ASTRAZENECA PLC Form 6-K
November 05, 2008 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 October 2008
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 Form 20-F X 40-F
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):
Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.
Yes No 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, "Repurchase of Shares in AstraZeneca PLC", dated 1 October 2008.
- 2. Press release entitled, "Repurchase of Shares in AstraZeneca PLC", dated 2 October 2008.
- 3. Press release entitled, "AstraZeneca and Pozen Informed of FDA Internal Review of Gastric Ulcers as a Primary Endpoint in Trials", dated 17 October 2008.
- 4. Press release entitled, "AstraZeneca's third quarter and nine months results 2008", dated 29 October 2008.
- 5. Press release entitled, "AstraZeneca PLC Third Quarter and Nine Months Results 2008" (front half), dated 30 October 2008.
- 6. Press release entitled, "AstraZeneca PLC Third Quarter and Nine Months Results 2008 Condensed Consolidated Income Statement" (back half), dated 30 October 2008.
- 7. Press release entitled, "Transparency Directive Voting Rights and Capital", dated 31 October 2008.

### **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: 4 November 2008 By: /s/ Justin Hoskins

Name: Justin Hoskins Title: Deputy Company

Secretary

Item 1

### REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 30 September 2008, it purchased for cancellation 1,053,640 ordinary shares of AstraZeneca PLC at a price of 2450 pence per share.

Some of these shares were purchased under the terms of the previously announced irrevocable, non-discretionary share repurchase programme for the period 5 August 2008 to 1 October 2008.

Upon the cancellation of these shares, the number of shares in issue will be 1,446,544,833.

G H R Musker Company Secretary 1 October 2008 Item 2

### REPURCHASE OF SHARES IN ASTRAZENECA PLC

Further to the announcement of its irrevocable, non-discretionary share repurchase programme for the period 5 August 2008 to 1 October 2008, AstraZeneca PLC announced that under the terms of that programme it purchased for cancellation 199,258 ordinary shares of AstraZeneca PLC at a price of 2508 pence per share on 1 October 2008. Upon the cancellation of these shares, the number of shares in issue will be 1,446,345,575.

G H R Musker Company Secretary 2 October 2008

#### Item 3

# ASTRAZENECA AND POZEN INFORMED OF FDA INTERNAL REVIEW OF GASTRIC ULCERS AS A PRIMARY ENDPOINT IN TRIALS

AstraZeneca and POZEN Inc., co-development partner for the investigational compound PN 400, have announced today that the U.S. Food and Drug Administration (FDA) has informed POZEN that it is conducting an internal review on the acceptability of endoscopic gastric ulcers as a primary endpoint in clinical studies. The FDA has not indicated when their internal review will be completed, although an FDA internal meeting has been scheduled to review this subject during the first quarter of 2009.

At the completion of the Special Protocol Assessment (SPA) for the PN 200 compound, POZEN had reached an agreement with the FDA on the design of its pivotal trials for PN 200 (omeprazole 20 mg and naproxen 500 mg), which specified the primary endpoint as the reduction in gastric ulcers versus enteric coated naproxen. The FDA confirmed that the development programme for PN 200 also applied to PN 400.

It is unclear at this time what impact, if any, the FDA's internal review will have. However, the PN 400 clinical programme will continue to progress under the SPA agreed development plan with the FDA.

#### About PN 400:

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

### About AstraZeneca

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

#### Media Enquiries:

Chris Sampson +44 20 7304 5130 (24 hours) Neil McCrae +44 207 304 5045 (24 hours)

### **Investor Enquiries**

UK:

Jonathan Hunt	+44 207 304 5087	mob: +44 7775 704032
Mina Blair	+44 20 7304 5084	mob: +44 7718 581021
Karl Hard	+44 207 304 5322	mob: +44 7789 654364

Investor Enquiries

US:

Ed Seage +1 302 886 4065 mob: +1 302 373 1361

Jorgen Winroth +1 212 579 0506 mob: +1 917 612 4043

Peter Vozzo +1 301 398 4358 mob: +1 301 252 7518

(MedImmune)

17 October 2008

- ENDS -

Item 4

AstraZeneca's third quarter and nine months results 2008

Tomorrow, Thursday, 30 October, AstraZeneca will be announcing third quarter and nine months results for 2008 at 11:00 (GMT), 12:00 (CET), 07:00 (EDT).

