

ASTRAZENECA PLC  
Form 20-F  
April 28, 2011

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 20-F

(Mark One)

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2010

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report \_\_\_\_\_

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-11960

ASTRAZENECA PLC  
(Exact name of Registrant as specified in its charter)

England  
(Jurisdiction of incorporation or organization)

2 Kingdom Street, London W2 6BD  
(Address of principal executive offices)

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Adrian Kemp  
AstraZeneca PLC  
2 Kingdom Street, London W2 6BD

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Telephone: +44 20 7604 8000

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(Name, Telephone, E-Mail or Facsimile number and Address of Company Contact Person)

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Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
American Depositary Shares, each representing one Ordinary Share of 25¢ each	The New York Stock Exchange
Ordinary Shares of 25¢ each	The New York Stock Exchange*

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\* Not for trading, but only in connection with the registration of American Depositary Shares representing such Ordinary Shares pursuant to the requirements of the Securities and Exchange Commission.

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None

                      
(Title of Class)

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Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None

(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

The number of outstanding shares of each class of stock of AstraZeneca PLC as of December 31, 2010 was:

Ordinary Shares of 25¢ each: 1,409,023,452  
Redeemable Preference Shares of £1 each: 50,000

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes  No

Note — checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).\*

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP

International Financial Reporting Standards as issued  
by the International Accounting Standards Board

Other

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17  Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court.

Yes  No

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\* This requirement does not apply to the registrant until its fiscal year ending December 31, 2011.

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Pursuant to Rule 12b-23(a) of the Securities Exchange Act of 1934, as amended, the information for the 2010 Form 20-F of AstraZeneca PLC (“AstraZeneca” or the “Company”) set out below is being incorporated by reference from the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated and submitted on April 28, 2011.

References below to major headings include all information under such major headings, including subheadings, unless such reference is a reference to a subheading, in which case such reference includes only the information contained under such subheading. Graphs and tabular data are not included unless specifically identified below. Photographs are also not included.

In addition to the information set out below, the information set forth under the headings “Cautionary statement regarding forward-looking statements”, “Inclusion of reported performance, Core financial measures and constant exchange rate growth rates”, “Statements of competitive position, growth rates and sales”, “AstraZeneca websites”, “External/third party websites”, “Definitions”, “Use of terms”, “Statements of dates” and “Figures” on the inside front cover, the paragraph regarding trade marks of the AstraZeneca group on the inside back cover, and “Glossary” on pages 217 to 219, in each case of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

On the date of this Form 20-F, the Company is announcing its quarterly financial results for the period ended March 31, 2011.

## PART 1

### ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

### ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

### ITEM 3. KEY INFORMATION

#### A. Selected Financial Data

The information (including graphs and tabular data) set forth under the headings “Financial Statements—Group Financial Record” on page 204 and the first table that appears under “Additional Information—Shareholder Information—AstraZeneca PLC share listings and prices” on page 211, in each case of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference. The selected financial data incorporated by reference herein is derived from audited financial statements of the Company and its consolidated entities, prepared in accordance with International Financial Reporting Standards (“IFRS”) as adopted by the European Union and as issued by the International Accounting Standards Board, included in the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011.

#### B. Capitalization and Indebtedness

Not applicable.

C. Reason for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

The information set forth or referenced under the heading “Corporate Governance—Risk—Principal risks and uncertainties” on pages 96 to 103 of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

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## ITEM 4. INFORMATION ON THE COMPANY

### A. History and Development of the Company

The information (including tabular data) set forth under the headings “Additional Information—Corporate Information—History and development of the Company” on page 216, “Business Review—Delivering our strategy—Research and Development—Our resources” on pages 29 to 30, “—Delivering our strategy—Supply and Manufacturing—Our resources” on page 35, “Business Review—Financial Review—Financial position – 2010—Investments, divestments and capital expenditure” on page 86, “Financial Statements—Notes to the Financial Statements—Note 7—Property, plant and equipment” on page 153 and “—Note 22—Acquisitions of business operations” on pages 167 to 168, in each case of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

### B. Business Overview

The information (including graphs and tabular data) set forth under the headings “Overview—Our year in brief” on pages 4 to 5, “—Chairman’s Statement” on pages 6 to 7, “—CEO’s Review” on pages 8 to 9, “—Our strategy and performance” on pages 10 to 21, “Business Review” on pages 24 to 77, “Additional Information—Development Pipeline” on pages 206 to 210”, “Financial Statements—Notes to the Financial Statements —Note 1—Product revenue information” on page 147, “—Note 6—Segment Information” on pages 151 to 152, and “Statements of competitive position, growth rates and sales” on the inside front cover, in each case of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

#### European Commission approves FLUENZ for prevention of seasonal influenza in children

On February 1, 2011 the Company announced that the European Commission (EC) has granted marketing authorization to FLUENZ Influenza Vaccine (Live Attenuated, Nasal), a nasally administered live attenuated influenza vaccine, for prevention of seasonal influenza for children 24 months to less than 18 years of age. This decision follows the positive opinion from the Committee for Medicinal Products for Human Use (CHMP) on October 22, 2010 and is applicable to the 27 Member States and the 3 European Economic Area countries of the European Union.

It is expected that the FLUENZ vaccine will be initially available in select European markets for the 2012-13 influenza season. The EC decision and CHMP positive opinion were reached after a review of data from 73 global clinical studies and US post-marketing studies of more than 141,000 subjects conducted in 38 countries. Study objectives included clinical safety and tolerability, clinical efficacy and effectiveness, and immunogenicity.

#### US FDA assigns new PDUFA date for BRILINTA

On February 4, 2011 the Company announced that the US Food and Drug Administration (FDA) has acknowledged receipt of the Company’s reply to the Complete Response Letter (CRL) for the ticagrelor New Drug Application (NDA). Accordingly, the agency has accepted AstraZeneca’s resubmission of the ticagrelor NDA, categorized it as a Class 2 resubmission to the CRL, and set a new Prescription Drug User Fee Act (PDUFA) date of July 20, 2011.

The FDA issued the CRL on December 16, 2010. On January 21, 2011, AstraZeneca announced it had submitted the requested supplementary analyses as part of its CRL response. AstraZeneca remains confident in the NDA submission for ticagrelor and will continue working with the FDA to progress towards completing the review of the NDA for ticagrelor.

AstraZeneca halts Phase III trial of ZIBOTENTAN in non-metastatic castrate resistant prostate cancer

On February 7, 2011 the Company announced that the phase III ENTHUSE Study 15, studying zibotentan monotherapy in patients with non-metastatic castrate resistant prostate cancer (CRPC), will be stopped following the results of an early efficacy review by the Independent Data Monitoring Committee. The decision was made after this review indicated that zibotentan monotherapy was unlikely to meet its primary efficacy endpoints (progression free survival and overall survival) and therefore unlikely to benefit patients with non-metastatic CRPC.



AstraZeneca felt it was prudent to take an early view on the progress of Study 15 following the announcement in September 2010 that ENTHUSE Study 14, evaluating zibotentan monotherapy, did not show a significant improvement in the primary endpoint of overall survival in patients with metastatic CRPC.

Study 15 is part of the Phase III clinical trial program, ENTHUSE, which was developed to evaluate the efficacy and safety of zibotentan in extending survival in men with CRPC. The discontinuation of Study 15 concludes the zibotentan monotherapy program in CRPC. The full data from Study 15 will be published in due course. ENTHUSE Study 33 is a trial using zibotentan in combination with standard chemotherapy in a more advanced metastatic CRPC setting. This trial will continue and full results are expected in the second half of 2011.

AstraZeneca and Targacept initiate Phase IIB clinical trial of TC-5214 as “switch” monotherapy treatment for MDD

On February 7, 2011 the Company and Targacept, Inc. announced the enrolment of the first patient in the Phase IIB clinical trial of TC-5214, a nicotinic channel blocker, as a “switch” monotherapy treatment for patients with major depressive disorder (MDD) who do not respond adequately to initial antidepressant therapy. This study is in addition to the companies’ Phase III RENAISSANCE program for TC-5214 as an adjunctive treatment for MDD. The RENAISSANCE program is designed to support an NDA filing in the US planned for the second half of 2012 and a Marketing Authorization Application (MAA) filing in Europe planned for 2015. AstraZeneca and Targacept are co-developing TC-5214.

In the Phase IIB study, patients with MDD who do not respond adequately, based on predefined criteria, to initial open label treatment with one of six commonly used SSRI or SNRI antidepressants will be switched to receive either one of two fixed doses of TC-5214, the active control duloxetine or placebo. Dosing in this double blind phase of the study is twice daily for eight weeks. The primary outcome measure for the study is change from double-blind baseline at the end of the dosing period for TC-5214 on the Montgomery-Åsberg Depression Rating Scale as compared to placebo. The study is projected to enrol approximately 350 patients into the double blind phase from approximately 75 centers worldwide.

ONGLYZA US label update provides further evidence regarding use in renally impaired adults with Type 2 diabetes

On February 23, 2011 the Company and Bristol-Myers Squibb Company announced that the FDA has approved the inclusion of data from two clinical studies in an update to the ONGLYZA (saxagliptin) US Prescribing Information for adult type 2 diabetes patients.

The renal study investigated the safety and efficacy of ONGLYZA in patients with moderate to severe renal impairment or end-stage renal disease (ESRD). The 12-week data showed that ONGLYZA 2.5 mg once daily significantly improved glycosylated hemoglobin (HbA1c) from baseline compared to placebo when added to patients’ current diabetes treatment. In patients with ESRD, ONGLYZA and placebo showed numerically comparable reductions in HbA1c. This finding is inconclusive because the trial was not adequately powered to show efficacy within specific subgroups of renal impairment. The incidence of adverse events was similar between ONGLYZA and placebo.

