ASTRAZENECA PLC Form 6-K November 05, 2003

# 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 2003

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	
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regula	ation
S-T Rule 101(b)(1):	
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regula S-T Rule 101(b)(7):	ation
Indicate by check mark whether the registrant by furnishing the information contained in this Form also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.	ıis
Yes No _X_  If Yes is marked, indicate below the file number assigned to the Registrant in connection with R	tule
12g3-2(b): 82-	

### AstraZeneca PLC

### INDEX TO EXHIBITS

- 1. Press release entitled, Repurchase of Shares in AstraZeneca PLC , dated 1 October 2003.
- Press release entitled, AstraZeneca Set to Deliver Top-Tier Financial Performance through US Marketing and R&D Success dated 2 October 2003.
- 3. Press release entitled, AstraZeneca Receives European Approval for Seroquel in Bipolar Mania dated 10 October 2003.

- 4. Press release entitled, AstraZeneca and Abgenix Announce Strategic Alliance to Discover and Develop Antibody Therapeutics for Cancer dated 16 October 2003
- 5. Press release entitled, Repurchase of Shares in AstraZeneca PLC dated 27 October 2003.
- 6. Press release entitled, Repurchase of Shares in AstraZeneca PLC dated 29 October 2003.
- 7. Press release entitled, Dealing by Directors dated 29 October 2003.
- 8. Press release entitled, Repurchase of Shares in AstraZeneca PLC dated 30 October 2003.
- 9. Press release entitled, AstraZeneca Receives FDA Approvable Letter for Seroquel (Quetiapine Fumarate) Tablets in Treatment of Mania dated 30 October 2003.
- 10. Press release entitled, Repurchase of Shares in AstraZeneca PLC dated 31 October 2003.

### **SIGNATURES**

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

AstraZeneca PLC

Date: 5 November 2003 By: /s/ G H R Musker

Name: GHR Musker

Title: Company Secretary & Solicitor

## Item 1

# REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 30 September 2003, it purchased for cancellation 900,000 ordinary shares of AstraZeneca PLC at a price of 2556 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,704,025,662.

G H R Musker Company Secretary 1 October 2003

### Item 2

# ASTRAZENECA SET TO DELIVER TOP-TIER FINANCIAL PERFORMANCE THROUGH US MARKETING AND R&D SUCCESS

CRESTOR and IRESSA US Launches Show Early Promise

**London** 2 October 2003 AstraZeneca is well positioned to compete in the dynamic, US marketplace where the demand for new, innovative medicines continues to be strong, the company s executives reported today at its Annual Business Review.

The meeting, held at AstraZeneca s North American headquarters in Wilmington, Del., included highlights on the positive progress of the US launches of CRESTOR and IRESSA and an in-depth review of AstraZeneca s US sales and marketing effectiveness. A report on the R&D pipeline outlined the opportunities for growth presented by new drugs and new treatment indications in development, focusing on EXANTA, NEXIUM, SYMBICORT, IRESSA, GALIDA and ATACAND, among others.

Sir Tom McKillop, Chief Executive said:

AstraZeneca is set to deliver top-tier financial performance through successful marketing of our exciting, patent-protected range of growth and newly launched products in the USA and other major markets. In addition, productivity improvements in R&D are delivering a flow of new product opportunities, which together with growth in many markets, will form the basis of sustained long-term performance.

### **US Business Highlights**

- CRESTOR captured one per cent share of new prescriptions in the US statin market in the first full week of launch ending 19 September with total prescription volume of 18,000. More recent daily data has shown over two percent market share of new prescriptions with 25,000 total prescriptions.
  - Within two weeks of FDA approval, AstraZeneca reached nearly three-quarters of the target physician audience with an early adopter sampling programme.
  - Pharmacies were fully stocked with CRESTOR in just eight days.
  - By 15 September, the official field launch of CRESTOR, AstraZeneca had secured formulary positions on numerous PBMs and health plans.
- With the launch of CRESTOR, AstraZeneca now competes in three of the five top therapeutic categories in the US market (cholesterol reducers, PPIs and antipsychotics).
- TOPROL-XL is now the most prescribed medicine by US cardiologists.
- An estimated 10,000 patients are receiving IRESSA in the US.
  - Current ex-factory US sales of IRESSA are averaging \$3m/week.
  - The company has successfully completed the transition of patients from the Expanded Access Program.

