

ASTRAZENECA PLC  
Form 6-K  
September 04, 2012

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 the month of August 2012

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

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

1. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated August 2012.
  2. Press release entitled, “Transaction by Person Discharging Managerial Responsibilities Disclosure Rule DTR 3.1.4”, dated 1 August 2012.
  3. Press release entitled, “Transparency Directive Voting Rights and Capital”, dated 1 August 2012.
  4. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 2 August 2012.
  5. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 3 August 2012.
  6. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 6 August 2012.
  7. Press release entitled, “AstraZeneca and Bristol-Myers Squibb complete expansion of diabetes alliance through Bristol-Myers Squibb’s acquisition of Amylin Pharmaceuticals”, dated 9 August 2012.
  8. Press release entitled, “AstraZeneca and Pfizer enter agreement for over-the-counter Nexium; AstraZeneca raises 2012 guidance”, dated 13 August 2012.
  9. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 15 August 2012.
  10. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 17 August 2012.
  11. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 20 August 2012.
  12. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 21 August 2012.
  13. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 22 August 2012.
  14. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 23 August 2012.
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15. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 24 August 2012.
  16. Press release entitled, “Transaction by Person Discharging Managerial Responsibilities Disclosure Rule DTR 3.1.4”, dated 24 August 2012.
  17. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 28 August 2012.
  18. Press release entitled, “Pascal Soriot appointed Chief Executive Officer of AstraZeneca”, dated 28 August 2012.
  19. Press release entitled, “European Commission approves ZINFOROTM (ceftaroline fosamil) for adult patients with serious skin infections or for Community Acquired Pneumonia”, dated 28 August 2012.
  20. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 29 August 2012.
  21. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 30 August 2012.
  22. Press release entitled, “Transaction by Person Discharging Managerial Responsibilities Disclosure Rule DTR 3.1.4”, dated 30 August 2012.
  23. Press release entitled, “Repurchase of shares in AstraZeneca PLC”, dated 31 August 2012.
  24. Press release entitled, “Transaction by Person Discharging Managerial Responsibilities Disclosure Rule DTR 3.1.4”, dated 31 August 2012.
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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: 4 September 2012

By: /s/ Adrian Kemp  
Name: Adrian Kemp  
Title: Company Secretary

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Item 1

REPURCHASE OF SHARES IN ASTRAZENECA PLC

Further to the announcement of its irrevocable, non-discretionary share repurchase programme for the period 25 June 2012 to 3 August 2012, AstraZeneca PLC announced that under the terms of that programme it purchased for cancellation 444,915 ordinary shares of AstraZeneca PLC at a price of 2994 pence per share on 31 July 2012. Upon the cancellation of these shares, the number of shares in issue will be 1,250,179,295.

A C N Kemp  
Company Secretary  
1 August 2012

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Item 2

Transaction by Person Discharging Managerial Responsibilities  
Disclosure Rule DTR 3.1.4

On 29 July 2012, the interest of Dr Martin Mackay, a person discharging managerial responsibilities, in AstraZeneca PLC Ordinary Shares of \$0.25 each has changed as detailed below.

The change in interest relates to an award made in July 2011 under the AstraZeneca Restricted Share Plan, whereby, in accordance with the terms of the award, 7,106 of the 21,320 shares originally awarded to Dr Mackay vested on 29 July 2012 and he has become beneficially entitled to these shares.

Following certain mandatory tax deductions, Dr Mackay has received 3,410 shares into a personal brokerage account.

For tax purposes, the fair market value of the shares at vest was 2951.5 pence per share being the closing price of AstraZeneca ordinary shares on the last trading day preceding the vesting day.

A C N Kemp  
Company Secretary  
1 August 2012

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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 July 2012 the issued share capital of AstraZeneca PLC with voting rights is 1,250,208,478 ordinary shares of US\$0.25. No shares are held in Treasury. Therefore, the total number of voting rights in AstraZeneca PLC is 1,250,208,478.

