

ASTRAZENECA PLC  
Form 6-K  
December 01, 2004

**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 November 2004

Commission File Number: 001-11960

**AstraZeneca PLC**

15 Stanhope Gate, London W1K 1LN, England

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

Form 20-F  Form 40-F

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

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

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

Yes  No

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

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**AstraZeneca PLC**

INDEX TO EXHIBITS

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

Press release entitled, AstraZeneca to add results from ongoing studies in resubmitted Symbicort single inhaler therapy file in the EU , dated 03 November 2004.

2. Press release entitled, Repurchase of Shares in AstraZeneca PLC , dated 05 November 2004.
3. Press release entitled, Repurchase of Shares in AstraZeneca PLC , dated 10 November 2004.
4. Press release entitled, Repurchase of Shares in AstraZeneca PLC , dated 12 November 2004.
5. Press release entitled, Repurchase of Shares in AstraZeneca PLC , dated 18 November 2004.
6. Press release entitled, AstraZeneca - Crestor , dated 19 November 2004.
7. Press release entitled, Repurchase of Shares in AstraZeneca PLC , dated 22 November 2004.
8. Press release entitled, AstraZeneca and Cambridge Antibody Technology announce major strategic alliance to discover and develop human antibody therapeutics in inflammatory disorders , dated 22 November 2004.
9. Press release entitled, Companies Act 1985 Section 198 Disclosure of Interest in Voting Shares in Public Companies , dated 23 November 2004.
10. Press release entitled, Repurchase of Shares in AstraZeneca PLC , dated 26 November 2004.
11. Press release entitled, Nexium receives FDA approval for risk reduction of NSAID-associated stomach ulcers , dated 29 November 2004.

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### 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: 01 December 2004

By: /s/ A C N Kemp

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Name: A C N Kemp

Title: Assistant Secretary

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### Item 1

## **ASTRAZENECA TO ADD RESULTS FROM ONGOING STUDIES IN RESUBMITTED SYMBICORT SINGLE INHALER THERAPY FILE IN THE EU**

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AstraZeneca announced today that it has withdrawn its Symbicort Single Inhaler Therapy file for the EU. As a result of discussions during the Mutual Recognition Process, AstraZeneca expects a file to be submitted in the second half of next year (2005), with additional data from recently completed (COSMOS) and ongoing studies designed to provide further confirmation of this new treatment concept.

Symbicort Single Inhaler Therapy is an innovative approach to the treatment of asthma. AstraZeneca has already provided clear evidence that, when compared to today's gold-standard treatments, it shows clinically significant benefits for patients. Symbicort Single Inhaler Therapy yields a reduction of asthma exacerbations, a reduced need for other treatments, a reduction in the number of hospitalisations/emergency room visits and a decrease in overall corticosteroid load. AstraZeneca firmly believes that this new treatment concept has a very important role to play in the future management of asthma.

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 \$18.8 billion and leading positions in sales of gastrointestinal, oncology, cardiovascular, neuroscience and respiratory products. AstraZeneca is listed in the Dow Jones Sustainability Index (Global) as well as the FTSE4Good Index.

3 November 2004

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## **Item 2**

### **REPURCHASE OF SHARES IN ASTRAZENECA PLC**

AstraZeneca PLC announced that on 4 November 2004, it purchased for cancellation 800,000 ordinary shares of AstraZeneca PLC at a price of 2300 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,658,390,800.

G H R Musker  
Company Secretary  
5 November 2004

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## **Item 3**

### **REPURCHASE OF SHARES IN ASTRAZENECA PLC**

AstraZeneca PLC announced that on 9 November 2004, it purchased for cancellation 750,000 ordinary shares of AstraZeneca PLC at a price of 2323 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,657,643,799.

G H R Musker  
Company Secretary  
10 November 2004

**Item 4**

**REPURCHASE OF SHARES IN ASTRAZENECA PLC**

AstraZeneca PLC announced that on 11 November 2004, it purchased for cancellation 550,000 ordinary shares of AstraZeneca PLC at a price of 2325 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,657,096,096.

G H R Musker  
Company Secretary  
12 November 2004

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**Item 5**

**REPURCHASE OF SHARES IN ASTRAZENECA PLC**

AstraZeneca PLC announced that on 17 November 2004, it purchased for cancellation 550,000 ordinary shares of AstraZeneca PLC at a price of 2350 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,656,546,096.

G H R Musker  
Company Secretary  
18 November 2004

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**Item 6**

**ASTRAZENECA - CRESTOR**

During the course of testimony yesterday, to the Committee of Finance of the US Senate Hearing on the worldwide withdrawal of VIOXX, Dr David Graham raised the possibility of safety concerns surrounding five other products including AstraZeneca's lipid lowering medicine Crestor.

