional currencies (sterling, Euro, Swedish krone and Japanese yen) against the US dollar. This time period was chosen as it is reflective of significant recent changes in the exchange rate between these principal currencies and the US dollar.

The Company has provided an updated currency sensitivity guide for 2009 in order to facilitate the estimation of the impact of varying exchange rates on 2009 sales and Core earnings. This can be found in the 'Investors' section of the Company's website [www.astrazeneca.com](http://www.astrazeneca.com)

---

Item 6

AstraZeneca PLC

FOURTH QUARTER AND FULL YEAR RESULTS 2008

---

London, 29 January 2009

Sales for the full year increased by 3 percent at CER; Core operating profit increased by 9 percent at CER.

-Core operating margin improved to 34.7 percent of sales on operational efficiencies.

Sales in Emerging Markets reached \$4,273 million for the full year, a 16 percent increase at CER.

Core EPS for the full year increased by 8 percent at constant exchange rates (CER) to \$5.10, in line with the Company's guidance.

Growth in Reported EPS for the full year, 2 percent at CER, was lower than Core EPS growth rate.

-Reflects higher intangible impairments and a full year of MedImmune amortisation compared with 2007.

New initiatives extend the scope of restructuring programme to sustain long-term competitiveness.

-When fully implemented, annual benefits anticipated to reach \$2.5 billion, up from \$1.4 billion.

Continued progress on the pipeline; up to four new compounds planned for regulatory filing in 2009.

Dividend increased by 10 percent to \$2.05 for the full year.

Net debt reduced by \$1.9 billion on strong cash performance and investment discipline.

-No share repurchases will take place in 2009 in order to maintain the flexibility to invest in the business.

Financial Summary

Group	4th Quarter 2008 \$m	4th Quarter 2007 \$m	Actual %	CER %	Full Year 2008 \$m	Full Year 2007 \$m	Actual %	CER %
Sales Reported	8,193	8,170	-	+4	31,601	29,559	+7	+3

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Operating Profit	1,892	1,929	-2	-9	9,144	8,094	+13	+4
Profit before Tax	1,816	1,837	-1	-10	8,681	7,983	+9	-1
Earnings per Share	\$0.86	\$0.86	-	-9	\$4.20	\$3.74	+12	+2
Core*								
Operating Profit	2,685	2,430	+11	+5	10,958	9,411	+16	+9
Profit before Tax	2,609	2,338	+12	+5	10,495	9,300	+13	+4
Earnings per Share	\$1.25	\$1.10	+13	+6	\$5.10	\$4.38	+16	+8

\* 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 9 for a definition of Core financial measures and pages 9 and 10 for a reconciliation of Core to Reported financial measures.

David Brennan, Chief Executive Officer, said: "AstraZeneca has delivered a robust performance in an increasingly challenging market environment. I am particularly pleased with our continued success in globalising our business, as shown by our strong performance in Emerging Markets. We are also making good headway in further improving the efficiency of our organisation. The expansion in the scope of our restructuring efforts is another important step towards sustaining our long-term competitiveness."

---

## AstraZeneca PLC

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

### Fourth Quarter

Sales in the fourth quarter increased by 4 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 3 percent, as the adverse impact from generic competition for Toprol-XL is now annualised. Sales in the Rest of World were up 5 percent. Sales in Established Markets were up 3 percent. Sales growth in Emerging Markets remained strong, with sales up 13 percent in the quarter to \$1,023 million.

There were a number of intangible asset impairment charges taken in the fourth quarter, some of which affected Core operating profit, others which are excluded from Core profit and only affect reported operating profit. Included within Core operating profit are intangible asset impairments charges totalling \$184 million, the largest of which is a \$115 million charge for impairment of intangible assets relating to Pulmicort Respules following the at risk generic launch by Teva and the subsequent settlement of patent litigation. There were a total of \$150 million of intangible asset impairments charged to reported operating profit which are excluded from operating profit on a Core basis. These intangible assets, arising from the acquisition of MedImmune, relate to revised forecasts for future royalties related to HPV vaccines (\$90 million) and other items (\$60 million) principally related to the return of rights to the heat shock protein 90 (Hsp90) drug candidates IPI-504 (MEDI-561) and IPI-493 to Infinity Pharmaceuticals.

Core operating profit in the fourth quarter was up 5 percent to \$2,685 million, chiefly as a result of sales growth and higher other income, partially offset by the impairment relating to Pulmicort Respules and other provisions within cost of goods sold. Reported operating profit decreased by 9 percent to \$1,892 million as a result of higher restructuring costs and intangible asset impairments taken in this quarter compared to the fourth quarter 2007.

Core earnings per share in the fourth quarter were \$1.25 compared with \$1.10 in the fourth quarter 2007, a 6 percent increase at CER. It is estimated that there was 7 cents of currency benefit to Core EPS in the fourth quarter. Core earnings per share benefited from lower net interest expense, the result of a fair value gain relating to certain long-term bonds in issue, and a lower number of shares outstanding. Reported earnings per share in the fourth quarter were \$0.86, a 9 percent decrease, as a result of higher restructuring and intangible asset impairment charges.

### Full Year

Sales for the full year increased by 3 percent at CER, or 7 percent on an as reported basis. Sales in the US were up 1 percent, as the inclusion of a full year of MedImmune sales and modest growth in the rest of the US business more than offset the sales of Toprol-XL lost to generic competition. Sales in the Rest of World were up 5 percent. Sales in Established Markets were up 2 percent, including a 1 percent increase in sales in Western Europe. Sales in Emerging Markets were up 16 percent.

Core operating profit increased by 9 percent to \$10,958 million as increased sales, improvements in gross margin and R&D efficiencies more than offset a modest increase in SG&A expense. Reported operating profit increased by 4 percent to \$9,144 million.

Core earnings per share for the full year were \$5.10, an increase of 8 percent. The increase in reported earnings per share was 2 percent, to \$4.20, with the lower growth rate versus Core EPS largely attributable to intangible asset

impairment charges and a full year of MedImmune amortisation, which are excluded from Core EPS.

#### Research and Development Update

Strengthening the pipeline remains a key priority for the Company. The AstraZeneca pipeline now includes 144 projects, including 98 projects in the clinical phase of development. There are 10 projects currently in late stage development, either in Phase III or under regulatory review. Of particular note, the Phase II pipeline is now more than fifty percent larger than it was at this time last year. Across the portfolio, 44 projects have successfully progressed to their next phase (including 17 molecules entering first human testing); 32 compounds have been added from Discovery research; 10 compounds have been withdrawn.

AstraZeneca PLC

Four important projects (including two new molecules) are awaiting registration at this time:

- MedImmune announced on 28 November 2008 the receipt of a Complete Response Letter (CRL) from the US FDA seeking additional information in connection with the Biologics License Application (BLA) for motavizumab for the prevention of serious respiratory syncytial virus disease. MedImmune is confident that it can respond to the outstanding questions and, based upon the Company's current understanding, does not foresee a need to conduct further trials, but will be submitting data from our already completed study in full term infants with congenital heart defects. MedImmune will continue discussions with the FDA reviewers and, subject to this dialogue, now expects to respond in the second half of 2009.
- Reviews of the regulatory submissions for ONGLYZATM (saxagliptin), the new diabetes compound developed in collaboration with Bristol-Myers Squibb, are progressing in the US and in Europe.
- Regulatory review continues for the Marketing Authorization Application submitted to the European Medicines Agency seeking approval for Iressa as a treatment for locally advanced or metastatic non-small cell lung cancer in patients who have been pre-treated with platinum-containing chemotherapy.
- On 24 December 2008, AstraZeneca announced that it received a CRL from the US FDA in conjunction with the supplemental New Drug Application for Seroquel XR for the treatment of Major Depressive Disorder (MDD). AstraZeneca will continue discussions with the FDA and will provide a response to the agency in due course. The MDD submission in Europe is also under regulatory review, as are the applications for Generalised Anxiety Disorder in the US and in Europe.

Up to four regulatory filings for new chemical entities are planned for 2009, including: Zactima for the treatment of pre-treated advanced non-small cell lung cancer in combination with chemotherapy; PN400, the combination of enteric coated naproxen and immediate release esomeprazole for the treatment of arthritic pain in patients at risk of developing gastric ulcers; Brilinta (formerly known as AZD6140), the oral antiplatelet agent in development for the treatment of patients with acute coronary syndrome; and the fixed dose combination product containing Crestor and Abbott's Trilipix, for the management of mixed dyslipidaemia.

On 11 December 2008, the Company announced that it returned worldwide rights to Infinity Pharmaceuticals for the development and commercialisation of Infinity's heat shock protein 90 (Hsp90) drug candidates IPI-504 (MEDI-561) and IPI-493. MEDI-561 was in Phase III development for the treatment of patients with refractory gastrointestinal stromal tumours (GIST), a rare tumour of the gastrointestinal tract.

The first regulatory submissions for Crestor based on the JUPITER trial results are planned starting in the second quarter of 2009.

A programme of work aimed at resolving the stability issues related to AZD0837 tablets remains underway, however the Company now estimates that the Phase III trial programme in atrial fibrillation will not start until the second half of 2009. Until then, AZD0837 will be reclassified as a Phase II project on the Company's pipeline table.

In late November 2008, the Company received the FDA Complete Response Letter regarding our Nexium I.V. supplemental New Drug Application for Peptic Ulcer Bleed. The application has not received the FDA's approval in its present form. The Company is reviewing their comments and will respond in due course. The EU submission is still being reviewed by the European regulatory authorities.

