ASTRAZENECA PLC Form 6-K February 06, 2006

# 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 & 1-2 February 2006

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 <u>X</u> Form 40-F <u></u> 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 _X_  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, [AstraZeneca Submits sNDA For Seroquel® For Biopolar Depression Treatment[], dated 3 January 2006.
- 2. Press release entitled, [Toprol-XL® (metoprolol succinate): AstraZeneca to appeal decision in US Patent Litigation[], dated 18 January 2006.

- 3. Press release entitled, "Dealing by Directors Companies Act 1985 Sections 324 / 329 Transaction by Persons Discharging Managerial Responsibilities Disclosure Rules DR 3.1.2R", dated 24 January 2006.
- 4. Press release entitled, "AstraZeneca PLC Fourth Quarter and Full Year Results 2005" (front half), dated 2 February 2006.
- 5. Press release entitled, "AstraZeneca PLC Fourth Quarter and Full Year Results 2005 Consolidated Income Statement" (back half), dated 2 February 2006.

## **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: 6 February 2006 By: /s/ G H R Musker

Name: G H R Musker Title: Secretary & Solicitor

# Item 1

# AstraZeneca Submits sNDA For Seroquel® For Bipolar Depression Treatment

Filing Seeks Approval of SEROQUEL as a Monotherapy Treatment for Bipolar Depression

AstraZeneca today announced submission of a supplemental New Drug Application (sNDA) to the US Food and Drug Administration (FDA) to seek approval for a new indication for SEROQUEL® (quetiapine fumarate) for the treatment of patients with depressive episodes associated with bipolar disorder. SEROQUEL is currently approved for the treatment of acute manic episodes associated with bipolar I disorder and the treatment of schizophrenia.

This sNDA submission is an important milestone in the history of SEROQUEL. If SEROQUEL receives approval from the FDA to treat bipolar depression, it would be the only single agent indicated to treat both the depressive and manic episodes associated with bipolar disorder.

The sNDA submission is based on results from the clinical trial programme known as BOLDER (**BipOL**ar **DEpR**ession), which comprises two studies: BOLDER I and BOLDER II. Both studies were double-blind, placebo-controlled trials of outpatients (N=1,045) with bipolar I or II disorder. Patients were randomised to receive eight weeks treatment with fixed doses of SEROQUEL (300 mg or 600 mg) or placebo administered once daily. In both studies, patients receiving SEROQUEL, as compared to those receiving placebo, showed a statistically significant decrease in depression scores at week one, and scores continued to decrease throughout the eight-week study. More than half of the SEROQUEL treated patients in each trial met the criteria for remission.

Additionally, SEROQUEL was shown to have similar safety profiles in both BOLDER I and II. The most common adverse effects reported in these trials included dry mouth, sedation, somnolence, dizziness, and constipation.

Bipolar disorder, which affects more than seven million American adults, consists of recurring episodes of mania and depression. Patients with bipolar disorder are symptomatic almost half of their lives, and approximately two-thirds of that time is spent in the depressed phase of the illness. Prolonged periods of sadness, unexplained loss of energy, persistent lethargy, and recurring thoughts of death or suicide characterise depressive episodes. Up to 50 per cent of

patients with bipolar depression attempt suicide, and approximately 10 to 15 per cent commit suicide. Furthermore, bipolar disorder is often misdiagnosed, and patients may suffer up to 10 years before a correct diagnosis is made.

SEROQUEL® (quetiapine fumarate) is the number one prescribed atypical antipsychotic in the United States and has a well-established safety and efficacy profile. In 2004, sales for SEROQUEL reached \$2 billion. SEROQUEL has had more than 13 million patient exposures worldwide since its launch in 1997.

## **ABOUT BIPOLAR DISORDER**

Bipolar I disorder consists of recurring episodes of mania with or without depression. Bipolar II disorder consists of recurring episodes of depression and hypomania, a milder form of mania. In the long term, patients with bipolar I disorder spend three times longer in the depressed state than in mania. Patients with bipolar II disorder have traditionally been difficult to treat as they spend almost 40 times longer in the depressed state than in mania. Without appropriate treatment, patients usually suffer for a lifetime with periods of wellness and functioning punctuated by severe episodes of illness. Both men and women are equally at risk for this illness, which most often emerges in adolescence or young adulthood and recurs throughout life.

## **ABOUT ASTRAZENECA**

AstraZeneca is a major international healthcare business engaged in the research, development, manufacture and marketing of prescription pharmaceuticals and the supply of healthcare services. It is one of the world's leading pharmaceutical companies with healthcare sales of over \$21.4 billion and leading positions in sales of gastrointestinal, cardiovascular, respiratory, oncology and neuroscience products. AstraZeneca is listed in the Dow Jones Sustainability Index (Global) as well as the FTSE4Good Index.

Depression scores were measured by the Montgomery-Åsberg Depression Rating Scale (MADRS). The MADRS scale measures the severity of a number of depressive symptoms including mood and sadness, tension, sleep, appetite, energy, concentration, and suicidal ideation. The MADRS score decreases as depressive symptoms improve. Remission was defined as a MADRS score of </=12. In BOLDER I, mean change in MADRS scores were at week eight from baseline (-)16.7 for SEROQUEL 600 mg and (-)16.4 for SEROQUEL 300 mg vs. (-)10.3 for placebo; (p<0.001) . The corresponding mean changes in BOLDER II were

(-)16.0, (-)16.9, and (-)11.9, respectively (p<0.001).

3 January 2006

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# Item 2

# TOPROL-XL® (metoprolol succinate): ASTRAZENECA TO APPEAL DECISION IN U.S. PATENT LITIGATION

AstraZeneca today announced that it has received a decision of Judge Rodney Sippel of the U.S. District Court for the Eastern District of Missouri in litigation titled In Re Metoprolol Succinate Patent Litigation. This case is a consolidation of the company scases against defendants KV Pharmaceutical Company, Andrx Pharmaceuticals LLC, Andrx Corporation, and Eon Labs Manufacturing, Inc. The decision was issued in response to motions by all parties argued on November 16-17, 2005, regarding the validity, enforceability and infringement of two of the U.S. patents associated with TOPROL-XL® (metoprolol succinate) extended release tablets.

In its decision, the Court found that the patents asserted by AstraZeneca in this litigation -- the compound patent (U.S. Patent Number 5,081,154; ) and the composition patent (U.S. Patent Number 5,001,161) that cover TOPROL-XL® are invalid. The Court also found that the patents asserted by AstraZeneca in the litigation are unenforceable. AstraZeneca disagrees with and is disappointed by these conclusions. The Company maintains that both patents are valid and enforceable and will appeal the Court $\Box$ s decision. Both patents are due to expire on September 17<sup>th</sup> 2007.

Sales for TOPROL-XL in the US in 2005 were \$1,291 million. TOPROL-XL is a registered trademark of the AstraZeneca group of companies.

# **TOPROL-XL** ® (metoprolol succinate) Extended-Release Tablets

TOPROL-XL® is a beta<sub>1</sub>-selective (cardioselective) adrenoceptor-blocking agent, for oral administration, available as extended-release tablets. TOPROL-XL has been formulated to provide a continuous release of metoprolol for once-daily administration.

Indications for TOPROL-XL® include the treatment of hypertension, alone or in combination with other antihypertensives; the long-term treatment of angina pectoris; and the treatment of stable, symptomatic (NYHA Class II or III) heart failure of ischemic, hypertensive, or cardiomyopathic origin.

Toprol-XL® is sold outside the US as Seloken-ZOK®.

# 18 January 2006

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## Item 3

Dealing by Directors
Companies Act 1985 Sections 324/329

## Transaction by Persons Discharging Managerial Responsibilities Disclosure Rules DR 3.1.2R

We hereby inform you that, on 23 January 2006, Dr H L Mogren, a Director of the Company, ceased to have an interest in an option over 9,826 AstraZeneca PLC Ordinary Shares of USD0.25 each following its expiry.

The option was originally granted to Dr Mogren in 1999 for a period of seven years over shares in Astra AB under the Astra Shareholder Value Incentive Plan. The option was subsequently converted into an option over Ordinary Shares in AstraZeneca PLC in April 1999. The option has not been exercised by Dr Mogren and has consequently expired on reaching the seventh anniversary of the date of grant. Details of the option are as follows:-

Number of AstraZeneca shares over which option was held

Effective option price per share

Market price of AstraZeneca shares when option expired

9,826 441.78SEK 356.50SEK

Following the expiry of this option, Dr Mogren holds options over 244,896 Ordinary Shares of AstraZeneca PLC.

G H R Musker Company Secretary 24 January 2006

## Item 4

# AstraZeneca PLC Fourth Quarter and Full Year Results 2005

# Strong growth from key products and improved efficiency drive 44 percent increase in Earnings per Share for 2005. □

# **Financial Highlights**

Group	4 <sup>th</sup> Quarter	4 <sup>th</sup> Quarter	Actual	CER	Full Year	Full Year	Actual	CER
	2005	2004	<u>%</u>	<u>%</u>	2005	2004	<u>%</u>	<u>%</u>
	<u>\$m</u>	<u>\$m</u>			<u>\$m</u>	<u>\$m</u>		
Sales	6,286	5,799	+8	+9	23,950	21,426	+12	+10
Operating Profit	1,636	1,271	+29	+26	6,502	4,547	+43	+39
Profit before Tax	1,689	1,295	+30	+29	6,667	4,844	+38	+34
Earnings per Share:								
Before exceptional items	\$0.77	\$0.55	+38	+37	\$2.91	\$2.01*	+44	+41
Statutory	\$0.77	\$0.55	+38	+37	\$2.91	\$2.18	+33	+30

<sup>\*</sup> There were two exceptional items in Q3 2004, which benefited profit before tax by \$219 million and earnings per share by \$0.17.

Excluding these benefits, earnings per share increased 44 percent on an as reported basis for the full year compared with 2004. *All narrative in this section refers to growth rates at constant exchange rates (CER) unless otherwise indicated* 

- Sales for the full year increased by 10 percent to \$23,950 million.
- Operating profit increased by 39 percent to \$6,502 million as a result of the strong sales growth and the impact of ongoing productivity gains. Operating margin for the year increased to 27.2 percent.
- AstraZeneca product portfolio now has 10 products with annual sales of \$1 billion or greater.
- Strong performance from five key products (Nexium<sup>TM</sup>, Seroquel<sup>TM</sup>, Crestor<sup>TM</sup>, Arimidex<sup>TM</sup> and Symbicort<sup>TM</sup>), with combined sales reaching \$10,849 million, up 27 percent for the full year.
- Supplemental New Drug Application submitted to US FDA in December for a new indication for SeroquelTM for the treatment of depressive episodes associated with bipolar disorder.
- Development pipeline strengthened. Four new chemical entities have been entered into Phase III development.
- Development pipeline augmented by three licensing transactions (one Phase III compound and two Phase II compounds) and the acquisition of KuDOS Pharmaceuticals announced in December.

