# Condensed Consolidated Statement of Comprehensive Income

| For the six months ended 30 June   | 2011<br>\$m | 2010<br>\$m |
|--|-------------|-------------|
| Revenue  | 16,722      | 16,754      |
| Cost of sales  | (2,821)     | (3,106)     |
| Gross profit   | 13,901      | 13,648      |
| Distribution costs   | (168)       | (166)       |
| Research and development   | (2,360)     | (2,311)     |
| Selling, general and administrative costs                                | (5,376)     | (4,912)     |
| Other operating income and expense                                       | 369         | 418         |
| Operating profit   | 6,366       | 6,677       |
| Finance income   | 273         | 259         |
| Finance expense  | (493)       | (500)       |
| Profit before tax  | 6,146       | 6,436       |
| Taxation   | (1,108)     | (1,541)     |
| Profit for the period  | 5,038       | 4,895       |
| Other comprehensive income:  |             |             |
| Foreign exchange arising on consolidation                                | 246         | (378)       |
| Foreign exchange differences on borrowings forming net investment hedges | (113)       | 196         |
| Amortisation of loss on cash flow hedge                                  | 1           | 1           |
| Net available for sale gains/(losses) taken to equity                    | 18          | (5)         |
| Actuarial gain/(loss) for the period                                     | 156         | (328)       |
| Income tax relating to components of other comprehensive income          | (6)         | 17          |
| Other comprehensive income for the period, net of tax                    | 302         | (497)       |
| Total comprehensive income for the period                                | 5,340       | 4,398       |
| Profit attributable to:  |             |             |
| Owners of the parent   | 5,020       | 4,884       |
| Non-controlling interests  | 18          | 11          |
|  | 5,038       | 4,895       |
| Total comprehensive income attributable to:                              |             |             |
| Owners of the parent   | 5,318       | 4,381       |
| Non-controlling interests  | 22          | 17          |
|  | 5,340       | 4,398       |
| Basic earnings per \$0.25 Ordinary Share                                 | \$3.61      | \$3.37      |
| Diluted earnings per \$0.25 Ordinary Share                               | \$3.60      | \$3.36      |
| Weighted average number of Ordinary Shares in issue (millions)           | 1,389       | 1,448       |
| Diluted weighted average number of Ordinary Shares in issue (millions)   | 1,395       | 1,454       |
|  | 1,000       |             |

## Condensed Consolidated Statement of Comprehensive Income

| For the <b>quarter</b> ended 30 June                                     | 2011<br>\$m | 2010<br>\$m |
|--|-------------|-------------|
| Revenue  | 8,430       | 8,178       |
| Cost of sales  | (1,482)     | (1,452)     |
| Gross profit   | 6,948       | 6,726       |
| Distribution costs   | (88)        | (88)        |
| Research and development   | (1,198)     | (1,320)     |
| Selling, general and administrative costs                                | (2,868)     | (2,450)     |
| Other operating income and expense                                       | 171         | 166         |
| Operating profit   | 2,965       | 3,034       |
| Finance income   | 136         | 126         |
| Finance expense  | (243)       | (243)       |
| Profit before tax  | 2,858       | 2,917       |
| Taxation   | (735)       | (801)       |
| Profit for the period  | 2,123       | 2,116       |
| Other comprehensive income:  |             |             |
| Foreign exchange arising on consolidation                                | 38          | (175)       |
| Foreign exchange differences on borrowings forming net investment hedges | (21)        | 92          |
| Amortisation of loss on cash flow hedge                                  | 1           | 1           |
| Net available for sale gains/(losses) taken to equity                    | 7           | (5)         |
| Actuarial gain/(loss) for the period                                     | 174         | (247)       |
| Income tax relating to components of other comprehensive income          | (33)        | 11          |
| Other comprehensive income for the period, net of tax                    | 166         | (323)       |
| Total comprehensive income for the period                                | 2,289       | 1,793       |
| Profit attributable to:  |             |             |
| Owners of the parent   | 2,113       | 2,107       |
| Non-controlling interests  | 10          | 9           |
|  | 2,123       | 2,116       |
| Total comprehensive income attributable to:                              |             |             |
| Owners of the parent   | 2,273       | 1,777       |
| Non-controlling interests  | 16          | 16          |
|  | 2,289       | 1,793       |
| Basic earnings per \$0.25 Ordinary Share                                 | \$1.53      | \$1.46      |
| Diluted earnings per \$0.25 Ordinary Share                               | \$1.53      | \$1.45      |
| Weighted average number of Ordinary Shares in issue (millions)           | 1,381       | 1,445       |
|  | 1,001       | 1,770       |

## **Condensed Consolidated Statement of Financial Position**

| Condensed Consolidated Statement of Financia                       | At 30 Jun<br>2011<br>\$m | At 31 Dec<br>2010<br>\$m | At 30 Jun<br>2010<br>\$m |
|--|--------------------------|--------------------------|--------------------------|
| ASSETS   |                          |                          |                          |
| Non-current assets   |                          |                          |                          |
| Property, plant and equipment                                      | 6,832                    | 6,957                    | 6,824                    |
| Goodwill   | 9,877                    | 9,871                    | 9,846                    |
| Intangible assets  | 12,072                   | 12,158                   | 12,832                   |
| Derivative financial instruments                                   | 319                      | 324                      | 370                      |
| Other investments  | 218                      | 211                      | 193                      |
| Deferred tax assets  | 1,397                    | 1,475                    | 1,206                    |
|  | 30,715                   | 30,996                   | 31,271                   |
| Current assets   |                          |                          |                          |
| Inventories  | 2,021                    | 1,682                    | 1,689                    |
| Trade and other receivables  | 8,320                    | 7,847                    | 7,307                    |
| Other investments  | 679                      | 1,482                    | 1,964                    |
| Derivative financial instruments                                   | 3                        | 9                        | -                        |
| Income tax receivable  | 1,538                    | 3,043                    | 3,328                    |
| Cash and cash equivalents  | 9,613                    | 11,068                   | 9,088                    |
| Assets classified as held for sale*                                | 517                      | -                        | -                        |
|  | 22,691                   | 25,131                   | 23,376                   |
| Total assets   | 53,406                   | 56,127                   | 54,647                   |
|  |                          |                          |                          |
| Current liabilities  |                          |                          |                          |
| Interest-bearing loans and borrowings                              | (372)                    | (125)                    | (1,275)                  |
| Trade and other payables   | (8,513)                  | (8,661)                  | (7,362)                  |
| Derivative financial instruments                                   | -                        | (8)                      | (201)                    |
| Provisions   | (1,097)                  | (1,095)                  | (947)                    |
| Income tax payable   | (3,660)                  | (6,898)                  | (6,519)                  |
| Liabilities classified as held for sale*                           | (196)                    | -                        | -                        |
|  | (13,838)                 | (16,787)                 | (16,304)                 |
| Non-current liabilities  | (10,000)                 | (10,101)                 | (10,001)                 |
| Interest-bearing loans and borrowings                              | (9,210)                  | (9,097)                  | (9,043)                  |
| Deferred tax liabilities   | (3,034)                  | (3,145)                  | (2,851)                  |
| Retirement benefit obligations                                     | (2,354)                  | (2,472)                  | (3,478)                  |
| Provisions   | (685)                    | (843)                    | (491)                    |
| Other payables   | (470)                    | (373)                    | (491)                    |
| Other payables   |                          |                          |                          |
| T-4-1 1:-1:14:   | (15,753)                 | (15,930)                 | (16,078)                 |
| Total liabilities  | (29,591)                 | (32,717)                 | (32,382)                 |
| Net assets   | 23,815                   | 23,410                   | 22,265                   |
| EQUITY   |                          |                          |                          |
| Capital and reserves attributable to equity holders of the Company | <b></b>                  | 050                      |                          |
| Share capital  | 341                      | 352                      | 360                      |
| Share premium account  | 3,010                    | 2,672                    | 2,372                    |
| Other reserves   | 1,915                    | 1,917                    | 1,939                    |
| Retained earnings  | 18,340                   | 18,272                   | 17,420                   |
|  | 23,606                   | 23,213                   | 22,091                   |
| Non-controlling interests  | 209                      | 197                      | 174                      |
| Total equity   | 23,815                   | 23,410                   | 22,265                   |

\* Assets and liabilities held for sale represent the assets and liabilities of Astra Tech (see Note 1).