The data from a separate 52-week study comparing ONGLYZA to titrated glipizide in patients with inadequate glycaemic control on metformin therapy plus diet and exercise showed that ONGLYZA plus metformin provided similar HbA1c reductions from baseline. This conclusion may be limited to patients with baseline HbA1c comparable to those in the trial. ONGLYZA plus metformin also resulted in significantly less confirmed hypoglycaemia, as well as weight loss compared to weight gain versus titrated glipizide plus metformin.

ONGLYZA is indicated as an adjunct to diet and exercise to improve blood sugar (glyceamic) control in adults with type 2 diabetes mellitus in multiple clinical settings. ONGLYZA should not be used for the treatment of type 1 diabetes or for the treatment of diabetic ketoacidosis (dangerously high levels of ketones in the blood or urine).

If used with an insulin secretagogue such as a sulfonylurea, a lower dose of the insulin secretagogue may be required to reduce the risk of hypoglycaemia. There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with ONGLYZA or any other antidiabetic drug.

ONGLYZA becomes first DPP4 inhibitor available for use in Europe in Type 2 Diabetes patients with moderate or severe renal impairment

On March 4, 2011 the Company and Bristol-Myers Squibb Company announced that the European Commission has approved a label update for ONGLYZA® (saxagliptin) in the treatment of adults with type 2 diabetes who have moderate or severe renal impairment. The approved dosage for the patient group is a new once-daily 2.5 mg dose.

ONGLYZA will be the first dipeptidyl peptidase-4 (DPP-4) inhibitor in Europe available for type 2 diabetes patients with moderate or severe renal impairment. ONGLYZA is indicated in adult patients with type 2 diabetes mellitus to improve glycaemic control in combination with metformin, sulphonylurea, or thiazolidinedione, when each treatment alone, with diet and exercise, does not provide adequate glycaemic control.

This label update was granted on the basis of clinical data submitted to the European Medicines Agency from a 12-week, multi-centre, randomized, double-blind, placebo-controlled study to evaluate the treatment effect of ONGLYZA 2.5 mg once daily compared with placebo in 170 patients with Type 2 diabetes and renal impairment (creatinine clearance [CrCl] <50 mL/min). In this study, 98.2% of the patients were treated with other antihyperglycaemic medication. The results of the study, which are described in the Summary of Product Characteristics (SmPc), demonstrated that ONGLYZA 2.5 mg was safe and effective, compared with placebo, in adults with type 2 diabetes who have moderate or severe renal impairment.

AstraZeneca to discontinue production of PULMICORT® pMDI

On March 7, 2011 the Company announced that it will discontinue the production of PULMICORT® (budesonide) 100 and 200 µg/dose HFA pMDI (pressurized metered dose inhaler) due to complex manufacturing issues related to technical aspects of the device, which prevents the ongoing manufacture of the product. This issue is not related to the active ingredient, budesonide, or any other AstraZeneca product.

The manufacturing decision took effect immediately; however, patients can continue using the PULMICORT pMDI 100 and 200 µg strength until their current supply is finished.

PULMICORT pMDI is manufactured using product-specific processes and components, the combination of which is not used with any other AstraZeneca respiratory products; therefore, this is a unique issue to PULMICORT pMDI.

AstraZeneca is working closely with the appropriate regulatory authorities and healthcare professionals (HCPs), and is informing manufacturers of similar asthma medications, where appropriate, to ensure all patients continue to receive the appropriate alternative treatment.

Other AstraZeneca respiratory products, including PULMICORT® Turbuhaler®, PULMICORT® Respules® and PULMICORT® Flexhaler® are not affected because they use different devices or device components. Other AstraZeneca pMDI products such as SYMBICORT® (budesonide/formoterol fumarate dihydrate) pMDI and VANNAIR© (budesonide/formoterol) are also not affected.

FDA accepts NDA for Dapagliflozin for treatment of Type 2 diabetes

On March 8, 2011 the Company and Bristol-Myers Squibb Company announced that the FDA has accepted for review an NDA for dapagliflozin, an investigational compound for the treatment of adults with type 2 diabetes mellitus. An MAA for dapagliflozin has also been validated by the European Medicines Agency (EMA). The NDA and MAA submissions for dapagliflozin were filed in December 2010. The PDUFA goal date for the FDA is October 28, 2011.

The US and European submissions included data of up to two years in duration from a global development program involving approximately 6,000 individuals in 40 clinical studies. In accordance with FDA guidelines, the US application also includes data assessing the cardiovascular safety of dapagliflozin in adults with type 2 diabetes.

AstraZeneca initiates phase III clinical program evaluating NKTR-118 for treatment of opioid-induced constipation

On March 15, 2011 the Company announced enrolment of the first patient in the Phase III clinical program for NKTR-118, an oral peripherally-acting opioid antagonist being investigated for the treatment of opioid-induced constipation. The Phase III clinical program is designed to investigate the safety and efficacy of NKTR-118 as a medicine to relieve opioid induced constipation, a common side effect of prescription opioids when used for chronic pain management. NKTR-118 is part of the exclusive worldwide license agreement announced on September 21, 2009 between AstraZeneca and Nektar Therapeutics.

The Phase III clinical program will consist of two 12-week, randomized, placebo-controlled efficacy studies (with approximately 630 randomized patients each) and an open-label, randomized, long-term safety study with a “usual care” comparator arm. The 12-week efficacy studies will compare response rate among placebo and two different doses of NKTR-118 with primary endpoint at 4 weeks. There is a three month safety extension following one of the two 12-week studies.

The long-term safety study will include patients from the 12-week treatment in the efficacy studies, as well as new patients not previously enrolled. All patients will be randomly assigned to open-label treatment of either NKTR-118 or physician’s choice (usual care) of laxative regimen. Safety assessments will also be collected throughout the trials.

The first regulatory filings based on the program are planned for 2013.

FDA approves orphan drug vandetanib

On April 7, 2011 the Company announced that the FDA has approved the orphan drug vandetanib for the treatment of medullary thyroid cancer that cannot be removed by surgery or that has spread to other parts of the body. Vandetanib is a kinase inhibitor indicated for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable (non-operable) locally advanced or metastatic disease.

### C. Organizational Structure

The information (including tabular data) set forth under the headings “Corporate Governance—Corporate Governance Report—Other matters—Subsidiaries and principal activities” on page 117 and “Financial Statements—Principal Subsidiaries” on page 197, in each case of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

### D. Property, Plants and Equipment

The information (including tabular data) set forth under the headings “Business Review—Delivering our strategy—Research and Development—Our resources” on pages 29 to 30, “—Delivering our strategy—Supply and Manufacturing—Our resources” on page 35, “Business Review—Financial Review—Financial position – 2010—Property, plant and equipment” and “—Financial position – 2009—Property, plant and equipment”, on pages 85 and 89, respectively, “Corporate Governance—Risk—Principal risks and uncertainties—Legal, regulatory and compliance risks—Environmental/occupational health and safety liabilities” on page 102, “Financial Statements—Notes to the Financial Statements—Note 7—Property, plant and equipment” on page 153, “—Note 25—Commitments and contingent liabilities—Environmental costs and liabilities” on page 180 and “Additional Information—Corporate Information—Articles—Property” on page 216, in each case of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

### ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The information (including graphs and tabular data) set forth under the headings “Business Review—Financial Review” on pages 78 to 93, “Business Review—Geographical Review” on pages 70 to 74, “Business Review—Therapy Area Review—Sales by Therapy Area” (consisting of tabular data) on page 50, “—Therapy Area Review—Our financial performance” (consisting of tabular data) on pages 53, 57, 59, 62, 65 and 68, “—Therapy

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Area Review—Financial performance 2010/2009” on pages 55, 57, 60, 63, 66 and 69, “Business Review—Other Businesses—Our financial performance” (consisting of tabular data) on page 75, “Business Review—Delivering our strategy—Research and Development” on pages 26 to 30, “Corporate Governance—Corporate Governance Report—Business organization—Portfolio Investment Board (PIB)” on page 116, “Corporate Governance—Risk—Principal risks and uncertainties—Commercialization and business execution risks—Competition, price controls and price reductions” on pages 99 to 100, “Financial Statements—Notes to the Financial Statements—Note 14—Interest-bearing loans and borrowings” on page 158, “—Note 15—Financial instruments” on pages 158 to 161, “—Note 19—Capital and reserves—Other reserves” on page 161, “—Note 23—Financial risk management objectives and policies” on pages 168 to 172 and “—Note 25—Commitments and contingent liabilities” on pages 178 to 195, in each case of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

#### Developments in Legal Proceedings

For further information in respect of material legal proceedings in which the Company is currently involved, including those discussed below, please see the information set forth under the heading “Financial Statements—Notes to the Financial Statements—Note 25—Commitments and contingent liabilities” on pages 178 to 195 of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011. Unless noted below or in the Company’s “Annual Report and Form 20-F Information 2010”, no provisions have been established in respect of the claims discussed below.

#### Atacand

##### Patent litigation – Canada

As previously disclosed, in December 2010, AstraZeneca received a second Notice of Allegation from Teva Canada Limited (Teva) in respect of Canadian Atacand substance patent no. 2,040,955 (the ‘955 patent) and formulation patent no. 2,083,305 (the ‘305 patent) listed on the Canadian Patent Register for Atacand. Teva has confirmed it will await the expiry of the ‘955 patent. AstraZeneca did not commence an application in response.

In March 2011, AstraZeneca received a Notice of Allegation from Apotex Inc. (Apotex) in respect of the ‘955 and ‘305 patents listed on the Canadian Patent Register for Atacand. Apotex has confirmed it will await the expiry of the ‘955 patent. AstraZeneca did not commence an application in response.

##### Patent litigation – Brazil

As previously disclosed, in October 2010, AstraZeneca filed an infringement action with a request for an interlocutory injunction against Sandoz do Brasil Industria Farmaceutica Ltda (Sandoz) in the Central Court of São Paulo. The Court denied the request for an interlocutory injunction. AstraZeneca appealed the decision and in February 2011, the Court of Appeal upheld the lower court’s decision to deny the request for an interlocutory injunction. The main infringement action continues.