- Dividend increased by 38 percent to \$1.30 for the full year.
- Free cash flow of \$6,052 million for the full year. Share repurchases totalled \$3,001 million in 2005. Share repurchases in 2006 are expected to be at a similar level.
- The Company anticipates EPS for 2006 in the range of \$3.40 to \$3.60. This includes around 45 cents of earnings related to Toprol-XL<sup>TM</sup> for the remaining eleven months of 2006.

**David Brennan, Chief Executive Officer, said**: Strong growth from our key products and further improvements in efficiency have contributed to AstraZenecas excellent financial performance. The output from our discovery organization has grown, and new medicines from both our own and external research have entered late stage development, including those from recent licensing transactions. However we will do more to further strengthen our product pipeline, and this is my number one priority.

## London, 2 February 2006

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Photos of David Brennan, Chief Executive Officer, Jonathan Symonds, Chief Financial Officer, and Dr. John Patterson, Executive Director Development are available on www.newscast.co.uk

### AstraZeneca PLC

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

## Full Year

Sales for the full year increased 10 percent at CER, or 12 percent on an as reported basis (including an exchange benefit of 2 percent) with good sales growth in all regions (US up 12 percent; Europe up 8 percent; Japan up 8 percent; Rest of World up 15 percent).

Combined expenditures in R&D and SG&A were up 2 percent at CER (3 percent as reported). Operating profit for the full year increased by 39 percent. Earnings per share for the year were \$2.91 versus \$2.18 in 2004, (which included \$0.17 in exceptional benefits from a disposal gain and a tax credit). Excluding these items from last year, earnings per share increased 41 percent. The Board has recommended an increase in the second interim dividend to \$0.92, which will bring the dividend for the full year to \$1.30, an increase of 38 percent.

The AstraZeneca portfolio now has ten products with annual sales of greater than \$1 billion. The combined sales of five key products (NexiumTM, SeroquelTM, CrestorTM, ArimidexTM and SymbicortTM) grew by 27 percent to \$10,849 million.

NexiumTM sales were up 18 percent to \$4,633 million. Sales in the US were up 15 percent to \$3,125 million, on continued strong volume growth partially offset by lower price realization. NexiumTM sales in other markets increased 25 percent.

CrestorTM sales reached \$1,268 million for the full year, up 38 percent. Sales in the US were up 34 percent. CrestorTM share of new prescriptions in the US statin market was 6.9 percent in the week ending 20 January. Sales

in other markets increased by 41 percent on good growth in France, Italy, and Canada.

SymbicortTM sales increased 22 percent to \$1,006 million. In November new clinical trial data were published (the COSMOS dose titration study) which demonstrate that the novel treatment concept Symbicort Maintenance and Reliever TherapyTM is more effective than fixed dose fluticasone/salmeterol. The regulatory process seeking European Union approval for Symbicort Maintenance and Reliever TherapyTM commenced in October 2005.

ArimidexTM sales increased 44 percent to \$1,181 million, on strong growth in the US (up 59 percent) and in other markets (up 35 percent). ArimidexTM value market share among hormonal treatments for breast cancer is now around 50 percent, more than twice the share of its closest competitor.

SeroqueITM sales reached \$2,761 million (up 35 percent) including \$2,003 million in the US (up 33 percent). In the US, SeroqueITM share of new prescriptions in the antipsychotic market increased to 29.8 percent in December, the only brand among the top three products to grow market share in 2005. Sales in other markets increased by 40 percent. On 30 December the Company submitted a supplemental New Drug Application with the US FDA seeking approval for a new indication for SeroqueITM for the treatment of patients with depressive episodes associated with bipolar disorder. If approved, it would be the only single agent indicated to treat both the depressive and manic episodes associated with bipolar disorder.

The Company continues to vigorously defend its intellectual property. In November the Company filed two lawsuits in the United States District Court for the District of New Jersey. The first was against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries, Ltd. for wilful infringement of AstraZeneca\[ \]s substance patent protecting SeroquelTM. The second lawsuit was filed against Ranbaxy Laboratories for wilful infringement of AstraZeneca\[ \]s patents protecting NexiumTM. On 17 January 2006 the Company received a decision of Judge Rodney Sippel of the United States District Court for the Eastern District of Missouri that found that the patents asserted by AstraZeneca that cover Toprol-XLTM were unenforceable based on the Company\[ \]s inequitable conduct in the prosecution of these patents in the US Patent and Trademark Office and invalid. The Company disagrees with and is disappointed by these conclusions. The Company maintains that both patents are valid and enforceable and will appeal the Court\[ \]s decision.

# Fourth Quarter

Sales in the fourth quarter were \$6,286 million, up 9 percent at CER, or 8 percent on an as reported basis (including a 1 percent adverse impact from currency movements). Sales increased 9 percent each in the US and in other markets. Sales for the five key growth products combined grew by 21 percent, led by SeroquelTM, NexiumTM, and ArimidexTM.

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## AstraZeneca PLC

Operating profit increased by 26 percent at CER in the fourth quarter (29 percent as reported, including a 3 percent benefit from currency). Included in the fourth quarter of this year were provisions of \$105 million for manufacturing efficiencies, whilst the comparative period included \$156 million provisions in respect of ExantaTM and Iressa<sup>TM</sup>. Earnings per share in the fourth quarter were \$0.77 compared with \$0.55 in 2004.

## **Future Prospects**

The Company is determined to further strengthen its product pipeline via a sustained commitment to discovery and development of new medicines, from within its own laboratories and from external partnerships. AstraZeneca is in a strong financial position from which to increase its investment in Research and Development and utilize its

strong cash generation to pursue attractive external opportunities to augment the pipeline. Continued focus on improved productivity remains essential to release resources for these priorities.

For 2006, the operating financial leverage stemming from good sales performance and cost control, and the delivery of productivity gains seen in 2005 are set to continue. On this basis, the Company expects to deliver earnings per share in the range of \$3.40 to \$3.60.

Included in this target, for the remaining eleven months of the year, is around 45 cents of earnings relating to Toprol-XL<sup>TM</sup>. This represents the maximum potential impact to earnings from Toprol-XL<sup>TM</sup> should generic companies receive final regulatory approval and seek to launch ☐at risk☐ before the conclusion of the judicial appeals process. This potential impact excludes any one-time asset or inventory adjustments that may be required.

Disclosure Notice: The preceding forward-looking statements relating to expectations for earnings and business prospects for AstraZeneca PLC are subject to risks and uncertainties, which may cause results to differ materially from those set forth in the forward-looking statements. These include, but are not limited to: when and if a generic competitor to Toprol-XL $\square$  were introduced in the US market prior to completion of Appellate Court process, the rate of growth in sales of generic omeprazole in the US, continued growth in currently marketed products (in particular Crestor<sup>TM</sup>, Nexium<sup>TM</sup>, Seroquel<sup>TM</sup>, Symbicort<sup>TM</sup>, Arimidex<sup>TM</sup> and Casodex<sup>TM</sup>), the growth in costs and expenses, interest rate movements, exchange rate fluctuations and the tax rate. For further details on these and other risks and uncertainties, see AstraZeneca PLC $\square$ s Securities and Exchange Commission filings, including the 2004 Annual Report on Form 20-F.

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## AstraZeneca PLC

#### Sales

All narrative in this section refers to growth rates at constant exchange rates (CER) unless otherwise indicated. All sales numbers are quoted in \$ million.

# Gastrointestinal

	Fourth Quarter		rth Quarter CER % Full Year		ear	CER %
	2005	2004		2005	2004	
Losec Prilosec	411	446	-8	1,652	1,947	-17
Nexium[]	1,247	1,106	+13	4,633	3,883	+18
Total	1,677	1,576	+6	6,355	5,918	+5

- In the US, Nexium<sup>TM</sup> sales for the full year increased by 15 percent to \$3,125 million. Nexium<sup>TM</sup> market share of total prescriptions in the US PPI market was 30.3 percent in December, up 3.4 percentage points versus December 2004. Nexium<sup>TM</sup> was the only branded PPI to gain market share in 2005.
- In the fourth quarter, US sales for Nexium<sup>TM</sup> were up 8 percent, as continued strong growth in dispensed

tablets (up 14 percent) was partially offset by lower realized prices resulting from performance-based contracts and Medicaid.

- Sales of Nexium<sup>TM</sup> in other markets reached \$1,508 million for the full year (up 25 percent) on a 2 point gain in market share. Sales in the fourth quarter were up 24 percent.
- Prilosec<sup>TM</sup> sales in the US were down 28 percent for the full year. In other markets, Losec<sup>TM</sup> sales declined 15 percent, although sales increased by 25 percent in Japan and by 16 percent in China.

## Cardiovascular

	Fourth Quarter		Fourth Quarter CER % Full Year		ear	CER %
	2005	2004		2005	2004	
Seloken Toprol-XL	455	381	+19	1,735	1,387	+24
Atacand [	247	240	+3	974	879	+8
Plendil□	73	94	-22	360	455	-23
Zestril□	84	113	-26	332	440	-27
Crestor <u></u>	353	312	+12	1,268	908	+38
Total	1,378	1,321	+4	5,332	4,777	+10

- Sales of Toprol-XL<sup>TM</sup> in the US increased by 32 percent for the full year, which was ahead of underlying growth of 23 percent as a result of the destocking which occurred in 2004. Fourth quarter sales in the US were up 29 percent.
- On 17 January 2006 the Company announced it had received a decision of Judge Rodney Sippel of the US
  District Court for the Eastern District of Missouri that found that the patents asserted by AstraZeneca that
  cover Toprol-XL<sup>TM</sup> were invalid and unenforceable. The Company disagrees with and is disappointed by
  these conclusions. The Company maintains that both patents are valid and enforceable and will appeal the
  Court
  selection.
- Sales of Seloken<sup>TM</sup> in other markets declined 4 percent in the fourth quarter, but were up 4 percent for the full year.
- Atacand<sup>TM</sup> sales in the US were down 8 percent for the full year, in line with the decline in total prescriptions. Increased promotion following the launch of the heart failure claim has stabilized Atacand<sup>TM</sup> prescription market share over the second half of 2005.
- ullet In other markets, Atacand TM sales were up 10 percent in the fourth quarter and were up 14 percent for the full year.

