

ASTRAZENECA PLC
Form 6-K
July 07, 2010

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 June 2010

Commission File Number: 001-11960

AstraZeneca PLC

15 Stanhope Gate, London W1K 1LN, England

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

Form 20-F ☒ Form 40-F ☐

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

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

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

Yes ☐ No ☒

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

AstraZeneca PLC

INDEX TO EXHIBITS

1. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 1 June 2010.
 2. Press release entitled, “AstraZeneca receives FDA Complete Response Letter for AXANUM New Drug Application”, dated 1 June 2010.
 3. Press release entitled, “Transparency Directive Voting Rights and Capital”, dated 1 June 2010.
 4. Press release entitled, “FDA Advisory Committee reviews MedImmune’s Motavizumab”, dated 3 June 2010.
 5. Press release entitled, “AstraZeneca submits Marketing Authorisation Application to European Union for cardiovascular drug Axanum”, dated 4 June 2010.
 6. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 8 June 2010.
 7. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 9 June 2010.
 8. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 16 June 2010.
 9. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 17 June 2010.
 10. Press release entitled, “Federal Court of Canada rules on applications for generic esomeprazole magnesium”, dated 17 June 2010.
 11. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 23 June 2010.
 12. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 24 June 2010.
 13. Press release entitled, “FDA resets its decision date for Motavizumab”, dated 25 June 2010.
 14. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 25 June 2010.
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15. Press release entitled, "Repurchase of shares in AstraZeneca PLC", dated 29 June 2010.
 16. Press release entitled, "Repurchase of shares in AstraZeneca PLC", dated 30 June 2010.
 17. Press release entitled, "CRESTOR patent upheld in US Court", dated 30 June 2010.
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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: 7 July 2010

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

Item 1

REPURCHASE OF SHARES IN ASTRAZENECA PLC

Further to the announcement of its irrevocable, non-discretionary share repurchase programme for the period 1 April 2010 to 28 May 2010, AstraZeneca PLC announced that under the terms of that programme it purchased for cancellation 132,737 ordinary shares of AstraZeneca PLC at a price of 2898 pence per share on 28 May 2010. Upon the cancellation of these shares, the number of shares in issue will be 1,441,926,895.

A C N Kemp
Company Secretary
1 June 2010

Item 2

AstraZeneca receives FDA Complete Response Letter for AXANUM New Drug Application

AstraZeneca has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for the new drug application for AXANUM (aspirin/esomeprazole magnesium) tablets. The company also received a CRL for the supplemental new drug application (sNDA) for NEXIUM (esomeprazole magnesium).

AstraZeneca is currently evaluating the CRLs, and will continue discussions with the FDA to determine next steps with respect to both the AXANUM NDA as well as the NEXIUM sNDA and will respond to the agency's request for additional information.

AstraZeneca submitted both applications to the FDA on April 30, 2009, seeking approval for AXANUM, for the risk reduction of low dose ASA-associated gastric and/or duodenal ulcers in patients at risk. The NEXIUM sNDA was submitted for the risk reduction of low-dose aspirin-associated peptic ulcers.

About AxanumTM

Axanum is a fixed-dose combination containing low-dose ASA (acetylsalicylic acid) and the active ingredient of the PPI Nexium® (esomeprazole, formulated as enteric coated pellets) developed by AstraZeneca for the prevention of cardio- and cerebrovascular (CV) events in patients requiring continuous low-dose ASA treatment, and at risk for developing ASA associated gastric and/or duodenal ulcers.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialisation of prescription medicines. As a leader in gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease medicines, AstraZeneca generated global revenues of US \$32.8 billion in 2009. For more information please visit: www.astrazeneca.com

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1 June 2010

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Item 3

Transparency Directive
Voting Rights and Capital

The following notification is made in accordance with the UK Financial Services Authority Disclosure and Transparency Rule 5.6.1. On 31 May 2010 the issued share capital of AstraZeneca PLC with voting rights is 1,441,929,537 ordinary shares of US\$0.25. No shares are held in Treasury. Therefore, the total number of voting rights in AstraZeneca PLC is 1,441,929,537.

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

A C N Kemp
Company Secretary
1 June 2010

Item 4

FDA ADVISORY COMMITTEE REVIEWS MEDIMMUNE'S MOTAVIZUMAB

MedImmune, AstraZeneca's biologics unit, today announced that the US Food and Drug Administration's (FDA) Antiviral Drugs Advisory Committee has voted 14 to 3 to recommend that motavizumab should not be licensed for marketing regarding the prevention of serious respiratory syncytial virus (RSV) disease in high-risk infants.

The committee's recommendation will be considered by FDA reviewers in their evaluation of the Biologics License Application (BLA) for motavizumab.

"We continue to believe motavizumab offers a meaningful clinical benefit to patients at high risk for a very common and serious illness," said Genevieve Losonsky, M.D., Vice President, Clinical Development, Infectious Disease at MedImmune.

"We thank the committee for the thoroughness of its review. We will work to address the issues raised by the committee and look forward to continuing to work with the FDA as it completes its review of our application."