- NEXIUM continues its strong performance despite entry of generic omeprazole. As the fastest growing PPI in terms of total prescriptions, NEXIUM is poised to become the market leader.
- NDA filing in the US of SYMBICORT for asthma treatment expected in 2005.
- Other key products, including TOPROL-XL, ARIMIDEX, PULMICORT RESPULES and RHINOCORT AQUA continue to gain market share, outpacing the market, in both sales and prescriptions.
- Investment in technology, award-winning training and strategic alignment of the company s 6,500 person sales force has significantly increased productivity and customer satisfaction, improving an already high industry ranking.

In the US, recently launched products and key growth products now comprise 51 percent of the portfolio, up from 19 percent 18 months ago.

Commenting on this success, David R. Brennan, President and CEO of AstraZeneca US, said:

AstraZeneca continues to deliver impressive results in the US because we have marshalled the energy and commitment of the entire organization to compete in this challenging yet dynamic marketplace.

## **Development Pipeline and New Indications**

Improved flow of high-quality new development projects leads to more compounds entering clinical development.

- 21 NCE s (New Chemical Entities) are in pre-clinical testing. A strong movement of NCE Projects into clinical phase I and II has taken place since last year Annual Business Review.
- EXANTA continues to confirm promise as the first new anticoagulant in 50 years.
  - Risk/benefit data from Exanta studies to date confirm efficacy equivalent to warfarin with a profile based on fixed dosing; no coagulation monitoring; low potential of food/drug interactions and acceptable bleeding. Elevated liver enzyme levels that decrease with treatment continuation or discontinuation and which are not typically associated with specific clinical symptoms have also been observed.
  - Filing in Europe for use in orthopaedic surgery is under regulatory review.
  - Regulatory submission for major indications of stroke prevention in atrial fibrillation and treatment of long-term prevention of venous thromboembolism is expected in Q4 2003.
- SYMBICORT continues to grow in Europe.
  - Recent data (SUND study) show that SYMBICORT adjustable dosing provides a 40 per cent greater reduction in severe exacerbations than both SYMBICORT and Seretide fixed dosing.
  - Regulatory filing in EU for Single inhaler Therapy (SiT) use of SYMBICORT for control and treatment of asthma is expected in Q4, 2003.
- SEROQUEL bipolar mania filings are under review in the US & EU with first approvals expected before the end of 2003.

- CHARM study shows ATACAND is the only Angiotensin Receptor Blocker to reduce cardiovascular death and hospitalisation in chronic heart failure when given together with conventional therapy including an ACE inhibitor.
  - Filing for this indication will be made in EU, US and other major markets during Q1 2004.
- New Phase II data on GALIDA, an oral anti-diabetic medicine confirms dual PPAR alpha/gamma activity that results in improvement in dyslipidemia and improvement of glycemic control. GALIDA is now entering Phase III development.
- AZD0865 for the treatment of GERD (gastro-oesophageal reflux disease) enters Phase II following promising early clinical studies showing advantages over Nexium.
- AZD7009 for the treatment of atrial fibrillation and AZD6140 for arterial thrombosis enter Phase II.
- ZD6126 for solid tumours and AR-A2 for anxiety and depression enter Phase II development.

Martin Nicklasson, Executive Vice President, Development said:

Major regulatory approvals have transformed AstraZeneca s product portfolio in 2003. With the emphasis on productivity and quality, we have added several new candidate drugs to the R&D pipeline in the last 12 months; made rapid progress with our early phase portfolio; and progressed major new treatment indications for existing products.

-Ends-

#### **Trade Marks**

The following brand names are trade marks of the AstraZeneca group of companies: EXANTA, NEXIUM, SYMBICORT, IRESSA, GALIDA, ATACAND, TOPROL-XL, ARIMIDEX, CRESTOR, SEROQUEL, PULMICORT RESPULES and RHINOCORT AQUA.

### **Media Enquiries:**

Steve Brown, +44 (0) 207 304 5033 Chris Major, +44 (0) 207 304 5028 Rachel Bloom-Baglin, +1 302 886 7858

### **Analyst Enquiries:**

Mina Blair-Robinson, +44 (0) 207 304 5084 Jonathan Hunt, +44 (0) 207 304 5087 Jorgen Winroth, +1 212 581 8720 Ed Seage, +1 302 886 4065

For copies of the presentations from today s annual business review and an up-date of AstraZeneca s development pipeline please visit http://www.astrazeneca.com from 14:15 BST onwards.