There will be an analyst teleconference at 13:00(GMT), 14:00(CET), 09:00 (EDT), for which the numbers are in the UK: 0808 100 5150, for International: +44 (0)844 8000 920, for Sweden: 0200 110 487 and for the US: 1 866 804 8688. These numbers, as well as details of the replay facility available through Friday, 14 November 2008, are available on the Investors section of the AstraZeneca website at www.astrazeneca.com.

#### Item 5

# AstraZeneca PLC Third Quarter and Nine Months Results 2008

- Robust third quarter performance.
- -Third quarter sales increased by 3 percent at constant exchange rates (CER). Core EPS increased by 20 percent at CER to \$1.32.
- -Third quarter sales in Emerging Markets increased by 18 percent at CER to \$1.1 billion. Sales in China increased by 35 percent.
- -Crestor sales up 28 percent (CER) in the third quarter. US sales increased by 23 percent fuelled by atherosclerosis indication. Crestor is the only branded statin to gain market share in the US this year.
- Nine months sales increased by 3 percent and Core EPS by 8 percent at CER.
- Core EPS target for the year increased to reflect stronger operational and financial performance as well as additional currency benefit.
- -Revised target range for Core EPS is \$4.90 to \$5.05.\*
- No further share repurchases will take place in 2008 in order to maintain the flexibility to invest in the business.

### **Financial Summary**

Group	3rd Quarter 2008 \$m	3rd Quarter 2007 \$m	Actual %	CER %	9 Months 2008 \$m	9 Months 2007 \$m	Actual %	CER %
Sales	7,775	7,150	+9	+3	23,408	21,389	+9	+3
Reported								
Operating Profit	2,522	2,022	+25	+19	7,252	6,165	+18	+8
Profit before Tax	2,443	1,888	+29	+22	6,865	6,146	+12	+1
Earnings per Share	\$1.20	\$0.91	+32	+24	\$3.34**	\$2.88	+16	+5
Core***								
Operating Profit	2,771	2,298	+21	+15	8,273	6,981	+19	+10
Profit before Tax	2,692	2,164	+24	+18	7,886	6,962	+13	+4

Earnings per

Share \$1.32 \$1.04 +27 +20 \$3.85 \$3.28 +17 +8

- \* For the fourth quarter of 2008 guidance is based on original assumptions for currency: fourth quarter 2007 average rates.
- \*\* Included in Reported EPS for Nine Months 2008 is a \$0.12 charge taken in Q1 08 for impairment of intangible assets related to Ethyol.
- \*\*\*Core financial measures are supplemental non-IFRS measures which management believe useful to understanding the Company's performance; it is upon these measures that financial guidance for 2008 is based. See pages 8 and 9 for a reconciliation of Core to Reported financial measures.

David Brennan, Chief Executive Officer, said: "AstraZeneca has delivered a robust set of results that deliver on our performance commitments despite an increasingly challenging environment for the pharmaceutical sector and business in general. We continue to make good progress on reshaping our cost base, including advancing innovation in our research and development activities with greater productivity and efficiency. I am pleased to be able to raise our financial guidance for the full year on the back of these results."

London, 30 October 2008

### AstraZeneca PLC

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

### Third Quarter

Sales in the third quarter increased by 3 percent at CER, or 9 percent on an as reported basis. Sales in the US were unchanged, as the \$141 million decline in sales of Toprol-XL from generic competition was offset by 5 percent growth in the rest of the US business. Sales in the Rest of World were up 6 percent. Sales in Established Markets were up 2 percent. The strong performance in Emerging Markets continues, with sales up 18 percent to \$1,116 million, and this accounted for two thirds of the Rest of World sales increase.

Core operating profit in the third quarter was up 15 percent to \$2,771 million, chiefly as a result of the sales increase, improvement in Core gross margin and R&D efficiencies. Reported operating profit increased by 19 percent to \$2,522 million.

Core earnings per share in the third quarter were \$1.32 compared with \$1.04 in the third quarter 2007, a 20 percent increase at CER. In addition to the increase in Core operating profit, Core earnings per share benefited from lower net interest expense, the result of a fair value gain relating to certain long term bonds in issue, and a lower number of shares outstanding. Reported earnings per share in the third quarter were \$1.20, an increase of 24 percent.

#### Nine Months

Sales for the nine months increased by 3 percent at CER, or 9 percent on an as reported basis. Sales in the US were unchanged as the sales decline in Toprol-XL was largely offset by the inclusion of MedImmune and modest growth in the rest of the US business. Sales in the Rest of World were up 6 percent. Sales in Established Markets were up 2 percent, with sales in Western Europe unchanged. Sales in Emerging Markets were up 16 percent.