NOTES TO EDITORS:

About RSV

Each year, up to 125,000 infants in the US are hospitalized with severe RSV infections, the leading cause of lower respiratory tract infections in infants in the United States. RSV is the most common respiratory infection in infancy or childhood. Approximately one-half of all infants are infected with RSV during the first year of life, and nearly all children have been infected at least once by the time they reach their second birthday. Children born prematurely as well as those with chronic lung disease (CLD) or congenital heart disease (CHD) are at highest risk for severe disease and hospitalization due to RSV.

About Motavizumab

Motavizumab is an investigational humanized monoclonal antibody being evaluated for its potential to prevent serious lower respiratory tract disease caused by RSV in pediatric patients at high risk of RSV disease. It is currently under review at the US FDA.

About MedImmune

MedImmune, the worldwide biologics unit for AstraZeneca PLC, has approximately 3,300 employees worldwide and is headquartered in Gaithersburg, Maryland, USA. For more information, visit MedImmune's website at www.medimmune.com

About AstraZeneca

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3 June 2010

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Item 5

ASTRAZENECA SUBMITS MARKETING AUTHORISATION APPLICATION TO EUROPEAN UNION FOR
CARDIOVASCULAR DRUG AXANUM

AstraZeneca announced today that it has submitted a Marketing Authorisation Application (MAA) in the European Union via the Decentralised Procedure (DCP) for a product combining low-dose ASA (acetylsalicylic acid) and the active ingredient of Nexium (esomeprazole) for the prevention of cardio- and cerebrovascular (CV) events in patients requiring continuous low-dose ASA treatment who are at risk of developing ASA-associated gastric and/or duodenal ulcers. Pending approval, the proposed trade name for the product is Axanum.

Low-dose ASA, commonly known as aspirin, is a mainstay of therapy for patients at high risk of a CV event such as myocardial infarction or stroke. However, upper GI problems (including symptoms, ulcers and ulcer-related complications) are common reasons for discontinuing low-dose ASA therapy. Up to 30% of patients with upper GI problems discontinue or take deliberate breaks from their low-dose ASA treatment, which can place them at risk of a potentially life-threatening CV event as early as 8-10 days after discontinuation.

Two phase III studies, ASTERIX and OBERON, including more than 3,400 patients, have demonstrated the clinical benefit of low-dose ASA plus esomeprazole compared to low-dose ASA plus placebo in patients who required low-dose ASA treatment and had an increased risk for ulcer development. ASTERIX reported that esomeprazole 20 mg once daily was significantly more effective compared to placebo in preventing gastric and/or duodenal ulcers and associated upper GI symptoms in this patient group. OBERON showed that acid-suppressive therapy with esomeprazole 20mg or 40mg given daily is effective in preventing the occurrence of gastric/duodenal ulcers as well as upper GI symptoms in patients at increased risk of ulcer development during low-dose ASA therapy.

NOTES TO EDITORS:

About Axanum

Axanum is a fixed-dose combination containing low-dose ASA (acetylsalicylic acid) and the active ingredient of the PPI Nexium (esomeprazole, formulated as enteric coated pellets) developed by AstraZeneca for the prevention of cardio- and cerebrovascular (CV) events in patients requiring continuous low-dose ASA treatment, and at risk for developing ASA associated gastric and/or duodenal ulcers. In EU, the fixed-dose combination contains 81 mg ASA/20mg esomeprazole.

About AstraZeneca

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4 June 2010

- ENDS -

Item 6

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 7 June 2010, it purchased for cancellation 150,000 ordinary shares of AstraZeneca PLC at a price of 2910 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,441,776,895.

A C N Kemp
Company Secretary
08 June 2010

Item 7

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 8 June 2010, it purchased for cancellation 330,000 ordinary shares of AstraZeneca PLC at a price of 2912 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,441,446,895.

A C N Kemp
Company Secretary
09 June 2010

Item 8

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 15 June 2010, it purchased for cancellation 310,000 ordinary shares of AstraZeneca PLC at a price of 3058 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,441,379,972.

A C N Kemp
Company Secretary
16 June 2010

Item 9

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 16 June 2010, it purchased for cancellation 210,000 ordinary shares of AstraZeneca PLC at a price of 3065 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,441,169,972.

A C N Kemp
Company Secretary
17 June 2010

Item 10

FEDERAL COURT OF CANADA RULES ON APPLICATIONS FOR GENERIC ESOMEPRAZOLE
MAGNESIUM

AstraZeneca today announced that the Federal Court of Canada has dismissed AstraZeneca's request to prohibit the Canadian Minister of Health from issuing a Notice of Compliance (NOC) for the regulatory applications for generic esomeprazole magnesium submitted by Apotex Inc. As a result, the Canadian Minister of Health is now free to issue an NOC to Apotex, if their regulatory submissions are in an approvable form, prior to the expiration of NEXIUM's Canadian patents.

In a Canadian proceeding seeking prohibition of an NOC, a presiding court does not rule on the validity of patents, and this decision has no bearing on cases in other jurisdictions. The proceedings, under the Patented Medicines Notice of Compliance Regulations, are summary in nature and involve no discovery process or witness testimony in court.