## **Condensed Consolidated Statement of Cash Flows**

| For the <b>six months</b> ended 30 June                    | 2011<br>\$m | Restated<br>2010<br>\$m |
|--|-------------|-------------------------|
| Cash flows from operating activities                       |             |                         |
| Profit before taxation                                     | 6,146       | 6,436                   |
| Finance income and expense                                 | 220         | 241                     |
| Depreciation, amortisation and impairment                  | 1,037       | 832                     |
| Increase in working capital and short-term provisions      | (1,053)     | (977)                   |
| Other non-cash movements                                   | (236)       | 32                      |
| Cash generated from operations                             | 6,114       | 6,564                   |
| Interest paid  | (282)       | (323)                   |
| Tax paid   | (3,003)     | (1,474)                 |
| Net cash inflow from operating activities                  | 2,829       | 4,767                   |
| Cash flows from investing activities                       |             |                         |
| Movement in short-term investments and fixed deposits*     | 852         | (483)                   |
| Purchase of property, plant and equipment                  | (381)       | (313)                   |
| Disposal of property, plant and equipment                  | 46          | 28                      |
| Purchase of intangible assets                              | (294)       | (1,172)                 |
| Disposal of intangible assets                              | -           | 210                     |
| Purchase of non-current asset investments                  | (6)         | (23)                    |
| Disposal of non-current asset investments                  | -           | 2                       |
| Acquisitions of business operations                        | -           | (348)                   |
| Interest received  | 85          | 77                      |
| Payments made by subsidiaries to non-controlling interests | (16)        | (10)                    |
| Net cash inflow/(outflow) from investing activities        | 286         | (2,032)                 |
| Net cash inflow before financing activities                | 3,115       | 2,735                   |
| Cash flows from financing activities                       |             |                         |
| Proceeds from issue of share capital                       | 340         | 193                     |
| Repurchase of shares for cancellation                      | (2,544)     | (709)                   |
| Repayment of loans   | -           | (717)                   |
| Dividends paid   | (2,646)     | (2,367)                 |
| Movement in derivative financial instruments*              | 41          | (156)                   |
| Movement in short-term borrowings                          | 19          | (27)                    |
| Net cash outflow from financing activities                 | (4,790)     | (3,783)                 |
| Net decrease in cash and cash equivalents in the period    | (1,675)     | (1,048)                 |
| Cash and cash equivalents at the beginning of the period   | 10,981      | 9,828                   |
| Amounts reclassified as held for sale                      | (47)        | -                       |
| Exchange rate effects                                      | 40          | (36)                    |
| Cash and cash equivalents at the end of the period         | 9,299       | 8,744                   |
| Cash and cash equivalents consists of:                     |             |                         |
| Cash and cash equivalents                                  | 9,613       | 9,088                   |
| Overdrafts   | (314)       | (344)                   |
|  | 9,299       | 8,744                   |

\*2010 restated to reclassify \$156m movement in derivative financial instruments associated with financing activities.

## **Condensed Consolidated Statement of Changes in Equity**

|  | Share<br>capital<br>\$m  | Share<br>premium<br>account<br>\$m | Other*<br>reserves<br>\$m_ | Retained<br>earnings<br>\$m  | Total<br>\$m_ | Non-<br>controlling<br>interests<br>\$m | Total<br>equity<br>\$m |
|--|--------------------------|------------------------------------|----------------------------|------------------------------|---------------|---|------------------------|
| At 1 January 2010  | 363                      | 2,180                              | 1,919                      | 16,198                       | 20,660        | 161                                     | 20,821                 |
| Profit for the period                                      | -                        | -                                  | -                          | 4,884                        | 4,884         | 11                                      | 4,895                  |
| Other comprehensive income                                 | -                        | -                                  | -                          | (503)                        | (503)         | 6                                       | (497)                  |
| Transfer to other reserve                                  | -                        | -                                  | 16                         | (16)                         | -             | -                                       | -                      |
| Transactions with<br>owners:                               |                          |                                    |                            |                              |               |   |                        |
| Dividends  | -                        | -                                  | -                          | (2,484)                      | (2,484)       | -                                       | (2,484)                |
| Issue of AstraZeneca<br>PLC Ordinary shares                | 1                        | 192                                | -                          | -                            | 193           | -                                       | 193                    |
| Repurchase of<br>AstraZeneca PLC<br>Ordinary shares        | (4)                      | -                                  | 4                          | (709)                        | (709)         | -                                       | (709)                  |
| Share-based payments                                       | -                        | -                                  | -                          | 50                           | 50            | -                                       | 50                     |
| Transfer from non-<br>controlling interests to<br>payables | -                        | -                                  | -                          | -                            | -             | (3)                                     | (3)                    |
| Dividend paid to non-<br>controlling interest              | -                        | -                                  | -                          | -                            | -             | (1)                                     | (1)                    |
| Net movement   | (3)                      | 192                                | 20                         | 1,222                        | 1,431         | 13                                      | 1,444                  |
| At 30 June 2010  | 360                      | 2,372                              | 1,939                      | 17,420                       | 22,091        | 174                                     | 22,265                 |
|  | Share<br>capital<br>\$m_ | Share<br>premium<br>account<br>\$m | Other*<br>reserves<br>\$m_ | Retained<br>earnings<br>\$m_ | Total<br>\$m  | Non-<br>controlling<br>interests<br>\$m | Total<br>equity<br>\$m |
| At 1 January 2011  | 352                      | 2,672                              | 1,917                      | 18,272                       | 23,213        | 197                                     | 23,410                 |
| Profit for the period                                      | -                        | -                                  | -                          | 5,020                        | 5,020         | 18                                      | 5,038                  |
| Other comprehensive income                                 | -                        | -                                  | -                          | 298                          | 298           | 4                                       | 302                    |
| Transfer to other reserve<br>Transactions with<br>owners:  | -                        | -                                  | (15)                       | 15                           | -             | -                                       | -                      |
| Dividends  | _                        | _                                  | _                          | (2,594)                      | (2,594)       | _                                       | (2,594)                |
| Issue of AstraZeneca<br>PLC Ordinary shares                | 2                        | 338                                | -                          | -                            | 340           | -                                       | 340                    |
| Repurchase of<br>AstraZeneca PLC<br>Ordinary shares        | (13)                     | -                                  | 13                         | (2,544)                      | (2,544)       | -                                       | (2,544)                |
| Share-based payments                                       | -                        | -                                  | -                          | (127)                        | (127)         | -                                       | (127)                  |
| Transfer from non-<br>controlling interests to<br>payables | -                        | -                                  | -                          | -                            | -             | (6)                                     | (6)                    |
| Dividend paid to non-<br>controlling interests             | -                        | -                                  | -                          | -                            | -             | (4)                                     | (4)                    |
| Net movement   | (11)                     | 338                                | (2)                        | 68                           | 393           | 12                                      | 405                    |
| At 30 June 2011  | 341                      | 3,010                              | 1,915                      | 18,340                       | 23,606        | 209                                     | 23,815                 |

\* Other reserves includes the capital redemption reserve and the merger reserve.

# Responsibility Statement of the Directors in Respect of the Half-Yearly Financial Report

We confirm that to the best of our knowledge:

- the condensed set of financial statements has been prepared in accordance with IAS 34 Interim Financial Reporting as adopted by the European Union;
- the half-yearly management report includes a fair review of the information required by:
  - (a) DTR 4.2.7R of the Disclosure and Transparency Rules, being an indication of important events that have occurred during the first six months of the financial year and their impact on the condensed set of financial statements; and a description of the principal risks and uncertainties for the remaining six months of the year; and
  - (b) DTR 4.2.8R of the Disclosure and Transparency Rules, being related party transactions that have taken place in the first six months of the current financial year and that have materially affected the financial position or performance of the entity during that period; and any changes in the related party transactions described in the last annual report that could do so.

#### The Board

The Board of Directors that served during all or part of the six-month period to 30 June 2011 and their respective responsibilities can be found on pages 106 and 107 of the AstraZeneca Annual Report and Form 20-F Information 2010 with the exception of Baroness Shriti Vadera, who was appointed on 1 January 2011. Jane Henney retired from the Board on 28 April 2011.

Approved by the Board and signed on its behalf by David R Brennan Chief Executive Officer **28 July 2011** 

## Independent Review Report to AstraZeneca PLC

#### Introduction

We have been engaged by the Company to review the condensed set of financial statements in the half-yearly financial report for the six months ended 30 June 2011 (but not for the quarter ended 30 June 2011) which comprises condensed consolidated statement of comprehensive income, condensed consolidated statement of financial position, condensed consolidated statement of cash flows, condensed consolidated statement of changes in equity and Notes 1 to 5 and 7. We have read the other information contained in the half-yearly financial report and considered whether it contains any apparent misstatements or material inconsistencies with the information in the condensed set of financial statements.

This report is made solely to the Company in accordance with the terms of our engagement to assist the Company in meeting the requirements of the Disclosure and Transparency Rules ("the DTR") of the UK's Financial Services Authority ("the UK FSA"). Our review has been undertaken so that we might state to the Company those matters we are required to state to it in this report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company for our review work, for this report, or for the conclusions we have reached.