Interviews with Sir Tom McKillop, Chief Executive Officer, Dr Martin Nicklasson, Executive Vice President, Global Development and Adele Gulfo, Vice President, Cardiovascular Therapy US, in video, audio and text will be available from 13:00h BST on Thursday 2<sup>nd</sup> October 2003 at <a href="http://www.astrazeneca.com">http://www.astrazeneca.com</a> and <a href="http://www.astrazeneca.com">ht

#### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

In order to utilise the 'Safe Harbor' provisions of the United States Private Securities Litigation Reform Act of 1995, AstraZeneca is providing the following cautionary statement. This Review 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.

### Item 3

# ASTRAZENECA RECEIVES EUROPEAN APPROVAL FOR SEROQUEL™ IN BIPOLAR MANIA

AstraZeneca announced today that it has successfully completed the Mutual Recognition Procedure (MRP) involving 14 European countries to extend the use of SEROQUEL (quetiapine) to the treatment of mania associated with bipolar disorder (manic-depressive illness). SEROQUEL is also under review for bipolar mania in the United States with the Food and Drug Administration (FDA) and in the UK with the Medicines and Healthcare products Regulatory Agency (MHRA).

In 2002, worldwide sales of SEROQUEL grew 67 per cent to \$1.14 billion.

Bipolar disorder is a serious mental illness that affects approximately 3-4 per cent of the adult population and is the sixth leading cause of disability in the world. More than half of those with bipolar disorder stop taking their medication at some point during their illness, subjecting themselves to a high risk of relapse and an increased risk of suicide. This lack of compliance is strongly associated with the occurrence of side effects, therefore, a well tolerated and effective treatment is pivotal to the successful treatment of this condition.

Health authorities involved in the MRP reviewed data from a comprehensive clinical trial programme in bipolar disorder undertaken by AstraZeneca, involving almost 1000 patients in 28 countries. The trials have delivered compelling results, which confirm SEROQUEL to be an excellent first line therapy for the treatment of manic episodes associated with bipolar disorder.

Individual licenses in the 14 European countries involved in the MRP will follow from the completion of this procedure. Health Authority approvals also have been received in Mexico and New Zealand.

Data from two trials from the clinical trial programme, which examined the efficacy of SEROQUEL as a monotherapy for the treatment of bipolar mania, were presented in May this year at the International Conference on Bipolar Disorder (ICBD), Pittsburgh, USA. The results confirmed that SEROQUEL monotherapy is as effective as current treatments for bipolar disorder and offers improved tolerability benefits. Data from

another trial examining SEROQUEL as an adjunctive therapy to mood stabilisers in the treatment of bipolar mania were presented at the 3rd European Stanley Foundation Conference on Bipolar Disorder in Freiburg, Germany, in September 2002. The results found that SEROQUEL is significantly more effective than mood stabilizers alone in the treatment of bipolar mania.

The MRP involves Austria, Belgium, Denmark, Finland, Germany, Greece, Iceland, Ireland, Luxembourg, The Netherlands, Norway, Portugal, Spain, and Sweden.

10 October 2003

Media Enquiries:

Steve Brown, +44 (0) 207 304 5033 Chris Major, +44 (0) 207 304 5028

### **Investor Enquiries:**

Mina Blair-Robinson, +44 (0) 207 304 5084 Jonathan Hunt, +44 (0) 207 304 5087

-Ends-

### Item 4

# ASTRAZENECA AND ABGENIX ANNOUNCE STRATEGIC ALLIANCE TO DISCOVER AND DEVELOP ANTIBODY THERAPEUTICS FOR CANCER

AstraZeneca makes \$100 million upfront equity investment to broaden oncology research scope

Abgenix to receive milestone, royalty and collaboration payments

**London and Fremont, CA** AstraZeneca and Abgenix, Inc, announced today thathey have entered into a broad collaboration, license and investment alliance to discover, develop and commercialise fully human monoclonal antibodies to treat cancer. The alliance involves:

- the joint discovery and development of therapeutic antibodies for up to 36 cancer targets to be commercialised exclusively worldwide by AstraZeneca. For these products, Abgenix will receive milestone payments at various stages of development and royalties on future product sales. In addition, the collaboration will involve the selection and development of an additional pool of antibodies by Abgenix, which the companies may elect to further develop on an equal cost and profit sharing basis.
- For those product candidates for which AstraZeneca holds exclusive commercialisation rights, Abgenix will conduct early clinical trials, process development and clinical manufacturing, as well as commercial manufacturing during the first five years of commercial sales. AstraZeneca will compensate Abgenix for those activities at competitive market rates.
- a \$100 million investment by AstraZeneca in Abgenix convertible preferred stock, initially convertible into Abgenix common stock at \$30 per share. Upon the achievement of certain milestones, Abgenix may also require AstraZeneca to invest an additional \$60 million in Abgenix convertible preferred stock.

AstraZeneca may select initial antibodies from Abgenix s existing preclinical oncology portfolio and both companies will also propose additional targets for selection. AstraZeneca will be responsible for late stage clinical development of the portfolio and will hold worldwide commercialisation rights for any resulting products. Upon commercialisation, royalties will be paid to Abgenix on sales of products that result from the collaboration. The royalty range will vary from product to product based on the level of product sales.

The alliance also includes a co-development component under which Abgenix will generate additional antibody product candidates that AstraZeneca will have the option to co-develop with Abgenix. The companies will share development costs and responsibilities for any co-development candidates selected.

This collaboration further strengthens our position at the forefront of cancer research, allowing us to combine our oncology development expertise and leading sales and marketing capabilities with Abgenix s expertise in the discovery, early development and manufacture of fully human antibodies. This alliance adds to our proven expertise with small molecules and has the potential to significantly broaden and strengthen AstraZeneca s oncology pipeline, said Sir Tom McKillop, Chief Executive of AstraZeneca.

This alliance reinforces the value of our antibody development platform and enables the next wave of oncology products beyond our lead candidate ABX-EGF, said Raymond Withy, PhD, President and Chief Executive Officer of Abgenix. By partnering with AstraZeneca, a global leader in oncology research and development, we take a major step towards bringing a portfolio of highly targeted and effective cancer drugs to patients, Withy continued.

The consummation of the collaboration and license agreement and the issuance of the convertible preferred stock to AstraZeneca are subject to customary closing conditions, including without limitation the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

A conference call with executives from both companies will be held on Thursday, October 16 at 6:00 AM PST, 2:00pm BST to discuss today s announcement. The

call will be webcast live and available for replay on Abgenix s website at www.abgenix.com. Participants can access the call by dialling 800-884-5695 (toll free from the US) or +1 617-786-2960 providing passcode 5717 6006.

# **About Abgenix**

Abgenix is a biopharmaceutical company focused on the discovery, development and manufacturing of human therapeutic antibodies. The company's antibody development platform includes a leading technology and state-of-the-art manufacturing capabilities that enable the rapid generation, selection and production of high affinity, fully human antibody product candidates to a variety of disease targets. Abgenix leverages its leadership position in human antibody technology to build a diversified product portfolio through the establishment of collaborations with multiple pharmaceutical and biotechnology companies. For more information on Abgenix, visit the company's website at <a href="https://www.abgenix.com">www.abgenix.com</a>.

### **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 top five pharmaceutical companies in the world with healthcare sales of over \$17.8 billion in 2002 and leading positions in sales of gastrointestinal, oncology, cardiovascular, neuroscience and respiratory products. AstraZeneca is listed in the Dow Jones Sustainability Index (Global and European) as well as the FTSE4Good Index.

AstraZeneca continues its tradition of research excellence and innovation in oncology that led to the development of its current anti-cancer therapies including Arimidex , Casodex , Faslodex , Nolvadex , Zoladex and Iressa . AstraZeneca is also harnessing rational drug design technologies to develop new compounds that offer advantages over current cytotoxic and hormonal treatment options. The company has over 20 different anti-cancer projects in research and development including a range of novel targeted products such as anti-proliferatives, anti-angiogenics, vascular targeting and anti-invasive agents. For more information about AstraZeneca, please visit <a href="https://www.astrazeneca.com">www.astrazeneca.com</a>

### Media Enquiries AstraZeneca:

Steve Brown, +44 (0) 207 304 5033 Chris Major, +44 (0) 207 304 5028

### **Analyst Enquiries AstraZeneca:**

Mina Blair-Robinson, +44 (0) 207 304 5084 Jonathan Hunt, +44 (0) 207 304 5087

### **Enquiries for Abgenix, Inc:**

Ami Knoefler, Director, Corporate Communications, Abgenix, Inc, +1 (510) 284-6350

### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

In order to utilise the 'Safe Harbor' provisions of the United States Private Securities Litigation Reform Act of 1995, AstraZeneca is providing the following cautionary statement. This 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.