In January 2009, the US Food and Drug Administration (FDA) granted an additional six-month period of market exclusivity to Seroquel for its licensed indications, based on studies the Company conducted in adolescents with schizophrenia and children and adolescents with bipolar mania. The Seroquel patent expires on 26 September 2011. The allowed six-month paediatric exclusivity period, which takes effect upon expiration of the patent, will extend the exclusivity of Seroquel to 26 March 2012. As previously disclosed, Seroquel US Prescribing Information is being updated to include additional safety information for children and adolescents. Seroquel is not currently indicated anywhere in the world for the paediatric population.

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

AstraZeneca PLC

Enhancing Productivity

In the fourth quarter, a further \$516 million in restructuring and synergy costs was charged to the accounts, bringing the total costs for the full year to \$881 million (of which \$219 million are non-cash items). This annual total reflects an extension in the scope of the previously announced \$1,975 million programme which commenced in 2007. New initiatives include further rationalisation of the global supply chain, additional restructuring of the sales and marketing organisation and business infrastructure. When fully implemented, these and other new business reshaping activities, combined with revised estimates for the original 2007 programme (7,600 job reductions), will result in the overall programme delivering a reduction of approximately 15,000 positions by 2013. All reductions in positions are subject to consultations with works councils, trade unions and other employee representatives and in accordance with local labour laws.

As a result of the expanded scope of these business reshaping programmes, total programme charges for restructuring and synergies are now estimated to reach \$2,950 million (up from \$1,975 million). The Company anticipates that most of the remaining \$1.1 billion will be charged by 2010. When fully implemented, programme benefits are now estimated to reach \$2.5 billion per annum (up from \$1.4 billion); with \$2.1 billion in savings expected before the end of 2010, and the balance to be realised by 2013.

Future Prospects

The Company has set its financial targets for 2009 in anticipation of the normal range of risks and opportunities typical for the pharmaceutical sector together with the turmoil in the financial markets and the broader economy. Management believes that successful execution of its business plan, underpinned by the underlying financial and operating strength of the Company, will result in achievement of a resilient financial performance even in this challenging business climate.

For 2009 the Company expects revenues to be in line with 2008 levels in constant currency terms with the exact outcome dependent, in part, on the extent of the impact of global economic conditions experienced over the course of the year.

The Company aims to grow Core earnings per share on a constant currency basis. Core EPS guidance has been based on January 2009 average exchange rates for our principal currencies. The target for Core EPS is in the range of \$5.15 to \$5.45. Actual performance within this range is dependent on the extent of the impact of the downside pressures from the global economy.

This target takes no account of the likelihood that average exchange rates for 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 is provided in conjunction with this results announcement, and can be found on the AstraZeneca web site.

This target Core EPS also takes account of the fact that no share repurchases will be undertaken in 2009.

## AstraZeneca PLC

## Sales

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

## Gastrointestinal

	Fourth Quarter		CER %	Full Year		CER %
	2008	2007		2008	2007	
	\$m	\$m		\$m	\$m	
Nexium	1,324	1,303	+6	5,200	5,216	-2
Losec/Prilosec	264	298	-11	1,055	1,143	-14
Total	1,611	1,625	+3	6,344	6,443	-4

- In the US, Nexium sales in the fourth quarter were \$832 million, up 2 percent compared with the fourth quarter last year. Dispensed retail tablet volume grew by 2.5 percent. As expected, the significant adverse price variance that was a feature of the performance in the first three quarters of the year normalised in the fourth quarter, with realised selling prices broadly flat.
- Nexium sales in the US for the full year were down 8 percent to \$3,101 million. Dispensed retail tablet volume for the full year increased by 2 percent. Nexium was the only major PPI brand to increase volume in 2008. On average over the course of the full year, realised selling prices declined by around 11 percent.
- Nexium sales in other markets in the fourth quarter were up 12 percent to \$492 million. There was continued strong growth in Emerging Markets, where sales were up 20 percent. Sales in Western Europe were up 8 percent despite a significant decrease in Germany.
- Nexium sales in other markets were up 9 percent for the full year to \$2,099 million.
- Prilosec sales in the US were down 43 percent in the fourth quarter and 25 percent for the full year as a result of the introduction of generic competition for the 40mg dosage form in the second half of 2008.
- Sales of Losec in the Rest of World were down 3 percent in the fourth quarter and 11 percent for the full year. Losec sales increased in China (up 19 percent) and in Japan (up 5 percent) for the full year.

## Cardiovascular

	Fourth Quarter		CER %	Full Year		CER %
	2008	2007		2008	2007	
	\$m	\$m		\$m	\$m	
Crestor	987	799	+30	3,597	2,796	+26
Seloken /Toprol-XL	207	209	+2	807	1,438	-46
Atacand	351	353	+9	1,471	1,287	+10
Plendil	67	66	+3	268	271	-7
Zestril	52	67	-16	236	295	-24

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Total	1,803	1,656	+15	6,963	6,686	-
-------	-------	-------	-----	-------	-------	---

- In the US, Crestor sales in the fourth quarter were \$490 million, a 27 percent increase over last year. Fuelled by the promotion of the atherosclerosis indication, Crestor prescriptions in the fourth quarter increased by 17 percent, more than four times the market growth rate of 4 percent. The other major branded statins experienced a nearly 18 percent decline in total prescriptions in aggregate.
- US sales for Crestor for the full year increased by 18 percent to \$1,678 million. Crestor total prescription share in the US statin market increased by 125 basis points during the year, to 9.9 percent in December 2008, and was the only branded statin to gain share.
- Crestor sales in the Rest of World were up 32 percent to \$497 million in the fourth quarter. Sales in Western Europe increased by 16 percent. Emerging Market sales increased by 50 percent. There were also strong performances achieved in Canada (up 29 percent), Japan (up 54 percent) and Australia (up 91 percent).
- Crestor sales in the Rest of World were up 34 percent for the full year to \$1,919 million.
- US sales of the Toprol-XL product range, which includes sales of the authorised generic, were up 2 percent in the fourth quarter to \$88 million, as the onset of full generic competition has been annualised. Generic products accounted for 89 percent of dispensed prescriptions in the fourth quarter.
- Toprol-XL sales in the US were down 70 percent for the full year to \$295 million.

## AstraZeneca PLC

- Sales of Seloken in other markets in the fourth quarter were up 2 percent to \$119 million, as the 16 percent growth in Emerging Markets more than offset the 18 percent decline in Western Europe. For the full year, Seloken sales in the Rest of World were up 1 percent to \$512 million.
- US sales for Atacand for the full year increased 1 percent to \$262 million. Sales in other markets were up 12 percent to \$1,209 million, on a 10 percent increase in Established Markets and an 18 percent increase in Emerging Markets.

## Respiratory and Inflammation

	Fourth Quarter		CER %	Full Year		CER %
	2008	2007		2008	2007	
	\$m	\$m		\$m	\$m	
Symbicort	514	436	+29	2,004	1,575	+22
Pulmicort	397	447	-10	1,495	1,454	-
Rhinocort	78	87	-8	322	354	-12
Accolate	18	19	-5	73	76	-5
Oxis	15	22	-27	71	86	-24
Total	1,059	1,056	+6	4,128	3,711	+7

- Symbicort sales in the US were \$90 million in the fourth quarter and reached \$255 million for the full year. Product trial rate among target specialist physicians is now approaching 90 percent; these specialists are starting more than 30 percent of patients new to combination therapy on Symbicort. More than half of target primary care physicians have tried Symbicort, and their share of new patient starts is just over 17 percent. Overall, Symbicort share of new prescriptions for fixed combinations reached 11.7 percent in the week ending 16 January, with market share among patients newly starting combination treatment at 18.3 percent.
- Symbicort sales in other markets in the fourth quarter were \$424 million, 13 percent ahead of the fourth quarter last year, chiefly on an 11 percent increase in Western Europe. Sales in Emerging Markets were up 21 percent. The Symbicort SMART concept has now been approved in 91 markets.
- US sales for Pulmicort were down 15 percent to \$260 million in the fourth quarter. Pulmicort Respules sales were down 18 percent as a result of the “at risk” launch of generic budesonide inhalation suspension (BIS) on 18 November. The patent litigation between Teva and AstraZeneca was subsequently settled on 26 November. The agreement allows Teva to commence sales of BIS under an exclusive license from AstraZeneca beginning 15 December 2009. The agreement also provided that any product already shipped by Teva would remain in the market to be further distributed and dispensed. As a result, Teva product accounted for nearly 15 percent of total prescriptions for BIS products dispensed during the fourth quarter, including a 40 percent share in December 2008.
- US sales for Pulmicort for the full year were \$982 million, a 2 percent increase over 2007. Pulmicort Respules accounted for around 90 percent of total Pulmicort sales in the US.
- Sales of Pulmicort in the Rest of World were down 2 percent for the full year to \$513 million.

## Oncology

	Fourth Quarter		CER %	Full Year		CER %
	2008	2007		2008	2007	
	\$m	\$m		\$m	\$m	
Arimidex	451	474	-1	1,857	1,730	+4
Casodex	284	370	-24	1,258	1,335	-12
Zoladex	278	307	-6	1,138	1,104	-3
Iressa	73	70	-1	265	238	+3
Faslodex	61	58	+10	249	214	+12
Nolvadex	23	24	-8	85	83	-6
Ethyol *	5	16	-69	28	43	n/m
Total	1,195	1,339	-9	4,954	4,819	-2

\* Sales of this MedImmune product were consolidated in AstraZeneca accounts from 1 June 2007. As a result, the prior year reflects seven months' sales.

- In the US, sales of Arimidex were down 5 percent in the fourth quarter to \$177 million. Total prescriptions for Arimidex declined by 3 percent, slightly more than the 1.5 percent decline in the overall market for hormonal treatments for breast cancer. Arimidex sales for the full year in the US were up 9 percent to \$754 million.