##### Patent litigation – EU

As previously disclosed, in Portugal, a request was filed with the Lisbon Administrative Court of First Instance in December 2009 seeking a preliminary injunction to suspend the marketing authorizations for generic candesartan cilexetil granted to Sandoz Farmacêutica Limitada (Sandoz). The Court denied the preliminary injunction. The decision was appealed and the Court of Appeal ordered the Court of First Instance to hold a hearing. After a hearing in February 2011 the Lisbon Administrative Court of First Instance granted the request for a preliminary injunction and ordered the suspension of the marketing authorizations granted to Sandoz until October 24, 2012, i.e. the date of

expiry of the supplementary protection certificate. This decision can be appealed.

Atacand Plus (candesartan cilexetil/hydrochlorothiazide)

Patent litigation – Canada

As previously disclosed, in April 2010, AstraZeneca received a Notice of Allegation from Pharmascience Inc. (PMS) in respect of the Atacand Plus formulation patent no. 2,083,305 (the '305 patent) listed on the Canadian Patent



Register for Atacand Plus. AstraZeneca commenced a proceeding in response in June 2010. In February 2011, AstraZeneca discontinued its application.

As previously disclosed, in December 2010, AstraZeneca received a Notice of Allegation from PMS in respect of the Atacand Plus combination patent no. 2,125,251 (the '251 patent). AstraZeneca commenced an application in response in February 2011.

In January 2011, AstraZeneca received two Notices of Allegation from Teva Canada Limited (Teva) in respect of the '251 and the '305 patents. Teva has agreed to await the expiry of the '955 patent. AstraZeneca commenced applications in response in March 2011.

Crestor (rosuvastatin calcium)

Patent litigation – US

US Patent No. RE37,314 (the '314 patent)

As previously disclosed, in June 2010, the US District Court for the District of Delaware found the '314 patent valid and enforceable and infringed by the eight generic defendants. The defendants appealed the decision to the Court of Appeals for the Federal Circuit. AstraZeneca and Shionogi Seiyaku Kabushiki Kaisha filed a comprehensive responsive brief in March 2011. The defendants filed reply briefs and briefing is now complete. A date for oral argument has not been set.

505(b)(2) New Drug Application for rosuvastatin zinc tablets (the '314 patent) and US Patent Nos. 6,858,618 (the '618 patent) and 7,030,152 (the '152 patent)

As previously disclosed, in October 2010, AstraZeneca and Shionogi Seiyaku Kabushiki Kaisha commenced a patent infringement action in the US District Court for the District of Delaware against Watson Laboratories, Inc. (Watson) for infringement of the '314 patent. In March 2011, the Court entered an order based on a stipulation which precludes Watson from re-litigating the invalidity and unenforceability issues currently pending before the Federal Circuit in the Crestor appeal involving the '314 patent. The Court has set a case-schedule for discovery and other litigation events, including a trial date in May 2012. On April 19, 2011, in this case, AstraZeneca moved to amend the complaint to add The Brigham's & Women's Hospital as a co-plaintiff and add claims of infringement of the '618 and '152 method patents.

Abbreviated New Drug Applications for rosuvastatin calcium tablets (the '618 and '152 patents)

In 2010, AstraZeneca and The Brigham's & Women's Hospital, AstraZeneca's licensor of the '152 patent (together the Plaintiffs), filed ten patent infringement actions involving Crestor in the US District Court for the District of Delaware, based on the '152 patent and the '618 patent. As previously disclosed in December 2010, the Court dismissed nine of the infringement actions for lack of subject-matter jurisdiction. In January 2011, the Plaintiffs appealed the dismissals to the Federal Circuit. The Plaintiffs also asked the District Court to stay the remaining action against Sandoz Inc. pending the outcome of the appeals. In March 2011, the Plaintiffs filed an opening brief in the Federal Circuit.

Palmetto Pharmaceuticals, LLC v. AstraZeneca Pharmaceuticals LP (Infringement Suit)

AstraZeneca Pharmaceuticals LP v. Palmetto Pharmaceuticals, LLC (Declaratory Judgment suit)

On April 5, 2011, Palmetto Pharmaceuticals, LLC (Palmetto) filed a patent infringement suit in the US District Court for the District of South Carolina asserting that AstraZeneca's sales of Crestor induce infringement of Palmetto's US patent no. 6,465,516 (the '516 patent), for which an Ex Parte Reexamination Certificate was issued on 5 April 2011.

On April 7, 2011, AstraZeneca filed a declaratory judgment action in the US District Court for the District of Delaware against Palmetto seeking a judgment of non-infringement and invalidity of Palmetto's '516 patent.

On April 26, 2011, AstraZeneca filed a motion seeking dismissal or, alternatively, summary judgement of non-infringement in Palmetto's patent infringement suit in the District of South Carolina.

#### Patent litigation – Canada

As previously disclosed, in February 2010, AstraZeneca received a Notice of Allegation from Pharmascience Inc. (PMS) in respect of Crestor substance patent no. 2,072,945 (the '945 patent) and formulation patent no. 2,313,783

(the '783 patent). AstraZeneca commenced an application in response in April 2010. A 4-day hearing will commence January 9, 2012.

As previously disclosed, in August 2010, AstraZeneca received a Notice of Allegation from Mylan Pharmaceuticals ULC (Mylan) in respect of the '945 and '783 patents and formulation patent 2,315,141 listed on the Canadian Patent Register for Crestor. In April 2011, AstraZeneca reached a comprehensive settlement resolving the litigation and as part of the agreement, Mylan may enter the Canadian market in April 2012, or earlier in certain circumstances.

#### Patent litigation – EU

In Portugal, in February and March 2011, the Appeal Court confirmed the preliminary injunctions to suspend the marketing authorizations granted to Teva Pharma Lda and Sandoz Farmaceutica Lda and dismissed the appeal. The suspension of the marketing authorizations will be maintained until a decision is rendered within the main administrative action.

#### Patent litigation – Brazil

AstraZeneca filed an administrative action against the administrative body ANVISA for a preliminary injunction for immediate suspension of the decision to grant market approval of Germed Farmacêutica Ltda's (Germed) generic rosuvastatin and to revoke the marketing approval. The preliminary injunction was partially granted on March 4, 2011. On March 15, 2011 the preliminary injunction was dismissed by the court of first instance. AstraZeneca has appealed the decision. On March 18, 2011, AstraZeneca filed a patent infringement action against Germed with a request for a preliminary injunction. On March 31, 2011 the court denied AstraZeneca's request. AstraZeneca appealed the decision and on April 14, 2011 the Reporting Judge of the Appeal Court rejected the request. AstraZeneca is awaiting the decision by the panel of the Appeal Court.

#### Iressa

Both the Osaka and Tokyo courts have issued decisions regarding the Iressa product liability litigation (the details of which have been previously disclosed). On February 25, 2011, the Osaka District Court issued its decision, dismissing one claim, and ordering AstraZeneca to pay approximately \$670,000 for the remaining three claims, plus interest. AstraZeneca is appealing the Osaka decision. On March 23, 2011, the Tokyo District Court issued its decision dismissing one Iressa claim and ordering AstraZeneca and the Japanese Ministry of Health, Labour and Welfare to pay approximately \$192,000 on the remaining two claims, plus interest. AstraZeneca is appealing the Tokyo decision.

#### Nexium (esomeprazole magnesium)

#### Patent litigation – US

#### Abbreviated New Drug Applications (ANDAs)

As previously disclosed, in January 2011, AstraZeneca entered into an agreement to settle the litigation with Dr Reddy's Laboratories Ltd and Dr Reddy's Laboratories Inc (together DRL), a prior ANDA filer. As a result of the DRL settlement and entry of a consent judgment, all of the DRL ANDA litigation was dismissed.

As to the remaining ANDA filers, as previously disclosed, in 2008, AstraZeneca received a Paragraph IV Certification notice-letter from Sandoz Inc. (Sandoz) stating that Sandoz had submitted an ANDA for approval to market

esomeprazole magnesium delayed-release capsules. In 2009, AstraZeneca commenced patent infringement litigation in the US District Court for the District of New Jersey. In 2009, the Court stayed the Sandoz patent infringement litigation. In view of the settlement with DRL in January 2011, the Court referred the matter back to Magistrate Judge Bongiovanni for scheduling and further proceedings. On April 26, 2011, the magistrate judge entered an order staying for one month the case-schedule that she entered for this case on April 14, 2011.

In addition, as previously disclosed, in 2009, AstraZeneca received a Paragraph IV Certification notice-letter from Lupin Limited (Lupin) stating that Lupin had submitted an ANDA for approval to market esomeprazole magnesium delayed-release capsules. In October 2009, AstraZeneca commenced patent infringement litigation against Lupin in the US District Court for the District of New Jersey. In March 2010, the Court stayed the Lupin

patent infringement litigation. In view of the settlement with DRL in January 2011, the Court has also referred the Lupin matter back to Magistrate Judge Bongiovanni for scheduling and further proceedings.

#### 505(b)(2) New Drug Application for esomeprazole strontium capsules

As previously disclosed, in December 2010, AstraZeneca received a Paragraph IV Certification notice-letter from Hanmi USA Inc. (Hanmi) stating that it had submitted a New Drug Application under section 505(b)(2) for FDA approval to market 20 and 40mg esomeprazole strontium capsules. Hanmi alleges non-infringement or invalidity of 11 patents listed in the FDA's Orange Book with reference to Nexium. AstraZeneca commenced a patent infringement action against Hanmi in the United States District Court for the District of New Jersey in February 2011.