Core operating profit increased by 10 percent to \$8,273 million, as a result of improvements in gross margin and R&D efficiencies that more than offset the effect of lower other income and a slight increase in SG&A costs. Reported operating profit increased by 8 percent to \$7,252 million.

Core earnings per share for the nine months were \$3.85, an increase of 8 percent. Reported earnings per share for the nine months were \$3.34, a 5 percent increase compared to last year.

### Research and Development Update

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

Developments since this last update include:

.

On 15 September, AstraZeneca and Targacept announced top line results from the first Phase IIb study of AZD3480 in Alzheimer's disease. In the 12-week placebo-controlled study, known as the Sirocco trial, neither the active comparator donepezil nor AZD3480 met the trial's criteria for statistical significance on the primary outcome measure, ADAS-Cog (Alzheimer's Disease Assessment Scale – Cognition Subscale.) Both results were impacted by an improvement in the placebo group. Analyses of the full data set from the Sirocco trial are ongoing. AstraZeneca and Targacept plan to discuss the data with leading medical experts and to present and publish more detailed results over the coming months. A decision by AstraZeneca with respect to potential further development of AZD3480 is expected in December 2008.

- On 10 October, the Company announced that the US FDA approved Seroquel XR for the acute treatment of the depressive episodes associated with bipolar disorder, the manic and mixed episodes associated with bipolar I disorder and the maintenance treatment of bipolar I disorder as adjunctive therapy to lithium or divalproex. Seroquel XR is the first medication approved by the FDA for the once-daily acute treatment of both depressive and manic episodes associated with bipolar disorder.
- Regulatory submissions for Seroquel XR for major depressive disorder are under review in the US and in Europe, as well as the US submission for use in generalised anxiety disorder (GAD). The European submission for GAD was announced on 21 October.

- In October 2008, AstraZeneca submitted an sNDA for Seroquel to the FDA for the treatment of schizophrenia in adolescents 13-17 years of age and for the treatment of acute manic episodes associated with bipolar I disorder in children and adolescents 10-17 years of age. Seroquel US Prescribing Information will be updated to include additional safety information for children and adolescents. Seroquel is not currently indicated anywhere in the world for the paediatric population.
- · On 2 September 2008, the US FDA announced that it had accepted the filing for ONGLYZATM (saxagliptin), which was submitted by AstraZeneca and its partner Bristol-Myers Squibb on 30 June.
- · Preparations for the AZD0837 Phase III clinical programme are well underway. However, AstraZeneca is investigating a stability limitation with the AZD0837 tablets required for the Phase III clinical programme. As a consequence, the start of the programme will be delayed from the fourth quarter of 2008 until 2009. The start date will be confirmed once this stability limitation has been resolved.
- · In October 2008, new marketing authorisation licenses were secured for Crestor in Germany, Spain, Poland, Norway and Malta. Crestor is now approved for use in every country in the European Union.
- It has been confirmed that presentation of the first results of the Crestor JUPITER study will take place on 9 November at the American Heart Association 2008 Scientific Sessions in New Orleans, US.

### **Enhancing Productivity**

In the third quarter, restructuring and synergy costs associated with the global programme to reshape the cost base were \$117 million. This brings the cumulative charges since the inception of the programme to \$1,331 million.

The Company remains on track to deliver two-thirds of the total programme benefits of \$1.4 billion per annum by the end of this year, with the full savings to be realised by 2010.

#### **Future Prospects**

The Company has increased its target range for Core earnings per share for the full year to between \$4.90 and \$5.05 reflecting stronger operational and financial performance, chiefly from improved gross margin and lower expenditures in R&D arising from efficiency improvements, as well as the \$0.06 per share of additional currency benefits realised in the third quarter relative to the currency assumptions upon which the targets were based (i.e. fourth quarter 2007 average exchange rates).

For the fourth quarter of 2008, guidance is based on the original assumptions for currency, being fourth quarter 2007 average exchange rates.

This revised target takes no account of the likelihood that average exchange rates for the remainder of 2008 may differ from the fourth quarter 2007 average rates upon which our guidance is based. The Company's estimate of the sales and earnings sensitivity to movements of our major currencies versus the US dollar was provided in conjunction with the full year 2007 results announcement, and remains available on the AstraZeneca website.