AstraZeneca PLC

- Arimidex sales in other markets were up 2 percent in the fourth quarter, and increased by 1 percent for the full year to \$1,103 million.
- Casodex sales in the US were down 1 percent in the fourth quarter. Sales for the full year were \$292 million, a 2 percent decrease compared with 2007.
- Casodex sales in the Rest of World in the fourth quarter were down 30 percent to \$207 million as a result of generic competition in Western Europe, where sales were down 56 percent. Sales for the full year in the Rest of World were down 15 percent to \$966 million.
- Worldwide sales of Iressa increased by 3 percent to \$265 million for the full year, as growth in China and other Emerging Markets more than offset a 3 percent sales decline in Japan.
- Faslodex sales for the full year were up 5 percent in the US and increased by 18 percent in other markets.

Neuroscience

	Fourth Quarter		CER %	Full Year		CER %
	2008	2007		2008	2007	
	\$m	\$m		\$m	\$m	
Seroquel	1,160	1,086	+10	4,452	4,027	+9
Zomig	112	114	+3	448	434	-1
Total	1,495	1,449	+7	5,837	5,340	+6

- In the US, Seroquel sales were up 8 percent to \$831 million in the fourth quarter. Total prescriptions were up 5 percent, in line with the anti-psychotic market growth. Around 44 percent of Seroquel prescription growth was attributable to Seroquel XR. Seroquel remains the market leader in the US anti-psychotic market, with a total prescription share of 31.6 percent in December 2008.
- US sales for Seroquel for the full year were \$3,015 million, 5 percent ahead of last year.
- Seroquel sales in other markets increased by 14 percent to \$329 million in the fourth quarter. Sales in Western Europe were up 26 percent.
- For the full year, Seroquel sales in the Rest of World increased by 17 percent to \$1,437 million, with value and volume growth well ahead of the market in all regions.
- Sales of Zomig for the full year were up 6 percent in the US to \$187 million. Sales in the Rest of World were down 5 percent to \$261 million.

Infection and Other

	Fourth Quarter		CER %	Full Year		CER %
	2008	2007		2008	2007	

Edgar Filing: ASTRAZENECA PLC - Form 6-K

	\$m	\$m		\$m	\$m	
Synagis*	506	480	+5	1,230	618	n/m
Merrem	217	215	+10	897	773	+13
FluMist*	33	53	-38	104	53	+96
Total	805	816	+2	2,451	1,714	n/m

\* Sales of these MedImmune products were consolidated in AstraZeneca accounts from 1 June 2007. As a result, the prior year reflects seven months' sales.

- Worldwide sales of Synagis in the fourth quarter were \$506 million, a 5 percent increase, chiefly on the 42 percent increase in sales outside the US. Sales in the US were down 3 percent to \$380 million.
- For the full year, Synagis sales were \$1,230 million. Sales in 2007 were \$618 million, but only reflect sales since the acquisition of MedImmune in June 2007.
- FluMist sales were \$33 million in the fourth quarter and \$104 million for the full year. In contrast to 2008, all of last year's FluMist sales of \$53 million were realised in the fourth quarter as a result of the timing of regulatory approvals for the new formulation and expanded label.

## AstraZeneca PLC

## Geographic Sales

	Fourth Quarter		CER %	Full Year		CER %
	2008	2007		2008	2007	
	\$m	\$m		\$m	\$m	
North America	4,080	3,996	+3	14,785	14,511	+2
US	3,784	3,665	+3	13,510	13,366	+1
Established ROW*	3,090	3,194	+3	12,543	11,491	+2
Emerging ROW	1,023	980	+13	4,273	3,557	+16

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

- In the US, sales were up 1 percent for the full year; the inclusion of a full year of MedImmune sales and growth from Crestor, Symbicort and Seroquel more than offset the generic erosion to Toprol-XL and the sales declines in the PPI products Nexium and Prilosec.
- Sales in the Established Rest of World segment were up 2 percent for the full year. Sales in Western Europe were up 1 percent; aside from the inclusion of a full year of Synagis sales, growth for Crestor, Seroquel and Symbicort helped offset the declines in Casodex and Losec. Sales in Japan were up 4 percent chiefly on the contribution for Crestor. Crestor and Nexium fuelled the 18 percent increase in sales in Australia.
- Sales in Emerging Markets were up 16 percent for the full year, accounting for more than 60 percent of the CER sales growth outside the US. Nearly every franchise showed sales growth in Emerging Markets, with notable performances for Crestor, Nexium, Seroquel, Symbicort and Zoladex. Sales in China were up 31 percent to \$627 million for the full year.

## AstraZeneca PLC

## 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.

## Fourth Quarter

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

	Reported 2008	Restructuring and Synergy Costs	MedImmune Amortisation	Ethiol and other Impairments	Merck Amortisation	Core 2008	Core 2007	Actual %	CER %
Sales	8,193	-	-	-	-	8,193	8,170	-	4
Cost of Sales	(2,112)	277	-	-	-	(1,835)	(1,726)		
Gross Profit	6,081	277	-	-	-	6,358	6,444	(1)	3
% sales	74.2%					77.6%	78.9%	-1.3	-0.7
Distribution	(71)	-	-	-	-	(71)	(67)	7	18
% sales	0.9%					0.8%	0.8%	-	-0.1
R&D	(1,355)	50	-	60	-	(1,245)	(1,396)	(11)	3
% sales	16.5%					15.2%	17.1%	+1.9	+0.1
SG&A	(2,856)	189	75	-	22	(2,570)	(2,685)	(4)	4
% sales	34.8%					31.4%	32.9%	+1.5	-
Other Income	93	-	30	90	-	213	134	60	70
% sales	1.1%					2.6%	1.6%	+1.0	+1.0
Operating Profit	1,892	516	105	150	22	2,685	2,430	11	5
% sales	23.1%					32.8%	29.7%	+3.1	+0.3
Net Finance Expense	(76)					(76)	(92)		
Profit before Tax	1,816	516	105	150	22	2,609	2,338	12	5
Taxation	(557)	(153)	(31)	(44)	-	(785)	(706)		
Profit after Tax	1,259	363	74	106	22	1,824	1,632	12	5
Minority Interests	(11)					(11)	(9)		

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Net Profit	1,248	363	74	106	22	1,813	1,623	12	5
Weighted Average Shares	1,447	1,447	1,447	1,447	1,447	1,447	1,464		
Earnings per Share	0.86	0.25	0.05	0.07	0.02	1.25	1.10	13	6

Sales were unchanged on a reported basis and grew by 4 percent on a constant currency basis. Currency movements resulted in a negative impact of 4 percent.

Core gross margin of 77.6 percent in the fourth quarter was 0.7 percentage points lower than last year in constant currency terms. Intangible asset impairments relating to Pulmicort Respules (\$115 million) and other provisions reduced gross margin by 3.0 percentage points. Higher royalty payments accounted for 0.3 percentage points of negative variance compared with last year. These were partially offset by lower payments to Merck (0.6 percentage points) and continued efficiency gains and mix factors (2.0 percentage points).

Core R&D expenditure was \$1,245 million in the fourth quarter, 3 percent higher than last year as a result of higher charges relating to intangible asset impairments, which amounted to \$45 million in the fourth quarter 2008, partially offset by continued delivery of R&D productivity initiatives.

Core SG&A costs of \$2,570 million were 4 percent higher than the fourth quarter of 2007 as a result of continued investment in Emerging Markets and increased marketing investment behind Symbicort and Crestor in the US, partially offset by operational efficiencies.

Core other income of \$213 million was \$79 million higher than the fourth quarter of 2007, chiefly as a result of a number of small one-time gains.

Core operating profit was \$2,685 million, an increase of 5 percent at CER, up 11 percent on an as reported basis. Currency movements increased Core operating profit by 6 percent. In comparison with last year, the dollar was 10 percent stronger against the euro (reducing sales and costs), 21 percent stronger against the Swedish krona (reducing costs), and 30 percent stronger against sterling (reducing costs). On a constant currency basis, Core operating margin increased by 0.3 percentage points to 32.8 percent of sales, chiefly a result of one-time gains in other income partly offset by charges in cost of sales.

## AstraZeneca PLC

Core earnings per share in the fourth quarter were \$1.25, up 6 percent at CER, as the increase in Core operating profit was supplemented by lower net finance expense and the benefit of a lower number of shares in issue. Core earnings per share on an as reported basis, including a currency benefit of 7 percent, increased by 13 percent.

Reported operating profit was down 9 percent at CER at \$1,892 million, reflecting higher restructuring and synergy costs and the impairment of intangible assets, chiefly as a result of the return of the rights to the Hsp90 drug candidates to Infinity Pharmaceuticals and revised forecasts from future royalties relating to HPV vaccines (\$90 million). Reported earnings per share were \$0.86.

## Full Year

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

	Reported 2008	Restructuring and Synergy Costs	MedImmune Amortisation	Ethyol and other Impairments	Merck Amortisation	Core 2008	Core 2007	Actual %	CER %
Sales	31,601	-	-	-	-	31,601	29,559	7	3
Cost of Sales	(6,598)	405	-	-	-	(6,193)	(6,004)		
Gross Profit	25,003	405	-	-	-	25,408	23,555	8	4
% sales	79.1%					80.4%	79.7%	+0.7	+0.8
Distribution	(291)	-	-	-	-	(291)	(248)	17	16
% sales	0.9%					0.9%	0.9%	-	-0.1
R&D	(5,179)	166	-	60	-	(4,953)	(5,089)	(3)	(1)
% sales	16.4%					15.7%	17.2%	+1.5	+0.8
SG&A	(10,913)	310	307	257	99	(9,940)	(9,535)	4	3
% sales	34.6%					31.4%	32.3%	+0.9	+0.1
Other Income	524	-	120	90	-	734	728	1	3
% sales	1.7%					2.3%	2.5%	-0.2	-
Operating Profit	9,144	881	427	407	99	10,958	9,411	16	9
% sales	28.9%					34.7%	31.8%	+2.9	+1.6
Net Finance Expense	(463)	-	-	-	-	(463)	(111)		
Profit before Tax	8,681	881	427	407	99	10,495	9,300	13	4
Taxation	(2,551)	(259)	(125)	(121)	-	(3,056)	(2,716)		
Profit after Tax	6,130	622	302	286	99	7,439	6,584	13	5

Minority Interests	(29)	-	-	-	-	(29)	(32)		
Net Profit	6,101	622	302	286	99	7,410	6,552	13	5
Weighted Average Shares	1,453	1,453	1,453	1,453	1,453	1,453	1,495		
Earnings per Share	4.20	0.43	0.21	0.19	0.07	5.10	4.38	16	8

Sales increased by 7 percent on a reported basis and by 3 percent on a constant currency basis. Currency movements increased sales by 4 percent.