#### Patent litigation – Canada

As previously disclosed, AstraZeneca commenced a patent infringement action against Apotex Inc. (Apotex) in October 2010. Trial is set to begin in September 2013. In response to indications in the Canadian market that Apotex launched its generic esomeprazole magnesium product on March 7, 2011, AstraZeneca brought a motion for interim and interlocutory injunctions on March 11, 2011 to prevent such sales pending determination of the patent infringement action between the parties. On April 19, 2011 the Canadian Federal Court conducted a hearing on the motion. The Court reserved judgment.

In March 2011, Apotex served AstraZeneca with a claim for damages pursuant to Section 8 of the Patented Medicines (Notice of Compliance) Regulations. AstraZeneca is considering its response.

#### Patent Litigation – EU: 10-year countries

In the UK, Consilient Health Limited (Consilient) was granted approval for a generic esomeprazole product manufactured by Krka, d.d., Novo Mesto (Krka) in Slovenia. AstraZeneca initiated infringement proceedings against both companies in September 2010. Consilient and Krka have agreed not to launch their product pending the outcome of the main infringement case and AstraZeneca has undertaken to be liable for losses of the defendants and third parties if the injunction is lifted at a later date. The trial will start on January 23, 2012.

In the UK, in October 2010 AstraZeneca was served an invalidity case in which Ranbaxy (UK) Ltd (Ranbaxy UK) claimed that the Nexium esomeprazole magnesium patent (EP 1020461) and the esomeprazole magnesium trihydrate patent (EP 0984957) are invalid in the UK. Ranbaxy UK further requested the court to confirm that its generic esomeprazole product does not infringe either patent if launched in the UK. In March 2011 AstraZeneca filed suit against Ranbaxy UK claiming that its generic esomeprazole product infringes the Nexium esomeprazole magnesium patent (EP 1020461). The trial of the non-infringement part will commence on June 7, 2011. The invalidity part has been stayed pending the non-infringement trial.

In Germany, in December 2010 the court rejected AstraZeneca's request for preliminary injunctions to prevent Krka, d.d., Novo Mesto, TAD Pharma GmbH, Abz-Pharma GmbH, CT Arzneimittel GmbH, ratiopharm GmbH, Teva GmbH, Hexal AG and Sandoz Pharmaceuticals GmbH from marketing and selling generic esomeprazole products in Germany. The decision was published in March 2011. AstraZeneca has decided not to appeal.

In Italy, in the Court of Turin, EG s.p.a. (a company in the Stada group) (EG) filed a law suit in June 2010 claiming the Nexium esomeprazole magnesium patent (EP 1020461) as invalid in Italy. These proceedings are in early stages. AstraZeneca has added a counterclaim of infringement against EG and in February 2011, AstraZeneca filed a request for and received a preliminary injunction against EG. The injunction was revoked in April 2011.

In February and March 2011, in the District Court of Trieste, AstraZeneca was granted preliminary injunctions against Teva Italia s.r.l., ratiopharm GmbH, ratiopharm Italia s.r.l., Doc Generici s.r.l., Sandoz Pharmaceuticals GmbH, Sandoz s.p.a. and Mylan s.p.a. The generic companies appealed and in March 2011 the injunctions were revoked. In February and March 2011 in Milan, generic companies including Mylan s.p.a., Sandoz s.p.a., Crinos s.p.a., Ranbaxy Italia s.p.a., Zentiva ks and Zentiva Italia s.r.l. initiated preliminary proceedings for declaratory judgments of non-infringement regarding esomeprazole magnesium patent (EP 1020461). Initial hearings are scheduled for May 2011. In February in Trieste, Mylan s.p.a. filed law suits claiming the Nexium esomeprazole magnesium patent (EP 1020461) and Nexium formulation patent (EP 0984773) as invalid in Italy. Separate hearings are set for July 13, 2011 and July 15, 2011 respectively.

In France, ratiopharm GmbH and Laboratoire ratiopharm S.A. (together ratiopharm) filed a law suit against AstraZeneca in August 2010 claiming the Nexium esomeprazole magnesium patent (EP 1020461) as invalid in France. ratiopharm has since withdrawn this law suit. Ethypharm S.A. filed a law suit against AstraZeneca in August 2010 claiming the Nexium esomeprazole magnesium patent (EP 1020461) and a cloud-point formulation patent (EP 1124539) as invalid in France. The next hearing in these cases will be in June 2011. In February 2011, Mylan S.A.S. filed a law suit against AstraZeneca claiming the Nexium esomeprazole magnesium patent (EP 1020461) as invalid in France. In April 2011, AstraZeneca filed a patent infringement suit against Ethypharm S.A. for infringement of the Nexium esomeprazole magnesium patent (EP1020461) and the Nexium process patent (EP 0773940) and requested a preliminary injunction against Ethypharm S.A. A preliminary injunction hearing is scheduled for May 2011.

#### Patent Litigation – EU: 6-year countries

In Denmark, in 2010, the court granted AstraZeneca preliminary injunctions preventing Sandoz from continuing to sell the product based on infringement of the Nexium esomeprazole magnesium patent (EP 1020461) and the Nexium process patent (EP 0773940). The injunctions were upheld by the Appeal Court in February 2011.

In Austria, in February 2011, the court denied AstraZeneca's request for preliminary injunction to prevent ratiopharm Arzneimittel Vertriebs-GmbH from marketing and selling generic esomeprazole magnesium product in Austria. AstraZeneca has appealed this decision.

In Finland in March 2011, AstraZeneca initiated a declaratory action requesting the District Court of Helsinki to confirm that Krka Sverige AB and ratiopharm GmbH would infringe a patent relating to esomeprazole if they were to commercialise generic esomeprazole magnesium products in Finland. AstraZeneca initiated a similar declaratory action against Ranbaxy (UK) Limited in December 2009 and the trial has been scheduled for May 25 and 26 2011.

In Spain, AstraZeneca's request for a preliminary injunction against Sandoz Farmacéutica S.A., Bexal Farmacéutica S.A., and Acost Comercial Genericpharma, S.L. (all in the Sandoz group) was initially granted by the court but revoked in July 2010 after a hearing. AstraZeneca has appealed this ruling and awaits the appellate decision. Separately, in AstraZeneca's main patent infringement action against Sandoz Farmacéutica S.A., Bexal Farmacéutica S.A., and Acost Comercial Genericpharma, S.L., trial is scheduled for September 2011.

In Ireland, in August 2010, AstraZeneca initiated a main action against Krka, d.d., Novo Mesto and Pinewood Laboratories Ltd claiming that the sale and marketing of their generic esomeprazole magnesium products infringes the Nexium esomeprazole magnesium patent (EP 1020461). The defendants have filed a counter action claiming that EP 1020461 is invalid in Ireland.

In Lithuania and Estonia in March 2011, the Appeal Courts upheld the interlocutory injunctions against Krka, d.d., Novo Mesto to restrain this company from commercializing generic magnesium esomeprazole product in Lithuania and Estonia.

#### Patent litigation – Norway

In Norway, in July 2008 Hexal AG, Sandoz AS and Sandoz A/S initiated an invalidity case regarding two esomeprazole-related patents. In December 2009, the Court of Oslo invalidated a formulation patent but upheld a substance patent related to esomeprazole. In March 2011 the Appeal Court confirmed the decision from the Court of Oslo.

#### Patent Proceedings

As previously disclosed, the European Patent Office (EPO) published the grant of two patents that relate to Nexium (EP 1020461) and Nexium i.v. (EP1020460) in July 2009. The period for filing Notices of Opposition to the grant of these new patents expired in April 2010. Thirteen Notices of Opposition have been filed in relation to EP 1020461 and six Notices of Opposition in relation to EP 1020460. The EPO has now issued summonses to attend oral hearing proceedings relating to both sets of oppositions. Oral proceedings relating to EP 1020461 will be held on June 7, 8 and 9, 2011. Oral proceedings relating to EP 1020460 will be held on June 30 and July 1, 2011.



#### Pulmicort Respules (budesonide inhalation suspension)

In January 2011, the Court of Appeals for the Federal Circuit denied Apotex Group's petition for an en banc rehearing of their appeal of the preliminary injunction entered by the US District Court for the District of New Jersey.

In March 2011, the Court ordered the patent case against Sandoz, Inc. to be consolidated with the already consolidated actions against Breath Ltd. (now Watson Pharmaceuticals, Inc.) and the Apotex Group. A new scheduling order for the consolidated cases was subsequently entered by the Court. No trial date has been set.

#### Seroquel (quetiapine fumarate)

##### Sales and marketing practices

In March 2011, AstraZeneca completed a previously announced settlement in principle to resolve Seroquel-related consumer protection and deceptive trade practice claims under state law with 37 states and Washington, DC as part of the National Association of Attorneys General for \$68.5 million in the aggregate (as to which AstraZeneca previously had established a provision).

As previously disclosed, the states of Alaska, Arkansas, Mississippi, Montana, New Mexico, South Carolina and Utah have sued AstraZeneca under various state laws generally alleging that AstraZeneca made false and/or misleading statements in connection with the marketing and promotion of Seroquel. In February 2011, the state of Utah filed an amended complaint after a federal judge had dismissed its complaint in December 2010.

In March 2011, the US Court of Appeals for the Eleventh Circuit affirmed the November 2008 dismissal by the Seroquel Multi-District Litigation (MDL) court of a putative nationwide class action lawsuit brought on behalf of all individual and non-governmental third-party payers of Seroquel, which had alleged that AstraZeneca promoted Seroquel for off-label uses and misled class members into believing that Seroquel was superior to lower-cost alternative medicines.

##### Product liability

As of March 31, 2011, approximately 26,085 claims have been settled in principle.

As of March 31, 2011, AstraZeneca was aware of approximately 2,600 Seroquel US product liability claims that have not been settled in principle. The majority of these remaining claims are pending in the New Jersey, New York and California state courts, although some claims are pending in a handful of other state courts and in the federal MDL.