#### Directors' responsibilities

The half-yearly financial report is the responsibility of, and has been approved by, the Directors. The Directors are responsible for preparing the half-yearly financial report in accordance with the DTR of the UK FSA.

As disclosed in Note 1, the annual financial statements of the group are prepared in accordance with International Financial Reporting Standards ("IFRSs") as adopted by the European Union ("EU") and as issued by the International Accounting Standards Board ("IASB"). The condensed set of financial statements included in this half-yearly financial report has been prepared in accordance with IAS 34 *Interim Financial Reporting* as adopted by the EU.

#### Our responsibility

Our responsibility is to express to the Company a conclusion on the condensed set of financial statements in the half-yearly financial report based on our review.

#### Scope of review

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410 *Review* of *Interim Financial Information Performed by the Independent Auditor of the Entity* issued by the Auditing Practices Board for use in the UK. A review of interim financial information consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK and Ireland) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

#### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the condensed set of financial statements in the half-yearly financial report for the six months ended 30 June 2011 is not prepared, in all material respects, in accordance with IAS 34 as adopted by the EU and the DTR of the UK FSA.

#### Jimmy Daboo

#### For and on behalf of KPMG Audit Plc

**Chartered Accountants** 

15 Canada Square London E14 5GL

28 July 2011

#### 1 BASIS OF PREPARATION AND ACCOUNTING POLICIES

These condensed consolidated interim financial statements ("interim financial statements") for the six months ended 30 June 2011 have been prepared in accordance with IAS 34 *Interim Financial Reporting* as adopted by the European Union. The annual financial statements of the Group are prepared in accordance with International Financial Reporting Standards (IFRSs) as adopted by the European Union and as issued by the International Accounting Standards Board. As required by the Disclosure and Transparency Rules of the Financial Services Authority, the interim financial statements have been prepared applying the accounting policies and presentation that were applied in the preparation of the Company's published consolidated financial statements for the year ended 31 December 2010, except where new or revised accounting standards have been applied. There has been no significant impact on the Group profit or net assets on adoption of new or revised accounting standards in the period.

In June 2011, the Group announced the agreement to sell the Astra Tech business to Dentsply International for approximately \$1.8 billion in cash. At 30 June 2011, Astra Tech's assets were \$517 million and liabilities were \$196 million and, in accordance with IFRS 5, these have been reclassified on the Group's balance sheet as assets and liabilities held for sale. The transaction is anticipated to be completed during the second half of 2011, subject to receipt of relevant regulatory clearances. Upon closing, a gain will be recorded as "other operating income" and excluded from Core financial measures.

The Group has considerable financial resources available. The Group's revenues are largely derived from sales of products which are covered by patents and for which, historically at least, demand has been relatively unaffected by changes in the general economy. As a consequence, the Directors believe that the Group is well placed to manage its business risks successfully and as such, the interim financial statements have been prepared on a Going Concern basis.

The information contained in Note 4 updates the disclosures concerning legal proceedings and contingent liabilities in the Group's Annual Report and Form 20-F Information 2010.

The comparative figures for the financial year ended 31 December 2010 are not the Company's statutory accounts for that financial year. Those accounts have been reported on by the Company's auditors and delivered to the registrar of companies. The report of the auditors was (i) unqualified, (ii) did not include a reference to any matters to which the auditors drew attention by way of emphasis without qualifying their report, and (iii) did not contain a statement under section 498(2) or (3) of the Companies Act 2006.

#### 2 NET FUNDS

The table below provides an analysis of net funds and a reconciliation of net cash flow to the movement in net funds.

|                                      | At 1 Jan<br>2011<br>\$m_ | Cash<br>flow<br>\$m | Amounts<br>reclassified<br>as held for<br>sale<br>\$m | Non-<br>cash<br>mvmts<br>\$m | Exchange<br>mvmts<br>\$m | At 30<br>Jun<br>2011<br>\$m |
|--------------------------------------|--------------------------|---------------------|---|------------------------------|--------------------------|-----------------------------|
| Loans due after one year             | (9,097)                  |                     |   | (3)                          | (110)                    | (9,210)                     |
| Other investments - current          | 1,482                    | (852)               | -   | 24                           | 25                       | 679                         |
| Net derivative financial instruments | 325                      | (41)                | -   | 38                           | -                        | 322                         |
| Cash and cash equivalents            | 11,068                   | (1,448)             | (47)  | -                            | 40                       | 9,613                       |
| Overdrafts                           | (87)                     | (227)               | -   | -                            | -                        | (314)                       |
| Short-term borrowings                | (38)                     | (19)                |   |                              | (1)                      | (58)                        |
|                                      | 12,750                   | (2,587)             | (47)  | 62                           | 64                       | 10,242                      |
| Net funds                            | 3,653                    | (2,587)             | (47)  | 59                           | (46)                     | 1,032                       |

Non-cash movements in the period include fair value adjustments under IAS 39.

#### 3 RESTRUCTURING COSTS

Profit before tax for the six months ended 30 June 2011 is stated after charging restructuring costs of \$281 million (\$138 million for the second quarter 2011). These have been charged to profit as follows:

|   | 2 <sup>nd</sup> Quarter<br>2011<br>\$m | 2 <sup>nd</sup> Quarter<br>2010<br>\$m_ | Half Year<br>2011<br>\$m | Half Year<br>2010<br>\$m |
|---|--|---|--------------------------|--------------------------|
| Cost of sales                             | 20                                     | 63                                      | 32                       | 91                       |
| Research and development                  | 79                                     | 354                                     | 169                      | 372                      |
| Selling, general and administrative costs | 39                                     | 53                                      | 80                       | 102                      |
| Total                                     | 138                                    | 470                                     | 281                      | 565                      |

#### 4 LEGAL PROCEEDINGS AND CONTINGENT LIABILITIES

AstraZeneca is involved in various legal proceedings considered typical to its business, including litigation and investigations relating to product liability, commercial disputes, infringement of intellectual property rights, the validity of certain patents, anti-trust law, sales and marketing practices. The matters discussed below constitute the more significant developments since publication of the disclosures concerning legal proceedings in the Company's Annual Report and Form 20-F Information 2010. Unless noted otherwise below or in the Annual Report and Form 20-F Information 2010, no provisions have been established in respect of the claims discussed below.

As discussed in the Company's Annual Report and Form 20-F Information 2010, for the majority of claims in which AstraZeneca is involved it is not possible to make a reasonable estimate of the expected financial effect, if any, that will result from ultimate resolution of the proceedings. In these cases, AstraZeneca discloses information with respect only to the nature and facts of the cases but no provision is made.

In cases that have been settled or adjudicated, or where quantifiable fines and penalties have been assessed and which are not subject to appeal, or where a loss is probable and we are able to make a reasonable estimate of the loss, we record the loss absorbed or make a provision for our best estimate of the expected loss.

The position could change over time and the estimates that we have made and upon which we have relied in calculating these provisions are inherently imprecise. There can, therefore, be no assurance that any losses that result from the outcome of any legal proceedings will not exceed the amount of the provisions that have been booked in the accounts. The major factors causing this uncertainty are described more fully in the Annual Report and Form 20-F Information 2010 and herein.

AstraZeneca has full confidence in, and will vigorously defend and enforce its intellectual property.

#### Matters previously disclosed in respect of first quarter of 2011 and April 2011

#### Atacand

#### Patent litigation – Canada

As previously reported, 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 reported, 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 Paolo. 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 reported, 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 authorisations 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 authorisations granted to Sandoz until 24 October 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 reported, 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 reported, 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. 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 reported, 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 19 April 2011, in this case, AstraZeneca moved to amend the complaint to add The Brighams & 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 Brighams & 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 reported 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 5 April 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 7 April 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 26 April 2011, AstraZeneca filed a motion seeking dismissal or, alternatively, summary judgment of non-infringement in Palmetto's patent infringement suit in the District of South Carolina.

#### Patent litigation – Canada

As previously reported, 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 9 January 2012.

As previously reported, 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 authorisations granted to Teva Pharma Lda and Sandoz Farmaceutica Lda and dismissed the appeal. The suspension of the marketing authorisations 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 4 March 2011. On 15 March 2011, the preliminary injunction was dismissed by the court of first instance. AstraZeneca has appealed the decision. On 18 March 2011, AstraZeneca filed a patent infringement action against Germed with a request for a preliminary injunction. On 31 March 2011 the court denied AstraZeneca's request. AstraZeneca appealed the decision and on 14 April 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 reported). On 25 February 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 23 March 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 reported, 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 reported, 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 26 April 2011, the magistrate judge entered an order staying for one month the case-schedule she entered for this case on 14 April 2011.