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### Item 5

# REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 24 October 2003, it purchased for cancellation 500,000 ordinary shares of AstraZeneca PLC at a price of 2835 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,703,681,791

G H R Musker Company Secretary 27 October 2003

## Item 6

### REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 28 October 2003, it purchased for cancellation 500,000 ordinary shares of AstraZeneca PLC at a price of 2850 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,703,204,773.

G H R Musker Company Secretary 29 October 2003

### Item 7

DEALING BY DIRECTORS
COMPANIES ACT 1985 SECTIONS 324/329

WE HEREBY INFORM YOU THAT ON 29 OCTOBER 2003 SIR TOM MCKILLOP, A DIRECTOR OF THE COMPANY, EXERCISED OPTIONS OVER ASTRAZENECA PLC USD0.25 ORDINARY SHARES UNDER THE COMPANY'S 1993 SENIOR STAFF SHARE OPTION SCHEME AND 1994 EXECUTIVE SHARE OPTION SCHEME. THE DETAILS OF THE EXERCISES ARE AS FOLLOWS:-

NAME OF DIRECTOR	NUMBER OF SHARES OVER WHICH OPTION EXERCISED	EXERCISE PRICE PER SHARE	PERIOD WHEN EXERCISABLE
SIR TOM MCKILLOP	1,900	748p	05.4.97-04.4.04
SIR TOM MCKILLOP	12,424	826p	17.4.97-16.8.04

AS A RESULT OF THESE EXERCISES SIR TOM MCKILLOP HOLDS OPTIONS OVER 453,242 ORDINARY SHARES OF ASTRAZENECA PLC.

WE ALSO INFORM YOU THAT ON 29 OCTOBER 2003, SIR TOM MCKILLOP SOLD 5,482 ASTRAZENECA PLC USD0.25 ORDINARY SHARES AT AN AVERAGE PRICE OF 2857p PER SHARE TO COVER THE COST OF THE EXERCISES AND TO MEET CERTAIN TAX OBLIGATIONS ARISING FROM THE TRANSACTIONS.

FOLLOWING THESE TRANSACTIONS SIR TOM MCKILLOP HAS INCREASED HIS HOLDING IN THE COMPANY BY 8,842 SHARES TO 78,402 SHARES WHICH REPRESENTS APPROXIMATELY 0.005 PER CENT OF THE ISSUED ORDINARY CAPITAL OF THE COMPANY.

G H R MUSKER COMPANY SECRETARY 29 OCTOBER 2003

### Item 8

### REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 29 October 2003, it purchased for cancellation 500,000 ordinary shares of AstraZeneca PLC at a price of 2842 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,702,724,190.

G H R Musker Company Secretary 30 October 2003

### Item 9

# ASTRAZENECA RECEIVES FDA APPROVABLE LETTER FOR SEROQUEL<sup>™</sup> (QUETIAPINE FUMARATE) TABLETS IN TREATMENT OF MANIA

AstraZeneca today announced that it has received an approvable letter from the U.S. Food and Drug Administration (FDA) in response to its Supplemental New Drug Applications (sNDAs) for the use of SEROQUEL as both an adjunct and monotherapy for the treatment of manic episodes associated with bipolar disorder. The company is working closely with the FDA to supply information and to finalize labelling.

30 October, 2003

# Media Enquiries:

Chris Major, +44 (0) 207 304 5028

### **Investor Enquiries:**

Mina Blair-Robinson, +44 (0) 207 304 5084 Jonathan Hunt, +44 (0) 207 304 5087

-Ends-

### <u>Item 10</u>

AstraZeneca PLC announced that on 30 October 2003, it purchased for cancellation 500,000 ordinary shares of AstraZeneca PLC at a price of 2827 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,702,249,614.

G H R Musker Company Secretary 31 October 2003