As of March 31, 2011, legal defense costs of approximately \$743 million have been incurred in connection with Seroquel-related product liability claims. As previously disclosed, AstraZeneca settled its claims against several of its insurers for a substantial part of those legal defense costs.

As previously disclosed, disputes continue with other insurers about the availability of coverage under certain insurance policies for legal defense costs and potential damages amounts. As of March 31, 2011, out of the legal defense costs of \$743 million mentioned above, AstraZeneca believes that approximately \$128 million is covered by these other insurance policies.

##### Patent litigation – Brazil

As previously disclosed, in January 2006 AstraZeneca filed a lawsuit before the Federal Courts of Rio de Janeiro seeking judicial declaration extending the term of one of its patents from 2006 to 2012. In March 2011, the Federal Courts of Rio de Janeiro denied AstraZeneca's request for an extension. AstraZeneca has decided not to appeal.

Seroquel XR

Patent litigation – US

As previously disclosed, in December 2010, Torrent Pharmaceuticals Ltd. (Torrent) filed a Motion for Clarification and Reconsideration of the decision by the US District Court for the District of New Jersey interpreting claims of the Seroquel XR formulation patent (US patent no. 5,948,437). In February 2011, the Court denied Torrent's motion.

As previously disclosed, in July 2010, AstraZeneca received a Paragraph IV Certification notice-letter from Osmotica Pharmaceutical Corporation (Osmotica) indicating that it was seeking approval to market generic versions of 200, 300 and 400mg Seroquel XR tablets before the expiration of US Patent No. 5,948,437 (the '437 patent). In August 2010, AstraZeneca filed a law suit in the US District Court for the District of New Jersey against Osmotica. In April 2011, AstraZeneca received another Paragraph IV Certification notice-letter from Osmotica indicating that it was seeking approval to market generic versions of 50 and 150mg Seroquel XR tablets before the expiration of the '437 patent.

As previously disclosed, in October 2010 AstraZeneca received a Paragraph IV Certification notice-letter from Mylan Pharmaceuticals Inc. (Mylan) indicating that it was seeking approval to market generic versions of 200mg Seroquel XR tablets before the expiration of the '437 patent. In October 2010, AstraZeneca filed a lawsuit in the US District Court for the District of New Jersey against Mylan. In April 2011, AstraZeneca received another Paragraph IV Certification notice-letter from Mylan indicating that it was seeking approval to market generic versions of 50, 150, 300 and 400 mg Seroquel XR tablets before expiration of the '437 patent.

#### Patent litigation – EU

In the UK, Teva UK Limited and Teva Pharmaceuticals Limited (together, Teva) issued revocation proceedings against AstraZeneca in December 2010. Teva claims that the formulation patent for Seroquel XR (EP 0907364) is invalid in the UK. Similar revocation actions were filed by Accord Healthcare Limited, Intas Pharmaceuticals Limited, Hexal AG and Sandoz Ltd in March and April 2011.

In Hungary, AstraZeneca was notified that Teva Pharmaceuticals Limited and Teva Gyógyszergyár Zrt (together Teva) had filed a request for nullity of the Hungarian formulation patent for Seroquel XR with the Hungarian Patent Office in January 2011. Teva claims that Hungarian patent no. 225 152 should be declared null and void. AstraZeneca is preparing its response.

In Germany, Teva Deutschland GmbH (Teva) issued revocation proceedings against AstraZeneca in February 2011. Teva claims that the formulation patent for Seroquel XR (EP 0907364) is invalid in Germany. AstraZeneca filed its response in March 2011.

#### Synagis (palivizumab)

As previously disclosed, this matter concerned MedImmune's action seeking a declaratory judgment that the Queen patents owned by PDL BioPharma, Inc. (PDL) are invalid and/or not infringed by either Synagis and/or motavizumab, and that no further royalties are owed under a patent license that MedImmune and PDL signed in 1997. The matter was settled in February 2011 with PDL agreeing to pay MedImmune \$92.5 million (\$65 million in February 2011 and \$27.5 million in February 2012). In addition, PDL agreed to the release of approximately \$9 million in escrow to MedImmune. MedImmune will pay no further royalties to PDL relative to Synagis.

#### Vimovo (fixed-dose combination of naproxen and esomeprazole)

In April 2010, the FDA approved Vimovo for marketing in the US. Vimovo was co-developed by POZEN Inc. (Pozen) and AstraZeneca via a collaboration agreement originating in August 2006. AstraZeneca commenced marketing of Vimovo in the US in the third quarter of 2010. Seven patents are listed in the FDA's Orange Book referencing Vimovo.

In March 2011, the FDA's web-site reported a filing of a first Abbreviated New Drug Application (ANDA) containing Paragraph IV Certifications and seeking approval to market generic copies of the 375/20 mg and 500/20 mg doses of

Vimovo.

On March 14, 2011, AstraZeneca received a Paragraph IV Certification Notice-letter in respect of Vimovo from Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (together, DRL). DRL certified under Paragraph IV in its ANDA that US Patent No. 6,926,907 (the '907 patent) is invalid, unenforceable, and/or not infringed. AstraZeneca licenses the '907 patent from Pozen and, with a February 2023 expiry, the patent is the last expiring of the seven Orange Book listed patents. On April 21, 2011, AstraZeneca and Pozen sued DRL in the US District Court for the District of New Jersey.

Zomig (zolmitriptan)

Patent litigation – Canada

In April 2011, AstraZeneca received a Notice of Allegation from Apotex Inc. (Apotex) in respect of Canadian Zomig product-by-process patent no. 2,572,508 listed on the Canadian Patent Register for Zomig. Apotex did not address the listed 2,064,815 substance patent (the '815 patent), which expires in June 2011. Therefore, Apotex cannot receive a marketing approval before expiration of the '815 patent. AstraZeneca is evaluating the allegations.

Other Commercial Litigation

Dr. George Pieczenik v. AstraZeneca Pharmaceuticals LP, AstraZeneca LP, et al

On March 23, 2011, the District Court granted the defendants' joint motion to dismiss the plaintiff's claims with prejudice. On March 24, 2011 the plaintiff filed a pro forma Notice of Appeal from the order granting dismissal of the patent infringement and Racketeering Institution and Corrupt Organisation Act claims and denying the motion for recusal.

Resonant Biotechnologies, LLC v. AstraZeneca LP, et al.

In April 2011, AstraZeneca LP, a number of AstraZeneca entities (collectively AstraZeneca) and multiple other entities were named in a patent infringement lawsuit filed in the United States District Court for the District of Delaware. Plaintiff purports to be the exclusive licensee of US patent no. 6,218,194 (the '194 Patent) which is titled "Analytical Methods And Apparatus Employing An Optical Sensor Device With Refractive Index Modulation." Specific to AstraZeneca, Plaintiff alleges that AstraZeneca infringes the '194 patent "by using the Corning Epic® system", described in the complaint as a "high-throughput label-free screening device." Plaintiff seeks monetary relief. AstraZeneca is considering its response.

Network Signatures, Inc. v. AstraZeneca Pharmaceuticals LP

In April 2011, AstraZeneca Pharmaceuticals LP was named in a patent infringement law suit filed in the United States District Court for the Central District of California. The plaintiff purports to have title to United States Patent No. 5,511,122 (the '122 patent) entitled "Intermediate Network Authentication." The plaintiff alleges that AstraZeneca's use of "digital certificates and digital signatures implemented through the use of public key infrastructure to facilitate communication with its employees and customers" infringes the '122 patent. The plaintiff seeks monetary and injunctive relief. AstraZeneca is considering its response.

Other Pricing Litigation

Average Wholesale Price Litigation

In February 2011, the US District Court for the District of Massachusetts granted final approval of two previously announced settlements that resolve class action law suits brought by Massachusetts-only and multi-state classes of payers of Zoladex for \$13 million and \$90 million, respectively (which amounts have been paid by AstraZeneca).

340B Class Action Litigation

In March 2011, the US Supreme Court reversed a decision of the US Court of Appeals for the Ninth Circuit and held that covered entities under the 340B program do not have enforceable rights to sue as third party beneficiaries of the Pharmaceutical Pricing Agreement, thereby dismissing this case and entitling AstraZeneca, and the other defendants, to judgment as a matter of law.

Other Anti-trust Litigation and Investigations

Drug importation anti-trust litigation

As previously disclosed, in August 2004, Californian retail pharmacy plaintiffs filed an action in the Superior Court of California alleging a conspiracy by AstraZeneca and approximately 15 other pharmaceutical manufacturer defendants to set the price of drugs sold in California at or above the Canadian sales price for those same drugs and otherwise restrict the importation of pharmaceuticals into the US.

In March 2011, the Superior Court of California granted the defendants' motion for summary judgment on grounds that the plaintiffs failed to prove their allegations of a conspiracy and that the defendants were entitled to judgment as a matter of law. In April 2011, the plaintiffs appealed the decision to the Court of Appeal of the State of California.

Other Actual and Threatened Government Investigations and Related Litigation

Foreign Corrupt Practices Act

As previously disclosed, AstraZeneca has received inquiries from the US Department of Justice and the Securities and Exchange Commission in connection with an investigation into Foreign Corrupt Practices Act issues in the pharmaceutical industry across several countries. AstraZeneca is co-operating with these inquiries and is investigating, among other things, sales practices, internal controls, certain distributors, and interactions with healthcare providers, institutions, and other government officials. AstraZeneca is investigating inappropriate conduct in certain countries, including China. AstraZeneca's investigations are ongoing and additional governmental authorities could become involved. It is not currently possible to predict the scope, duration or outcome of these matters, which could involve the payment of fines or other penalties.