In addition, as previously reported, 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 reported 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 reported, 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 7 March 2011, AstraZeneca brought a motion for interim and interlocutory injunctions on 11 March 2011 to prevent such sales pending determination of the patent infringement action between the parties. On 19 April 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 23 January 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 7 June 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 Artzneimittel 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 0984773) as invalid in Italy. Separate hearings are set for 13 July 2011, and 15 July 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 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 25 and 26 May 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 commercialising 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 esomeprazolerelated 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.* (EP 1020460) 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 7, 8 and 9 June 2011. Oral proceedings relating to EP 1020460 will be held on 30 June and 1 July 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 \$68.5m in the aggregate (as to which AstraZeneca previously had established a provision).

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

As of 31 March 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 31 March 2011, legal defence costs of approximately \$743m 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 defence costs.

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

#### Patent litigation – Brazil

As previously reported, 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 reported, 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 reported, 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 reported, 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 400mg *Seroquel XR* tablets before the 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 reported, 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 licence MedImmune and PDL signed in 1997. The matter was settled in February 2011 with PDL agreeing to pay MedImmune \$92.5m (\$65m in February 2011 and \$27.5m in February 2012). In addition, PDL agreed to the release of approximately \$9m 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 14 March 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 21 April 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 23 March 2011, the District Court granted the defendants' joint motion to dismiss the plaintiff's claims with prejudice. On 24 March 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 \$13m and \$90m, 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 reported, 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.

#### Тах

#### Transfer pricing and other international tax contingencies

On 28 March 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 \$2,310m disclosed in Note 25 of the Financial Statements on page 195 of the AstraZeneca Annual Report and Form 20-F Information 2010.

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

#### Matters disclosed in respect of the second quarter of 2011 and July 2011

#### Arimidex

Patent Proceedings pursuant to Patented Medicines (Notice of Compliance) Regulations—Canada (NOC Proceedings) Between 31 May and 2 June 2011, the Canadian Federal Court conducted a hearing in the previously disclosed NOC Proceeding, filed by AstraZeneca against Mylan Pharmaceuticals ULC in respect of AstraZeneca's Canadian substance Patent No. 1,337,420 (the '420 patent).

In May 2011, AstraZeneca commenced a NOC Proceeding against Teva Canada Limited in respect of the '420 patent.

In May 2011, AstraZeneca commenced a NOC Proceeding against Pharmascience Inc. in respect of the '420 patent.

In June 2011, AstraZeneca received a Notice of Allegation (NOA) from Apotex Inc. under the Canadian Patented Medicines (Notice of Compliance) regulations with respect to the '420 patent. AstraZeneca commenced a NOC Proceeding in response in July 2011.

#### Atacand

#### Patent litigation – EU

In Portugal, in addition to the previously disclosed cases regarding Sandoz Farmacêutica Lda. (Sandoz), Teva Pharma – Produtos Farmacêuticos Lda., PTR Pharma Consulting Lda., Laboratórios Azevados – Industria Farmacêutica, Ceamed Servico e Consultadoria Farmacêutica Lda and Labesfal – Laboraórios Almiro S.A. (Labesfal), approvals have been granted for generic candesartan cilexetil and candesartan cilexetil and hydrochlorothiazide products to companies such as Actavis Group PTC ehf, Ratiopharm - Comércio e Indústria de Produtos Farmacêuticos, Ranbaxy Portugal - Comércio e Desenvolvimento de Produtos Farmacêuticos, Unipessoal Lda., Mylan Lda., Laboratórios Anova - Produtos Farmacêuticos, Lda, Krka d.d., Novo mesto, and Mepha - Investigação, Desenvolvimento e Fabricação Farmacêutica, Lda. Preliminary injunctions to suspend those marketing approvals as well as correspondent administrative main actions have been filed during the second quarter of 2011. In July 2011, the Court of Appeal decided to suspend the marketing approvals for Sandoz and Labesfal until the main actions have been decided.

#### Atacand Plus (candesartan cilexetil / hydrochlorothiazide)

Patent Proceedings pursuant to Patented Medicines (Notice of Compliance) Regulations — Canada (NOC Proceedings)

In May 2011, AstraZeneca settled the previously disclosed NOC Proceeding pending with Sandoz Canada Inc. (Sandoz) with respect to Canadian Patent Nos. 2,040,955 (the '955 substance patent), 2,083,305 (the '305 formulation patent) and 2,125,251 (the '251 patent). The settlement resolves the litigation and allows Sandoz to enter the Canadian market on 23 September 2012, or earlier, in certain circumstances.

#### Patent proceedings – EU

An *Atacand Plus* patent, European Patent No. 753 301 (the '301 patent), has been the subject of opposition proceedings before the European Patent Office (EPO). Takeda owns the '301 patent and AstraZeneca holds a licence to the patent. The '301 patent claims a pharmaceutical composition comprising candesartan cilexetil and hydrochlorothiazide. The '301 patent was maintained as granted by the Opposition Division of the EPO in a decision delivered in September 2007. The two opponents, Hexal AG and Strawman Ltd, appealed the decision of the Opposition Division to a Technical Board of Appeal at the EPO.

Oral proceedings were held before a Technical Board of Appeal at the EPO on 5 July 2011. At the conclusion of the proceedings, the Technical Board of Appeal decided to revoke Takeda's '301 patent. A written decision will be issued in due course. Takeda has several patents covering *Atacand Plus* in Europe and the '301 patent is not the only protection for the product in Europe.

#### Crestor (rosuvastatin calcium)

#### Patent litigation – US

Section  $\overline{505}(b)(2)$  New Drug Application for rosuvastatin zinc tablets and US Patent Nos. RE37,314 (the '314 patent), 6,858,618 (the '618 patent) and 7,030,152 (the '152 patent)

The US District Court for the District of Delaware set a modified schedule, including a new trial date of 24 September 2012, in the previously disclosed patent infringement action by AstraZeneca and Shionogi Seiyaku Kabushiki Kaisha against Watson Laboratories, Inc. for alleged infringement of the '314 patent.

#### Palmetto Pharmaceuticals, LLC v. AstraZeneca Pharmaceuticals LP (Infringement action)

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

In April 2011, AstraZeneca filed a motion in the US District Court for the District of South Carolina seeking dismissal or, alternatively, summary judgment of non-infringement, responding to the patent infringement suit Palmetto Pharmaceuticals, LLC (Palmetto) filed against AstraZeneca in the US District Court for the District of South Carolina in April 2011, with respect to Palmetto's US Patent No. 6,465,516 and its re-examination certificate (collectively the '516 patent). In May 2011, Palmetto filed an Amended Complaint in response to AstraZeneca's motion. In June 2011, based on the Amended Complaint, AstraZeneca filed a second motion in the South Carolina District Court seeking dismissal or, alternatively, summary judgment of non-infringement of the '516 patent.

In April 2011, Palmetto filed with the US District Court for the District of Delaware a motion to dismiss, stay, or in the alternative transfer the declaratory judgment suit to the US District Court for the District of South Carolina. In May 2011, the US District Court for the District of Delaware entered a stipulation and consent order staying the declaratory judgment suit until the South Carolina District Court resolves the pending second motion for dismissal or summary judgment. AstraZeneca and Palmetto also agreed that if the South Carolina motion does not result in a dismissal, AstraZeneca would not oppose a motion to transfer the declaratory judgment suit to the US District Court for the District of South Carolina.

## Patent Proceedings pursuant to Patented Medicines (Notice of Compliance) Regulations — Canada (NOC Proceedings)

In July 2011, AstraZeneca received a Notice of Allegation (NOA) from Laboratoire Riva Inc. (Riva) under the Canadian Patented Medicines (Notice of Compliance) regulations respecting the 2,072,945 substance patent (the '945 patent), the 2,313,783 formulation patent (the '783 patent) and the 2,315,141 formulation patent (the '141 patent). AstraZeneca is considering the allegations and whether to commence a proceeding.

#### Patent litigation/Data exclusivity – Brazil

In May 2011, AstraZeneca filed a patent infringement action against EMS S/A (EMS) with a request for a preliminary injunction. In June 2011, the court granted AstraZeneca's request. EMS appealed the decision and the Reporting Judge of the Appeal Court suspended the effects of the preliminary injunction. Later in June 2011, the Reporting Judge reinstated the preliminary injunction. In July 2011, the new Reporting Judge suspended the effects of the preliminary injunction. In July 2011, AstraZeneca sued the health authority ANVISA in the first instance court in Brasilia and requested a preliminary injunction. AstraZeneca requests that ANVISA shall not take advantage of the data referring to *Crestor* (rosuvastatin calcium), refrain from granting new marketing approvals and cancel those previously approved. AstraZeneca claims that AstraZeneca's exclusivity for the data should last for 10 years beginning from the granting of the marketing approval i.e. until February 2014. On 22 July 2011, the Court denied the request for the preliminary injunction.