Core gross margin of 80.4 percent for the full year was 0.8 percentage points higher than last year in constant currency terms. Principal drivers were lower payments to Merck (1.0 percentage points), continued efficiency gains and mix factors (1.2 percentage points), partially offset by higher royalty payments (0.6 percentage points) and intangible asset impairments and other provisions (0.8 percentage points).

Core R&D costs of \$4,953 million were down 1 percent over last year. The inclusion of MedImmune for a full year was offset by improved productivity and efficiency, restructuring benefits, portfolio changes and lower charges relating to intangible asset impairments (\$84 million in 2008) charged to Core R&D expense.

Core SG&A costs of \$9,940 million were 3 percent higher than 2007 due chiefly to the inclusion of MedImmune, increased investment in our Emerging Markets and some higher legal expenses.

Core other income of \$734 million was \$6 million higher than last year with MedImmune's licensing and royalty income streams offset by expected lower one-time gains and royalty income.

Core operating profit of \$10,958 million was up 9 percent at CER or 16 percent on an as reported basis. Currency movements increased Core operating profit by 7 percent. On a constant currency basis, Core operating margin increased by 1.6 percentage points to 34.7 percent of sales as a result of improvements in gross margin, lower R&D costs and SG&A efficiencies.

## AstraZeneca PLC

Core earnings per share in 2008 were \$5.10, an increase of 8 percent at CER, as the increase in Core operating profit and the benefit of a low number of shares outstanding was partially offset by increased net finance expense. Core earnings per share on a reported basis increased 16 percent.

Reported operating profit of \$9,144 million was up 4 percent, against 9 percent on a Core basis. This is in part a result of MedImmune-related intangible asset impairments, including the \$257 million Ethyol impairment in the first quarter of 2008, and twelve months of MedImmune-related amortisation (versus a seven month charge incurred in the prior year period), being only partially offset by slightly lower restructuring and synergy costs in 2008.

Reported earnings per share in 2008 were \$4.20, an increase of 2 percent at CER. Including the currency benefit, reported earnings per share increased 12 percent.

## Finance Income and Expense

Net finance expense was \$463 million for the year, (\$76 million for quarter four), versus \$111 million in 2007 (\$92 million for quarter four 2007). Key drivers for the full year were the interest payable on additional borrowings alongside reduced interest received on the lower average cash holdings arising as a result of the acquisition of MedImmune.

Net finance expense also included a net fair value gain of \$130 million for the full year (\$82 million in the fourth quarter) 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 bonds will also reflect changes in credit spreads. As such, the widening credit spreads seen during the year have reduced the fair value of the bonds, resulting in the net gain noted above. The Company anticipates that this gain will largely reverse as credit markets stabilise.

## Taxation

The effective tax rate for the fourth quarter was 30.7 percent (2007 30.6 percent) and 29.4 percent for the year (2007 29.5 percent). The full year tax rate for 2009 is currently anticipated to be around 29.5 percent.

## Cash Flow

Cash generated from operating activities was \$8,742 million in the year, compared with \$7,510 million in 2007. The increase of \$1,232 million was principally driven by an increase in operating profit before depreciation, amortisation and impairment costs of \$1,814 million, a decrease in tax payments of \$354 million and lower working capital outflows of \$233 million offset by an increase in interest payments of \$355 million and a decrease in non-cash items of \$814 million which includes movement on provisions.

Net cash outflows from investing activities were \$3,896 million in the year compared with \$14,887 million in 2007. Stripping out acquisitions of \$14,891 million, primarily MedImmune, the increase in cash outflow of \$3,900 million is due primarily to the net payment of \$2,630 million to Merck as part of the partial retirement, a reduction in the inflows from the movement in short term investments and fixed deposits of \$893 million and from the disposal of non-current asset investments of \$389 million, and a decrease in interest received of \$209 million, offset by lower purchases of other intangible assets of \$235 million.

Cash distributions to shareholders were \$3,190 million through dividend payments of \$2,739 million and net share repurchases of \$451 million.

#### Debt and Capital Structure

As at 31 December 2008, outstanding gross debt (including loans, short-term borrowings and overdrafts) was \$11,848 million (31 December 2007: \$15,156 million). Of this debt, \$993 million is due within one year (31 December 2007: \$4,280 million), which we currently anticipate repaying from current cash balances of \$4,286 million and business cash flows, without the need to refinance. Outstanding net debt of \$7,174 million has decreased by \$1,938 million from 31 December 2007.



Edgar Filing: ASTRAZENECA PLC - Form 6-K

Anne-Charlotte Knutsson (Södertälje) (8) 553 213 75

Analyst/Investor Enquiries	Karl Hard/James Mead (London)	(020) 7304 5322/5084
	Jonathan Hunt (London)	(020) 7304 5087
	Ed Seage/Jörgen Winroth (US)	(302) 886 4065/(212) 579 0506

## Item 7

## Condensed Consolidated Income Statement

	2008	2007
	\$m	\$m
For the year ended 31 December		
Revenue	31,601	29,559
Cost of sales	(6,598)	(6,419)
Gross profit	25,003	23,140
Distribution costs	(291)	(248)
Research and development	(5,179)	(5,162)
Selling, general and administrative costs	(10,913)	(10,364)
Other operating income and expense	524	728
Operating profit	9,144	8,094
Finance income	854	959
Finance expense	(1,317)	(1,070)
Profit before tax	8,681	7,983
Taxation	(2,551)	(2,356)
Profit for the period	6,130	5,627
Attributable to:		
Equity holders of the Company	6,101	5,595
Minority interests	29	32
	6,130	5,627
Basic earnings per \$0.25 Ordinary Share	\$4.20	\$3.74
Diluted earnings per \$0.25 Ordinary Share	\$4.20	\$3.73
Weighted average number of Ordinary Shares in issue (millions)	1,453	1,495
Diluted average number of Ordinary Shares in issue (millions)	1,453	1,498
Dividends for the period	2,971	2,740

## Condensed Consolidated Income Statement

	2008	2007
	\$m	\$m
For the quarter ended 31 December		
Revenue	8,193	8,170
Cost of sales	(2,112)	(1,821)
Gross profit	6,081	6,349
Distribution costs	(71)	(67)
Research and development	(1,355)	(1,432)
Selling, general and administrative costs	(2,856)	(3,055)
Other operating income and expense	93	134
Operating profit	1,892	1,929
Finance income	217	256
Finance expense	(293)	(348)
Profit before tax	1,816	1,837
Taxation	(557)	(562)
Profit for the period	1,259	1,275
Attributable to:		
Equity holders of the Company	1,248	1,266
Minority interests	11	9
	1,259	1,275
Basic earnings per \$0.25 Ordinary Share	\$0.86	\$0.86
Diluted earnings per \$0.25 Ordinary Share	\$0.86	\$0.86
Weighted average number of Ordinary Shares in issue (millions)	1,447	1,464
Diluted average number of Ordinary Shares in issue (millions)	1,447	1,466

## Condensed Consolidated Balance Sheet

	2008	2007
	\$m	\$m
As at 31 December		
<b>ASSETS</b>		
Non-current assets		
Property, plant and equipment	7,043	8,298
Goodwill	9,874	9,884
Intangible assets	12,323	11,467
Other investments	156	182
Deferred tax assets	1,236	1,044
	30,632	30,875
Current assets		
Inventories	1,636	2,119
Trade and other receivables	7,261	6,668
Other investments	388	177
Income tax receivable	2,581	2,251
Cash and cash equivalents	4,286	5,867
	16,152	17,082
Total assets	46,784	47,957
<b>LIABILITIES</b>		
Current liabilities		
Interest bearing loans and borrowings	(993)	(4,280)
Trade and other payables	(7,178)	(6,968)
Provisions	(600)	(387)
Income tax payable	(4,549)	(3,552)
	(13,320)	(15,187)
Non-current liabilities		
Interest bearing loans and borrowings	(10,855)	(10,876)
Deferred tax liabilities	(3,126)	(4,119)
Retirement benefit obligations	(2,732)	(1,998)
Provisions	(542)	(633)
Other payables	(149)	(229)
	(17,404)	(17,855)
Total liabilities	(30,724)	(33,042)
Net assets	16,060	14,915
<b>EQUITY</b>		
Capital and reserves attributable to equity holders of the Company		
Share capital	362	364
Share premium account	2,046	1,888
Other reserves	1,932	1,902
Retained earnings	11,572	10,624
	15,912	14,778
Minority equity interests	148	137
Total equity	16,060	14,915