Tax

Transfer pricing and other international tax contingencies

On March 28, 2011 AstraZeneca announced that HM Revenue & Customs in the UK and the US Internal Revenue Service had agreed the terms of an Advance Pricing Agreement regarding transfer pricing arrangements for AstraZeneca's US business covering the 13 year period from 2002 to the end of 2014. The Company also announced that an agreement had been reached on a related valuation matter arising on integration of the legacy Astra and legacy Zeneca US businesses in 2000 following the global AstraZeneca merger in 1999. The provision for US transfer pricing and related valuation matters is a substantial proportion of the total net accrual for transfer pricing and other international tax contingencies of \$2,310 million disclosed under the heading "Financial Statements—Notes to the Financial Statements—Note 25—Commitments and contingent liabilities" on page 195 of the Company's "Annual Report and Form 20-F Information 2010" included as exhibit 15.1 to this Form 20-F dated April 28, 2011, incorporated by reference.

Based on the above mentioned agreements, AstraZeneca now expects to pay a net amount of \$1.1 billion to resolve all US transfer pricing and related valuation matters for the period from 2000 to the end of 2010 and \$540 million of provisions have been released to earnings in the first quarter of 2011. The net amount payable of \$1.1 billion reflects expected US tax payments and updated estimates of corresponding tax refunds in other jurisdictions.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The information set forth under the headings "Corporate Governance—Board of Directors and Senior Executive Team—Board of Directors at 31 December" and "—Board of Directors and Senior Executive Team—Senior Executive Team at 31 December" on pages 106 and 107, and page 108, respectively, "Corporate Governance—Directors' Remuneration Report—Policy on external appointments and retention of fees" on page 128 and "—Directors' Remuneration Report—Directors' emoluments in 2010—Directors' remuneration-US dollars" (last sentence only) on page 130, in each case of the Company's "Annual Report and Form 20-F Information 2010" included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

B. Compensation

The information (including graphs and tabular data) set forth under the headings "Corporate Governance—Directors' Remuneration Report" on pages 119 to 134, "Financial Statements—Notes to the Financial Statements—Note 18—Post-retirement benefits" on pages 162 to 166, "—Note 24—Employee costs and share option plans for employees" on pages 173 to 177 and "—Note 27—Statutory and other information—Key management personnel compensation", on page 196 in each case of the Company's "Annual Report and Form 20-F Information 2010" included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

C. Board Practices

The information (including tabular data) set forth under the headings "Corporate Governance—Board of Directors and Senior Executive Team—Board of Directors at 31 December" and "—Senior Executive Team at 31 December" on pages 106 and 107, and page 108, respectively, "Corporate Governance—Corporate Governance Report—Leadership" on pages 109 to 110, "—Board effectiveness" on pages 110 to 111, "—Board Committee membership" (consisting of tabular data) on page 112 "—Audit Committee" on pages 113 to 114, "—Remuneration Committee", "—Nomination and Governance Committee" and "—Science Committee", each on page 115, "—Business organization—Compliance and Group Internal Audit (GIA)" on pages

116 and 117, “Corporate Governance—Directors’ Remuneration Report—Service contracts” and “—Non-Executive Directors’ terms and conditions” each on page 128, and “—Directors’ Remuneration Report—Audit—Details of Executive Directors’ service contracts at 31 December 2010” and “—Non-Executive Directors’ terms and conditions” each on page 129, in each case of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.



Jane Henney, who is a current Non-Executive Director of the Company, will not present herself for re-election at the Company's 2011 Annual General Meeting, which is being held on the date of this Form 20-F, and will leave the Company's Board of Directors at the close of the Annual General Meeting.

#### D. Employees

The information set forth under the headings "Business Review—Delivering our strategy—People" (comprising the graphical data, and the final two paragraphs set forth under "Simplifying our organizational design" only) on pages 36 and 38 respectively, "Business Review—Delivering our strategy—Research and Development—Our resources" (first and second paragraph only) on pages 29 to 30, "Business Review—Delivering our strategy—Supply and Manufacturing—Our resources" (second paragraph only) on page 35, and "Financial Statements—Notes to the Financial Statements—Note 24—Employee costs and share option plans for employees—Employee costs" (including the tabular data) on page 173, in each case of the Company's "Annual Report and Form 20-F Information 2010" included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

#### E. Share Ownership

The information (including graphs and tabular data) set forth under the headings "Financial Statements—Notes to the Financial Statements—Note 24—Employee costs and share option plans for employees" on pages 173 to 177, "Corporate Governance—Corporate Governance Report—Other matters—Directors' shareholdings" on page 117, "Corporate Governance—Directors' Remuneration Report—Directors' interests in shares" on pages 132 to 134, and "Additional Information—Shareholder Information—Options to purchase securities from registrant or subsidiaries" on page 213, in each case of the Company's "Annual Report and Form 20-F Information 2010" included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

### ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

#### A. Major Shareholders

The information set forth under the heading "Additional Information—Shareholder Information—Major shareholdings" (including tabular data) on pages 212 to 213 of the Company's "Annual Report and Form 20-F Information 2010" included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

#### B. Related Party Transactions

The information set forth under the headings "Financial Statements—Notes to the Financial Statements—Note 27—Statutory and Other Information—Related party transactions" on page 196 and "Additional Information—Shareholder Information—Related party transactions" on page 213, in each case of the Company's "Annual Report and Form 20-F Information 2010" included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

#### C. Interests of Experts and Counsel

Not applicable.

### ITEM 8. FINANCIAL INFORMATION

#### A. Consolidated Statements and Other Financial Information

The information (including graphs and tabular data) set forth under the headings “Financial Statements” on pages 138 to 196 (including the information set forth under the subheading “Notes to the Financial Statements”), “Financial Statements—Principal Subsidiaries” on page 197, “Financial Statements—Group Financial Record” on page 204, “Additional Information—Shareholder Information” on pages 211 to 215, “Business Review—Financial Review—Capitalization and shareholder return—Dividend and share repurchases” on page 87 and “Corporate Governance—Corporate Governance Report—Other matters—Distributions to shareholders and dividends for 2010” on page 117, in each case of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

Please see the information above under the heading Item 5 – “Operating and Financial Review and Prospects—Developments in Legal Proceedings” for information as to recent developments in certain legal proceedings disclosed under the heading “Financial Statements—Notes to the Financial Statements—Note 25—Commitments and contingent liabilities” on pages 178 to 195 of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011.

#### B. Significant Changes

Please see the information above under the heading Item 5 – “Operating and Financial Review and Prospects—Developments in Legal Proceedings” for information as to recent developments in certain legal proceedings disclosed under the heading “Financial Statements—Notes to the Financial Statements—Note 25—Commitments and contingent liabilities” on pages 178 to 195 of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011.

Other than as disclosed herein, since the date of the annual consolidated financial statements included in this Form 20-F dated April 28, 2011, no significant change has occurred.

### ITEM 9. THE OFFER AND LISTING

#### A. Offer and Listing Details

The information (including graphs and tabular data) set forth under the heading “Additional Information—Shareholder Information—AstraZeneca PLC share listings and prices” on pages 211 to 212 of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

In addition, the table below sets forth, for the periods indicated, the reported high and low share prices of AstraZeneca PLC, on the following bases:

- for shares listed on the London Stock Exchange (LSE) the reported high and low middle market closing quotations are derived from the Daily Official List;
- for shares listed on the Stockholm Stock Exchange (SSE) the high and low closing sales prices are as stated in the Official List; and
- for American Depositary Shares (ADS) listed on the New York Stock Exchange the reported high and low sales prices are as reported by Dow Jones (ADR quotations).

	Ordinary LSE		AstraZeneca ADS		Ordinary SSE(1)	
	High (GB pence)	Low (GB pence)	High (US\$)	Low (US\$)	High (SEK)	Low (SEK)
2011 – March	2,987	2,802	48.82	45.40	307.2	289.0
2011 – February	3,035	2,933	49.38	47.56	315.3	303.9
2011 – January	3,074	2,923	48.90	46.36	320.6	310.1
2010 – December	3,153	2,922	49.28	45.80	336.5	309.3
2010 – November	3,144	2,996	50.34	46.93	336.9	325.7
2010 – October	3,359	3,130	53.50	50.43	354.7	336.7

	Ordinary LSE		AstraZeneca ADS		Ordinary SSE(1)	
	High (GB pence)	Low (GB pence)	High (US\$)	Low (US\$)	High (SEK)	Low (SEK)
2010	3,385	2,732	53.50	40.91	382.2	309.3
2010 – Quarter 4	3,359	2,922	53.50	45.80	354.7	309.3
2010 – Quarter 3	3,385	3,052	53.41	47.05	382.2	345.0
2010 – Quarter 2	3,169	2,772	48.74	40.91	368.0	314.0
2010 – Quarter 1	3,103	2,732	50.40	43.05	363.8	310.1
2009	2,947	2,147	47.54	30.24	365.0	261.5
2009 – Quarter 4	2,930	2,691	47.00	43.64	339.5	308.0
2009 – Quarter 3	2,878	2,644	47.54	43.01	356.0	305.0
2009 – Quarter 2	2,728	2,276	45.01	33.40	351.0	279.5
2009 – Quarter 1	2,947	2,147	41.60	30.24	331.0	261.5
2008	2,888	1,748	49.85	34.10	340.5	211.5
2007	2,984	2,093	59.04	42.82	414.0	272.0
2006	3,529	2,574	66.37	45.12	484.0	352.5

(1) Principally held in bearer form.

#### B. Plan of Distribution

Not applicable.

#### C. Markets

The information set forth under the heading “Additional Information—Shareholder Information—AstraZeneca PLC share listings and prices” on pages 211 to 212 of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

#### D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

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B. Memorandum and Articles of Association

The information set forth under the heading “Additional Information—Corporate Information—Articles” on page 216 of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

C. Material Contracts

Not applicable.