#### AstraZeneca PLC

- Crestor<sup>TM</sup> has now been approved in 75 markets and launched in 69. Since first launch in early 2003 nearly 6 million patients have been treated with Crestor<sup>TM</sup> and 40 million prescriptions have been written. Crestor<sup>TM</sup> sales for the full year reached \$1,268 million, up 38 percent.
- Crestor<sup>TM</sup> sales in the US increased by 34 percent to \$730 million for the full year, but were up just 4 percent against a difficult comparison versus fourth quarter last year. Crestor<sup>TM</sup> share of new prescriptions in the US statin market was 6.9 percent in the week ending 20 January. Market share in the dynamic segment (new and switch patients) was 8.8 percent in the latest week.
- In other markets, Crestor<sup>TM</sup> sales increased 27 percent in the fourth quarter. Sales for the full year were up 41 percent, on good growth in Europe (up 44 percent) and Canada (up 25 percent). Volume share of the statin market for Crestor<sup>TM</sup> is now 13.4 percent in Canada; 11.2 percent in the Netherlands; 11.7 percent in Italy; and 6.0 percent in France.
- Plendil<sup>TM</sup> sales for the full year were down 23 percent as a result of generic competition in the US market, where sales declined by 49 percent.

## Respiratory

	Fourth Quarter		CER %	Full Ye	ear	CER %
	2005	2004		2005	2004	
Symbicort[]	264	219	+22	1,006	797	+22
Pulmicort <b></b>	338	313	+8	1,162	1,050	+9
Rhinocort□	92	93	-2	387	361	+6
Accolate[	17	32	-47	72	116	-39
Oxis□	22	25	-12	91	101	-14
Total	773	722	+7	2,873	2,583	+9

- Symbicort<sup>TM</sup> sales for the full year reached \$1,006 million. Sales growth was 22 percent for both the fourth quarter and the full year, as market share continues to increase in the fast-growing combination product segment of the asthma and COPD markets.
- The regulatory file for the pMDI formulation of Symbicort<sup>TM</sup> for the treatment of asthma in the US was submitted on 23 September.
- In 2005 data from the STAY and COSMOS clinical trials were published. These studies are part of a large clinical trial programme, data from which consistently indicate that the novel treatment concept□Symbicort Maintenance and Reliever Therapy<sup>TM</sup>□prevents patients from developing potentially life-threatening asthma attacks better than fixed dose inhaled corticosteroids or combination therapy. An application seeking regulatory approval for this treatment concept in the European Union was submitted in October 2005.
- Sales of Pulmicort<sup>TM</sup> were up 9 percent for the full year, as the 18 percent growth in the US (fuelled by a 28 percent increase in Pulmicort<sup>TM</sup> Respules<sup>TM</sup>) more than offset a 2 percent decline in other markets.
- Rhinocort<sup>TM</sup> sales were up 6 percent for the full year, chiefly on sales of Rhinocort<sup>TM</sup> Aqua in the US (up 7 percent), where price changes and managed care rebate adjustments more than offset the 10 percent

decline in total prescriptions.

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#### AstraZeneca PLC

## **Oncology**

	Fourth Quarter		Fourth Quarter		Fourth Quarter CER %		Full Y	CER %
	2005	2004		2005	2004			
Casodex[]	283	276	+5	1,123	1,012	+10		
Zoladex□	252	242	+5	1,004	917	+7		
Arimidex□	325	233	+40	1,181	811	+44		
Iressa[]	72	80	-9	273	389	-31		
Faslodex[]	39	26	+50	140	99	+39		
Nolvadex□	28	35	-17	114	134	-16		
Total	1,001	895	+13	3,845	3,376	+12		

- Casodex<sup>TM</sup> sales in the US were down 5 percent in the fourth quarter, but increased by 3 percent for the full year to \$239 million. Total prescriptions were 3 percent lower than last year.
- Casodex<sup>TM</sup> sales in other markets were up 7 percent in the fourth quarter and 11 percent for the full year, with Japan accounting for nearly half of this sales growth.
- Arimidex<sup>TM</sup> sales increased 44 percent to \$1,181 million for the full year. Arimidex<sup>TM</sup> value share of the market for hormonal treatments for breast cancer reached 50 percent in the latest month, a share more than twice that of its closest competitor. Arimidex<sup>TM</sup> is the leading aromatase inhibitor as a result of its well- established profile in primary adjuvant treatment for breast cancer, where the ATAC trial demonstrated its superiority over tamoxifen as initial adjuvant therapy. In December, data from a new meta-analysis of three international clinical trials demonstrated that switching patients from tamoxifen therapy to Arimidex<sup>TM</sup> results in an overall survival benefit versus remaining on tamoxifen treatment.
- In the US, sales of Arimidex<sup>TM</sup> were up 58 percent in the fourth quarter and increased 59 percent for the full year. Total prescriptions increased by 40 percent versus last year, on a 7.1 percentage point increase in market share.
- Arimidex<sup>TM</sup> sales in other markets increased by 31 percent in the fourth quarter. For the full year sales were up 35 percent on excellent growth in Europe (up 35 percent) and Japan (up 27 percent).
- Iressa<sup>TM</sup> sales were down 31 percent for the full year, chiefly as a result of the 63 percent decline in the US. Iressa<sup>TM</sup> sales in Asia Pacific increased 7 percent for the full year, as sales in China and other markets more than offset a 15 percent sales decline in Japan.

- Sales for Faslodex<sup>TM</sup> for the full year reached \$140 million (up 39 percent) as a result of good growth in Europe since marketing approval in March 2004. Sales in the US were up 11 percent for the year.
- Zoladex<sup>TM</sup> sales for the full year increased 7 percent to \$1,004 million, as good sales growth in other markets (up 13 percent) more than offset a 23 percent decline in the US.

## **Neuroscience**

	Fourth Quarter		Fourth Quarter		CER %	Full Year		R % Full Year		CER %
	2005	2004	_	2005	2004					
Seroquel[]	755	562	+34	2,761	2,027	+35				
Zomig∏	94	89	+6	352	356	-3				
Total	1,084	938	+16	4,059	3,496	+15				

- Seroquel<sup>TM</sup> sales reached \$2,761 million for the full year (up 35 percent), including \$2,003 million in the US. Seroquel<sup>TM</sup> value share of the global atypical antipsychotic market increased 2.7 percentage points in the twelve months ended 30 September 2005.
- In the US, Seroquel<sup>TM</sup> sales were up 34 percent in the fourth quarter and increased 33 percent for the full year, ahead of prescription growth of 20 percent as a result of higher realized prices and favourable contract rebate adjustments. Seroquel<sup>TM</sup> share of new prescriptions in the US antipsychotic market increased to 29.8 percent in December 2005, up 2.2 percentage points over last year.

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#### AstraZeneca PLC

- In other markets, Seroquel<sup>TM</sup> sales were up 35 percent in the fourth quarter. Sales for the full year increased by 40 percent on strong growth in Europe (up 48 percent), Asia Pacific (up 22 percent) and Canada (up 29 percent).
- In October 2005 top-line results were released from the BOLDER II study, reinforcing the findings from the landmark BOLDER I study which demonstrate that monotherapy with Seroquel<sup>TM</sup> results in statistically significant reductions in levels of bipolar depression compared with placebo. On 30 December a supplemental New Drug Application was submitted to the US FDA seeking approval for Seroquel<sup>TM</sup> for the treatment of patients with depressive episodes associated with bipolar disorder. If approved, Seroquel<sup>TM</sup> would be the only single agent indicated to treat both the depressive and manic episodes associated with bipolar disorder.

- Zomig<sup>TM</sup> sales for the full year declined by 3 percent, as growth in other markets (up 8 percent) was more than offset by an 18 percent decline in the US.
- Diprivan<sup>TM</sup> sales in other markets were down 8 percent for the full year. US sales declined 44 percent, chiefly on lower prices as a result of the introduction of another generic product.

## Geographic Sales

	Fourth Quarter		Fourth Quarter CER % Full Year		ear	CER %
	2005	2004		2005	2004	
US	2,907	2,657	+9	10,771	9,631	+12
Europe	2,089	1,988	+7	8,463	7,649	+8
Japan	424	412	+8	1,527	1,430	+8
RoW	866	742	+10	3,189	2,716	+11

- In the US sales were up 12 percent for the full year. Sales growth for NexiumTM, SeroquelTM, Toprol-XLTM, Arimidex<sup>TM</sup> and Crestor<sup>TM</sup> more than offset the declines in Prilosec<sup>TM</sup>, Plendil<sup>TM</sup>, and Iressa<sup>TM</sup>.
- Sales in Europe increased by 8 percent for the full year, with good volume growth partially offset by lower realized prices. Sales for the five key products combined grew by 30 percent, which more than compensated for a 24 percent decline in Losec<sup>TM</sup>.
- Sales in Japan were up 8 percent for the full year as a result of good growth for LosecTM, CasodexTM, ZoladexTM and ArimidexTM.
- Sales in China were up 33 percent to \$272 million for the full year on good growth in cardiovascular products and Losec<sup>TM</sup> and the launch of Iressa<sup>TM</sup>.

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## AstraZeneca PLC

# **Operating Review**

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

Reported sales increased by 8 percent and operating profit by 29 percent. At constant exchange rates, sales increased by 9 percent and operating profit by 26 percent.

Reported US sales growth in the fourth quarter of 9 percent compares to underlying growth of 8 percent after adjusting for a slight increase in inventory levels in the quarter and the phasing of managed care accruals in the prior year. Individual product level performances continue to be affected as a result of prior year buying patterns.

Currency movements in the quarter adversely affected sales by 1 percent and benefited operating profit by 3 percent. Overall, currency movements in the quarter benefited EPS by 2 cents. Currency movements in the quarter compared to quarter four last year were stronger than anticipated with the euro 9 percent weaker than the dollar, decreasing sales, while the Swedish krona and sterling were 15 percent and 6 percent weaker respectively, decreasing costs. This profile yielded a net positive currency impact compared to the negative impact anticipated at quarter three.

Reported operating margin increased by 4.0 percentage points from 22.0 percent to 26.0 percent. Currency benefited margin by 0.7 percentage points implying an underlying margin improvement of 3.3 percentage points for the quarter.

Gross margin increased by 3.7 percentage points to 77.9 percent of sales. The 0.1 percent benefit to gross margin due to lower payments to Merck at 4.9 percent of sales was offset by currency. Included in quarter four this year were provisions of around \$100 million for manufacturing efficiencies, however the prior year included the ExantaTM and IressaTM provisions totalling \$156 million. Taken together this implies an underlying margin increase of 2.7 percentage points due mostly to favourable product mix and continued operational efficiencies.

In aggregate, R&D and SG&A expenses of \$3,276 million increased 11 percent over last year. In comparison to quarter four last year, combined R&D and SG&A reduced operating margin by 0.9 percentage points. Reported R&D expenditures were down 3 percent on an as reported basis, but up 1 percent over last year in constant currency terms. SG&A increased by 15 percent over last year largely as the result of increased product investment in the US and Rest of World markets, together with investments in a Medicare Outreach programme to boost patient awareness.

The fair value adjustments relating to financial instruments amounted to a \$38 million benefit in quarter four; \$20 million benefit in cost of sales, \$22 million benefit to R&D and \$4 million charge to interest.

#### **Full Year**

Reported sales increased by 12 percent and operating profit by 43 percent. At constant exchange rates, sales increased by 10 percent and operating profit by 39 percent. Overall, exchange benefited EPS by around 8 cents.