## Condensed Consolidated Cash Flow Statement

	2008	2007
	\$m	\$m
For the year ended 31 December		
Cash flows from operating activities		
Profit before taxation	8,681	7,983
Finance income and expense	463	111
Depreciation, amortisation and impairment	2,620	1,856
Increase in working capital	(210)	(443)
Other non-cash movements	87	901
Cash generated from operations	11,641	10,408
Interest paid	(690)	(335)
Tax paid	(2,209)	(2,563)
Net cash inflow from operating activities	8,742	7,510
Cash flows from investing activities		
Acquisition of business operations	-	(14,891)
Movement in short term investments and fixed deposits	1	894
Purchase of property, plant and equipment	(1,095)	(1,130)
Disposal of property, plant and equipment	38	54
Purchase of intangible assets	(2,944)	(549)
Purchase of non-current asset investments	(40)	(35)
Disposal of non-current asset investments	32	421
Interest received	149	358
Dividends paid by subsidiaries to minority interest	(37)	(9)
Net cash outflow from investing activities	(3,896)	(14,887)
Net cash inflow/(outflow) before financing activities	4,846	(7,377)
Cash flows from financing activities		
Proceeds from issue of share capital	159	218
Repurchase of shares	(610)	(4,170)
Dividends paid	(2,739)	(2,641)
Repayment of loans	-	(1,165)
Issue of loans	787	9,692
Movement in short term borrowings	(3,959)	4,117
Net cash (outflow)/inflow from financing activities	(6,362)	6,051
Net decrease in cash and cash equivalents in the period	(1,516)	(1,326)
Cash and cash equivalents at the beginning of the period	5,727	6,989
Exchange rate effects	(88)	64
Cash and cash equivalents at the end of the period	4,123	5,727
Cash and cash equivalents consists of:		
Cash and cash equivalents	4,286	5,867
Overdrafts	(163)	(140)
	4,123	5,727

## Condensed Consolidated Statement of Recognised Income and Expense

	2008	2007
For the year ended 31 December	\$m	\$m
Profit for the period	6,130	5,627
Foreign exchange and other adjustments on consolidation	(1,336)	492
Foreign exchange differences on borrowings forming net investment hedges	291	(40)
Cash flow hedge in anticipation of debt issue	1	(21)
Available for sale gains/(losses) taken to equity	2	(9)
Actuarial loss for the period	(1,232)	(113)
Tax on items taken directly to reserves	368	33
Income and expense recognised directly in equity	(1,906)	342
Total recognised income and expense for the period	4,224	5,969
Attributable to:		
Equity holders of the Company	4,176	5,934
Minority interests	48	35
	4,224	5,969

## Notes to the Preliminary Announcement

## 1 BASIS OF PREPARATION AND ACCOUNTING POLICIES

The preliminary announcement for the year ended 31 December 2008 has been prepared in accordance with International Accounting Standards and International Financial Reporting Standards (collectively “IFRS”) as adopted by the European Union and as issued by the International Accounting Standards Board. Details of the accounting policies applied are those set out in AstraZeneca PLC’s Annual Report and Form 20-F Information 2007. The annual financial information presented in this preliminary announcement for the year ended 31 December 2008 is based on, and is consistent with, that in the Group’s audited Financial Statements for the year ended 31 December 2008, and those Financial Statements will be delivered to the Registrar of Companies following the Company’s Annual General Meeting. The auditor’s report on those Financial Statements is unqualified and does not contain any statement under section 237 of the Companies Act 1985.

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 Group’s 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 Company’s Annual Report and Form 20-F Information 2007 and the Third Quarter and Nine Months Results 2008.

The preliminary announcement does not constitute statutory accounts of the Group within the meaning of Section 240 of the Companies Act 1985. Statutory accounts for the year ended 31 December 2007 have been filed with the Registrar of Companies. The auditor’s report on those accounts was unqualified and did not contain any statement under Section 237 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 2008 \$m	Cash flow \$m	Non-cash movements \$m	Exchange movements \$m	At 31 Dec 2008 \$m
Loans due after one year	(10,876)	(787)	436	372	(10,855)
Current instalments of loans	-	-	(650)	-	(650)
Total loans	(10,876)	(787)	(214)	372	(11,505)
Other investments - current	177	(1)	226	(14)	388
Cash and cash equivalents	5,867	(1,493)	-	(88)	4,286
Overdrafts	(140)	(23)	-	-	(163)
Short term borrowings	(4,140)	3,959	-	1	(180)
	1,764	2,442	226	(101)	4,331
Net debt	(9,112)	1,655	12	271	(7,174)

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

## 3 RESTRUCTURING AND SYNERGY COSTS

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Profit before tax for the year ended 31 December 2008 is stated after charging restructuring and synergy costs of \$881 million (\$966 million in 2007). These have been charged to the income statement as follows:

	4th Quarter 2008 \$m	4th Quarter 2007 \$m	Full Year 2008 \$m	Full Year 2007 \$m
Cost of sales	277	95	405	415
Research and development	50	36	166	73
Selling, general and administrative costs	189	231	310	478
Total	516	362	881	966

18

---

#### 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 the publication of the disclosures concerning legal proceedings in the Company's Annual Report and Form 20-F Information 2007 and Third Quarter and Nine Month results 2008.

Unless noted otherwise below or in the Annual Report and Form 20-F Information 2007, no provisions have been established in respect of the claims discussed below.

**Abraxane® (paclitaxel protein-bound particles for injectable suspension) (albumin-bound)**

As previously disclosed, AstraZeneca is party to an agreement with Abraxis BioScience, LLC, (Abraxis) to co-promote Abraxane®. In November 2008, AstraZeneca entered into an agreement with Abraxis under which Abraxis re-acquired exclusive rights to market Abraxane® in the United States. Under the agreement, the Board of Directors of Abraxis' parent ended the Co-Promotion Agreement. Upon termination, Abraxis will pay AstraZeneca a \$268 million fee on 31 March 2009.

**Crestor (rosuvastatin)**

**Patent litigation - US**

In January 2008, each of the previously disclosed seven abbreviated new drug application-filers sued by AstraZeneca in the District of Delaware for infringement of the Patent No. RE37,314 (the '314 patent), answered, counterclaimed, or otherwise responded to AstraZeneca's pleadings. AstraZeneca replied or responded as allowed. In response, some defendants submitted jurisdictional motions seeking dismissals of parties and claims. The District Court heard oral argument on the jurisdictional motions in July 2008. In November 2008, the court issued a magistrate's Report and Recommendation Regarding Motions to Dismiss deciding the defendants' various jurisdictional motions. In December 2008, Aurobindo filed objections to the Report. In January 2009, the Court adopted the magistrate's recommendations in respect of all parties except as to Aurobindo and its pending objections. Later in January 2009, AstraZeneca responded to Aurobindo's objections.

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. (together AstraZeneca) in the Eastern District of Pennsylvania. The complaint alleges that the manufacture, use and sale of Crestor 5mg, 10mg, 20mg and 40mg tablets infringe a formulation patent owned by Teva. In January 2009, AstraZeneca responded to Teva's pleading.

**Patent litigation - Canada**

In November 2008, AstraZeneca Canada Inc. received a Notice of Allegation from Apotex Inc. (Apotex) 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. Apotex claims that the '945 patent is invalid and that the '783 patent would not be infringed and is invalid. AstraZeneca responded in December 2008 by commencing a court application under the Patented Medicines (Notice of Compliance) Regulations, seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance (marketing approval) to Apotex until after expiry of the patents.

As a consequence of AstraZeneca Canada's legal actions seeking a Prohibition Order, Apotex cannot obtain a Notice of Compliance for its rosuvastatin calcium tablets until the earlier of the disposition of the court application in its favour or, unless a Prohibition Order is granted, 24 months after the date on which the court application is commenced (assuming its regulatory submission is approvable by that date).

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

Losec/Prilosec (omeprazole)

Patent litigation - Canada

AstraZeneca continues to be involved in proceedings in Canada involving various patents relating to omeprazole capsules or omeprazole magnesium tablets. Apotex Corp. and Apotex, Inc. (together Apotex), launched a generic omeprazole capsule product in Canada in January 2004.

In February 2006, the Federal Court of Appeal upheld a lower court decision that prohibited Apotex from obtaining a Notice of Compliance for omeprazole magnesium tablets until the expiry of a relevant formulation patent in December 2008. In December 2008, the Federal Court of Appeal dismissed Apotex's appeal of an order dismissing a motion by Apotex to set aside a Prohibition Order.

European Commission investigation

The Oral Hearing in the above appeal to the Court of First Instance took place on 26 and 27 November 2008. The Court indicated its intention to hand down judgment in Spring 2009.

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. Oral argument on the California motions was held in December 2008 and a decision is expected by the second quarter of 2009.

#### Patent litigation

In December 2008, AstraZeneca received a Paragraph IV Certification notice-letter from Sandoz, Inc. (Sandoz) that Sandoz had submitted an abbreviated new drug application (ANDA) to the US Food and Drug Administration (FDA) for 20mg and 40mg esomeprazole magnesium delayed-release capsules. The ANDA alleged invalidity and/or non-infringement in respect of certain AstraZeneca US patents listed in the FDA Orange Book with reference to Nexium. In January 2009, AstraZeneca commenced patent infringement litigation in the US District Court for the District of New Jersey against Sandoz in response to Sandoz's Paragraph IV certifications regarding Nexium. 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 Laboratories Inc. and Dr. Reddy's Laboratories Limited (together Dr. Reddy's) for declaratory judgments of non-infringement and/or invalidity for patents listed in the FDA Orange Book with reference to Nexium 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 litigation. No trial date has been set.