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 August 2012

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Item 4

REPURCHASE OF SHARES IN ASTRAZENECA PLC

Further to the announcement of its irrevocable, non-discretionary share repurchase programme for the period 25 June 2012 to 3 August 2012, AstraZeneca PLC announced that under the terms of that programme it purchased for cancellation 441,531 ordinary shares of AstraZeneca PLC at a price of 3016 pence per share on 1 August 2012. Upon the cancellation of these shares, the number of shares in issue will be 1,249,766,947.

A C N Kemp  
Company Secretary  
2 August 2012

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Item 5

REPURCHASE OF SHARES IN ASTRAZENECA PLC

Further to the announcement of its irrevocable, non-discretionary share repurchase programme for the period 25 June 2012 to 3 August 2012, AstraZeneca PLC announced that under the terms of that programme it purchased for cancellation 437,496 ordinary shares of AstraZeneca PLC at a price of 3042 pence per share on 2 August 2012. Upon the cancellation of these shares, the number of shares in issue will be 1,249,418,534.

A C N Kemp  
Company Secretary  
3 August 2012

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Item 6

REPURCHASE OF SHARES IN ASTRAZENECA PLC

Further to the announcement of its irrevocable, non-discretionary share repurchase programme for the period 25 June 2012 to 3 August 2012, AstraZeneca PLC announced that under the terms of that programme it purchased for cancellation 431,566 ordinary shares of AstraZeneca PLC at a price of 3080 pence per share on 3 August 2012. Upon the cancellation of these shares, the number of shares in issue will be 1,249,042,099.

A C N Kemp  
Company Secretary  
6 August 2012

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Item 7

ASTRAZENECA AND BRISTOL-MYERS SQUIBB COMPLETE EXPANSION OF  
DIABETES ALLIANCE THROUGH BRISTOL-MYERS SQUIBB'S ACQUISITION OF  
AMYLIN PHARMACEUTICALS

AstraZeneca and Bristol-Myers Squibb today announced that following the successful completion of the acquisition of Amylin Pharmaceuticals by Bristol-Myers Squibb, AstraZeneca has made an initial payment of approximately \$3.2 billion to Amylin Pharmaceuticals, now a wholly-owned subsidiary of Bristol-Myers Squibb. As previously disclosed, the payment is being made in connection with the expansion of the diabetes alliance between AstraZeneca and Bristol-Myers Squibb to incorporate the development and marketing of Amylin's portfolio of diabetes products, and profits and losses arising from the collaboration will be shared equally.

AstraZeneca has also informed Bristol-Myers Squibb of its intention to exercise its option to acquire certain additional governance rights over key strategic and financial decisions regarding Amylin's portfolio. The rights to this option will become effective once the applicable anti-trust and competition approvals are received by AstraZeneca. Upon the exercise of the option an additional payment of \$135 million will be made to Bristol-Myers Squibb.

Simon Lowth, Interim Chief Executive Officer, AstraZeneca, said: "We are delighted to have successfully completed the expansion of our diabetes alliance with Bristol-Myers Squibb through the addition of Amylin's GLP-1 franchise, creating a broader disease management platform for patients, physicians and payers. We are looking forward to working with the team at Amylin to build on their success and maximise AstraZeneca's and Bristol-Myers Squibb's combined capabilities to make these innovative treatments available to diabetes patients across the world."

Lamberto Andreotti, Chief Executive Officer, Bristol-Myers Squibb, said: "The completion of our acquisition of Amylin and the expansion of our diabetes alliance with AstraZeneca will increase and strengthen our innovative portfolio of diabetes medicines, extending its reach across the spectrum of treatment options. We are pleased to have the opportunity to work together to build on the innovative portfolio, state-of-the art manufacturing facilities and dedicated customer focus that the talented people at Amylin have created."

AstraZeneca's share of the transaction was financed through existing cash resources and credit facilities.