AstraZeneca is reviewing the ruling, which relates to only one of NEXIUM's Canadian patents, and evaluating its options. AstraZeneca's options include initiating a comprehensive patent infringement action. The company will continue to vigorously defend its intellectual property for NEXIUM.

After receiving the Court's decision, Apotex must obtain an NOC or regulatory approval from the Minister of Health before being able to launch a generic esomeprazole magnesium product in Canada. Any launch prior to patent expiration would be 'at-risk' and subject to a patent infringement action by AstraZeneca. AstraZeneca has many patents protecting NEXIUM in Canada, including Canadian patent number 2139653. AstraZeneca's patents protecting NEXIUM in Canada expire between 2013 and 2019.

NEXIUM sales in Canada in 2009 were \$217 million (USD). In the event of a near term 'at risk' launch of generic esomeprazole magnesium in Canada the company does not expect to alter its 2010 Core EPS guidance range of \$6.05-\$6.35.

About AstraZeneca

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17 June 2010

- ENDS -

Item 11

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 22 June 2010, it purchased for cancellation 500,000 ordinary shares of AstraZeneca PLC at a price of 3041 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,440,669,972.

A C N Kemp
Company Secretary
23 June 2010

Item 12

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 23 June 2010, it purchased for cancellation 610,000 ordinary shares of AstraZeneca PLC at a price of 2997 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,440,059,972.

A C N Kemp
Company Secretary
24 June 2010

Item 13

FDA RESETS ITS DECISION DATE FOR MOTAVIZUMAB

AstraZeneca today announced that MedImmune, its wholly owned biologics unit, received notice that the U.S. Food and Drug Administration (FDA) has reset the decision date for its review of motavizumab to 27 August 2010.

Motavizumab is an investigational monoclonal antibody (MAb) being considered to help prevent serious respiratory syncytial virus (RSV) disease. MedImmune filed the original Biologics License Application (BLA) on 30 January 2008, and received a Complete Response Letter (CRL) in November 2008. It filed the response to the CRL in December 2009. Motavizumab was reviewed by the FDA's Antiviral Drugs Advisory Committee on 2 June 2010.

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About Motavizumab

Motavizumab is an investigational humanized MAb being evaluated for its potential to prevent serious lower respiratory tract disease caused by RSV in pediatric patients at high risk of RSV disease.

About MedImmune

MedImmune, the worldwide biologics unit for AstraZeneca, has approximately 3,300 employees worldwide and is headquartered in Gaithersburg, Maryland.

About AstraZeneca

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25 June 2010

Item 14

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 24 June 2010, it purchased for cancellation 300,000 ordinary shares of AstraZeneca PLC at a price of 2985 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,439,974,029.

A C N Kemp
Company Secretary
25 June 2010

Item 15

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 28 June 2010, it purchased for cancellation 600,000 ordinary shares of AstraZeneca PLC at a price of 2962 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,439,393,420.

A C N Kemp
Company Secretary
29 June 2010

Item 16

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 29 June 2010, it purchased for cancellation 700,000 ordinary shares of AstraZeneca PLC at a price of 2955 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,438,693,420.

A C N Kemp
Company Secretary
30 June 2010

Item 17

CRESTOR PATENT UPHOLD BY US COURT

AstraZeneca announced today that Judge Joseph Farnan, Jr., US District Court, District of Delaware, has found that the substance patent protecting CRESTOR (RE37,314 – the ‘314 patent) is valid and enforceable. In its ruling, the court found that no inequitable conduct was committed by any Shionogi employee. The court also held the ‘314 patent to be non-obvious and properly reissued.

Judge Farnan’s subsequent entry of judgment will preclude the FDA from issuing final approvals for the defendants’ Abbreviated New Drug Applications (ANDAs) prior to the expiration of the ‘314 patent in 2016.

“We are pleased with the court’s decision upholding the validity and enforceability of the ‘314 substance patent,” said David Brennan, Chief Executive Officer, AstraZeneca. “The court’s decision reaffirms the strength of the intellectual property protecting CRESTOR.”

Judge Farnan also held that Apotex USA was liable as a submitter and is therefore bound to the court’s decision.

About the trial

Beginning in 2007, nine generic drug manufacturers filed ANDAs along with Paragraph IV certifications of non-infringement, invalidity, or unenforceability with respect to the CRESTOR patents. AstraZeneca and Shionogi (the owner of the ‘314 patent) filed patent infringement suits against eight manufacturers (various parent or subsidiary entities of Apotex, Aurobindo, Cobalt, Mylan, Par, Sandoz, Sun and Teva) who had challenged the ‘314 patent. The ‘314 patent, which expires in 2016, covers rosuvastatin calcium, the active ingredient in CRESTOR. These suits were consolidated by order of the Judicial Panel on Multidistrict Litigation and tried in the US District Court, District of Delaware. Trial commenced on 22 February 2010 before Judge Farnan and ended on 3 March 2010.

About AstraZeneca

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30 June 2010

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