#### Patent litigation – Singapore

AstraZeneca was notified by the Health Sciences Authority in Singapore that Sanofi-Aventis Singapore Pte Ltd. (Sanofi) has applied for a product licence for a generic rosuvastatin product alleging that its product does not infringe AstraZeneca's Singapore Patent No. SG 89993. In June 2011, AstraZeneca filed an action for a declaration that Singapore Patent No. SG 89993 would be infringed by Sanofi if exercising the product licence.

#### Entocort (budesonide)

#### Patent litigation – US

As previously disclosed, in 2008, AstraZeneca sued Mylan Pharmaceuticals, Inc. (Mylan) for infringement of US Patent Nos. 6,423,340 (the '340 patent) and 5,643,602 (the '602 patent) in the US District Court for the District of Delaware. In May 2010, AstraZeneca proceeded to trial against Mylan before Judge Gregory Sleet on the sole issue of infringement of the '602 patent. In June 2011, Judge Sleet issued his opinion, finding that Mylan's generic budesonide product did not infringe the '602 patent. On 18 July 2011, AstraZeneca filed a Notice of Appeal.

#### Faslodex (fulvestrant)

#### Patent litigation - US

As previously disclosed, in January 2010, AstraZeneca filed a patent infringement action against Teva Parenteral, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd (together, Teva) in the US District Court for the District of Delaware for infringement of US Patent Nos. 6,774,122 and 7,456,160. In June 2011, the case was dismissed without prejudice due to withdrawal of Teva's Abbreviated New Drug Application (ANDA) for its fulvestrant injection product.

#### Nexium (esomeprazole magnesium)

#### Patent litigation – US

In May 2011, AstraZeneca entered into an agreement with Sandoz Inc. (Sandoz) to settle AstraZeneca's previously disclosed patent infringement suit against Sandoz in the US District Court for the District of New Jersey for patent infringement in respect of Sandoz's ANDA for esomeprazole magnesium delayed-release capsules. As part of the settlement agreement, AstraZeneca has granted Sandoz a licence to enter the US market with its generic esomeprazole magnesium on 27 May 2014, subject to regulatory approval, or earlier in certain circumstances.

The terms of AstraZeneca's US *Nexium* settlement with Sandoz are generally consistent with AstraZeneca's previous US *Nexium* settlements. The US District Court for the District of New Jersey has dismissed the *Nexium* patent litigation pending against Sandoz.

#### Product liability - US

Since April 2011, AstraZeneca has been named as a defendant in three product liability lawsuits involving 99 plaintiffs alleging bone deterioration, loss of bone density, and/or bone fractures caused by *Nexium* and/or *Prilosec*. The first lawsuit, filed in the United States District Court for the Southern District of Texas by a single plaintiff, was dismissed. AstraZeneca intends to vigorously defend itself against these claims.

#### Abbreviated New Drug Applications (ANDAs)

In June 2011, AstraZeneca received a Paragraph IV Certification notice letter from Hetero Drug Limited Unit III (Hetero) stating that it had submitted an ANDA for approval to market 20 and 40mg esomeprazole magnesium capsules. Hetero alleges non-infringement and/or invalidity of 11 patents listed in the FDA's Orange Book with reference to *Nexium*.

#### Patent litigation – Canada

As previously disclosed, in October 2010, AstraZeneca commenced a patent infringement action against Apotex Inc. alleging infringement of five Canadian patents related to *Nexium*. AstraZeneca brought a motion seeking both interim and interlocutory injunctions. The Court denied the motion and AstraZeneca's appeal, heard in June 2011, was dismissed.

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

As previously disclosed, 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 would 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/infringement part took place in June 2011. On 15 July 2011, the court confirmed that Ranbaxy's generic esomeprazole product does not infringe EP 1020461. The invalidity part has been stayed pending the non-infringement trial.

As previously disclosed, in France, in April 2011, AstraZeneca filed patent infringement suit against Ethypharm S.A. (Ethypharm) for infringement of the *Nexium* esomeprazole magnesium patent (EP 1020461) and the *Nexium* process patent (EP 0773940) and requested a preliminary injunction against Ethypharm to enjoin the manufacture and sale of Ethypharm's generic esomeprazole magnesium products. A preliminary injunction hearing regarding EP 0773940 took place in May 2011, and in June 2011 the court denied the request. AstraZeneca has appealed. A preliminary injunction hearing against Ethypharm regarding the esomeprazole magnesium trihydrate patent (EP 0984957) took place in June 2011, and in July 2011 the court denied the request. In July 2011, AstraZeneca filed a patent infringement suit against Ethypharm for infringement of EP 0984957.

In Sweden, AstraZeneca's request for a preliminary injunction prohibiting Krka Sverige AB from commercialising its generic esomeprazole product in Sweden was rejected by the court in June 2011. AstraZeneca has decided not to appeal this decision.

In the Netherlands, on 6 July 2011, the District Court of the Hague upheld the Optical Purity patent (EP 1020461) as valid. Sandoz B.V./Hexal AG (both within the Sandoz group) and Stada Arzneimittel AG/Centrafarm Services B.V. (both within the Stada group) are able to appeal within three months.

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

As previously disclosed, in Austria, in February 2011, the court denied AstraZeneca's request for a preliminary injunction to prevent ratiopharm Arzneimittel Vertriebs-GmbH from marketing and selling a generic esomeprazole magnesium product in Austria. In June 2011, the Appeal Court rejected AstraZeneca's appeal and AstraZeneca has decided not to appeal this decision. As previously disclosed, AstraZeneca requested a preliminary injunction against Krka, d.d., Novo Mesto. In June 2011, the court denied AstraZeneca's request and AstraZeneca has decided not to appeal this decision.

As previously disclosed, in Finland, AstraZeneca initiated a declaratory action requesting the District Court of Helsinki to confirm that Ranbaxy (UK) Limited would infringe a patent relating to esomeprazole if commercialising generic esomeprazole magnesium products in Finland. The trial took place in May 2011. In June 2011, the Court denied AstraZeneca's claim. AstraZeneca has the opportunity to appeal until the end of July. In July 2009, AstraZeneca initiated similar declaratory actions against Sandoz Oy AB and Sandoz A/S. In September 2009, Hexal AG, Sandoz Oy AB and Sandoz A/S (all in the Sandoz group) initiated an invalidity case requesting the court to invalidate the same patent. These cases will be heard together in September 2011.

#### Patent litigation – Norway

As previously disclosed, in Norway, in December 2010, the Court of Oslo granted a preliminary injunction prohibiting Krka Sverige AB from commercialising its generic esomeprazole product in Norway. In June 2011, the Appeal Court confirmed the decision of the Court of Oslo.

#### Patent litigation – Singapore

In July 2011, AstraZeneca initiated patent infringement proceedings against Ranbaxy (Malaysia) SDN BHD based on an esomeprazole-related patent.

#### Patent litigation – Turkey

In July 2011, AstraZeneca initiated patent infringement proceedings against Logus Ilac, Integri Ilac, Vem Ilac, Biofarma Ilac and Sandoz Ilac San.ve Tic.AS based on esomeprazole-related patents.

#### Patent Proceedings – EU

As previously disclosed, the European Patent Office (EPO) published the grant of two patents that relate to *Nexium* (EP 1020461) and *Nexium i.v.* (EP 1020460) 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 were filed in relation to EP 1020461 and six Notices of Opposition in relation to EP 1020460.

Oral proceedings relating to EP 1020461 were held before the Opposition Division of the EPO in June 2011, when the Opposition Division of the EPO decided to revoke EP 1020461 following thirteen oppositions from generic drug manufacturers. The decision is appealable. A written decision will be delivered in due course by the EPO.

Oral proceedings relating to EP 1020460 were held on 30 June and 1 July 2011. On 1 July 2011, the Opposition Division of the EPO decided to revoke EP 1020461 following six oppositions from generic drug manufacturers. The decision is appealable. A written decision will be delivered in due course by the EPO.

#### Pulmicort Respules (budesonide)

#### Patent litigation – US

In May 2011, AstraZeneca received a Paragraph IV Certification notice letter from Watson Laboratories, Inc. (Watson) indicating that it is seeking approval to market a generic version of the 1.0 mg/2.0 ml dosage form of *Pulmicort Respules* before the expiration of US Patent Nos. 6,598,603, 6,899,099 and 7,524,834. In June 2011, AstraZeneca filed a patent infringement suit against Watson in the US District Court for the District of New Jersey.

#### Seroquel (quetiapine fumarate)

#### Product liability

As of July 2011, approximately 28,461 claims have been settled in principle, 28,446 of which are subject to written agreements.