US sales increased by 12 percent with inventory movements neutral across the year following the successful introduction of Distribution Service Agreements. Adjustments to managed care accruals at the half year benefited annual US sales growth by 2 percent resulting in an underlying demand growth of 10 percent for the year.

Operating margin increased by 6.0 percent from 21.2 percent to 27.2 percent. Currency benefited margin by 0.4 percentage points resulting in an underlying margin improvement of 5.6 percentage points for the year.

Gross margin increased by 1.8 percentage points to 77.6 percent of sales. Lower payments to Merck (4.8 percent of sales) and currency each benefited gross margin by 0.1 percentage points. Excluding prior year ExantaTM and IressaTM provisions totalling \$236 million, the costs associated with the termination of the Medpointe ZomigTM distribution agreement in the first quarter of this year, and the manufacturing efficiency provisions charged in the fourth quarter of 2005, underlying margin improved by 1.2 percentage points.

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R&D and SG&A combined grew by 2 percent (3 percent as reported) with R&D declining by 4 percent and SG&A growing by 4 percent. The combined effect of these movements added 4.1 percentage points to operating margin for the full year. Excluding the LosecTM European Commission fine and the investments made on the Medicare Outreach programme in the fourth quarter of this year SG&A growth was around 2 percent.

Lower other income reduced margin by 0.3 percentage points due principally to the gain on the disposal of the Durascan business in the prior year.

The fair value adjustments relating to financial instruments amounted to a \$23 million charge for the full year; \$32 million charge in cost of sales, \$17 million benefit to R&D and \$8 million charge to interest.

#### Interest and Dividend Income

Net interest and dividend income for the fourth quarter was \$53 million (2004 \$24 million) and for the full year was \$165 million (2004 \$78 million). The increase over 2004 is primarily attributable to higher average investment balances and yields. The reported amount includes net income of \$15 million in the full year and \$2 million in the fourth quarter arising from employee benefit fund assets and liabilities as required by IAS 19.

## **Taxation**

The effective tax rate for the fourth quarter was 27.4 percent (2004 rate excluding exceptional items 28.3 percent) and for the twelve months was 29.1 percent (2004 rate excluding exceptional items 26.6 percent). The charge for the year increases mainly due to the movements in provisions relating to foreign tax credits and transfer pricing. The increase over 2004 also reflects the release of provisions following a settlement of prior year issues in 2004, and no relief in respect of the LosecTM fine. Taxation in 2004 also benefited from a one-off reduction in the deferred tax liability in relation to rolled over gains following agreements with the relevant tax authorities.

# **Cash Flow**

Cash generated from operating activities was \$6,743 million compared with \$4,817 million in 2004. This increase is principally a result of a \$1,955 million increase in operating profits and the effects of a net \$399 million cash inflow from favourable movements in working capital, particularly with inventory, offset by a \$360 million increase in tax paid.

Free cash flow (which represents net cash flows before financing activities, as adjusted for movements in short term deposits) for the year was \$6,052 million compared with \$3,932 million in 2004. After accounting for net share repurchases of \$2,858 million, the \$1,717 million dividend payment to shareholders and foreign exchange effects, there is a \$968 million increase in cash and cash equivalents.

Cash outflows from investing activities of \$1,182 million in the year compared with \$970 million inflows in 2004. The inflows in 2004 were mainly a result of a change in investment strategy that led to the bulk of group cash being transferred to more liquid funds and which require classification as cash equivalents under IFRS, rather than short-term investments.

Capital expenditure fell by \$253 million to \$810 million and expenditure on non-current asset investments was \$105 million lower in 2005 as a result of the \$110 million investment in Cambridge Antibody Technology made in the fourth quarter 2004. In 2004, the disposal proceeds of \$355 million were principally in respect of the disposal of Advanta.

Net funds at 31 December 2005 of \$5,402 million were \$1,406 million higher than at 31 December 2004.

#### AstraZeneca PLC

#### Investments

New collaboration agreements signed during 2005 with Avanir and Astex created intangible assets worth \$20 million. Further payments were made in respect of existing licensed in products amounting to \$44 million.

In December, new collaboration agreements with Protherics PLC, Targacept Inc and Atherogenics Inc. were announced and are recorded as post balance sheet events. We will invest \$41 million in the global development and commercialisation agreement with Protherics, being a 4.3% investment in equity and an intangible asset. The licensing and commercialisation agreement with Atherogenics Inc. will initially require a \$50 million payment by AstraZeneca and the licensing and research collaboration agreement with Targacept Inc. will initially require a \$10 million payment by AstraZeneca. Both of these payments will be recorded as intangible assets.

We have also entered into an agreement to acquire the total share capital of KuDOS Pharmaceuticals Limited for \$210 million, subject to cash and working capital adjustment. Most of the cost of the investment reflects an intangible representing the oncology technology platform of KuDOS.

Our recent focus on licensing in opportunities with third parties will result in additional intangible asset investment in the balance sheet. Should any of these products fail in development, the associated intangibles will need to be written off.

## **Dividends and Shareholder Return**

The Board has recommended a 43 percent increase in the second interim dividend to \$0.92 (51.8 pence, 7.02 SEK) to be paid on 20 March 2006. This brings the full year dividend to \$1.30 (73.7 pence, 10.01 SEK) an increase of 38 percent.

In line with the policy stated last year the Board intends to continue its practice of growing dividends in line with earnings (maintaining dividend cover in the two to three times range) whilst substantially distributing the balance of cash flow via share repurchases. In 2005 \$4.7 billion was distributed from free cash flow of \$6.1 billion via dividends and share repurchases. The Board intends to continue this policy, but firmly believes that the first call on free cash flow is business need and, having fulfilled that, will return surplus cash flow to shareholders. The primary business need is to build the research pipeline by supporting internal and external opportunities. On this basis the Board intends to repurchase shares at around the same level as 2005.

## **Share Repurchase Programme**

During the fourth quarter, 17.9 million shares were repurchased for cancellation at a total cost of \$819 million bringing the total repurchase for the full year to 67.7 million shares at a total cost of \$3,001 million.

The total number of shares in issue at 31 December 2005 is 1,581 million.

Based on an estimate of interest income foregone, the share buy back programme is calculated to have added 8 cents to EPS.

#### AstraZeneca PLC

## **Updated R&D Pipeline Table**

The US submission for the pMDI formulation of Symbicort for the fixed dose treatment of asthma in adults and adolescents was filed on 23 September and the FDA review is ongoing as are US Phase III COPD studies. In Europe, where the Turbuhaler version of Symbicort has been registered for a number of years in asthma and COPD as a maintenance therapy, our enlarged submission package for use as Maintenance and Reliever Therapy (SMART) was filed on schedule in the third quarter and is now going through mutual recognition with Sweden as the reference member state. The European development programme for the pMDI version of Symbicort is being expanded to include data on two extra strengths of the product. This will allow easier switching between the existing Turbuhaler and the new pMDI device. Data will be ready to supplement the registration package in 2008.

New data on Crestor will be presented in the first half of 2006, including the top line results of the ASTEROID study, looking at the effect of Crestor on the regression of coronary artery atheroma. The results of recently completed pharmacoepidemiology studies will also be presented during this time period.

The European and US submissions for the Sustained Release formulation of Seroquel for the treatment of schizophrenia is now scheduled for Q3 2006. Seroquel is now in Phase III development for Generalised Anxiety Disorder (GAD) and Major Depressive Disorder (MDD) using the Sustained Release formulation.

Exanta was submitted to the European regulatory authorities in December 2005 under the new centralised procedure for the indication of prevention of stroke in atrial fibrillation. In the US, the company continues discussions with the FDA, but the current assessment is that it is unlikely a way forward for Exanta registration in the US will be identified.

Zactima[], a VEGF/EGF TKI inhibitor for the treatment of NSCLC and medullary thyroid cancer, has been granted fast track and orphan status by the FDA for the thyroid indication. In January 2006, the EU COMP (Committee for Orphan Medicinal Products) positive opinion of December 2005 regarding orphan drug status for Zactima[] in the treatment of medullary thyroid cancer, was adopted.

The submission target dates for Galida[], a PPAR agonist for diabetes/metabolic syndrome, currently 2H 2007 for the US and Europe, are subject to the results of Phase III studies currently ongoing and regulatory discussions.

AZD6140, an ADP receptor antagonist being developed in the area of arterial thrombosis, has progressed to Phase III for the treatment of acute coronary syndrome.

Phase II data on AZD0837 has confirmed that it could be differentiated from Exanta with regard to the liver signal but also showed a short half-life, which precludes once daily dosing. It has been decided to develop this product through an extended release formulation, and whilst early data shows that such a formulation is feasible, AZD0837 will not enter Phase III development for launch until data on the definitive formulation has been generated which could take up to two years.

In December 2005 rights to a late Phase III compound (AGI-1067) for the treatment of atherosclerosis were obtained from Atherogenics Inc. Two compounds in Phase II development were also acquired: TC-1734, a product for the treatment of Alzheimer significant disease from Targacept Inc, and Cytofab, Protherics compound in development for the treatment of severe sepsis.

Our oncology discovery capability and early pipeline has been further strengthened by the acquisition of KuDOS Pharmaceuticals.

An updated R&D pipeline table is appended to this press release and is also available on the Company

s website,

www.astrazeneca.com

under information for investors.

## AstraZeneca PLC

# Calendar

14 March 2006 Education seminar on Merck payments
27 April 2006 Announcement of first quarter 2006 results
27 April 2006 Annual General Meeting 2006
8 June 2006 Business Review meeting (London)
27 July 2006 Announcement of second quarter and half year 2006 results
26 October 2006 Announcement of third quarter and nine months 2006 results

**David Brennan** 

Chief Executive Officer

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# Item 5

# **Consolidated Income Statement**

For the <b>year ended</b> 31 December	2005 \$m	As restated 2004 \$m
Sales	23,950	21,426
Cost of sales	(5,356)	(5,193)
Distribution costs	(211)	(177)
Research and development	(3,379)	(3,467)
Selling, general and administrative expenses	(8,695)	(8,268)
Other operating income	193	226
Operating profit	6,502	4,547
Profit on sale of interest in joint venture	-	219
Finance income	665	532
Finance expense	(500)	(454)
Profit before tax	6,667	4,844
Taxation	(1,943)	(1,161)

Profit for the period		4,724		3,683
Attributable to:		4 706		2.664
Equity holders of the Company Minority interests		4,706 18		3,664
		4,724		3,683
Basic earnings before exceptional items per \$0.25 Ordinary Share	\$	2.91	\$	2.01
Basic earnings after exceptional items per \$0.25 Ordinary Share Diluted earnings after exceptional items per \$0.25 Ordinary Share	\$ \$	2.91 2.91	\$ \$	2.18 2.18
Weighted average number of Ordinary Shares in issue (millions) Diluted average number of Ordinary Shares in issue (millions)		1,617 1,618		1,673 1,675

Exceptional items in 2004 comprised profit on sale of interest in joint venture (\$219 million) and exceptional tax credits (\$67 million).