As previously disclosed, in March 2008 AstraZeneca received a Paragraph IV Certification notice-letter from Teva Parental Medicines (Teva) that Teva had submitted a new drug application (NDA) to the FDA regarding 20mg/vial and 40mg/vial esomeprazole for injection. The notice contains certifications of invalidity, unenforceability, and/or non-infringement in respect of US Patent No. 5,877,192, which is listed in the FDA Orange Book with reference to Nexium in intravenous form. In April 2008, AstraZeneca commenced patent infringement litigation against Teva in the United States District Court for the District of New Jersey. In October 2008, Teva informed AstraZeneca that Teva was withdrawing its NDA relating to esomeprazole for injection. As a result of Teva withdrawing its NDA, the Court has dismissed the litigation.

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

#### Pulmicort Respules (budesonide inhalation suspension)

In November 2008, AstraZeneca entered into a settlement agreement in its Pulmicort Respules patent infringement litigation against Ivax Pharmaceuticals, Inc., a wholly owned subsidiary of Teva Pharmaceuticals USA (Teva).

The agreement settles the patent infringement litigation filed by AstraZeneca following Teva's submission to the US Food and Drug Administration of an abbreviated new drug application for a generic version of Pulmicort Respules. Under the settlement agreement, Teva concedes that the patents asserted by AstraZeneca in the patent litigation are valid and enforceable. Teva also concedes that its generic version of Pulmicort Respules infringes AstraZeneca's patents.

The settlement agreement will allow Teva to commence sales of budesonide inhalation suspension, a generic version of Pulmicort Respules, under an exclusive license from AstraZeneca, beginning in December 2009. AstraZeneca will

receive a significant undisclosed royalty on sales of Teva's product, with a marked step-down in payments if additional at-risk generic products enter the market place. Teva also agrees to pay AstraZeneca an undisclosed sum in respect of damages resulting from the unauthorised launch of its generic budesonide inhalation suspension product in November 2008. Except as described, the terms of the settlement are confidential. The agreement releases Teva from all past US sales of its generic budesonide inhalation suspension and provides that any product already shipped by Teva will remain in the market to be further distributed and dispensed.

In March 2008, AstraZeneca filed a lawsuit in the US District Court for the District of New Jersey against Breath Ltd. (Breath) for patent infringement. The lawsuit is the result of an ANDA filed by Breath with the FDA concerning Breath's intent to market a generic version of AstraZeneca's Pulmicort Respules in the US prior to the expiration of AstraZeneca's patents. The basis for AstraZeneca's complaint is that the action by Breath of filing an ANDA infringes certain of AstraZeneca's patents directed to Pulmicort Respules and their use. In May 2008, Breath responded and filed counterclaims alleging non-infringement and invalidity. Discovery in the litigation is ongoing.

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

Seroquel (quetiapine fumarate)

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. In most of these cases, the nature of the plaintiffs' alleged injuries is not clear from the complaint and, in most cases, little or no factual information regarding the alleged injury has been provided in the complaint. However, the plaintiffs generally contend that they developed diabetes and/or other related injuries as a result of taking Seroquel and/or other atypical anti-psychotic medications.

As of 5 January 2009, AstraZeneca was defending approximately 9,210 served or answered lawsuits involving approximately 15,461 plaintiff groups. To date, approximately 2,363 additional cases have been dismissed by order or agreement and approximately 1,500 of those cases have been dismissed with prejudice. Approximately 24% of the cases that were or are pending in the federal court Multi-District Litigation (MDL) have been dismissed. Approximately 60% of the plaintiffs' currently pending Seroquel claims are in state courts (primarily Delaware, New Jersey, New York and Missouri) with the other 40% pending in the federal court.

Plaintiffs' discovery of AstraZeneca has largely been completed, although additional discovery may take place. AstraZeneca's discovery of specific plaintiffs' cases is ongoing in most jurisdictions. Bellwether case systems have been implemented by the courts in Delaware, New Jersey and the federal MDL court due to the larger volume of consolidated cases in those jurisdictions.

On 28 January 2009, the federal judge presiding over the Seroquel MDL in the District Court for the Middle District of Florida orally informed the parties that she was granting AstraZeneca's motions for summary judgment in the first two Seroquel product liability cases set for trial. Therefore, the trial scheduled for 2 February 2009 in Florida has been cancelled.

AstraZeneca expects that an additional seven to nine 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.

As of 31 December 2008, legal defence costs of approximately \$512 million have been incurred (of which approximately \$335 million was incurred during 2008). AstraZeneca has product liability insurance that is considered to respond to the vast majority of claims brought in these Seroquel cases, subject to a retention. This insurance provides coverage for legal defence costs and potential damage amounts in connection with the Seroquel product liability cases. AstraZeneca has recorded an insurance receivable of \$426 million at 31 December 2008 (2007 \$139 million). The Company's insurance coverage with respect to the Seroquel cases may not be adequate to cover its defence costs and potential damage amounts.

#### Patent litigation - Seroquel

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. Oral argument is scheduled for 6 March 2009.

#### 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 abbreviated new drug application (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 US District Court, District of New Jersey against Handa alleging infringement of AstraZeneca's patents covering the active ingredient and formulation of Seroquel XR 50mg tablets; and 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. Biovail's certification notice-letter alleged non-infringement and invalidity in respect of AstraZeneca's patents. In January 2009, AstraZeneca filed a lawsuit in US District Court, District of New Jersey, against Biovail and related entities 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.

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

#### Sales and marketing practices

In February 2007, the Commonwealth of Pennsylvania (Commonwealth) filed a lawsuit against AstraZeneca, Eli Lilly & Co. (Lilly), and Janssen Pharmaceutica Inc. (Janssen) claiming damages incurred by the Commonwealth as a result of alleged off-label promotion of atypical anti-psychotic medications by the three manufacturers. The lawsuit is filed in state court in Philadelphia and seeks to recover the cost to the Pennsylvania Medicaid programme and other state-funded health insurance programmes for prescriptions written as a result of the alleged off-label promotion, and also seeks 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 December 2007, the Court granted the defendants' motion to sever the claims against AstraZeneca and Janssen from those against Lilly and directed the Commonwealth to file separate complaints against the two severed defendants, which the Commonwealth did in January 2008. In December 2008, the Court granted AstraZeneca's motion to dismiss all but two counts of the complaint, including dismissal of the Commonwealth's claims alleging violations of the Pennsylvania Medicaid False Claims Act. Similar lawsuits were filed by the State of Montana in February 2008, the State of Arkansas in May 2008, and the State of South Carolina in January 2009. AstraZeneca believes these claims to be without merit and intends to vigorously defend against them. As of the date of this announcement, the Montana action has not been served.

In May 2007, the New Jersey Ironworkers Local Union No. 68 filed a class action lawsuit against AstraZeneca on behalf of all individuals and non-governmental entities that paid for Seroquel from January 2000 to date. The lawsuit was filed in the federal District Court in New Jersey and alleged that AstraZeneca promoted Seroquel for off-label uses and misled class members into believing that Seroquel was superior to other, lower-cost alternative medicines. Two similar class action lawsuits were filed in June and July 2007 in the New Jersey and Pennsylvania federal courts. In December 2007, the three lawsuits were transferred to the Middle District of Florida by the US Judicial Panel on MDL. In November 2008, the MDL Court granted AstraZeneca's motion and dismissed these cases in their entirety with prejudice. The plaintiffs filed a Notice of Appeal in December 2008. AstraZeneca intends to vigorously defend against the appeal, which it expects will be heard by the Eleventh Circuit Court of Appeals some time in 2009.

In September 2008, the Pennsylvania Employees Benefit Trust Fund (PEBTF) served AstraZeneca Pharmaceuticals LP with a complaint filed in the Pennsylvania Court of Common Pleas of Philadelphia County seeking economic damages stemming from allegedly improper marketing practices that caused the PEBTF to reimburse for allegedly overpriced Seroquel prescription and the medical care of Fund members allegedly injured from Seroquel use. In October 2008, AstraZeneca removed this lawsuit to federal court and immediately requested that it be transferred to the Seroquel MDL. The decision regarding transfer is pending. AstraZeneca intends to vigorously defend itself against this lawsuit.

#### Symbicort (budesonide/formoterol)

As previously disclosed, following an appeal by the generic manufacturers Norton Healthcare (Norton) and Generics UK, the European Patent Office (EPO) Technical Board of Appeal revoked the European patent, EPB 1,014,993, covering the use of Symbicort for the treatment of chronic obstructive pulmonary disease (COPD). The stays granted in the revocation proceedings instituted by IVAX Pharmaceuticals (UK) Limited (IVAX) in the UK and Ireland with respect to the national parts of the Symbicort combination patent EPB 613,371 and EPB 1,014,993 will remain in place until IVAX applies to the Court to lift these stays in light of the EPO decisions.

In December 2008, following an opposition by Norton, the EPO Opposition Division revoked the European patent, EPB 1,210,943, covering the use of Symbicort, with a specific ratio of the active ingredients and a specific particle size, for the treatment of COPD.

In June 2008, the US Patent and Trademark Office issued a final determination that US Patent No. 5,674,860 was not eligible for patent term extension. AstraZeneca filed a request for reconsideration.

AstraZeneca will vigorously defend and enforce its remaining intellectual property portfolio protecting Symbicort, which has patent expiry dates up to 2019 in Europe.

#### Anti-trust

The European Commission (Commission) is conducting a sector-wide inquiry into the pharmaceutical industry. AstraZeneca and several other pharmaceutical companies were the subject of unannounced inspections in January 2008. The inquiry relates to the introduction of innovative and generic medicines and it will cover

commercial practices, including the use of patents and generics. We understand that several companies have been similarly approached.

The Commission has stated that this inquiry is not aimed at investigating practices where there have been any indications of wrongdoing, although it could address any competition law breaches found by means of separate proceedings. The Commission has also stated that the final results of its inquiry will be available in Spring 2009. It is possible that companies, including AstraZeneca, may be the subject of investigation.

AstraZeneca is cooperating fully with the Commission in relation to its inquiry.