As of July 2011, AstraZeneca was aware of approximately 250 *Seroquel* US product liability claims that have not been settled in principle. The majority of these remaining claims are pending in California courts, although some claims are pending in other state and federal courts including the multi-district litigation court. The Company has increased its provision by \$55m to account for the current and anticipated future settlement costs regarding the *Seroquel* product liability claims, past and future defence costs associated with defending the claims since the fourth quarter 2010, and the previously disclosed provision regarding certain *Seroquel* state attorney general claims. The amount of this provision remains subject to a number of significant uncertainties, as previously disclosed. It is not possible at this time to provide any reasonable indication as to when remaining claims may be settled. Furthermore, it is possible that the actual cost of ultimately settling or adjudicating the *Seroquel* product liability claims may differ significantly from the total amount provided.

As of 30 June 2011, legal defence costs of approximately \$749m 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 defence costs.

As previously disclosed, disputes continue with other insurers about the availability of coverage under certain insurance policies for legal defence costs and potential damages amounts. As of 30 June 2011, out of the legal defence costs of \$749m mentioned above, AstraZeneca believes that approximately \$134m is covered by these other insurance policies.

While no insurance receivable can be recognised under applicable accounting standards at this time, AstraZeneca believes that it is more likely than not that further insurance recoveries will be secured under the additional policies, but there can be no assurance of this or the amount of any potential future recovery.

#### Patent litigation – EU

In Portugal, as previously disclosed, in July and November 2010, AstraZeneca filed preliminary injunction proceedings with the aim of suspending the effect of the retail price decision granted to Bluescience Unipessoal Lda and Cinfa Portugal Lda as well as corresponding main actions. In June 2011, a negative decision on the suspension of the retail prices was granted. AstraZeneca has appealed the decision. In another case, where the parties are waiting for a final decision regarding the suspension of the marketing approvals and the suspension of the retail prices granted to Generis Farmacêutica S.A., KRKA Farmacêutica Sociedade Unipessoal Lda (KRKA) and Mer Medicamentos Lda, KRKA has obtained reimbursement approval and now launched its product. AstraZeneca is evaluating its options.

In Italy, AstraZeneca found out in June 2011, that the Italian Patent Office (IPO) had erroneously decided that AstraZeneca's supplementary protection certificate for the Seroguel substance patent had lapsed due to non-payment. After AstraZeneca had informed the IPO of its mistake, the IPO issued a Certificate of Correction. AstraZeneca was informed of generics preparing for launch and filed a motion for a preliminary injunction in the Court of Milan against Teva Italia S.p.A, Mylan S.p.A, Doc Generici s.r.I, EG S.p.A and Sandoz S.p.A. A hearing is scheduled for 23 August 2011.

#### Seroquel XR

#### Patent litigation - US

In April 2011, AstraZeneca filed a lawsuit in the US District Court for the District of New Jersey against Osmotica Pharmaceutical Corporation, which had sent a Paragraph IV Certification notice letter to AstraZeneca indicating that it was seeking approval to market generic versions of Seroquel XR before the expiration of US Patent No. 5,948,437 (the '437 patent).

In April 2011, AstraZeneca filed a lawsuit in the US District Court for the District of New Jersey against Mylan Pharmaceuticals Inc. and Mylan Inc. (Mylan), which had sent a Paragraph IV Certification notice letter to AstraZeneca indicating that it was seeking approval to market generic versions of Seroquel XR before the expiration of the '437 patent.

In May 2011, following conversion of the Paragraph IV Certification of Biovail Laboratories International SRL, Biovail Corporation and BTA Pharmaceuticals, Inc. (together, Biovail) to a Paragraph III Certification, the Court entered a consent order dismissing without prejudice the pending patent infringement case against Biovail in the US District Court for the District of New Jersey for Biovail's Abbreviated New Drug Application (ANDA) seeking approval to market generic copies of Seroquel XR.

In May 2011, AstraZeneca received a Paragraph IV Certification notice letter from Intellipharmaceutics Corp. (IPC) seeking approval to market generic versions of 150, 200, 300 and 400mg Seroguel XR before the expiration of the '437 patent. In its notice letter, IPC claims that certain of the claims of the '437 patent will not be infringed by its proposed ANDA products and that the '437 patent is invalid. In May 2011, AstraZeneca filed a lawsuit in the US District Court for the District of New Jersey against IPC alleging infringement of the '437 patent. In June 2011, IPC filed a motion seeking to have the case dismissed for lack of personal jurisdiction or alternatively, for the action to be transferred to New York. AstraZeneca filed an amended complaint in the New Jersey suit against IPC adding Intellipharmaceutics International Inc. (IPC-I) as a codefendant.

Also in June 2011, AstraZeneca filed a second, essentially identical lawsuit in the US District Court for the Southern District of New York against IPC and IPC-I alleging infringement of the '437 patent.

Patent Proceedings pursuant to Patented Medicines (Notice of Compliance) regulations—Canada (NOC Proceedings) In June 2011, AstraZeneca received a Notice of Allegation from Teva Canada Limited (Teva) in respect of Seroguel XR Canadian formulation Patent No. 2,251,944 listed on the Canadian Patent Register. Teva alleges certain of the claims will not be infringed by its generic version of 50mg Seroquel XR and that the patent is invalid. AstraZeneca is considering the allegations and whether to initiate a NOC Proceeding.

#### Patent litigation – EU

In the Netherlands, Accord Healthcare B.V., Accord Healthcare Ltd, Sandoz B.V. and Hexal AG issued revocation proceedings against AstraZeneca in June 2011, claiming that the formulation patent for Seroquel XR (EP 0907364) is invalid in the Netherlands. The court has scheduled a trial in January 2012.

#### Symbicort (fixed-dose combination of budesonide and formoterol)

Patent litigation – Turkey In July 2011, AstraZeneca initiated patent infringement proceedings against Logus Ilac in relation to a budesonide/formoterol related patent.

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

In April 2011, AstraZeneca and Pozen, Inc (AstraZeneca's licensor) filed a patent infringement suit in the US District Court for the District of New Jersey against Dr. Reddy's Laboratories and Dr. Reddy's Laboratories, Ltd. (together, DRL), which had sent a Paragraph IV Certification notice letter indicating that they were seeking approval to market generic versions of Vimovo tablets before expiration of US Patent No. 6,926,907. In June 2011, DRL filed an answer to the patent infringement suit.

AstraZeneca received a Paragraph IV Certification notice letter from Lupin Ltd. (Lupin) dated 10 June 2011, indicating that it is seeking approval to market generic versions of 375/20mg and 500/20mg Vimovo tablets before expiration of US Patent Nos. 5,714,504; 5,900,424; 6,369,085; 6,875,872; 6,926,907; 7,411,070; and 7,745,466. AstraZeneca is evaluating Lupin's certifications. On 25 July 2011, AstraZeneca and Pozen, Inc (AstraZeneca's licensor) filed a patent infringement suit in the US District Court for the District of New Jersey against Lupin for patent infringement.

#### Zomig (zolmitriptan)

Patent Proceedings pursuant to Patented Medicines (Notice of Compliance) regulations—Canada (NOC Proceedings) In June 2011, AstraZeneca discontinued the NOC Proceeding brought in response to the Notice of Allegation from Apotex Inc. respecting Canadian Zomig product-by-process Patent No. 2,572,508.

#### Other Commercial Litigation

#### Verus Pharmaceuticals litigation

As previously disclosed, in May 2009, Verus Pharmaceuticals Inc. (Verus) filed a lawsuit against AstraZeneca AB and its subsidiary, Tika Läkemedel AB (Tika), alleging breaches of several related collaboration agreements to develop novel paediatric asthma treatments. In August 2010, the United States District Court for the Southern District of New York granted AstraZeneca AB and Tika's motion to dismiss the case in its entirety. On 24 June 2011, the United States Court of Appeals for the Second Circuit affirmed the Federal District Court's decision and upheld the dismissal of all of Verus' claims.

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

As previously disclosed, in March 2011, the District Court granted the defendants' joint motion to dismiss the plaintiff's claims with prejudice. In March 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. The appeals were dismissed by the Federal Circuit for ripeness. A new Notice of Appeal was filed with the Federal Circuit in June 2011.

#### Other Pricing Litigation

#### Average Wholesale Price Litigation

As previously disclosed, AstraZeneca is a defendant, along with many other pharmaceutical manufacturers, in several sets of cases involving allegations that, by causing the publication of allegedly inflated wholesale list prices, the defendants caused entities to overpay for prescription drugs. In June 2011, AstraZeneca agreed in principle to settle those lawsuits brought by the Attorneys General of the States of Alaska, Idaho, and Illinois, subject to documentation. Provision has been made for these settlements.