D. Exchange Controls

The information set forth under the headings “Additional Information—Shareholder Information—Exchange controls and other limitations affecting security holders” on page 215 of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

E. Taxation

The information set forth under the headings “Additional Information—Shareholder Information—Taxation for US residents”, “—UK and US income taxation of dividends”, “—Taxation on capital gains”, “—Passive Foreign Investment Company (PFIC) rules”, “—UK inheritance tax” and “—UK stamp duty reserve tax and stamp duty” on pages 214 to 215 of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

The information set forth under the heading “Additional Information—Shareholder Information—Documents on display” on page 214 of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

In addition, we file reports and other information with the United States Securities and Exchange Commission (the “SEC”). You can read and copy these reports and other information at the SEC’s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You can call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. The SEC also maintains a website at [www.sec.gov](http://www.sec.gov) which contains in electronic form each of the reports and other information that we have filed electronically with the SEC.

I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The information (including graphs and tabular data) set forth under the headings “Business Review—Financial Review—Financial risk management” on page 90 and “Financial Statements—Note 23—Financial risk management objectives and policies” on pages 168 to 172, in each case of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Fees and Charges Payable by ADR Holders

The Company's American Depositary Receipt ("ADR") program is administered by JPMorgan Chase Bank, N.A. ("J.P. Morgan"), as the depositary. The holder of an ADR may have to pay the following fees and charges to J.P. Morgan in connection with ownership of the ADR:

Category	Depositary actions	Associated fee or charge
(a) Depositing or substituting the underlying shares	Issuances against deposits of shares, including deposits and issuances pursuant to a stock dividend or stock split declared by the Company or issuances pursuant to a merger, exchange of securities or any other transaction or event affecting the American Depositary Shares ("ADSs") or the deposited securities	Up to US \$5.00 for each 100 ADSs (or portion thereof) issued or delivered (as the case may be)  The depositary may sell (by public or private sale) sufficient securities and property received in respect of share distributions, rights and other distributions prior to such deposit to pay such charge
(b) Receiving or distributing dividends(1)	Cash distributions made pursuant to the deposit agreement	US \$0.05 or less per ADS
(c) Selling or exercising rights	Distribution or sale of securities, the fee being in an amount equal to the fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities	Up to US \$5.00 for each 100 ADSs (or portion thereof)
(d) Withdrawing, cancelling or reducing an underlying security	Acceptance of ADSs surrendered for withdrawal, cancellation or reduction of deposited securities	Up to US \$5.00 for each 100 ADSs (or portion thereof) surrendered, cancelled or reduced (as the case may be)  The depositary may sell (by public or private sale) sufficient



securities and property received  
in respect of share distributions,  
rights and other distributions  
prior to such deposit to pay  
such charge

(e) Transferring, combination or split-up of receipts	Transfer, combination and split-up of ADRs	US \$1.50 per ADR
(f) General depositary services, particularly those charged on an annual basis(1)	Services performed by the depositary in administering the ADRs	US \$0.05 or less per ADS per calendar year (or portion thereof), payable at the sole discretion of the depositary by billing ADR holders or by deducting such charge from one or more cash

Category	Depository actions	Associated fee or charge
(g) Fees and expenses of the depository	<p>Fees and expenses incurred by the depository or the depository's agents on behalf of holders, including in connection with:</p> <ul style="list-style-type: none"> <li>· compliance with foreign exchange control regulations or any law or regulation relating to foreign investment</li> <li>· stock transfer or other taxes and governmental charges</li> <li>· cable, telex and facsimile transmission and delivery charges</li> <li>· fees for the transfer or registration of deposited securities in connection with the deposit or withdrawal of deposited securities</li> <li>· expenses of the depository in connection with the conversion of foreign currency into US dollars</li> <li>· any other charge payable by the depository or the depository's agents in connection with the servicing of the shares or other deposited securities (which charge shall be assessed against holders as of the record date or dates set by the depository)</li> </ul>	<p>dividends or other cash distributions</p> <p>Expenses payable at the sole discretion of the depository by billing ADR holders or by deducting such charges from one or more cash dividends or other cash distributions</p>

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(1) J.P. Morgan has agreed that it shall not charge ADR holders any of these fees without the Company's prior written consent. No such fees have been charged for the year ended December 31, 2010 or from January 1, 2011 to the

date hereof.

Fees and Payments Made by the Depositary to us

J.P. Morgan, as ADR depositary, has agreed to reimburse certain expenses related to the Company's ADR program and incurred by the Company in connection with the program. For the year ended December 31, 2010, the ADR depositary reimbursed to the Company, or paid on its behalf to third parties, a total sum of US \$1,605,085 (comprised of reimbursements of US \$1,524,267 and payments to third parties of US \$80,818, in each case as detailed in the tables below). The ADR depositary also waived certain of its fees for standard costs associated with the administration of the ADR program in a total amount of US \$215,000.

The table below sets forth the types of expenses that the ADR depositary has agreed to reimburse and the amounts reimbursed within each such category for the year ended December 31, 2010:

Category of Expenses – Direct Payments	Reimbursement for the year ended December 31, 2010
ADR program expenses, including investor relations costs and legal fees	\$ 1,524,267

Category of Expenses – Direct Payments	Reimbursement for the year ended December 31, 2010
<b>Total</b>	<b>\$ 1,524,267</b>

The ADR depository has paid certain expenses directly to third parties on behalf of the Company and has agreed to waive certain of its fees for standard costs associated with the administration of the ADR program. The table below sets forth those expenses that the ADR depository paid directly to third parties, and those fees waived, in each case for the year ended December 31, 2010.

Category of Expenses – Indirect Payment	Amount paid for the year ended December 31, 2010
Expenses paid by depository to third parties on behalf of the Company – NYSE listing fees	\$ 80,818
Fees waived by depository for standard ADR program costs	\$ 215,000
<b>Total</b>	<b>\$ 295,818</b>

Under certain circumstances, including removal of the ADR depository or termination of the ADR program by the Company, the Company is required to repay the ADR depository certain amounts reimbursed and/or expenses paid to or on behalf of the Company. No such repayments were made during the year ended December 31, 2010.

## PART II

### ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

- (a) There has been no material default in payment of principal, interest, a sinking or purchase fund installment, or any other material default with respect to any indebtedness of the Company or any of its significant subsidiaries.
- (b) There have been no arrears in the payment of dividends on, and no material delinquency with respect to, any class of preferred stock of any significant subsidiary of the Company.

### ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Not applicable.

### ITEM 15. CONTROLS AND PROCEDURES

The information set forth under the heading “Corporate Governance—Corporate Governance Report—Accountability” on pages 111 and 112, “—Audit Committee” on page 114 (the last four paragraphs of the “Audit Committee” section only, excluding the “Code of Conduct” section), “—US corporate governance requirements” on page 115 (the first and second paragraphs of the “US corporate governance requirements” section only) and “Financial Statements—Directors’ Responsibilities for, and Report on, Internal Control over Financial Reporting” on page 136, in each case of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28,

2011 is incorporated by reference.

Management's Annual Report on Internal Control over Financial Reporting

As required by US regulations, management is responsible for establishing and maintaining adequate internal control over financial reporting for the company, and is required to identify the framework used to evaluate the effectiveness of the Company's internal control over financial reporting and to assess the effectiveness of such internal control. In this regard, management has made the same assessment and reached the same conclusion as that set forth in the section entitled "Financial Statements—Director's Responsibilities for, and Report on, Internal Control over Financial Reporting" on page 136 of the Company's "Annual Report and Form 20-F Information 2010" included as exhibit 15.1 to this Form 20-F dated April 28, 2011, which is incorporated herein by reference.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders  
AstraZeneca PLC:

We have audited AstraZeneca PLC's ("AstraZeneca") internal control over financial reporting as of 31 December 2010, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). AstraZeneca's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, AstraZeneca maintained, in all material respects, effective internal control over financial reporting as of 31 December 2010, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the PCAOB, the consolidated statements of financial position of AstraZeneca and subsidiaries as of 31 December 2010, 2009 and 2008, and the related consolidated statements of comprehensive income, changes in equity, and cash flows for each of the years in the three-year period ended 31 December 2010, and our report dated 27 January 2011 expressed an unqualified opinion on those consolidated financial statements.

KPMG Audit Plc  
15 Canada Square

London  
United Kingdom  
E14 5GL

27 January 2011

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## ITEM 16. RESERVED

## ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

The information set forth under the heading “Corporate Governance—Corporate Governance Report—Board Committee membership” (consisting of tabular data) on page 112 and in the first paragraph under the heading “—Audit Committee” on page 113, in each case of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

## ITEM 16B. CODE OF ETHICS

The information set forth under the heading “Corporate Governance—Corporate Governance Report—Audit Committee—Code of Conduct” on page 114 of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

The Company’s Code of Conduct is available at [www.astrazeneca.com](http://www.astrazeneca.com).

## ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Audit Fees	Year ended December 31,	
	2010	2009
	(\$ million)	
Audit Fees	2.3	2.4
Audit-Related Fees	7.1	7.1
Tax Fees	1.1	1.0
All Other Fees	3.4	3.6
Total	13.9	14.1

Audit-related fees consist of \$6.5 million for the audit of subsidiaries pursuant to legislation and fees of \$0.6 million for the audit of subsidiaries’ pension schemes.

Tax fees consist of tax compliance services and, to a lesser extent, tax advice.

All other fees consist of fees of \$0.1 million for assurance services in relation to third party compliance with manufacturing and distribution agreements and advisory services supporting management in their development of competency and development frameworks for staff and fees of \$3.3 million for other services pursuant to legislation (including fees of \$2.4 million in respect of section 404 of the Sarbanes-Oxley Act).