About the Bristol-Myers Squibb and AstraZeneca Collaboration

Bristol-Myers Squibb and AstraZeneca entered into a collaboration in January 2007 to enable the companies to research, develop and commercialise certain investigational drugs for type 2 diabetes. The Bristol-Myers Squibb/AstraZeneca diabetes collaboration is focused around ONGLYZA® (saxagliptin), part of the innovative class of DPP-4 inhibitors, KOMBIGLYZE® (saxagliptin and metformin HCl extended-release) and FORXIGA® (dapagliflozin), an investigational SGLT2 inhibitor, and is dedicated to global patient care, improving patient outcomes and creating a new vision for the treatment of diabetes. ONGLYZA has been submitted for regulatory approval in 93 countries and is approved in 77 countries including the US, Canada, Mexico, EU, India, Brazil and China. FORXIGA received a positive opinion from the CHMP in Europe in April 2012.

The expansion of the collaboration covers the co-development and marketing of products in the Amylin Pharmaceuticals portfolio, which include GLP-1 agonists, BYETTA® (exenatide) and BYDUREON® (exenatide extended-release for injectable suspension/exenatide 2 mg powder and solvent for prolonged release suspension for injection), for the treatment of type 2 diabetes, metreleptin, an investigational leptin analogue currently under review by the U.S. Food and Drug Administration (FDA) for the treatment of lipodystrophy, and SYMLIN® (pramlintide acetate), an amylin analogue, approved by the FDA for the treatment of type 1 and type 2 diabetes patients with inadequate glycaemic control on meal-time insulin.

#### About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialisation of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: [www.astrazeneca.com](http://www.astrazeneca.com).

#### About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information, please visit <http://www.bms.com> or follow us on Twitter at <http://twitter.com/bmsnews>.

#### About Amylin Pharmaceuticals

Amylin Pharmaceuticals is a biopharmaceutical company dedicated to improving lives of patients through the discovery, development and commercialisation of innovative medicines. Amylin is committed to delivering novel therapies that transform the way diabetes and other metabolic disorders are treated. The acquisition of Amylin by Bristol-Myers Squibb was completed 9 August 2012. More information about Amylin Pharmaceuticals is available at [www.amylin.com](http://www.amylin.com).

AstraZeneca:

AstraZeneca:

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9 August 2012

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Item 8

ASTRAZENECA AND PFIZER ENTER AGREEMENT  
FOR OVER-THE-COUNTER NEXIUM;  
ASTRAZENECA RAISES 2012 GUIDANCE

NEXIUM 20mg retail launch targeted for 2014, subject to regulatory approval

AstraZeneca today announced that it has entered into an agreement with Pfizer Inc. for the over-the-counter (OTC) rights for NEXIUM (esomeprazole magnesium), a leading prescription drug currently approved to treat the symptoms of gastroesophageal reflux disease (GERD). Under the terms of the agreement, Pfizer will acquire the exclusive global rights to market non-prescription NEXIUM for the treatment of frequent heartburn in adults in the US, and similar indications in Europe and the rest of the world. Under the agreement, Pfizer will make an upfront payment of \$250 million to AstraZeneca and AstraZeneca is eligible to receive milestone and royalty payments based on product launches and sales.

Based on the anticipated timing of the close of the transaction, AstraZeneca will recognise the upfront of \$250 million as other income in 2012. This will increase core earnings per share for 2012 by approximately \$0.16. As a consequence the Core EPS target for 2012 is increased to the range \$6.00 to \$6.30.

NEXIUM, a Proton Pump Inhibitor, was launched by AstraZeneca in Europe in 2000 and the US in 2001. AstraZeneca will continue to manufacture and market the prescription product, as well as supply Pfizer with the OTC product. A Marketing Authorisation Application for OTC NEXIUM in a 20mg tablet form was filed with the European Medicines Agency in June 2012. A New Drug Application filing for OTC NEXIUM in the US in 20 mg capsules is targeted for the first half of 2013 and if approved Pfizer anticipates commercialising this product in the US beginning in 2014 with launches in other markets to follow.

In addition, both companies are exploring the potential for a strategic partnership that would include similar agreements for other AstraZeneca prescription brands for which an OTC version might be appropriate. The companies have signed a right of first refusal regarding OTC rights for Rhinocort Aqua, a pump spray containing the glucocorticosteroid budesonide, with a local anti-inflammatory effect for the treatment of non-infectious rhinitis (such as hay fever and house dust mite allergy).