#### Other Actual and Threatened Government Investigations and Related Litigation

AstraZeneca understands that the US Attorney's Office for the District of Delaware, Criminal Division is conducting an investigation relating to AstraZeneca's relationship with MedCo and sales of *Nexium, Plendil, Toprol XL*, and *Prilosec*. The precise parameters of this investigation are unknown, and AstraZeneca is not in a position at this time to predict its scope, duration or outcome, including whether it will result in any liability to AstraZeneca.

On 30 June 2011, and 1 July 2011 respectively, AstraZeneca's biologics unit, MedImmune received a Civil Investigative Demand from the US Attorney's Office for the Southern District of New York and a subpoena *duces tecum* from the Office of the Attorney General for the State of New York Medicaid and Fraud Control Unit pursuant to what the government attorneys advised was a joint investigation relating to the sales and marketing of *Synagis*. In addition, AstraZeneca has received a subpoena *duces tecum* from the Office of the Attorney General for the State of New York Medicaid and Fraud Control Unit. The precise parameters of this investigation are unknown, and AstraZeneca is not in a position at this time to predict its scope, duration or outcome, including whether it will result in any liability to AstraZeneca.

#### Тах

#### Transfer pricing and other international tax contingencies

As previously disclosed, in March 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 \$2,310m disclosed in Note 25 of the Financial Statements on page 195 of AstraZeneca's Annual Report and Form 20-F Information 2010.

Based on the above mentioned agreements, AstraZeneca now expects to pay a net amount of \$1.1bn to resolve all US transfer pricing and related valuation matters for the period from 2000 to the end of 2010 and \$520m of provisions have been released to earnings in the first half. The net amount payable of \$1.1bn reflects expected US tax payments and updated estimates of corresponding tax refunds in other jurisdictions. During the second quarter a net amount of \$1.1bn was paid. Further US tax payments in respect of state taxes are required in respect of the period from 2000 to the end of 2010 but are expected to be offset by amounts recoverable from the US and other jurisdictions.

#### 5 HALF YEAR TERRITORIAL REVENUE ANALYSIS

|                              | -                                   |                                     | % Growth |                      |  |
|------------------------------|-------------------------------------|-------------------------------------|----------|----------------------|--|
|                              | 1 <sup>st</sup> Half<br>2011<br>\$m | 1 <sup>st</sup> Half<br>2010<br>\$m | Actual   | Constant<br>Currency |  |
| US                           | 6,596                               | 7,094                               | (7)      | (7)                  |  |
| Western Europe <sup>1</sup>  | 4,429                               | 4,672                               | (5)      | (8)                  |  |
| Canada                       | 840                                 | 723                                 | 16       | 10                   |  |
| Japan                        | 1,367                               | 1,222                               | 12       | 1                    |  |
| Other Established ROW        | 590                                 | 494                                 | 19       | 4                    |  |
| Established ROW <sup>2</sup> | 2,797                               | 2,439                               | 15       | 4                    |  |
| Emerging Europe              | 636                                 | 596                                 | 7        | 5                    |  |
| China                        | 625                                 | 511                                 | 22       | 18                   |  |
| Emerging Asia Pacific        | 484                                 | 429                                 | 13       | 7                    |  |
| Other Emerging ROW           | 1,155                               | 1,013                               | 14       | 14                   |  |
| Emerging ROW <sup>3</sup>    | 2,900                               | 2,549                               | 14       | 11                   |  |
| Total Revenue                | 16,722                              | 16,754                              | -        | (3)                  |  |
|                              |                                     |                                     |          |                      |  |

<sup>1</sup> Western Europe comprises France, Germany, Italy, Sweden, UK and others.
 <sup>2</sup> Established ROW comprises Australia, Canada, Japan and New Zealand.
 <sup>3</sup> Emerging ROW comprises Brazil, China, India, Mexico, Russia, Turkey and all other ROW countries.

#### 6 SECOND QUARTER TERRITORIAL REVENUE ANALYSIS

|                              | nd                                     | nd                                     | % Grow | /th                  |
|------------------------------|--|--|--------|----------------------|
|                              | 2 <sup>nd</sup> Quarter<br>2011<br>\$m | 2 <sup>nd</sup> Quarter<br>2010<br>\$m | Actual | Constant<br>Currency |
| US                           | 3,292                                  | 3,396                                  | (3)    | (3)                  |
| Western Europe <sup>1</sup>  | 2,194                                  | 2,213                                  | (1)    | (9)                  |
| Canada                       | 423                                    | 371                                    | 14     | 8                    |
| Japan                        | 736                                    | 644                                    | 14     | 2                    |
| Other Established ROW        | 317                                    | 262                                    | 21     | 3                    |
| Established ROW <sup>2</sup> | 1,476                                  | 1,277                                  | 16     | 4                    |
| Emerging Europe              | 316                                    | 286                                    | 10     | 5                    |
| China                        | 303                                    | 252                                    | 20     | 15                   |
| Emerging Asia Pacific        | 242                                    | 210                                    | 15     | 9                    |
| Other Emerging ROW           | 607                                    | 544                                    | 11     | 10                   |
| Emerging ROW <sup>3</sup>    | 1,468                                  | 1,292                                  | 13     | 10                   |
| Total Revenue                | 8,430                                  | 8,178                                  | 3      | (2)                  |
|                              |  |  |        |                      |

<sup>1</sup> Western Europe comprises France, Germany, Italy, Sweden, UK and others.
 <sup>2</sup> Established ROW comprises Australia, Canada, Japan and New Zealand.
 <sup>3</sup> Emerging ROW comprises Brazil, China, India, Mexico, Russia, Turkey and all other ROW countries.