The information (including tabular data) set forth under the heading “Corporate Governance—Corporate Governance Report—Audit Committee” (excluding the “Code of Conduct” section) on pages 113 to 114 of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

## ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.



## ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Period	(a) Total number of Shares (or units) Purchased(1)	(b) Average Price Paid per Share (or Units)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
Month #1				
Jan 1 - Jan 31	0	0	0	2.6
Month #2				
Feb 1 - Feb 28	500,000	43.62	500,000	2.6
Month #3				
Mar 1 - Mar 31	4,295,000	44.80	4,295,000	2.4

Period	(a) Total number of Shares (or units) Purchased(1)	(b) Average Price Paid per Share (or Units)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
Month # 4				
Apr 1 - Apr 30	2,634,654	44.98	2,634,654	2.3
Month #5				
May 1 - May 31	4,999,209	42.19	4,999,209	2.1
Month #6				
Jun 1 - Jun 30	3,710,000	44.67	3,710,000	1.9
Month #7				
Jul 1 - Jul 31	500,000	52.17	500,000	1.9
Month #8				
Aug 1 - Aug 31	11,010,024	51.01	11,010,024	1.3
Month #9				
Sep 1 - Sep 30	8,498,823	52.39	8,498,823	0.9
Month #10				
Oct 1 - Oct 31	3,681,746	51.93	3,681,746	0.7
Month #11				
Nov 1 - Nov 30	8,600,491	49.17	8,600,491	0.3
Month #12				
Dec 1 - Dec 31	5,261,560	47.03	5,261,560	0.0
Total	53,691,507	48.50	53,691,507	N/A

(1) All of the purchases reflected in the table above were made pursuant to our publicly announced share repurchase program, which was announced by the Company on January 28, 2010. On January 28, 2010, the Company announced that share repurchases (net of new issues) for the full year were anticipated to be approximately \$1 billion, and on July 29, 2010, announced that share repurchases (net of new issues) for the full year were to be increased to \$2 billion. On January 27, 2011, the Company announced that share repurchases (net of new issues) for the full year amounted to \$2.1 billion. Excluding new issues, share repurchases for the full year amounted to \$2.6 billion.

#### ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

#### ITEM 16G. CORPORATE GOVERNANCE

AstraZeneca PLC is a public limited company incorporated in England and Wales, listed on the London Stock Exchange and is subject to the authority of the Financial Services Authority in the UK. As a result, it follows the UK Corporate Governance Code (the “UK Code”), which came into effect for the Company as of January 1, 2011 (formerly, the UK Combined Code on Corporate Governance), in respect of its corporate governance practices. The Company has ADRs listed on the NYSE and, under the NYSE Corporate Governance Standards (the “NYSE Standards”) applicable to listed companies, as a foreign private issuer, the Company is permitted to follow the corporate governance practice of its home country in lieu of certain provisions of the NYSE Standards.

A summary of the significant ways in which the Company’s corporate governance practices differ from those followed by US domestic companies under the NYSE Standards is set forth below.

NYSE Standards

AstraZeneca Corporate Governance Practice

1. Under the NYSE Standards, the audit committee is to be directly responsible for the appointment, compensation, retention and oversight of a listed company’s external auditor, unless there is a conflicting requirement under the home country laws of the company.

Under the UK Code, a company’s external auditors are appointed by its shareholders. As a result, the Company’s audit committee is responsible for making recommendations to the Board of Directors, for the Board of Directors to propose to the Company’s shareholders in general meeting, in relation to the appointment, re-appointment and removal of the external auditors, and

NYSE Standards

AstraZeneca Corporate Governance Practice

2. NYSE Standards, the nominating/corporate governance committee and compensation committee are to be composed entirely of independent directors.

for approving the remuneration and terms of engagement of the external auditor.

Under the UK Code, a majority of the members of a company's nomination committee, and all of the members of its remuneration committee, should be independent non-executive directors.

3. Under the NYSE Standards, the compensation committee is to make recommendations to the listed company's Board of Directors with respect to non-CEO executive officer compensation and certain other compensation plans which are subject to Board approval.

The Company's Nomination and Governance Committee and Remuneration Committee each includes four members, including the chairman of the Company's Board of Directors, with the remainder all being considered by the Company's Board of Directors to be independent in accordance with the principles and criteria of the UK Code. The Company's chairman was considered to be independent upon his appointment as chairman (under the UK Code, the test of independence is not appropriate in relation to the chairman thereafter).

In compliance with the UK Code, the Company's Remuneration Committee determines the Company's global remuneration frameworks and principles, approves individual salary decisions and related matters for members of the Company's Board of Directors, Senior Executive Team ("SET") and the Company Secretary, and reviews annual bonus payments for all executives reporting directly to SET members. While the Remuneration Committee does not make initial recommendations to the Board of Directors in this respect, it does report to the Board of Directors on these matters.

4. Under the NYSE Standards, shareholders are entitled to vote on all equity compensation plans and material revisions thereto, with certain limited exemptions.

Under the listing rules of the UK Listing Authority (the "UKLA Rules"), with which the Company complies, shareholder approval is required to be obtained by the Company for the adoption of equity compensation plans which are either long-term incentive schemes in which directors of the Company can participate or schemes which may involve the issue of new shares. Under the UKLA Rules, these plans may not be changed to the benefit of the plan participants unless shareholder approval is obtained (with certain minor exceptions, for example, to benefit the administration of the

plan or to take account of tax benefits). The UKLA Rules in respect of shareholder approval regarding equity compensation plans, or any material revision thereto, may differ from the NYSE Standards.

5. Under the NYSE Standards, each listed company Chief Executive Officer must certify to the NYSE each year that he or she is not aware of any violation by the listed company of any NYSE corporate governance listing standards.

As the Company is a foreign private issuer, the Company's Chief Executive Officer is not required to make this certification. He is, however, required to promptly notify the NYSE in writing after any executive officer of the Company become aware of any non-compliance with any NYSE corporate governance rules applicable to the Company.

The information set forth under the heading “Corporate Governance—Corporate Governance Report—US corporate governance requirements” (final paragraph only) on page 115 of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

### PART III

#### ITEM 17. FINANCIAL STATEMENTS

The Company has responded to Item 18 in lieu of this item.

#### ITEM 18. FINANCIAL STATEMENTS

The information set forth in Exhibit 15.2 hereto “Report of Independent Registered Public Accounting Firm to the members of AstraZeneca PLC by KPMG Audit Plc is incorporated in this section by reference. The information (including graphs and tabular data) set forth under the headings “Financial Statements” on pages 138 to 196 (including the information set forth under the subheading “Notes to the Financial Statements” on pages 147 to 196), “Group Financial Record” on page 204 and “Principal Subsidiaries” on page 197, in each case of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011 is incorporated by reference.

Please see the information above under the heading Item 5 – “Operating and Financial Review and Prospects—Developments in Legal Proceedings” for information as to recent developments in certain legal proceedings disclosed under the heading “Financial Statements—Notes to the Financial Statements—Note 25—Commitments and contingent liabilities” on pages 178 to 195 of the Company’s “Annual Report and Form 20-F Information 2010” included as exhibit 15.1 to this Form 20-F dated April 28, 2011.

The information set out in the above-referenced financial statements does not constitute the Company’s statutory accounts under the UK Companies Acts for the years ended December 31, 2010, 2009 or 2008. Those accounts have been reported on by the Company’s auditors; their reports were unqualified and did not contain a statement under section 237(2) or (3) of the Companies Act 1985 or under section 498(2) or (3) of the Companies Act 2006. The accounts for 2009 and 2008 have been delivered to the registrar of companies and those for 2010 will be delivered in due course.

#### ITEM 19. EXHIBITS

- 1.1 Articles of Association.
- 4.1 Master Restructuring Agreement dated as of June 19, 1998 between Astra AB, Merck & Co., Inc., Astra Merck Inc., Astra USA, Inc., KB USA, L.P., Astra Merck Enterprises, Inc., KBI Sub Inc., Merck Holdings, Inc. and Astra Pharmaceuticals, L.P.(1)
- 4.2 Agreement for Service between AstraZeneca PLC and Simon Lowth, dated September 27, 2007.(2)
- 4.3 Agreement for Service between AstraZeneca PLC and David R. Brennan dated December 16, 2005 (effective as of January 1, 2006).(3)
- 4.5 Form of Deed of Indemnity for Directors.(4)

- 7.1 Statement explaining calculation of ratio of earnings to fixed charges.
- 8.1 List of subsidiaries.
- 12.1 Certification of David R. Brennan filed pursuant to 17 CFR 240.13a-14(a).

- 12.2 Certification of Simon Lowth filed pursuant to 17 CFR 240.13a-14(a).
- 13.1 Certification of David R. Brennan and Simon Lowth furnished pursuant to 17 CFR 240.13a-14(b) and 18 U.S.C. 1350.
- 15.1 Annual Report and 20-F Information.(5)
- 15.2 Report of Independent Registered Public Accounting Firm to the members of AstraZeneca PLC by KPMG Audit Plc.
- 15.3 Consent of KPMG Audit Plc, independent registered public accounting firm.
- 15.4 Consent of IMS Health.
- 15.5 Consent of Bureau Veritas HS&E Ltd.

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- (1) Incorporated into this Form 20-F by reference to AstraZeneca PLC's Form 20-F filed March 25, 2003 (File No. 001-11960).
  - (2) Incorporated into this Form 20-F by reference to AstraZeneca PLC's Form 20-F filed March 12, 2008 (File No. 001-11960).
  - (3) Incorporated into this Form 20-F by reference to AstraZeneca PLC's Form 20-F filed March 23, 2006 (File No. 001-11960).
  - (4) Incorporated into this Form 20-F by reference to AstraZeneca PLC's Form 20-F filed March 27, 2007 (File No. 001-11960).
  - (5) Certain of the information included within exhibit 15.1, which is provided pursuant to Rule 12b-23(a)(3) of the Securities Exchange Act of 1934, as amended, is incorporated by reference in this Form 20-F, as specified elsewhere in this Form 20-F. With the exception of the items and pages so specified, the Annual Report and Form 20-F Information is not deemed to be filed as part of this Annual Report on Form 20-F.



SIGNATURE

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

AstraZeneca PLC

By: /s/ A C N Kemp  
Name: A C N Kemp  
Title: Authorized Signatory

London, England  
April 28, 2011