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# **Consolidated Income Statement**

	As restate				
For the <b>quarter</b> ended 31 December	2005	2004			
	\$m 	\$m			
Sales	6,286	5,799			
Cost of sales	(1,388)	(1,498)			
Distribution costs	(56)	(45)			
Research and development	(873)	(899)			
Selling, general and administrative expenses	(2,403)	(2,138)			
Other operating income	70	52			
Operating profit	1,636	1,271			
Finance income	181	136			
Finance expense	(128)	(112)			
Profit before tax	1,689	1,295			
Taxation	(462)	(366)			
Profit for the period	1,227	929			

Attributable to: Equity holders of the Company Minority interests	1,224 3	923 6
	1,227	929
Basic earnings before exceptional items per \$0.25 Ordinary Share	\$0.77	\$0.55
Basic earnings after exceptional items per \$0.25 Ordinary Share Diluted earnings after exceptional items per \$0.25 Ordinary Share	\$0.77 \$0.77	\$0.55 \$0.55
Weighted average number of Ordinary Shares in issue (millions)  Diluted average number of Ordinary Shares in issue (millions)	1,590 1,592	1,654 1,656

Conso	lidated	Balance	Sneet
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As at 31 December	2005 \$m	As restated 2004 \$m
ASSETS		
Non-current assets		
Property, plant and equipment	6,985	8,097
Intangible assets	2,712	3,050
Other investments	256	262
Deferred tax assets	1,117	1,218
	11,070	12,627
Current assets		
Inventories	2,206	3,020
Trade and other receivables	4,961	4,740
Other investments	1,624	1,198
Cash and cash equivalents	4,979	4,067
	13,770	13,025
Total assets	24,840	25,652

LIABILITIES		
Current liabilities		
Interest bearing loans and borrowings	(90)	(142)
Other payables	(6,749)	(6,445)
	(6,839)	(6,587)
Non-current liabilities		
Interest bearing loans and borrowings	(1,111)	(1,127)
Deferred tax liabilities	(1,112)	(1,328)
Retirement benefit obligations	(1,706)	(1,761)
Provisions	(309)	(266)
Other payables	(72)	(86)
	(4,310)	(4,568)
Total liabilities	(11,149)	(11,155)
Net assets	13,691	14,497
EQUITY		
Capital and reserves attributable to equity holders		
Share capital	395	411
Share premium account	692	550
Other reserves	1,831	1,853
Retained earnings	10,679	11,590
	13,597	14,404
Minority equity interests	94	93
Total equity and reserves	13,691	14,497

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# **Consolidated Cash Flow Statement**

For the <b>year ended</b> 31 December	2005 \$m	As restated 2004 \$m
Cash flows from operating activities Operating profit before taxation	6,502	4,547

Depreciation and amortisation Decrease/(increase) in working capital Other non-cash movements	1,327 332 220	1,268 (67) 384
Cash generated from operations Interest paid Tax paid	8,381 (32) (1,606)	6,132 (69) (1,246)
Net cash inflow from operating activities	6,743	4,817
Cash flows from investing activities		
Disposal of business operations	-	355
Movement in short term investments and fixed deposits	(491)	1,855
Purchases of property, plant and equipment	(810)	(1,063)
Disposals of property, plant and equipment	87	35
Purchase of intangible assets	(157)	(215)
Purchase of non-current asset investments	(12)	(117)
Interest received	206	119
Dividends paid by subsidiaries to minority interests	(5)	(5)
Dividends received	-	6
Net cash (outflow)/inflow from investing activities		970
Net cash inflow before financing activities	5,561	5,787
Cash flows from financing activities		
Proceeds from issue of share capital	143	102
Repurchase of shares	(3,001)	(2,212)
Increase in loans	-	725
Dividends paid	(1,717)	(1,378)
Movement in short term borrowings	3	2
Net cash outflow from financing activities	(4,572)	(2,761)
Net increase in cash and cash equivalents in the period	989	3,026
Cash and cash equivalents at beginning of the period	3,927	872
Exchange rate effects	(21)	29
Cash and cash equivalents at the end of the period	4,895	3,927
Cash and cash equivalents consists of:		
Cash and cash equivalents	4,979	4,067
Overdrafts	(84)	(140)
	<u> </u>	
	4,895	3,927

# **Consolidated Statement of Recognised Income and Expense**

	A	s restated
For the <b>year ended</b> 31 December	2005	2005
<u></u>	\$m 	\$m
Profit for the period	4,724	3,683
Foreign exchange adjustments on consolidation	(1,052)	744
Available for sale (losses)/gains taken to equity, net of tax	(10)	31
Actuarial loss for the period	(35)	(179)
Tax on items taken directly to reserves	(25)	416
Total recognised income and expense for the period	3,602	4,695
Attributable to:		
Equity holders of the Company	3,595	4,690
Minority interests	7	5

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# **Notes to the Preliminary Announcement**

## 1 BASIS OF PREPARATION AND ACCOUNTING POLICIES

The preliminary announcement for the full year ended 31 December 2005 has been prepared in accordance with International Accounting Standards and International Financial Reporting Standards (collectively <code>[IFRS[]</code>) as adopted by the European Union (EU) at 31 December 2005. Details of the accounting policies applied are set out in the IFRS Restatement information in AstraZeneca PLC[s Annual Report and Form 20-F Information 2004, except that, in the period under review, the amendment to IAS 39 <code>[Financial Instruments: Recognition and Measurement []</code> The Fair Value Option[] has been adopted. As a result, the accounting for long term loans has been changed; such loans are now categorised as fair value through profit and loss with changes in value recognised in the income statement. Previously these loans had been recognised at cost except where hedge accounting had been applied. The comparative information has been restated accordingly. The effect of adoption on comparative results was not significant: net assets at 31 December 2004 were reduced by \$21m. The annual financial information presented in this preliminary announcement for the year ended 31 December 2005 is extracted from, and is consistent with, that in the Group[s audited financial statements for the year ended 31 December 2005, and those financial statements will be delivered to the Registrar of Companies following the Company[s Annual General Meeting.

The information contained in Note 3 updates the disclosures concerning legal proceedings and contingent liabilities in the Company

S Annual Report and Form 20-F Information 2004 and the Third Quarter and Nine Months Results 2005.

Information in this 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 2004, which were prepared under accounting practices generally accepted in the UK, have been filed with the Registrar of Companies. The auditors report on those accounts was unqualified and did not contain any statement under Section 237 of the Companies Act 1985.

## 2 NET FUNDS

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

	As restated 1 Jan 2005 \$m	Cash flow \$m	Other non-cash \$m	Exchange movements \$m	At 31Dec 2005 \$m
Loans due after 1 year	(1,127)	_	16		(1,111)
Total loans	(1,127)	-	16		(1,111)
Other investments - current	1,198	491	(63)	(2)	1,624
Cash and cash equivalents	4,067	935	-	(23)	4,979
Overdrafts	(140)	54	-	2	(84)
Short term borrowings	(2)	(3)		(1)	(6)
	5,123	1,477	(63)	(24)	6,513
Net funds	3,996	1,477	(47)	(24)	5,402

Other non-cash movements in the period consist of fair value adjustments under IAS 39.

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## 3 LEGAL PROCEEDINGS AND CONTINGENT LIABILITIES

AstraZeneca is involved in various legal proceedings considered typical to its business, including litigation relating to employment matters, product liability, commercial disputes, infringement of intellectual property rights and the validity of certain patents. The matters discussed below constitute the more significant developments since publication of the disclosures concerning legal proceedings in the Company Annual Report and Form 20-F Information 2004 and the Third Quarter and Nine Months Results 2005.

Matters disclosed in respect of the fourth quarter of 2005 and January 2006

## Diprivan (propofol)

In respect of the notification received from Amphastar Pharmaceuticals, Inc. in September 2005 under section 505(b)(2) of the US Food, Drug, and Cosmetic Act, AstraZeneca did not file a patent infringement complaint against Amphastar.

## Losec | / Prilosec | (omeprazole)

In January 2006, AstraZeneca Canada Inc. was served with a claim in the Federal Court of Canada for payment of an undetermined sum based on damages allegedly suffered by Apotex, due to the delay from January 2002 to January 2004 in the issuance to Apotex of a notice of compliance (marketing approval) in Canada for its 20mg omeprazole capsule product. AstraZeneca believes the claim is without merit and intends to defend it and to pursue its already pending patent infringement action against Apotex vigorously.

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As previously disclosed, in November 2005 AstraZeneca commenced patent infringement litigation in the US District Court for the District of New Jersey against Ranbaxy Pharmaceuticals, Inc. and its affiliates in response to Ranbaxy[]s paragraph IV certifications regarding Nexium[], received in October 2005.

In January 2006, AstraZeneca received a notice from IVAX Pharmaceuticals Inc. that IVAX Corporation had submitted an Abbreviated New Drug Application to the US FDA for esomeprazole magnesium delayed-release capsules, 20mg and 40mg. The ANDA contained paragraph IV certifications of invalidity and/or non-infringement in respect of certain AstraZeneca US patents listed in the FDA\(\sigma\) Orange Book with reference to Nexium\(\sigma\), the latter of which expires in 2019. IVAX also certified in respect of certain other AstraZeneca US patents listed in the Orange Book with reference to Nexium\(\sigma\) that IVAX will not launch its product prior to the expiry of those patents, the latter of which expires in October 2007. AstraZeneca has 45 days within which to commence a patent infringement lawsuit against IVAX that would automatically stay, or bar, the FDA from approving IVAX\(\sigma\) s ANDA for 30 months (or until an adverse court decision, whichever occurs earlier). AstraZeneca is evaluating IVAX\(\sigma\) s notice and continues to have full confidence in its intellectual property protecting Nexium\(\sigma\).

## **Seroquel** (quetiapine fumarate)

As previously disclosed, in November 2005 in response to Teva[s Abbreviated New Drug Application and Teva[s intent to market a generic version of Seroquel[] in the US prior to the expiration of AstraZeneca[s patent, AstraZeneca filed a lawsuit against Teva in the US District Court for the District of New Jersey for wilful patent infringement.

AstraZeneca has now been served in the US with a total of approximately 60 lawsuits in which plaintiffs contend that they developed diabetes or other allegedly related injuries as a result of taking Seroquel and/or atypical antipsychotics made by other pharmaceutical companies. The Company has also been made aware that a putative nationwide class action complaint was recently filed in federal court in the Southern District of Illinois. The complaint is very similar in form and content to the complaint filed in the US District Court for the Middle District of Florida in 2003 (Susan Zehel-Miller et al. v. AstraZenaca [sic], AstraZenaca Pharmaceuticals LP, [sic], described in the Company Annual Report and Form 20-F Information 2004) that sought certification of a nationwide class of Seroquel users and others, including individuals who were alleged to have developed diabetes as a result of using Seroquel. The federal court in Florida denied certification of the class in the Zehel-Miller case. In early 2005, after the plaintiffs efforts in that case to secure appellate relief failed, the plaintiffs agreed to a voluntary dismissal of all of their claims with prejudice. AstraZeneca has been informed that more than 100 additional complaints involving Seroquel have just been filed in various courts in the US, but these have not been served. It is possible that plaintiffs lawyers are contemplating the filing of potentially numerous additional lawsuits against AstraZeneca and other manufacturers of atypical anti-psychotics involving allegations concerning diabetes.