#### Average wholesale price class action litigation

As previously disclosed, AstraZeneca is a defendant along with many other pharmaceutical manufacturers in several sets of cases involving allegations that plaintiffs overpaid for prescription drugs as a result of defendants causing the publication of allegedly inflated wholesale list prices.

In December 2008, the US District Court in Boston, Massachusetts approved the proposed settlement resolving Class 1 claims on a nationwide basis. The settlement will involve payments of up to \$24 million to reimburse individual class members submitting claims, plus attorneys' fees of \$8.58 million. AstraZeneca has agreed that a portion of any unclaimed settlement amounts will be donated to charitable organisations funding cancer patient care and research. In January 2009, one of the class members filed a notice of appeal challenging the settlement.

In June 2007 and November 2007, the Multi District Litigation (MDL) Court issued decisions, after a bench trial, on liability and damages on Classes 2 and 3. The Court found AstraZeneca liable under the Massachusetts consumer protection statute for engaging in unfair and deceptive conduct in connection with the pricing of Zoladex during the period 1998 to 2003. In November 2008, the Court of Appeals heard oral argument on AstraZeneca's appeal of that decision.

In September 2008, the MDL Court granted, in part, the plaintiffs' motion for certification of multi-state class actions relating to Zoladex. In January 2009, the Court granted AstraZeneca's motion to stay the entry of the order pending AstraZeneca's appeal of the Court's award relating to Massachusetts-only claims.

In December 2008, AstraZeneca filed its opening brief supporting its appeal of the judgment rendered by the Alabama court, after a jury trial, in favour of the State of Alabama. The appeal seeks to have the entire judgment reversed or, in the alternative, a new trial.

As previously disclosed, MedImmune is also involved in various lawsuits brought by various states and counties in the US alleging manipulation of average wholesale prices by several defendants. In December 2008, the State of Kansas filed a suit against a number of defendants, including MedImmune, in the District Court of Wyandotte County, Kansas.

The allegations made in respect of the average wholesale price lawsuits described in this section are denied and will be vigorously defended.

#### 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 41 lawsuits, involving approximately 48 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, 25 plaintiffs have dismissed their cases against the AstraZeneca defendants while the case was in preliminary stages, and the AstraZeneca defendants have filed pending motions to dismiss several other cases. In addition, three 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 six of the active claims to Abraxis.

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

AstraZeneca faces a number of transfer pricing audits in jurisdictions around the world and, in some cases, is in dispute with the tax authorities. These disputes usually result in taxable profits being increased in one territory and correspondingly decreased in another. Our balance sheet positions for these matters reflect appropriate corresponding relief in the territories affected. The total net accrual included in the Financial Statements to cover the worldwide exposure to transfer pricing audits is \$1,628 million, an increase of \$306 million due to a number of new audits, revisions of estimates relating to existing audits, offset by a number of negotiated settlements and exchange rate effects.

Included in the total net accrual are amounts in respect of the following transfer pricing arrangements:

- 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.

- AstraZeneca has applied for two advance pricing agreements (APA's) in relation to intra-group transactions
- between the UK and the US and the UK and Japan. Both APA's are being progressed through competent authority proceedings under the relevant double tax treaties.

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 ACCOUNTING IMPACT FROM MERCK ARRANGEMENTS

### Introduction

In 1982, Astra AB set up a joint venture with Merck & Co., Inc. for the purposes of selling, marketing and distributing certain Astra products in the US. In 1998, this joint venture was restructured (the “Restructuring”). Under the agreements relating to the Restructuring (the “Agreements”), a US limited partnership was formed, in which Merck is the limited partner and AstraZeneca is the general partner, and AstraZeneca obtained control of the joint venture’s business subject to certain limited partner and other rights held by Merck and its affiliates. These rights provide Merck with safeguards over the activities of the partnership and place limitations on AstraZeneca’s commercial freedom to operate. The Agreements provide for:

- Annual contingent payments.

A payment to Merck in the event of a business combination between Astra and a third party in order for Merck to

- relinquish certain claims to that third party’s products.
- Termination arrangements which, if and when triggered, cause Merck to relinquish its interests in AstraZeneca’s products and activities.

Further details are set out in the 2007 Annual Report and Form 20-F Information.

### Payment made on 17 March 2008

On 17 March, under the termination arrangements included in the Agreements, AstraZeneca made a net cash payment to Merck of approximately \$2.63 billion. This payment resulted in AstraZeneca acquiring Merck’s interests in certain AstraZeneca products including Pulmicort, Rhinocort, Symbicort and Toprol-XL. Consequently AstraZeneca no longer has to pay contingent payments on these products to Merck and has obtained the ability to fully exploit these products and to fully exploit other opportunities in the Respiratory therapy area that AstraZeneca was previously prevented from doing by Merck’s interests in these products. Intangible assets aggregating to \$994 million have been recognised in respect of these acquired product rights and these are being amortised over various periods giving rise to an annual expense of approximately \$55 million per annum. Approximately \$45 million of this amortisation relates to relief from contingent payments, and will be charged to Cost of Goods Sold (COGS), with the balance related to the Respiratory therapy area, which will be charged to SG&A. For the purposes of calculating Core financial measures, the Company will exclude only the amortisation expense related to therapy area intangibles (i.e. that charged to SG&A) from the Core financial measures calculations.

The balance of the net payment made on 17 March represents payments on account for the product rights that will be acquired in the event that the First Option and the Second Option (see below) are exercised by AstraZeneca. Intangible assets aggregating to \$1,656 million have been recognised. These balances are not subject to amortisation until each of the options is exercised and the related product rights are acquired. Should it become probable that the First Option will not be exercised, all the payments on account will be expensed immediately. If after the First Option has been exercised it becomes probable that the Second Option will not be exercised, the payments on account for the product rights to be acquired under the Second Option will be expensed immediately.

### Further optional payments

AstraZeneca has the right in 2010 to acquire Merck’s interests in all the products still covered by the Agreements other than Prilosec and Nexium for \$647 million (“the First Option”). These products comprise marketed products (Entocort, Atacand, Plendil, Lexxel) and products still in development (including AZD6140, AZD3355 and AZD2327). If the First Option is exercised, AstraZeneca will no longer have to pay contingent payments on these products to Merck and will obtain the ability to fully exploit these products and to fully exploit other opportunities in the Cardiovascular and Neuroscience therapy areas that AstraZeneca was previously prevented from doing by Merck’s interests in these products. If the First Option is exercised, this will give rise to an additional amortisation expense in the range of \$15

to \$50 million per annum charged to COGS, the precise amount dependent upon the launch status of the covered pipeline compounds, and an additional charge to SG&A of around \$60 million.

Provided that the First Option is exercised, AstraZeneca may exercise a further option (“the Second Option”) two years later (or in 2017, or if combined annual sales of the two products fall below a minimum amount) which will end the contingent payments in respect of Nexium and Prilosec and effectively end AstraZeneca’s relationship with and obligations to Merck (other than some residual manufacturing arrangements). The exercise price for the Second Option is the net present value of the future annual contingent payments on Prilosec and Nexium as determined at the time of exercise. If the Second Option is exercised then amortisation related to the ability to exploit opportunities in the Gastrointestinal therapy area will commence, in the amount of \$15 million per annum (charged to SG&A), as well as an as yet indeterminable amount of amortisation related to relief from contingent payments.

The intangible assets relating to purchased product rights and the intangible assets relating to payments on account will be subject to impairment testing and would be partially or wholly impaired if a product is withdrawn or if activity in any of the affected therapy areas is significantly curtailed.

## 6 FULL YEAR TERRITORIAL SALES ANALYSIS

	Full Year 2008 \$m	Full Year 2007 \$m	% Growth	
			Actual	Constant Currency
US	13,510	13,366	1	1
Canada	1,275	1,145	11	8
North America	14,785	14,511	2	2
Western Europe**	9,743	9,115	7	1
Japan	1,957	1,661	18	4
Other Established ROW	843	715	18	15
Established ROW*	12,543	11,491	9	2
Emerging Europe	1,215	1,028	18	10
China	627	437	43	31
Emerging Asia Pacific	802	749	7	10
Other Emerging ROW	1,629	1,343	21	18
Emerging ROW	4,273	3,557	20	16
Total Sales	31,601	29,559	7	3

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

\*\* For the full year, Western Europe sales growth excluding Synagis would be 5 percent on an actual basis and -1 percent on a constant currency basis.

## 7 FOURTH QUARTER TERRITORIAL SALES ANALYSIS

	4th Quarter 2008 \$m	4th Quarter 2007 \$m	% Growth	
			Actual	Constant Currency
US	3,784	3,665	3	3
Canada	296	331	(11)	6
North America	4,080	3,996	2	3
Western Europe**	2,298	2,453	(6)	2
Japan	602	532	13	-
Other Established ROW	190	209	(9)	13
Established ROW*	3,090	3,194	(3)	3
Emerging Europe	291	293	(1)	10
China	171	124	38	27
Emerging Asia Pacific	184	204	(10)	4
Other Emerging ROW	377	359	5	17
Emerging ROW	1,023	980	4	13
Total Sales	8,193	8,170	-	4

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

\*\* For the fourth quarter, Western Europe sales growth excluding Synagis would be -8 percent on an actual basis and 1 percent on a constant currency basis.