Tony Zook, Executive Vice President of AstraZeneca's Global Commercial Organisation said: "AstraZeneca has long been a leader in the gastrointestinal sector, and we believe that an OTC version of NEXIUM will complement this globally successful prescription medicine and help bring relief to more patients around the world. We're pleased to work with Pfizer Consumer Healthcare and believe their expertise in the sales and marketing of consumer health products makes them the optimal partner to commercialise OTC NEXIUM globally. This agreement will help AstraZeneca realise the substantial, long-term value of this brand and potentially other brands in our portfolio."

Pfizer Consumer Healthcare President Paul Sturman said: "NEXIUM is one of the most recognized and respected products in its class with tremendous brand equity and loyalty. We are proud to be AstraZeneca's partner of choice for NEXIUM OTC. By working with AstraZeneca to potentially offer an over-the-counter version of NEXIUM, a brand people know and trust, we are taking another crucial step to empower consumers by providing convenient access to important health care products."



“Pfizer is continuing to enhance the value of our Consumer Healthcare business,” stated Ian Read, Pfizer’s Chairman and Chief Executive Officer. “Through its strong connection to our core biopharmaceutical business and to emerging markets and pharmacy customers worldwide, Pfizer Consumer Healthcare will have the opportunity to help more consumers better manage their health, while extending the value of certain important pharmaceutical brands.”

#### About Pfizer

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world’s best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world’s leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at [www.pfizer.com](http://www.pfizer.com).

#### About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialisation of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: [www.astrazeneca.com](http://www.astrazeneca.com).

#### CONTACTS

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##### Pfizer Investor Enquiries

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Item 9

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 14 August 2012, it purchased for cancellation 250,000 ordinary shares of AstraZeneca PLC at a price of 3011 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,249,443,353.

A C N Kemp  
Company Secretary  
15 August 2012

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Item 10

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 16 August 2012, it purchased for cancellation 200,000 ordinary shares of AstraZeneca PLC at a price of 3016 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,249,292,044.

A C N Kemp  
Company Secretary  
17 August 2012

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Item 11

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 17 August 2012, it purchased for cancellation 292,000 ordinary shares of AstraZeneca PLC at a price of 2998 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,249,010,395.

A C N Kemp  
Company Secretary  
20 August 2012

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Item 12

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 20 August 2012, it purchased for cancellation 250,000 ordinary shares of AstraZeneca PLC at a price of 2983 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,248,765,153.

A C N Kemp  
Company Secretary  
21 August 2012

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Item 13

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 21 August 2012, it purchased for cancellation 250,000 ordinary shares of AstraZeneca PLC at a price of 2987 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,248,525,577.

A C N Kemp  
Company Secretary  
22 August 2012

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Item 14

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 22 August 2012, it purchased for cancellation 250,000 ordinary shares of AstraZeneca PLC at a price of 2961 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,248,285,705.

A C N Kemp  
Company Secretary  
23 August 2012

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Item 15

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 23 August 2012, it purchased for cancellation 250,000 ordinary shares of AstraZeneca PLC at a price of 2966 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,248,038,428.

A C N Kemp  
Company Secretary  
24 August 2012

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Item 16

Transaction by Person Discharging Managerial Responsibilities  
Disclosure Rule DTR 3.1.4

The interest of David Smith, a person discharging managerial responsibilities, in AstraZeneca ordinary shares, has changed as detailed below.

On 23 August 2012, Mr Smith exercised options over 36,131 and 33,333 AstraZeneca ordinary shares at option prices of 1882 pence per share and 2280 pence per share respectively.

Following these exercises, Mr Smith sold 58,259 of the 69,464 shares so acquired at a price of 2968 pence per share to cover the cost of exercise and associated taxes.

A C N Kemp  
Company Secretary  
24 August 2012

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Item 17

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 24 August 2012, it purchased for cancellation 200,000 ordinary shares of AstraZeneca PLC at a price of 2976 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,247,919,041.