AstraZeneca intends to defend vigorously all of the pending cases relating to Seroquel \(\prec{\pi}\).

# **Toprol-XL** (metoprolol succinate)

In the patent litigation continuing in the US against KV Pharmaceutical Company, Andrx Pharmaceuticals LLC and Eon Labs Manufacturing Inc. relating to those companies notifications of their intentions to market generic versions of Toprol-XL tablets prior to the expiration of AstraZeneca s relevant patents, summary judgement motions were filed by the defendants and AstraZeneca on validity, enforceability and infringement in 2005. Oral argument on all of the pending summary judgement motions was heard in November 2005. As previously disclosed, in January 2006 the US District Court for the Eastern District of Missouri issued a ruling on the summary judgement motions. The court found that the two patents-in-suit are unenforceable based on the Company inequitable conduct in the prosecution of these patents in the US Patent and Trademark Office and invalid. The Company disagrees with and is disappointed by these conclusions. AstraZeneca will appeal this decision. None of the Abbreviated New Drug Applications filed by KV, Andrx or Eon has received tentative approval from the US Food and Drug Administration. Under the ANDA statute, the January 2006 adverse decision concerning the validity and enforceability of the ANDAs.

In January 2006, AstraZeneca was served with a complaint filed in the US District Court for the District of Delaware entitled Meijer, Inc. and Meijer Distribution, Inc. v. AstraZeneca Pharmaceuticals LP, AstraZeneca LP, AstraZeneca AB and Aktiebolaget Hassle. The complaint is a putative class action that alleges that the AstraZeneca defendants attempted to illegally maintain monopoly power in the US over Toprol-XL\(\) in violation of the Sherman Act through the listing of invalid and unenforceable patents in the FDA\(\) Orange Book and the enforcement of such patents through litigation against generic manufacturers seeking to market metoprolol succinate. The complaint seeks treble damages based on alleged overcharges to the putative class of plaintiffs. The lawsuit is based upon the finding described above by the US District Court for the Eastern District of Missouri in the consolidated litigation against KV, Andrx and Eon that the AstraZeneca patents relating to Toprol-XL\(\) are invalid and unenforceable. As noted above, AstraZeneca is appealing this ruling in the patent litigation. AstraZeneca denies the allegations of this anti-trust complaint and will vigorously defend the lawsuit.

AstraZeneca continues to maintain that its patents for Toprol-XL are valid, enforceable and infringed by the proposed generic products of KV, Andrx and Eon and that its enforcement of its patents did not violate anti-trust laws.

# Average wholesale price class action litigation

Since the original class action suit in Massachusetts naming AstraZeneca as a defendant along with other pharmaceutical manufacturers, AstraZeneca and other manufacturers have been sued in similar lawsuits filed by the state Attorneys General of Pennsylvania, Nevada, Montana, Wisconsin, Illinois, Alabama, Kentucky, Arizona and Mississippi, as well as by multiple individual counties in the State of New York. The Attorney General lawsuits seek to recover alleged overpayments under Medicaid and other state-funded healthcare programmes.

Since the decision on class certification issued by the District Court in Boston in August 2005 and previously disclosed in the Third Quarter and Nine Months Results 2005, as to the proposed classes involving physician-administered drugs, the court has certified a nationwide class of Part B beneficiaries against AstraZeneca and three other manufacturers. The additional proposed classes involving physician-administered drugs, third-party payers who reimbursed for physician-administered drugs or who covered Part B co-payments have been certified only as Massachusetts state, as opposed to nationwide, classes. For all classes, the only AstraZeneca drug at issue is Zoladex[] (goserelin acetate implant).

There is a possibility that the decision on class certification will be appealed. Following a decision on the appeal, the court will set a schedule for summary judgement proceedings and trial. In the interim, Attorney General cases are proceeding independently of the consolidated action in Pennsylvania, Alabama, Mississippi, Arizona and Wisconsin.

AstraZeneca denies the allegations made in all the average wholesale price lawsuits and will vigorously defend the actions.

## Avorelin

The legal proceedings with Mediolanum farmaceutici S.p.A. in respect of the licence agreement for avorelin have now been settled by the parties on terms satisfactory to AstraZeneca (which admits no liability).

# Matters previously disclosed in respect of the third quarter of 2005

## Diprivan (propofol)

In September 2005, AstraZeneca received notification from Amphastar Pharmaceuticals, Inc. under section 505(b)(2) of the US Food, Drug, and Cosmetic Act that it intends to manufacture and sell propofol in the US prior to the expiration of certain of AstraZeneca\[ \]s propofol-related patents. Amphastar contends that these patents would not be infringed by such manufacture and sale.

AstraZeneca is evaluating Amphastar[]s notification and continues to have full confidence in its intellectual property protecting Diprivan[].

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## Losec (omeprazole)

As previously disclosed, in June 2005 the European Commission notified AstraZeneca PLC and AstraZeneca AB of its Decision to impose fines totaling [60 million on the companies for infringements of European competition law (Article 82 of the EC Treaty and Article 54 of the EEA Agreement). The fine was fully provided for in the half year results through a charge to operating profit of \$75 million. AstraZeneca does not accept the Commission[s Decision and has appealed it to the Court of First Instance. AstraZeneca denies that it had a dominant position or that it engaged in the behaviours as characterised by the Commission. It is alleged by the Commission that these activities had the effect of hindering the entry of the generic version of Losec[] and of parallel trade. It is possible that third parties could seek damages for alleged losses arising from this. Any such claims would be vigorously resisted.

## **Nexium** (esomeprazole magnesium)

In October 2005, AstraZeneca received a notice from Ranbaxy Pharmaceuticals Inc. that Ranbaxy Laboratories Limited has submitted an Abbreviated New Drug Application to the US Food and Drug Administration for esomeprazole magnesium delayed-release capsules, 20mg and 40mg, containing paragraph IV certifications of invalidity and/or non-infringement with respect to certain AstraZeneca US patents listed in the FDA□s Orange Book in reference to Nexium□, the latter of which expires in 2019.

The 45 day time period within which AstraZeneca can commence a patent infringement lawsuit against Ranbaxy that would automatically stay, or bar, the FDA from approving Ranbaxy ANDA for 30 months (or until an adverse court decision, whichever occurs earlier) has not yet expired.

Ranbaxy has also certified with respect to certain other AstraZeneca US patents listed in the Orange Book in reference to Nexium that Ranbaxy will not launch its product prior to the expiry of those patents, the latter of which expires in October 2007.

AstraZeneca is evaluating Ranbaxy[s notice and continues to have full confidence in its intellectual property protecting Nexium[].

## Pulmicort Respules (budesonide inhalation suspension)

In September 2005, AstraZeneca received a notice from IVAX Pharmaceuticals, Inc. that IVAX has submitted an Abbreviated New Drug Application to the US Food and Drug Administration for a budesonide inhalation suspension containing a paragraph IV certification alleging invalidity and non-infringement in respect of certain of AstraZeneca\(\sigma\) patents relating to budesonide inhalation suspension.

In October 2005, AstraZeneca filed a patent infringement action against IVAX in the US District Court for the District of New Jersey.

## Seroquel (quetiapine fumarate)

In September 2005, AstraZeneca received a notice from Teva Pharmaceuticals USA that Teva has submitted an Abbreviated New Drug Application to the US Food and Drug Administration for quetiapine fumarate tablets (25mg base) containing a paragraph IV certification alleging invalidity and non-infringement in respect of AstraZeneca\[ \]s US patent number 4,879,288. AstraZeneca\[ \]s US patent number 4,879,288 is listed in the FDA\[ \]s Orange Book in reference to Seroquel\[ \].

AstraZeneca is evaluating Teva□s notice and continues to have full confidence in its intellectual property protecting Seroquel□.

The 45 day time period within which AstraZeneca can commence a patent infringement lawsuit against Teva that would automatically stay, or bar, the FDA from approving Teva ANDA for 30 months (or until an adverse court decision, whichever occurs earlier) has not yet expired.

AstraZeneca has been served in the US with approximately 40 Seroquel cases in which plaintiffs have alleged that they developed diabetes, and in some cases pancreatitis, as a result of taking Seroquel or other atypical anti-psychotics made by other pharmaceutical companies. Eli Lilly, the maker of olanzapine, is a defendant in all but four of these cases and Janssen Pharmaceutica is a defendant in more than a dozen of the matters. The vast majority of these cases recently were filed in Missouri. All of the Missouri cases were filed a day or two before Missouri stort reform laws became effective. AstraZeneca has been informed that other cases involving Seroquel were filed in Missouri but have not yet been served. Only two of the pending Seroquel cases involving diabetes allegations have gone beyond the pleadings stage. AstraZeneca intends vigorously to defend the claims in these actions.

## **Toprol-XL** (metoprolol succinate)

As disclosed in the Annual Report and Form 20-F Information 2004, patent litigation is continuing in the US against KV Pharmaceutical Company, Andrx Pharmaceuticals LLC and Eon Labs Manufacturing Inc. relating to those companies notifications of their intentions to market generic versions of Toprol-XL tablets prior to the expiration of AstraZeneca s relevant patents. All of the patent litigation has been consolidated for pre-trial discovery purposes and motion practice in the US District Court for the Eastern District of Missouri. As previously disclosed, in January 2005 AstraZeneca filed a terminal disclaimer of the Toprol-XL patents-in-suit over one of the other patents raised by the defendants, which will result in a revision of the expiration date of the Toprol-XL patents-in-suit from March 2008 to September 2007. Under the Abbreviated New Drug Application statute, the US Food and Drug Administration may not approve Andrx product before June 2006 or Eon product before August 2006, unless there is an earlier adverse court decision. The 30 months stay in respect of KV product has expired.

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The trial in the proceedings is scheduled to commence in February 2006 and will likely consolidate the cases against KV, Andrx and Eon. Oral arguments on the pending summary judgement motions on the infringement and validity of the patents, those motions having been filed by the defendants in December 2004, were scheduled for November 2005.

In September 2005, AstraZeneca received a paragraph IV notification from KV of its intention to market metoprolol succinate tablets in the 25mg dose prior to the expiration of AstraZeneca\(\sigma\) s patents. AstraZeneca has filed a patent infringement suit against KV in the US District Court for the Eastern District of Missouri.

AstraZeneca maintains that its patents are valid, enforceable and infringed by the KV, Andrx and Eon products.