Sales

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

#### Gastrointestinal

	CER					CER
	Third Quarter		%	Nine Months		%
	2008 \$m	2007 \$m		2008 \$m	2007 \$m	
Nexium	1,315	1,293	-2	3,876	3,913	-5
Losec/Prilosec	249	268	-15	791	845	-15
Total	1,589	1,581	-4	4,733	4,818	-7

- In the US, Nexium sales in the third quarter were \$779 million, an 8 percent decline compared with last year. Dispensed retail tablet volume grew by 3 percent compared with the third quarter last year. The back-loaded phasing of lower price realisation over the course of last year continues to give rise to a significant price variance, although in the third quarter this has narrowed to around ten percent. Further narrowing of this price variance is anticipated in the fourth quarter.
- · Nexium sales in the US in the nine months were down 12 percent to \$2,269 million.
- · Nexium sales in other markets in the third quarter were up 11 percent to \$536 million, on a 22 percent sales increase in Emerging Markets and a 7 percent increase in Established Markets.
- · Nexium sales in other markets were up 8 percent for the nine months to \$1,607 million.
- The Company continues to expect a mid-single digit decline for worldwide sales of Nexium for the full year.
- · Prilosec sales in the US were down 30 percent in the third quarter and 19 percent year to date as a result of the recent introduction of generic competition for the 40mg dosage form.
- · Sales of Losec in the Rest of World markets were down 11 percent in the third quarter and 13 percent for the nine months.

#### Cardiovascular

	Third Quarter		CER %	Nine M	CER %	
	2008 \$m	2007 \$m	70	2008 \$m	2007 \$m	,,
Crestor	922	691	+28	2,610	1,997	+24
Seloken /Toprol-XL	204	328	-42	600	1,229	-55
Atacand	386	320	+12	1,120	934	+10

Plendil	65	66	-9	201	205	-10
Zestril	60	72	-24	184	228	-27
Total	1 782	1 621	+4	5 160	5 029	-4

- · In the US, Crestor sales in the third quarter were \$420 million, a 23 percent increase over last year, fuelled by promotion of the atherosclerosis indication. While generic simvastatin continues to gain share in the US statin market, Crestor is the only branded statin to gain share during 2008; Crestor share of total prescriptions increased to 9.3 percent in September, up 0.7 points since December 2007. Crestor prescriptions increased by 12.3 percent compared with third quarter 2007, nearly three times the market rate.
- · US sales for Crestor for the nine months increased 14 percent to \$1,188 million.
- · Crestor sales in the Rest of World were up 33 percent to \$502 million in the third quarter, on good growth in Western Europe (up 19 percent), Emerging Markets (up 37 percent), Canada (up 26 percent) and Japan (up 79 percent).
- · Crestor sales in the Rest of World were up 34 percent in the nine months to \$1,422 million.
- US sales of the Toprol-XL product range, which includes sales of the authorised generic, were down 66 percent in the third quarter to \$72 million. Generic products accounted for 89 percent of dispensed prescriptions in the third quarter.
- Sales of Seloken in other markets in the third quarter were up 3 percent to \$132 million, as good growth in China (up 37 percent) and other Emerging Markets more than offset the decline in Western Europe.

• US sales of Atacand in the third quarter were up 3 percent to \$67 million. Sales in the Rest of World were up 14 percent to \$319 million.

### Respiratory and Inflammation

	Third Quarter		CER %	Nine Months		CER %
	2008 \$m	2007 \$m	70	2008 \$m	2007 \$m	70
Symbicort	501	371	+25	1,490	1,139	+19
Pulmicort	304	286	+3	1,098	1,007	+5
Rhinocort	72	80	-14	244	267	-13
Accolate	18	19	-5	55	57	-5
Oxis	18	18	-11	56	64	-23
Total	951	813	+10	3,069	2,655	+8

- Symbicort sales in the US were \$64 million in the third quarter. Trial rates among target specialists are now 85 percent; these specialists are starting nearly 29 percent of patients new to combination therapy on Symbicort. The trial rate among target primary care physicians has increased to 48 percent and primary care physicians are now using Symbicort in one out of six patients newly starting combination therapy. Overall, Symbicort share of new prescriptions for fixed combinations reached 10.6 percent in the week ending 17 October, with market share among patients newly starting combination treatment running well ahead of this, at 18.4 percent.
- Symbicort sales in other markets were \$437 million, 9 percent ahead of the third quarter last year on a 6 percent increase in Western Europe and a 19 percent increase in Emerging Markets.
- US sales for Pulmicort were up 7 percent to \$196 million in the third quarter. Pulmicort Respules sales were up 2 percent in the quarter and were up 11 percent for the nine months.
- On 24 September, Ivax Pharmaceuticals' (IVAX) (now known as Teva Pharmaceutical Industries Ltd.) Motion for Summary Judgement of no infringement of AstraZeneca's patents covering Pulmicort Respules was denied. The Court has set a 12 January 2009 start date for the trial.
- · Sales of Pulmicort in the Rest of World in the third quarter were down 4 percent to \$108 million.