A C N Kemp  
Company Secretary  
28 August 2012

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Item 18

PASCAL SORIOT APPOINTED CHIEF EXECUTIVE OFFICER  
OF ASTRAZENECA

AstraZeneca today announced that Pascal Soriot has been appointed as the company's Chief Executive Officer. Pascal Soriot will take on his new responsibilities and join the AstraZeneca PLC Board as an Executive Director on 1 October 2012.

Simon Lowth will remain as AstraZeneca's Interim Chief Executive Officer until Pascal Soriot joins. At that point, Simon Lowth will resume his responsibilities as Chief Financial Officer and will continue to serve as an Executive Director on the AstraZeneca PLC Board.

A French national, 53 year old Pascal Soriot joins AstraZeneca from Roche AG where he has served as Chief Operating Officer of the company's pharmaceuticals division since 2010. In his current role he has global responsibility for development, manufacturing, commercial operations and administration for a pharmaceuticals business that recorded sales of \$34 billion in 2011 and has approximately 44,000 employees worldwide. Prior to that Pascal Soriot was Chief Executive Officer of Genentech, where he was credited with leading the successful merger between the San Francisco-based biologics business and Roche. Pascal Soriot joined the pharmaceutical industry in 1986 and has worked in senior management roles in the US, Asia and Europe.

Pascal Soriot said: "I am excited and honoured to have been asked to lead AstraZeneca. Throughout my career I have had enormous respect for the people of AstraZeneca and what they have achieved. No-one is blind to the challenges that confront the pharmaceutical sector and this company, but the underlying strengths of AstraZeneca in delivering on its strategy are clear. AstraZeneca will continue to make a positive difference to patients over the longer term and I'm looking forward to playing my part in shaping that future."

Leif Johansson, Chairman of AstraZeneca PLC, commented: "This is a key appointment at an important time for AstraZeneca and we are certain that Pascal's leadership qualities combined with his strategic thinking and relevant experience make him the right person to drive the company to success over the coming years. I am confident that Pascal's approach and his track record of delivering results in innovation-driven businesses will be valued by shareholders and employees alike."

"The Board would like to record its appreciation for the excellent job done by Simon Lowth as interim CEO and his impressive leadership in this period. Supported by a highly capable and committed executive team, Simon has maintained the organisation's focus on key business priorities during a period of significant change for the company."

No disclosure obligations arise under paragraphs (1) to (6) of LR 9.6.13 R of the UK Listing Authority's Listing Rules in respect of this appointment.

## About Pascal Soriot

2006-2012

Roche Holding AG, Basel  
Chief Operating Officer, Head of Pharmaceuticals  
Chief Executive Officer, Genentech  
Head of Commercial Operation  
Head of Global Strategic Marketing

1986-2005

Sanofi-Aventis, INC, New York, Tokyo, Sydney, Paris  
Chief Operating Officer, US Commercial, Aventis  
Senior Vice President, Global Marketing & Medical Affairs, Aventis  
Vice President, Asia-Pacific Region, Hoechst Marion Roussel, Japan  
Managing Director, Hoechst Marion Roussel, Australia  
Global Marketing Director, Roussel UCLAF Pharmaceutical Division, Paris  
Managing Director, Roussel Australia/New Zealand  
Financial Controller, Asia Pacific Region, Pharmaceutical Division, Roussel UCLAF, Paris

Prior to his commercial career, Pascal Soriot practiced as a veterinarian. He holds an MBA with a major in finance from HEC Paris.

To obtain a photograph of Pascal Soriot please visit [www.astrazeneca.com/media/photo-library](http://www.astrazeneca.com/media/photo-library) or contact the media team (details below).

## About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialisation of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit:

[www.astrazeneca.com](http://www.astrazeneca.com)

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28 August 2012

- ENDS -



Item 19

EUROPEAN COMMISSION APPROVES ZINFOROTM (CEFTAROLINE FOSAMIL) FOR ADULT PATIENTS WITH SERIOUS SKIN INFECTIONS OR COMMUNITY ACQUIRED PNEUMONIA

AstraZeneca today announced that the European Commission has granted Marketing Authorisation to ZINFOROTM (ceftaroline fosamil), a new intravenous cephalosporin antibiotic, for the treatment of adult patients with complicated Skin and Soft Tissue Infections (cSSTI) or Community Acquired Pneumonia (CAP). This makes ZINFOROTM the only approved cephalosporin monotherapy in Europe with demonstrated clinical efficacy against methicillin-resistant *Staphylococcus aureus* (MRSA), a common cause of serious and difficult to treat complicated skin infections\*.