# Average wholesale price class action litigation

As disclosed in the Annual Report and Form 20-F Information 2004, AstraZeneca was named as a defendant along with 24 other pharmaceutical manufacturers in a class action suit, in Massachusetts, brought on behalf of a putative class of plaintiffs alleged to have overpaid for prescription drugs as a result of inflated wholesale list prices. The suit seeks to recover unspecified damages. AstraZeneca was also named as a co-defendant with various other pharmaceutical manufacturers in similar suits filed in nine other states. Most of these suits were consolidated with the Massachusetts action for pre-trial purposes, pursuant to federal multi-district litigation procedures.

In August 2005, the District Court in Boston issued a decision on class certification favourable to the defendants. The plaintiffs had sought to certify three nationwide classes of plaintiffs: (1) Medicare Part B beneficiaries who paid allegedly inflated co-payments for certain physician-administered (injectable) drugs reimbursed under the Medicare Part B programme; (2) third-party payers offering MediGap coverage for the same physician-administered drugs or otherwise reimbursed outside Medicare for the drugs; and (3) payers for certain non-Part B (self-administered) drugs.

The court denied the self-administered drug class entirely. As to the two proposed classes involving physician-administered drugs, the court conditionally certified a nationwide class of Part B beneficiaries, provided that the plaintiffs can amend the complaint to include as class representatives individual Part B beneficiaries who actually paid Medicare co-payments for the named drugs. The second proposed physician-administered drug class, third-party payers who reimbursed for physician-administered drugs or covered Part B co-payments, was certified only as a Massachusetts state, as opposed to a nationwide, class. In both classes, the only AstraZeneca drug at issue is Zoladex[] (goserelin acetate implant).

## **Drug importation anti-trust litigation**

As disclosed in the Annual Report and Form 20-F Information 2004 and Half Year Results 2005, AstraZeneca Pharmaceuticals LP and eight other pharmaceutical manufacturers have been defending a purported class action filed in the US District Court for Minnesota which alleged that the defendants conspired to prevent American consumers from purchasing prescription drugs from Canada, [depriving consumers of the ability to purchase] drugs at competitive prices. Earlier in 2005, the chief magistrate judge assigned to the case issued a report on the defendants motion to dismiss the case, making certain recommendations to the presiding district court judge. The report recommended dismissal of the plaintiffs federal anti-trust claims, but not dismissal of the state statutory and common law claims. In August 2005, the district court dismissed with prejudice the plaintiffs federal anti-trust claims. As to the state statutory and common law claims, the district court declined to exercise supplemental jurisdiction and dismissed them without prejudice. The plaintiffs have appealed the district court section. In the similar California state court proceedings, the trial is scheduled to commence in July 2006.

## **Avorelin**

In 1999, AstraZeneca UK Limited entered into a licence agreement with Mediolanum farmaceutici S.p.A. under which Mediolanum licensed to AstraZeneca certain rights in respect of avorelin, a luteinising hormone-releasing hormone agonist. At the end of 2000, AstraZeneca terminated the agreement. Mediolanum has commenced proceedings against AstraZeneca alleging that AstraZeneca breached the terms of the agreement and claiming damages. AstraZeneca denies any breach of the agreement and is vigorously defending the proceedings. The trial in the proceedings is scheduled to commence in the English courts in February 2006.

## **General**

With respect to each of the legal proceedings described above, we are unable to make estimates of the loss or range of losses at this stage, other than where noted in the case of the European Commission fine. We also do not believe that disclosure of the amount sought by plaintiffs, if that is known, would be meaningful with respect to those legal proceedings.

## **Arrangements with Merck**

As described in more detail in the Annual Report and Form 20-F Information 2004, AstraZeneca has significant arrangements with Merck & Co., Inc. relating to certain of our products and development compounds (the agreement products). These arrangements include exit provisions from 2008 onwards and we regularly monitor the value of the benefits we expect to receive.

The exit provisions are subject to a minimum overall net payment of \$3.3 billion and will offer AstraZeneca unencumbered discretion in its operations in the US market (except in respect of Prilosec[] and Nexium[]) without the restrictions of various contractual obligations that are currently imposed as a result of Merck[]s interests, together with relief from contingent payment obligations. The projected value of the benefits obtained in 2008 depends on a number of factors including the future contributions from products that have already been launched, those that are due to be launched in the US and those that are in development together with the further value AstraZeneca can extract from greater freedom to operate in the US.

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# **4 FULL YEAR TERRITORIAL SALES ANALYSIS**

			% Growth	
	Full Year 2005 \$m	Full Year 2004 \$m	Actual	Constant Currency
US	10,771	9,631	12	12
Canada	976	876	11	2
North America	11,747	10,507	12	11
France	1,654	1,597	4	1
UK	757	589	29	27
Germany	1,223	994	23	20
Italy	1,152	1,082	6	3
Sweden	295	298	(1)	(3)
Europe others	3,382	3,089	9	6
Total Europe	8,463	7,649	11	8
Japan	1,527	1,430	7	8
China	272	203	34	33
Rest of World	1,941	1,637	19	13
Total	23,950	21,426	12	10

## 5 FOURTH QUARTER TERRITORIAL SALES ANALYSIS

	_	% Gr	owth
4th Quarter	4th Quarter		
2005	2004		Constant
\$m	\$m	Actual	Currency

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US	2,907	2,657	9	9
Canada	257	225	14	5
North America	3,164	2,882	10	9
France	389	389	-	3
UK	196	157	25	28
Germany	306	277	10	13
Italy	274	273	-	3
Sweden	63	76	(17)	(12)
Europe others	861	816	6	7
Total Europe	2,089	1,988	5	7
Japan	424	412	3	8
China	76	57	33	31
Rest of World	533	460	16	10
Total	6,286	5,799	8	9

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# **6 FULL YEAR PRODUCT SALES ANALYSIS**

	World				US	
	Full Year 2005 \$m	Full Year 2004 \$m	Actual Growth %	Constant Currency Growth %	Full Year 2005 \$m	Actual Growth %
Gastrointestinal:						
Losec	1,652	1,947	(15)	(17)	264	(28)
Nexium	4,633	3,883	19	18	3,125	15
Others	70	88	(20)	(21)	14	(58)
Total Gastrointestinal	6,355	5,918	7	5	3,403	9
Cardiovascular:						
Zestril	332	440	(25)	(27)	6	(91)
Seloken/Toprol-XL	1,735	1,387	25	24	1,291	32

Atacand	974	879	11	8	232	(8)
Plendil	360	455	(21)	(23)	84	(49)
Tenormin	352	368	(4)	(5)	25	(29)
Crestor	1,268	908	40	38	730	34
Others	311	340	(9)	(12)	4	(71)
Total Cardiovascular	5,332	4,777	12	10	2,372	15
Respiratory:						
Pulmicort	1,162	1,050	11	9	682	18
Rhinocort	387	361	7	6	277	7
Symbicort	1,006	797	26	22	-	-
Accolate	72	116	(38)	(39)	46	(45)
Oxis	91	101	(10)	(14)	-	-
Others	155	158	(2)	(5)	-	-
Total Respiratory	2,873	2,583	11	9	1,005	9
Oncology:	<del></del>					
Zoladex	1,004	917	9	7	117	(23)
Casodex	1,123	1,012	11	10	239	3
Nolvadex	114	134	(15)	(16)	5	150
Arimidex	1,181	811	46	44	476	59
Iressa	273	389	(30)	(31)	66	(63)
Faslodex	140	99	41	39	90	11
Others	10	14	(29)	(36)	-	-
Total Oncology	3,845	3,376	14	12	993	5
Neuroscience:						
Seroquel	2,761	2,027	36	35	2,003	33
Zomig	352	356	(1)	(3)	121	(18)
Diprivan	369	500	(26)	(27)	147	(44)
Local anaesthetics	511	542	(6)	(8)	70	(47)
Others	66	71	(7)	(8)	18	(10)
Total Neuroscience	4,059	3,496	16	15	2,359	14
Infection and Other:		_			_	
Merrem	505	423	19	15	85	25
Other Products	334	293	14	13	190	36
Total Infection and Other	839	716	17	14	275	32
Aptium Oncology	335	304	10	10	335	10
Astra Tech	312	256	22	19	29	53
Total	23,950	21,426	12	10	10,771	12

# **7 FOURTH QUARTER PRODUCT SALES ANALYSIS**

	World				US	
	4th Quarter 2005 \$m	4th Quarter 2004 \$m	Actual Growth %	Constant Currency Growth %	4th Quarter 2005 \$m	Actual Growth %
Gastrointestinal:						
Losec	411	446	(8)	(8)	73	(8)
Nexium	1,247	1,106	13	13	849	8
Others	19	24	(21)	(17)	6	(45)
Total Gastrointestinal	1,677	1,576	6	6	928	6
Cardiovascular:						
Zestril	84	113	(26)	(26)	10	(52)
Seloken/Toprol-XL	455	381	19	19	346	29
Atacand	247	240	3	3	53	(16)
Plendil	73	94	(22)	(22)	6	(77)
Tenormin	90	97	(7)	(5)	8	(11)
Crestor	353	312	13	12	203	4
Others	76	84	(10)	(10)	1	(50)
Total Cardiovascular	1,378	1,321	4	4	627	7
Respiratory:						
Pulmicort	338	313	8	8	212	13
Rhinocort	92	93	(1)	(2)	63	(7)
Symbicort	264	219	21	22	-	-
Accolate	17	32	(47)	(47)	11	(54)
Oxis	22	25	(12)	(12)	-	-
Others	40	40	-	3		-
Total Respiratory	773	722	7	7	286	2
Oncology:						
Zoladex	252	242	4	5	23	(32)
Casodex	283	276	3	5	60	(5)
Nolvadex	28	35	(20)	(17)	2	-
Arimidex	325	233	39	40	131	58

Iressa	72	80	(10)	(9)	17	_
Faslodex	39	26	50	50	23	21
Others	2	3	(33)	(33)	-	-
Total Oncology	1,001	895	12	13	256	19
Neuroscience:						
Seroquel	755	562	34	34	553	34
Zomig	94	89	6	6	39	11
Diprivan	88	126	(30)	(29)	35	(44)
Local anaesthetics	131	144	(9)	(9)	22	(41)
Others	16	17	(6)	-	5	-
Total Neuroscience	1,084	938	16	16	654	18
Infection and Other:					_	
Merrem	130	113	15	14	24	71
Other Products	72	86	(16)	(16)	36	(28)
Total Infection and Other	202	199	2	1	60	(6)
Aptium Oncology	88	78	13	13	88	13
Astra Tech	83	70	19	20	8	33
Total	6,286	5,799	8	9	2,907	9

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# **Convenience Translation of Key Financial Information**