AstraZeneca has followed up these remarks with speed and diligence. We have been assured today at senior levels in the FDA that there is no concern in relation to Crestor's safety and that they have issued a statement explaining that Dr Graham's testimony does not reflect the views of the agency.

To date over 12 million prescriptions have been written for Crestor worldwide and 3.5 million patients have been prescribed the drug. Crestor has been approved in 65 countries worldwide and with the latest information on Crestor patient safety, available as recently as Friday 12 November 2004, (available on [www.rosuvastatininformation.com](http://www.rosuvastatininformation.com)) AstraZeneca is confident in both the safety and the efficacy of Crestor.

- Ends -

19 November 2004

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**Item 7**

**REPURCHASE OF SHARES IN ASTRAZENECA PLC**

AstraZeneca PLC announced that on 19 November 2004, it purchased for cancellation 2,500,000 ordinary shares of AstraZeneca PLC at a price of 2180 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,654,046,096.

G H R Musker

Company Secretary

22 November 2004

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**Item 8**

**ASTRAZENECA AND CAMBRIDGE ANTIBODY TECHNOLOGY  
ANNOUNCE MAJOR STRATEGIC ALLIANCE TO DISCOVER  
AND DEVELOP HUMAN ANTIBODY THERAPEUTICS IN  
INFLAMMATORY DISORDERS**

**AstraZeneca makes £75 million upfront equity investment.**

**Complements earlier alliance with Abgenix, Inc. in oncology.**

AstraZeneca today announced a five-year research and development alliance with Cambridge Antibody Technology (CAT) in monoclonal antibody research, principally in inflammatory disorders, including respiratory diseases. AstraZeneca will pay £75 million in cash for an issue of 10,217,983 new ordinary shares in CAT, representing a 19.9 per cent shareholding. The equity subscription requires the approval of CAT shareholders.

The alliance offers an excellent balance and fit between CAT's established expertise and capabilities in monoclonal antibody generation and optimisation, together with their process technology and early clinical skills, with AstraZeneca's drug development capabilities and global market strength and representation.

- ◆ Both AstraZeneca and CAT will contribute targets to the alliance, which will be co-funded and co-managed by the partners. A minimum of 25 programmes in discovery will be initiated during the five-year duration of the Discovery phase.
  - ◆ Following the completion of the discovery phase, the parties may each elect to continue funding programmes into development. If both parties so elect, the programme will be jointly funded until Clinical Proof of Concept (end of Phase IIb trials), unless either party opts-out earlier. In addition, CAT has the option to continue to fund jointly the development of one in every five products that reach Clinical Proof of Concept up to product
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launch; in this case CAT would have an option to co-promote such products in the US.

- ◆ AstraZeneca will receive the rights to opt into, and develop jointly, CAT discovery programmes existing at the commencement of this alliance and also to opt into certain future CAT discovery programmes that CAT may independently initiate. CAT has limited rights to co-promote in the US drugs resulting from these programmes.
- ◆ CAT will be principally responsible for antibody discovery, manufacturing process development and the supply of material for exploratory clinical trials. AstraZeneca will be principally responsible for translational biology, clinical development programmes, regulatory filings and commercialisation. Joint teams will be established to oversee the full discovery and development process.

This is the second such research alliance in monoclonal antibodies agreed by AstraZeneca in just over a year. Last October, the company announced a major agreement with Abgenix, Inc. for monoclonal antibody research in oncology.

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 \$18.8 billion and leading positions in sales of gastrointestinal, oncology, cardiovascular, neuroscience and respiratory products. AstraZeneca is listed in the Dow Jones Sustainability Index (Global) as well as the FTSE4Good Index.

CAT is a biopharmaceutical company using its proprietary technologies and capabilities in human monoclonal antibodies for drug discovery and drug development. Based near Cambridge, England, CAT currently employs around 270 people. CAT is a leader in the discovery and development of

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human therapeutic antibodies and has an advanced proprietary platform technology for rapidly isolating human monoclonal antibodies using phage display and ribosome display systems. CAT has extensive phage antibody libraries, currently incorporating more than 100 billion distinct antibodies. These libraries form the basis for the company's strategy to develop a portfolio of antibody-based drugs.