ZINFOROTM was designed to be different from previously approved cephalosporins and has a novel mode of action which results in bactericidal activity and broad coverage against common causative pathogens, such as *Staphylococcus aureus*, including MRSA, and *Streptococci* in cSSTI and *Streptococcus pneumoniae* and methicillin-susceptible *Staphylococcus aureus* (MSSA) in CAP.

The Marketing Authorization of ZINFOROTM is based on data from the Phase III clinical trial programme which included four pivotal registration trials, CANVAS 1 and 2 (cSSTI) and FOCUS 1 and 2 (CAP). These studies demonstrated consistent clinical efficacy in the treatment of cSSTI and CAP with the recognised tolerability profile of the cephalosporin class. The most common adverse reactions occurring in  $\geq 3\%$  of patients treated with ZINFOROTM were diarrhoea, headache, nausea, and pruritus and were generally mild or moderate in severity.

ZINFOROTM also demonstrated clinical efficacy in vulnerable\*\* patient groups, for example the elderly, or those with underlying comorbidities (such as diabetes mellitus or peripheral vascular disease in cSSTI or chronic obstructive pulmonary disease [COPD] or asthma in CAP)\*. This may help to overcome some of the current treatment challenges faced by physicians when treating this patient population, who require an effective treatment without compromising on tolerability.

“We are delighted that ZINFOROTM has received regulatory approval across Europe and believe it will make a valuable contribution to addressing the significant unmet need for new antibiotics,” said Martin Mackay, President, R&D, AstraZeneca. “This is a key step in making ZINFOROTM more widely available to patients across the globe and we will work with the appropriate health authorities, formulary and protocol reviews, and clinicians to bring this new antibiotic to patients as soon as possible.”

In 2009, Forest Laboratories Inc. granted AstraZeneca exclusive worldwide commercial rights and co-exclusive development rights for ceftaroline fosamil, excluding US, Canada and Japan. Forest launched ceftaroline fosamil with similar indications under the trade name Teflaro® in the US in March 2011.

The European Commission decision follows a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) on 21 June 2012 and is applicable to all 27 Member States and the three European Economic Area countries of the European Union.

#### NOTES TO EDITORS

\* There is no experience with ZINFOROTM in the treatment in the following patient groups:

- In cSSTI: the immunocompromised, patients with severe sepsis/septic shock, necrotising fasciitis, perirectal abscess and patients with third degree and extensive burns. There is limited experience in treating patients with diabetic foot infections. Caution is advised when treating such patients
- In CAP: immunocompromised; patients with severe sepsis/septic shock, severe underlying lung disease; patients with PORT Risk Class V, and/or CAP requiring ventilation at presentation, CAP due to MRSA; patients requiring intensive care; the available clinical data cannot substantiate efficacy against penicillin non-susceptible strains of *Streptococcus pneumoniae* (PNSP). Caution is advised when treating such patients

\*\* Vulnerable patients with co-morbidities are defined as those:

1. With a reduced ability to fight the infection or tolerate treatment
2. In whom a resistant or difficult to treat pathogen is known or suspected
3. Where there is an urgent need for action

These patients can pose additional treatment challenges for the physician.

#### About ZINFOROTM

ZINFORO™ is a new intravenous cephalosporin antibiotic indicated for the treatment of adult patients with cSSTI or CAP.

ZINFORO™ is bactericidal and works by binding to and inhibiting penicillin-binding proteins (PBPs). PBPs are involved in bacterial cell wall synthesis and repair and their inhibition leads to reduced bacterial cell replication and/or cell death.

ZINFORO™ has been designed with a specific mode of action which contributes to its bactericidal activity against the common causative pathogens of cSSTI, and CAP and unlike other cephalosporins, shows a high affinity for particular PBPs in MRSA in cSSTI and *Streptococcus pneumoniae* in CAP .