For the <b>quarter ended</b> 31 December	2005 \$m	2004 \$m	2005 £m	2004 £m	2005 SEKm	2004 SEKm
Total Sales	6,286	5,799	3,646	3,364	49,951	46,081
Operating profit	1,636	1,271	949	737	13,000	10,100
Profit before tax	1,689	1,295	980	751	13,421	10,291
Net profit for the period	1,227	929	712	539	9,750	7,382
Earnings per Ordinary Share	\$0.77	\$0.55	£0.45	£0.32	SEK6.12	SEK4.37

For the <b>year ended</b> 31 December	2005 \$m	2004 \$m	2005 £m	2004 £m	2005 SEKm	2004 SEKm
Total Sales	23,950	21,426	13,893	12,429	190,315	170,258
Operating profit	6,502	4,547	3,772	2,638	51,667	36,132
Profit before tax	6,667	4,844	3,867	2,810	52,978	38,492
Net profit for the year	4,724	3,683	2,740	2,136	37,539	29,266
Basic earnings per Ordinary	\$2.91	\$2.18	£1.69	£1.26	SEK23.12	SEK17.32
Share Earnings per Ordinary Share before exceptional items	\$2.91	\$2.01	£1.69	£1.17	SEK23.12	SEK15.97
Dividend per Ordinary Share	\$1.30	\$0.94	£0.737	£0.503	SEK10.01	SEK6.697
Net cash inflow from operating	6,743	4,817	3,911	2,794	53,582	38,278
activities Increase in cash & cash equivalents	989	3,026	574	1,755	7,859	24,046
Capital and Reserves Attributable to Equity Holders	13,597	14,404	7,887	8,355	108,047	114,459

All Sterling (£) and Swedish krona (SEK) equivalents are shown for convenience and have been calculated using the current period end rates of \$1=\$£ 0.58008 and \$1=\$SEK 7.94635, respectively. Dividend per Ordinary Share is shown as the actual amount payable using the rates at the date of declaration of the dividend.

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# Information for US Investors

# **RECONCILIATION TO UNITED STATES ACCOUNTING PRINCIPLES**

The consolidated income statement and balance sheet set out on pages 13 and 15 are prepared in accordance with IASs and IFRSs (collectively [IFRS]) endorsed by the European Union and available for use by European companies at 31 December 2005. The following is a summary of the differences between IFRS and accounting principles generally accepted in the United States (US GAAP) as they apply to AstraZeneca PLC.

## **Purchase accounting adjustments**

Under IFRS, the merger of Astra and Zeneca is accounted for as a <code>[merger</code> of equals[] (pooling-of-interests) as a result of the business combinations exemption permitted by IFRS 1 <code>[First-time</code> Adoption of International Financial Reporting Standards[]. Under US GAAP the merger was accounted for as the acquisition of Astra by Zeneca using <code>[purchase</code> accounting[]. Under purchase accounting, the assets and liabilities of the acquired entity are recorded at fair value. As a result of the fair value exercise, increases in the values of Astra[]s tangible fixed assets and inventory were recognised and values attributed to its in-process research and development and existing products, together with appropriate deferred taxation effects. The difference between the cost of investment and the fair value of the assets and liabilities of Astra was recorded as goodwill. The amount allocated to in-process research and development was, as required by US GAAP, expensed immediately in the first reporting period after the business combination. Fair value adjustments to the recorded amount of inventory were expensed in the period the inventory was utilised. Additional amortisation and depreciation have also been recorded in respect of the fair value adjustments to tangible and intangible assets.

Under IFRS, up until 31 December 2002, goodwill was required to be capitalised and amortised. From 1 January 2003 goodwill is tested annually for impairment but not amortised. Under US GAAP, there is an equivalent requirement, but the effective date was 1 January 2002.

# **Capitalisation of interest**

AstraZeneca does not capitalise interest under IFRS. US GAAP requires interest incurred as part of the cost of constructing fixed assets to be capitalised and amortised over the life of the asset.

## **Deferred taxation**

The IFRS full provision for deferred taxation is made although there are a number of different bases from US GAAP on which this calculation is made, for example, the elimination of intra-group profit on inventories and share-based payment transactions. Deferred taxation is provided on a full liability basis under US GAAP, which requires deferred tax assets to be recognised without a valuation allowance if their realisation is considered to be more likely than not.

# Pension and post-retirement benefits

IFRS requires that in respect of defined benefit plans, obligations are measured at discounted fair value whilst plan assets are recorded at fair value. The operating and financing costs of such plans are recognised separately in the income statement; service costs are spread systematically over the lives of employees and financing costs are recognised in the periods in which they arise. US GAAP adopts a similar approach. Under IFRS, actuarial gains and losses are permitted to be recognised immediately in the statement of recognised income and expense. Under US GAAP, such actuarial gains and losses are permitted to be amortised on a straight-line basis over the average remaining service period of employees. A minimum pension liability is also recognised through other comprehensive income in certain circumstances when there is a deficit of plan assets relative to the accumulated benefits obligation.

## Intangible assets

Under IFRS certain payments for rights to compounds in development are capitalised. Under US GAAP these payments are generally expensed.

## Financial instruments and hedging activities

Under IFRS, financial assets and certain financial liabilities (including derivatives) are recognised at fair value; movements in the fair value may be recorded in equity or through income, depending upon their categorisation. Under US GAAP, marketable equity and all debt securities are recognised at fair value, with movements in fair value taken to a separate component of equity. Derivatives are also measured at fair value with movements taken through income. However, financial liabilities are recorded at amortised cost.

# New accounting standards adopted

AstraZeneca has adopted the provisions of SFAS No. 123 (R) [Share-Based Payment] in the period under review. SFAS No. 123 (R) requires compensation cost related to share based payments to be recognised in the financial statements. AstraZeneca has used the transitional arrangements for modified retrospective application in adopting SFAS No. 123 (R). As a consequence, the comparative US GAAP income before tax has been reduced by \$147 million with a related tax credit of \$58 million and the shareholders equity at 31 December 2004 increased by \$163m.

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# **RECONCILIATION TO UNITED STATES ACCOUNTING PRINCIPLES (CONTINUED)**

The approximate effects on income and shareholders equity of the GAAP differences are shown in the following tables.

Income attributable to Shareholders For the year ended	2005 \$m	As restated 2004 \$m
Net income for the period under IFRS from continuing		
operations	4,706	3,664
Adjustments to conform to US GAAP		
Purchase accounting adjustments (amortisation and depreciation)	(1,019)	(1,014)
Capitalisation less disposals and amortisation of interest	(13)	(1)
Deferred taxation		
- on purchase accounting adjustments	283	283
- others	65	55
Pension expense and other post-retirement benefits expense	(74)	(52)
Financial instruments	(35)	61
In-licensed development intangibles	(29)	(46)
Other		1
Net income in accordance with US GAAP	3,884	2,951
Net income per Ordinary Share under US GAAP $\hfill \square$ basic and diluted	\$2.40	\$1.76

# RECONCILIATION TO UNITED STATES ACCOUNTING PRINCIPLES (CONTINUED)

Shareholders' equity As at 31 December	2005 \$m	As restated 2004 \$m
Shareholders' equity under IFRS	13,597	14,404
Adjustments to conform to US GAAP		
Purchase accounting adjustments:		
- goodwill	13,562	15,229
- tangible and intangible fixed assets	5,229	6,988
Capitalisation, less disposals and amortisation of interest	241	254
Deferred taxation		
- on purchase accounting adjustments	(1,629)	(2,134)
- others	(492)	(618)
Pension and other post-retirement benefits	1,483	1,418
Financial instruments	18	22
In-licensed development intangibles	(112)	(83)
Other	(3)	(3)
Shareholders' equity in accordance with US GAAP	31,894	35,477

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# **Shareholder Information**

# **ANNOUNCEMENTS AND MEETINGS**

Announcement of first quarter 2006 results

Annual General Meeting 2006

Announcement of second quarter and half year 2006 results

Announcement of third quarter and nine months 2006 results

27 April 2006

27 April 2006

27 July 2006

26 October 2006

## **DIVIDENDS**

The record date for the first interim dividend paid on 19 September 2005 was 12 August 2005. Ordinary Shares traded ex-dividend on the London and Stockholm Stock Exchanges from 10 August 2005. ADRs traded ex-dividend on the New York Stock Exchange from the same date.

The record date for the second interim dividend for 2005 payable on 20 March 2006 (in the UK, Sweden and the US) will be 10 February 2006. Ordinary Shares will trade ex-dividend on the London and Stockholm Stock Exchanges from 8 February 2006. ADRs will trade ex-dividend on the New York Stock Exchange from the same date.

Dividends will normally be paid as follows:

First interim Announced in July and paid in September

Second interim Announced in January/February and paid in March

#### **TRADEMARKS**

The following brand names used in this interim report are trademarks of the AstraZeneca group of companies:

Accolate Arimidex Astra Tech Atacand Casodex Crestor Diprivan Exanta Faslodex Iressa Losec Merrem Nexium Nolvadex Oxis Plendil Prilosec Pulmicort Pulmicort Respules Rhinocort Rhinocort Aqua Seloken Seroquel Symbicort Symbicort Maintenance and Reliever Therapy Tenormin Toprol-XL Zactima Zestril Zoladex Zomig

# ADDRESSES FOR CORRESPONDENCE

Registrar and Transfer Office	Depositary for ADRs	Registered Office	Swedish Securities Registration Centre
The AstraZeneca Registrar	JP Morgan Chase Bank	15 Stanhope Gate	VPC AB
Lloyds TSB Registrars	JP Morgan Service Center	London	PO Box 7822
The Causeway	PO Box 3408	W1K 1LN	SE-103 97 Stockholm
Worthing	South Hackensack	UK	Sweden
West Sussex	NJ 07606-3408		
BN99 6DA	US		
UK		Tel: +44 (0)20 7304 5000	Tel: +46 (0)8 402 9000
Tel (freephone in UK):	Tel (toll free in US):		
0800 389 1580	888 697 8018		
Tel (outside UK):	Tel (outside US):		
+44 (0)121 415 7033	+ 1 (201) 680 6630		

# **CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

In order to utilise the <code>[Safe Harbor]</code> provisions of the United States Private Securities Litigation Reform Act of 1995, AstraZeneca is providing the following cautionary statement. This preliminary announcement contains forward-looking statements with respect to the financial condition, results of operations and businesses of AstraZeneca. By their nature, forward-looking statements and forecasts involve risk and uncertainty because they relate to events and depend on circumstances that will occur in the future. There are a number of factors that could cause actual results and developments to differ materially from that expressed or implied by these forward-looking statements. These factors include, among other things, the loss or expiration of patents, marketing exclusivity or trade marks; exchange rate fluctuations; the risk that R&D will not yield new products that achieve commercial success; the impact of competition, price controls and price reductions; taxation risks; the risk of substantial product liability claims; the impact of any failure by third parties to supply materials or services; the risk of delay to new product launches; the difficulties of obtaining and maintaining governmental approvals for products; and the risk of environmental liabilities.