## 8 FULL YEAR PRODUCT SALES ANALYSIS

	World				US	
	Full Year 2008 \$m	Full Year 2007 \$m	Actual Growth %	Constant Currency Growth %	Full Year 2008 \$m	Actual Growth %
<b>Gastrointestinal:</b>						
Nexium	5,200	5,216	-	(2)	3,101	(8)
Losec/Prilosec	1,055	1,143	(8)	(14)	171	(25)
Others	89	84	6	2	33	10
Total Gastrointestinal	6,344	6,443	(2)	(4)	3,305	(9)
<b>Cardiovascular:</b>						
Crestor	3,597	2,796	29	26	1,678	18
Seloken/Toprol-XL	807	1,438	(44)	(46)	295	(70)
Atacand	1,471	1,287	14	10	262	1
Tenormin	313	308	2	(6)	18	(5)
Zestril	236	295	(20)	(24)	20	11
Plendil	268	271	(1)	(7)	25	(29)
Others	271	291	(7)	(12)	1	(50)
Total Cardiovascular	6,963	6,686	4	-	2,299	(16)
<b>Respiratory:</b>						
Symbicort	2,004	1,575	27	22	255	410
Pulmicort	1,495	1,454	3	-	982	2
Rhinocort	322	354	(9)	(12)	182	(21)
Oxis	71	86	(17)	(24)	-	-
Accolate	73	76	(4)	(5)	53	(4)
Others	163	166	(2)	(5)	-	-
Total Respiratory	4,128	3,711	11	7	1,472	13
<b>Oncology:</b>						
Arimidex	1,857	1,730	7	4	754	9
Casodex	1,258	1,335	(6)	(12)	292	(2)
Zoladex	1,138	1,104	3	(3)	72	(22)
Iressa	265	238	11	3	7	(22)
Ethyol	28	43	n/m	n/m	28	n/m
Others	408	369	11	6	173	4
Total Oncology	4,954	4,819	3	(2)	1,326	2
<b>Neuroscience:</b>						
Seroquel	4,452	4,027	11	9	3,015	5
Local anaesthetics	605	557	9	2	34	(24)
Zomig	448	434	3	(1)	187	6
Diprivan	278	263	6	(1)	39	(3)
Others	54	59	(8)	(12)	9	(40)
Total Neuroscience	5,837	5,340	9	6	3,284	5
<b>Infection and Other:</b>						
Synagis	1,230	618	n/m	n/m	923	n/m
Merrem	897	773	16	13	207	39
FluMist	104	53	96	96	104	96
Other Products	220	270	(19)	(20)	115	(22)
Total Infection and Other	2,451	1,714	n/m	n/m	1,349	n/m

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Aptium Oncology	395	402	(2)	(2)	395	(2)
Astra Tech	529	444	19	14	80	33
Total	31,601	29,559	7	3	13,510	1

26

---

## 9 FOURTH QUARTER PRODUCT SALES ANALYSIS

	4th Quarter 2008 \$m	World 4th Quarter 2007 \$m	Actual Growth %	Constant Currency Growth %	US 4th Quarter 2008 \$m	Actual Growth %
<b>Gastrointestinal:</b>						
Nexium	1,324	1,303	2	6	832	2
Losec/Prilosec	264	298	(11)	(11)	33	(43)
Others	23	24	(4)	4	10	11
Total Gastrointestinal	1,611	1,625	(1)	3	875	(1)
<b>Cardiovascular:</b>						
Crestor	987	799	24	30	490	27
Seloken/Toprol-XL	207	209	(1)	2	88	2
Atacand	351	353	(1)	9	64	(3)
Tenormin	77	84	(8)	(8)	4	(20)
Zestril	52	67	(22)	(16)	5	150
Plendil	67	66	2	3	10	43
Others	62	78	(21)	(14)	-	-
Total Cardiovascular	1,803	1,656	9	15	661	20
<b>Respiratory:</b>						
Symbicort	514	436	18	29	90	463
Pulmicort	397	447	(11)	(10)	260	(15)
Rhinocort	78	87	(10)	(8)	43	(22)
Oxis	15	22	(32)	(27)	-	-
Accolate	18	19	(5)	(5)	14	-
Others	37	45	(18)	(7)	-	-
Total Respiratory	1,059	1,056	-	6	407	4
<b>Oncology:</b>						
Arimidex	451	474	(5)	(1)	177	(5)
Casodex	284	370	(23)	(24)	77	(1)
Zoladex	278	307	(9)	(6)	17	(29)
Iressa	73	70	4	(1)	2	-
Ethyol	5	16	(69)	(69)	5	(69)
Others	104	102	2	4	46	5
Total Oncology	1,195	1,339	(11)	(9)	324	(8)
<b>Neuroscience:</b>						
Seroquel	1,160	1,086	7	10	831	8
Local anaesthetics	147	159	(8)	(1)	8	(38)
Zomig	112	114	(2)	3	49	11
Diprivan	65	74	(12)	(11)	10	(9)
Others	11	16	(31)	(25)	2	(50)
Total Neuroscience	1,495	1,449	3	7	900	7
<b>Infection and Other:</b>						
Synagis	506	480	5	5	380	(3)
Merrem	217	215	1	10	56	33
FluMist	33	53	(38)	(38)	33	(38)
Other Products	49	68	(28)	(21)	27	(31)
Total Infection and Other	805	816	(1)	2	496	(6)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Aptium Oncology	101	102	(1)	(1)	101	(1)
Astra Tech	124	127	(2)	6	20	5
Total	8,193	8,170	-	4	3,784	3

27

---

## Convenience Translation of Key Financial Information

For the quarter ended 31 December	2008 \$m	2007 \$m	2008 £m	2007 £m	2008 SEKm	2007 SEKm
Total Sales	8,193	8,170	5,675	4,099	63,692	52,330
Operating profit	1,892	1,929	1,310	968	14,708	12,355
Profit before tax	1,816	1,837	1,258	922	14,118	11,766
Net profit for the period	1,259	1,275	872	640	9,787	8,167
Earnings per Ordinary Share	\$0.86	\$0.86	£0.60	£0.43	SEK6.69	SEK5.51

For the year ended 31 December	2008 \$m	2007 \$m	2008 £m	2007 £m	2008 SEKm	2007 SEKm
Total Sales	31,601	29,559	21,888	14,830	245,666	189,328
Operating profit	9,144	8,094	6,334	4,061	71,085	51,843
Profit before tax	8,681	7,983	6,013	4,005	67,486	51,132
Net profit for the year	6,130	5,627	4,246	2,823	47,655	36,041
Earnings per Ordinary Share	\$4.20	\$3.74	£2.91	£1.88	SEK32.65	SEK23.96
Dividend per Ordinary Share	\$2.05	\$1.87	£1.33	£0.93	SEK15.36	SEK12.10
Net cash inflow from operating activities	8,742	7,510	6,055	3,768	67,960	48,102
Decrease in cash & cash equivalents	(1,516)	(1,326)	(1,050)	(665)	(11,785)	(8,493)
Capital and Reserves Attributable to Equity Holders	15,912	14,778	11,021	7,414	123,700	94,655

All Sterling (£) and Swedish krona (SEK) equivalents are shown for convenience and have been calculated using the current period end rates of \$1= £0.692641 and \$1= SEK7.774000 respectively. Dividend per Ordinary Share is shown as the actual amount payable using the rates at the date of declaration of the dividend.

Shareholder Information

ANNOUNCEMENTS AND MEETINGS

---

Announcement of first quarter 2009 results	30 April 2009
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

---

The record date for the first interim dividend payable on 15 September 2008 (in the UK, Sweden and the US) was 8 August 2008. Ordinary shares traded ex-dividend on the London and Stockholm Stock Exchanges from 6 August 2008. ADRs traded ex-dividend on the New York Stock Exchange from the same date.

The record date for the second interim dividend for 2008 payable on 16 March 2009 (in the UK, Sweden and the US) will be 6 February 2009. Ordinary shares will trade ex-dividend on the London and Stockholm Stock Exchanges from 4 February 2009. ADRs will trade ex-dividend on the New York Stock Exchange from the same date.

Future dividends will normally be paid as follows:

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

TRADEMARKS

---

Trademarks of the AstraZeneca group of companies appear throughout this document in italics. AstraZeneca, the AstraZeneca logotype and the AstraZeneca symbol are all trademarks of the AstraZeneca group of companies. Trademarks of companies other than AstraZeneca appear with a ® or ™ sign and include: Abraxane®, a registered trademark of Abraxis BioScience, LLC. and ONGLYZA™, a trademark of Bristol-Myers Squibb Company.

ADDRESSES FOR CORRESPONDENCE

Registrar and Transfer Office	Depository for ADRs	Registered Office	Swedish Securities Registration Centre
The AstraZeneca Registrar Equiniti Limited	JPMorgan Chase Bank	15 Stanhope Gate	VPC AB
Aspect House	JPMorgan Service Center	London	PO Box 7822
Spencer Road	PO Box 3408	W1K 1LN	SE-103 97 Stockholm
	South Hackensack	UK	Sweden

Lancing  
West Sussex  
BN99 6DA  
UK

NJ 07606-3408  
US

Tel (freephone in UK):  
0800 389 1580

Tel (toll free in US):  
888 697 8018  
Tel: +1 (201) 680 6630

Tel: +44 (0)20 7304 5000  
Tel: +46 (0)8 402 9000

Tel (outside UK):  
+44 (0)121 415 7033

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

---

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: This preliminary announcement contains 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 this preliminary announcement 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; 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.

Item 8

Transparency Directive  
Voting Rights and Capital

The following notification is made in accordance with the UK Financial Services Authority Disclosure and Transparency Rule 5.6.1. On 30 January 2009 the issued share capital of AstraZeneca PLC with voting rights is 1,447,634,123 ordinary shares of US\$0.25. No shares are held in Treasury. Therefore, the total number of voting rights in AstraZeneca PLC is 1,447,634,123.

The above figure for the total number of voting rights may be used by shareholders as the denominator for the calculations by which they will determine if they are required to notify their interest in, or a change to their interest in, AstraZeneca PLC under the FSA's Disclosure and Transparency Rules.

A C N Kemp  
Company Secretary  
30 January 2009

---