No cases of CAP due to MRSA were enrolled into the studies; the available clinical data cannot substantiate efficacy against PNSP. ZINFORO™ is not active against strains of Enterobacteriaceae producing extended-spectrum beta-lactamases (ESBLs) or *Pseudomonas aeruginosa*. In addition in vitro data in CAP indicate that the following atypical species are not susceptible to ceftaroline: *Chlamydia* spp. *Legionella* spp. *Mycoplasma* spp.

#### About cSSTI and CAP

Complicated Skin and Soft tissue Infections (cSSTI) are difficult-to-treat infections of the skin and underlying soft tissues such as fascia and muscle layers e.g. deep soft tissue abscesses, cellulitis and surgical site infections. cSSTIs are among the most common antibiotic treated infections in the hospital setting and represent approximately 12% of all antibiotic-treated hospital patients in Europe.

Community Acquired Pneumonia (CAP) is an acute infection of the lungs (pneumonia) in a patient who has not been exposed to a hospital or long-term care facility. The estimated incidence of CAP is between two and 12 cases per 1000 inhabitants in Europe each year. The annual incidence of CAP in the elderly has been estimated to be four-times that of younger populations, and with an expected 30% of the European population reaching 'elderly' status by 2060, the burden of CAP is anticipated to be even more significant in the coming years.

CAP and cSSTI are commonly associated with considerable morbidity, mortality, resource use and healthcare costs and despite the availability of a variety of antibiotics to treat CAP and cSSTI, studies show that many patients do not receive effective first-line empiric treatment.

In addition, emerging antimicrobial resistance is a global concern.

Across Europe, methicillin-resistant *Staphylococcus aureus* (MRSA), a common cause of serious and difficult to treat complicated skin infections, affects 150,000 patients per year, resulting in attributable extra in-hospital costs of €380 million.

#### About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialisation of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: [www.astrazeneca.com](http://www.astrazeneca.com)

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28 August 2012

- ENDS -

Item 20

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 28 August 2012, it purchased for cancellation 250,000 ordinary shares of AstraZeneca PLC at a price of 2969 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,247,682,680.

A C N Kemp  
Company Secretary  
29 August 2012

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Item 21

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 29 August 2012, it purchased for cancellation 250,000 ordinary shares of AstraZeneca PLC at a price of 2957 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,247,454,972.

A C N Kemp  
Company Secretary  
30 August 2012

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Item 22

Transaction by Person Discharging Managerial Responsibilities  
Disclosure Rule DTR 3.1.4

We hereby inform you that on 30 August 2012, Mr Leif Johansson, a Director of the Company, notified us that, on 30 August 2012, he purchased 3,000 AstraZeneca PLC ordinary shares at a price of SEK 311.70 per share.

Following this purchase, Mr Johansson has a total interest in 28,509 AstraZeneca shares.

A C N Kemp  
Company Secretary  
30 August 2012

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Item 23

REPURCHASE OF SHARES IN ASTRAZENECA PLC

AstraZeneca PLC announced that on 30 August 2012, it purchased for cancellation 250,000 ordinary shares of AstraZeneca PLC at a price of 2966 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,247,216,793.

A C N Kemp  
Company Secretary  
31 August 2012

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Item 24

Transaction by Person Discharging Managerial Responsibilities  
Disclosure Rule DTR 3.1.4

On 27 August 2012, the interest of Dr Martin Mackay, a person discharging managerial responsibilities, in AstraZeneca PLC Ordinary Shares of \$0.25 each changed as detailed below.

The change in interest relates to an award made in August 2010 under the AstraZeneca Restricted Share Plan, whereby, in accordance with the terms of the award, 27,072 of the 81,217 shares originally awarded to Dr Mackay vested on 27 August 2012 and he has become beneficially entitled to these shares

Following certain tax deductions, Dr Mackay has received 22,469 shares into a personal brokerage account.

For tax purposes, the fair market value of the shares at vest was 2981.5 pence per share being the closing price of AstraZeneca ordinary shares on the last trading day preceding the vesting day.

A C N Kemp  
Company Secretary  
31 August 2012

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