### Oncology

27	Third Q	Third Quarter		Nine Months		CER %
	2008 \$m	2007 \$m		2008 \$m	2007 \$m	
Arimidex	486	425	+9	1,406	1,256	+6

Casodex	300	324	-14	974	965	-7
Zoladex	295	273	-	860	797	-2
Iressa	67	55	+13	192	168	+5
Faslodex	67	54	+17	188	156	+12
Nolvadex	20	20	-5	62	59	-5
Ethyol *	3	19	-84	23	27	n/m
Total	1,256	1,189	-1	3,759	3,480	_

<sup>\*</sup> Sales of this MedImmune product were consolidated in AstraZeneca accounts from 1 June 2007. As a result, the prior year to date reflects four months' sales.

- · In the US, sales of Arimidex were up 16 percent in the third quarter to \$193 million. Total prescriptions increased by 1 percent year on year in the first nine months in what was essentially an unchanged total market for hormonal treatments for breast cancer. Sales for the nine months in the US were up 14 percent.
- · Arimidex sales in other markets were up 5 percent in the third quarter to \$293 million, but were unchanged for the nine months.
- Casodex sales in the US were down 1 percent in the third quarter to \$71 million, and down 2 percent for the nine months. On 22 September, the Company announced that the US FDA has granted an additional six-month period of exclusivity to market Casodex for its licensed advanced prostate cancer indication until 1 April 2009.
- · Casodex sales in Rest of World in the third quarter were down 18 percent to \$229 million as a result of generic competition in some markets in Western Europe. Sales for the nine months were down 9 percent to \$759 million.

- · Worldwide sales of Iressa increased by 13 percent in the third quarter, chiefly as a result of a 56 percent increase in sales in China. Third quarter sales in Japan were up 4 percent.
- Faslodex sales in the third quarter were up 12 percent in the US and increased by 21 percent in other markets.

#### Neuroscience

	Third Q	Third Quarter		Nine M	CER %	
	2008 \$m	2007 \$m		2008 \$m	2007 \$m	
Seroquel	1,130	1,055	+4	3,292	2,941	+8
Zomig	115	107	+2	336	320	-2
Total	1,476	1,371	+3	4,342	3,891	+6

- · In the US, Seroquel sales were down 1 percent to \$749 million in the third quarter compared with the third quarter last year, which included around \$80 million of initial stocking sales for Seroquel XR. Adjusting for this effect, sales growth would have been around 10 percent. Total prescriptions were up 7 percent in the quarter, with 43 percent of the growth attributable to Seroquel XR. Seroquel is the market leading antipsychotic, with a total prescription share of 31.7 percent in September 2008.
- Seroquel sales in other markets increased by 18 percent to \$381 million in the third quarter, with sales in Western Europe up 20 percent. Sales in Rest of World for the nine months were up 18 percent.
- · On 10 October, the Company announced that the US FDA approved Seroquel XR for the acute treatment of the depressive episodes associated with bipolar disorder, the manic and mixed episodes associated with bipolar I disorder and the maintenance treatment of bipolar I disorder as adjunctive therapy to lithium or divalproex.
- · Sales of Zomig in the third quarter were up 9 percent in the US and were down 3 percent in other markets.

### Infection and Other

	Third Quarter		CER %	Nine M	CER %	
	2008 \$m	2007 \$m		2008 \$m	2007 \$m	
Synagis*	124	122	+1	724	138	n/m
Merrem	241	186	+23	680	558	+14
FluMist*	71	_	n/m	71	-	n/m

Total 494 371 +28 1,646 899 n/m

- \* Sales of these MedImmune products were consolidated in AstraZeneca accounts from 1 June 2007. As a result, the prior year to date reflects four months' sales.
- Synagis sales, which have a pronounced seasonal pattern (with modest sales in the second and third quarters of the year), were \$124 million in the third quarter.
- FluMist recorded sales of \$71 million in the quarter. There were no sales in the third quarter last year as the timing of regulatory approvals pushed sales into the fourth quarter.

Geographic Sales

Third Quarter CER % Nine Months CER %

2008

\$m