### **Abgenix Alliance**

The alliance between AstraZeneca and Abgenix, Inc., of Freemont, California, was announced on October 16, 2003. This is aimed at discovering fully humanised monoclonal antibodies for the treatment of cancer. Abgenix is providing antibody expertise and will take projects into clinical trials. AstraZeneca is providing cancer expertise to guide the choice of targets, the properties required out of the candidate drugs and clinical development. Under the terms of the deal, AstraZeneca made a \$100 million upfront equity investment, while Abgenix will also receive milestone, royalty and collaboration payments. Further details can be found in the Press release announcing the alliance on ([www.astrazeneca.com](http://www.astrazeneca.com)).

-Ends-

22 November 2004

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**Item 9**

**Companies Act 1985 Section 198**

**Disclosure of Interest in Voting Shares in Public Companies**

On 23 November 2004 we were informed by The Capital Group Companies, Inc., a registered investment manager in the U.S., that on 19 November 2004 its interest in the USD0.25 Ordinary Shares of AstraZeneca PLC had decreased to 244,411,808 shares (14.78 per cent of the current issued ordinary capital) from the level notified in July 2004 of 265,952,778 shares (15.89 per cent). Within the said holding of 14.78 per cent of the issued ordinary capital of AstraZeneca PLC, Capital Guardian Trust Company, an affiliate of The Capital Group Companies, Inc., has decreased its interest in these shares to 93,016,769 shares (5.62 per cent).

**G H R Musker**

**Company Secretary**

**23 November 2004**

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**Item 10**

**REPURCHASE OF SHARES IN ASTRAZENECA PLC**

AstraZeneca PLC announced that on 25 November 2004, it purchased for cancellation 1,000,000 ordinary shares of AstraZeneca PLC at a price of 2085 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,653,049,596.

G H R Musker

Company Secretary

26 November 2004

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**Item 11**

**Reference Announcement RNS 7666F**

**CORRECTION to end of paragraph one : addition of the word NSAIDs in the last sentence.**

**NEXIUM RECEIVES FDA APPROVAL FOR RISK REDUCTION  
OF NSAID-ASSOCIATED STOMACH ULCERS**

AstraZeneca today announced that a new indication for its prescription proton pump inhibitor Nexium® (esomeprazole magnesium) has been approved by the US Food and Drug Administration (FDA). Nexium is now also indicated for reducing the risk of gastric (stomach) ulcers developing among at risk patients on continuous therapy with non-steroidal anti-inflammatory drugs (NSAIDs). The FDA also issued an approvable letter for the indication of the healing of gastric ulcers associated with NSAIDs therapy.

NSAIDs play a crucial role in providing relief to many pain sufferers. However potentially serious gastrointestinal side effects are often a deterrent to continue long-term treatment. Health care professionals now can offer their patients on NSAID therapy, who may be at risk for developing gastric ulcers, a therapeutic option that may lessen possibility of such stomach injury occurring.

A total of 1,429 patients, ranging in age from 19 to 89 were evaluated in two separate multi-center, double-blind, placebo-controlled clinical studies. Patients included in both studies had a chronic condition requiring daily NSAID treatment (including COX-2 selective NSAIDs). They were randomised to treatment with Nexium, 40 mg or 20 mg once daily, or placebo for up to 6 months.

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Nexium 20 mg and 40 mg demonstrated comparable benefits in providing risk reduction with the proportion of NSAID patients remaining free of gastric ulcers ranging from 95.4 percent to 96.7 percent in one study and 94.7 percent to 95.3 percent in the second study.

It is estimated that over 100 million prescriptions are written for NSAIDs each year in the United States. Everyday approximately 30 million people worldwide take NSAIDs. NSAIDs, which include such popular pain medications as aspirin, ibuprofen and naproxen, are a common cause of stomach ulcers and have been associated with side effects ranging from stomach upset to potentially life threatening stomach

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bleeding. In fact, NSAID use leads to more than 103,000 hospitalizations and 16,500 deaths each year in the United States.

Beyond its newest indication in the US for the reduction in the occurrence of gastric ulcers associated with continuous NSAIDs therapy in patients at risk for developing gastric ulcers, Nexium is also approved for healing erosive esophagitis. Studies show that up to 94 percent of patients were healed with Nexium. Most erosions heal in 4 to 8 weeks. Individual results may vary, and only a doctor using endoscopy can determine if erosions to the esophagus have occurred. The drug is also indicated for treating heartburn and other symptoms associated with acid reflux disease.

AstraZeneca announced that the European Union (Mutual Recognition Procedure (MRP) for new indications for Nexium had been successfully finalized in September this year. The new indications in the EU are for the healing of gastric ulcers and, for patients at risk, the prevention of gastric and duodenal ulcers, associated with NSAID therapy. Nexium has been launched in 89 markets and with strong continued growth in many large markets, is expected to become the leading branded PPI by value in 2005.

-Ends-

29th November 2004

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