#### 7 FIRST HALF PRODUCT REVENUE ANALYSIS

|                         | World US N                          |                       | Western Europ                       | e                                   |                       | Established RO                      | w                     | Emerging ROW                        |                                     |                       |                                     |                                     |                       |                                     |
|-------------------------|-------------------------------------|-----------------------|-------------------------------------|-------------------------------------|-----------------------|-------------------------------------|-----------------------|-------------------------------------|-------------------------------------|-----------------------|-------------------------------------|-------------------------------------|-----------------------|-------------------------------------|
|                         | 1 <sup>st</sup> Half<br>2011<br>\$m | Actual<br>Growth<br>% | Constant<br>Currency<br>Growth<br>% | 1 <sup>st</sup> Half<br>2011<br>\$m | Actual<br>Growth<br>% | 1 <sup>st</sup> Half<br>2011<br>\$m | Actual<br>Growth<br>% | Constant<br>Currency<br>Growth<br>% | 1 <sup>st</sup> Half<br>2011<br>\$m | Actual<br>Growth<br>% | Constant<br>Currency<br>Growth<br>% | 1 <sup>st</sup> Half<br>2011<br>\$m | Actual<br>Growth<br>% | Constant<br>Currency<br>Growth<br>% |
| Gastrointestinal:       | <u> </u>                            |                       |                                     | . <u> </u>                          |                       | <u> </u>                            |                       |                                     | <u> </u>                            |                       |                                     | <u> </u>                            |                       |                                     |
| Nexium                  | 2,273                               | (9)                   | (10)                                | 1,213                               | (10)                  | 454                                 | (28)                  | (29)                                | 239                                 | 9                     | -                                   | 367                                 | 23                    | 22                                  |
| Losec/Prilosec          | 474                                 | (7)                   | (14)                                | 21                                  | (33)                  | 127                                 | (8)                   | (13)                                | 213                                 | 1                     | (9)                                 | 113                                 | (14)                  | (17)                                |
| Others                  | 75                                  | 7                     | 6                                   | 47                                  | 12                    | 22                                  |                       | (5)                                 | 4                                   | 33                    | 33                                  | 2                                   | (33)                  | (33)                                |
| Total Gastrointestinal  | 2,822                               | (8)                   | (10)                                | 1,281                               | (10)                  | 603                                 | (24)                  | (26)                                | 456                                 | 6                     | (4)                                 | 482                                 | 11                    | 10                                  |
| Cardiovascular:         |                                     |                       |                                     |                                     |                       |                                     |                       |                                     |                                     |                       |                                     |                                     |                       |                                     |
| Crestor                 | 3,192                               | 17                    | 13                                  | 1,478                               | 17                    | 613                                 | 10                    | 7                                   | 766                                 | 25                    | 15                                  | 335                                 | 12                    | 8                                   |
| Atacand                 | 740                                 | (1)                   | (4)                                 | 95                                  | (17)                  | 360                                 | (4)                   | (8)                                 | 122                                 | 13                    | 4                                   | 163                                 | 8                     | 7                                   |
| Seloken/Toprol-XL       | 477                                 | (30)                  | (32)                                | 192                                 | (55)                  | 41                                  | (11)                  | (15)                                | 19                                  | -                     | (11)                                | 225                                 | 14                    | 11                                  |
| Plendil                 | 130                                 | 1                     | (3)                                 | 4                                   | (50)                  | 12                                  | (20)                  | (20)                                | 6                                   | -                     | (17)                                | 108                                 | 8                     | 4                                   |
| Tenormin                | 134                                 | (4)                   | (9)                                 | 6                                   | (14)                  | 30                                  | (6)                   | (9)                                 | 60                                  | (2)                   | (11)                                | 38                                  | (3)                   | (5)                                 |
| Zestril                 | 72                                  | (12)                  | (15)                                | 5                                   | (17)                  | 36                                  | (14)                  | (17)                                | 9                                   | -                     | -                                   | 22                                  | (12)                  | (16)                                |
| Onglyza™                | 81                                  | 350                   | 350                                 | 59                                  | 321                   | 15                                  | 275                   | 275                                 | 2                                   | n/m                   | n/m                                 | 5                                   | n/m                   | n/m                                 |
| Brilinta/Brilique       | 3                                   | n/m                   | n/m                                 | -                                   | -                     | 2                                   | n/m                   | n/m                                 | _                                   | -                     | -                                   | 1                                   | n/m                   | n/m                                 |
| Others                  | 129                                 | (5)                   | (9)                                 | -                                   | (100)                 | 63                                  | 5                     | 2                                   | 12                                  | (8)                   | (15)                                | 54                                  | 13                    | 8                                   |
| Total Cardiovascular    | 4,958                               | 6                     | 3                                   | 1,839                               | (100)                 | 1,172                               | 4                     |                                     | 996                                 | 20                    | 10                                  | 951                                 | 10                    | 7                                   |
| Respiratory:            | 4,330                               |                       |                                     | 1,000                               |                       | 1,172                               |                       |                                     |                                     |                       |                                     | 331                                 |                       |                                     |
| Symbicort               | 1,554                               | 14                    | 10                                  | 403                                 | 14                    | 724                                 | 2                     | (1)                                 | 198                                 | 62                    | 48                                  | 229                                 | 28                    | 25                                  |
| •                       | 484                                 |                       | 3                                   | 403                                 |                       | 103                                 | (10)                  | (1)                                 |                                     |                       |                                     | 156                                 |                       | 25                                  |
| Pulmicort               |                                     | 5                     |                                     |                                     | (6)                   |                                     |                       | (13)                                | 59                                  | 13                    | 4                                   |                                     | 34                    | 30                                  |
| Rhinocort               | 110                                 | (8)                   | (11)                                | 43                                  | (19)                  | 21                                  | (5)                   | (9)                                 | 9                                   | 50                    | 33                                  | 37                                  | (5)                   | (8)                                 |
| Others                  | 110                                 | (17)                  | (21)                                | 4                                   | (83)                  | 56                                  | (8)                   | (13)                                | 12                                  |                       |                                     | 38                                  | 6                     |                                     |
| Total Respiratory       | 2,258                               | 9                     | 5                                   | 616                                 | 1                     | 904                                 | -                     | (4)                                 | 278                                 | 45                    | 33                                  | 460                                 | 24                    | 21                                  |
| Oncology:               |                                     |                       |                                     |                                     |                       |                                     |                       |                                     |                                     |                       |                                     |                                     |                       |                                     |
| Arimidex                | 414                                 | (56)                  | (58)                                | 29                                  | (93)                  | 161                                 | (48)                  | (48)                                | 147                                 | 7                     | (3)                                 | 77                                  | -                     | (4)                                 |
| Zoladex                 | 577                                 | 6                     | 2                                   | 22                                  | 5                     | 132                                 | (9)                   | (12)                                | 234                                 | 8                     | (3)                                 | 189                                 | 16                    | 21                                  |
| Casodex                 | 271                                 | (8)                   | (14)                                | (1)                                 | (109)                 | 45                                  | (26)                  | (28)                                | 172                                 | 2                     | (8)                                 | 55                                  | 2                     | -                                   |
| Iressa                  | 260                                 | 48                    | 39                                  | 1                                   | (50)                  | 59                                  | 293                   | 280                                 | 94                                  | 12                    | 1                                   | 106                                 | 41                    | 35                                  |
| Others                  | 312                                 | 57                    | 53                                  | 131                                 | 93                    | 97                                  | 56                    | 52                                  | 31                                  | 15                    | 4                                   | 53                                  | 26                    | 24                                  |
| Total Oncology          | 1,834                               | (15)                  | (19)                                | 182                                 | (66)                  | 494                                 | (16)                  | (18)                                | 678                                 | 7                     | (3)                                 | 480                                 | 17                    | 17                                  |
| Neuroscience:           |                                     |                       |                                     |                                     |                       |                                     |                       |                                     |                                     |                       |                                     |                                     |                       |                                     |
| Seroquel IR             | 2,156                               | 3                     | 1                                   | 1,643                               | 6                     | 280                                 | (3)                   | (7)                                 | 109                                 | (10)                  | (19)                                | 124                                 | (6)                   | (11)                                |
| Seroquel XR             | 726                                 | 30                    | 28                                  | 381                                 | 19                    | 239                                 | 45                    | 39                                  | 43                                  | 59                    | 44                                  | 63                                  | 37                    | 37                                  |
| Local Anaesthetics      | 305                                 | -                     | (5)                                 | 9                                   | (50)                  | 126                                 | (8)                   | (12)                                | 96                                  | 9                     | (2)                                 | 74                                  | 21                    | 18                                  |
| Zomig                   | 204                                 | (5)                   | (8)                                 | 77                                  | (13)                  | 85                                  | (3)                   | (7)                                 | 35                                  | 9                     | -                                   | 7                                   |                       | -                                   |
| Diprivan                | 156                                 | -                     | (5)                                 | 12                                  | (52)                  | 23                                  | (18)                  | (21)                                | 42                                  | 31                    | 19                                  | 79                                  | 11                    | 7                                   |
| Vimovo                  | 10                                  | n/m                   | n/m                                 | 8                                   | n/m                   |                                     | n/m                   | n/m                                 | 1                                   | n/m                   | n/m                                 | 1                                   | n/m                   | n/m                                 |
| Others                  | 19                                  | (5)                   | (10)                                | 1                                   | -                     | 11                                  | (29)                  | (36)                                | 3                                   | -                     | -                                   | 4                                   | 100                   | 100                                 |
| Total Neuroscience      | 3,576                               | 7                     | 4                                   | 2,131                               | 6                     | 764                                 | 6                     | 2                                   | 329                                 | 9                     | (2)                                 | 352                                 | 10                    | 7                                   |
|                         | 3,370                               |                       |                                     | 2,131                               |                       | /04                                 |                       |                                     |                                     |                       | (2)                                 | 552                                 |                       |                                     |
| Infection & Other:      | 450                                 | (0)                   | (0)                                 | 201                                 | (16)                  | 154                                 | 0                     | 0                                   |                                     |                       |                                     | 1                                   |                       |                                     |
| Synagis                 | 456                                 | (9)                   | (9)                                 | 301                                 | (16)                  | 154                                 | 8                     | 8                                   | -                                   | -                     | -                                   | 1                                   | -                     | -                                   |
| Merrem                  | 330                                 | (23)                  | (26)                                | 28                                  | (61)                  | 112                                 | (39)                  | (40)                                | 33                                  | 14                    | 3                                   | 157                                 | 8                     | 4                                   |
| FluMist                 | 3                                   | -                     | -                                   | 2                                   | (33)                  | -                                   | -                     | -                                   | -                                   | -                     | -                                   | 1                                   | n/m                   | n/m                                 |
| Others                  | 74                                  | (20)                  | (23)                                | 45                                  | (37)                  | 7                                   | (14)                  | (14)                                | 7                                   | 17                    | (67)                                | 15                                  | 100                   | 125                                 |
| Total Infection & Other | 863                                 | (16)                  | (17)                                | 376                                 | (26)                  | 273                                 | (18)                  | (19)                                | 40                                  | 14                    | (9)                                 | 174                                 | 13                    | 11                                  |
| Aptium Oncology         | 113                                 | (8)                   | (8)                                 | 113                                 | (8)                   | -                                   | -                     | -                                   | -                                   | -                     | -                                   | -                                   | -                     | -                                   |
| Astra Tech              | 298                                 | 12                    | 8                                   | 58                                  | 16                    | 219                                 | 11                    | 6                                   | 20                                  | 5                     | (5)                                 | 1                                   | n/m                   | n/m                                 |
| Total                   | 16,722                              | -                     | (3)                                 | 6,596                               | (7)                   | 4,429                               | (5)                   | (8)                                 | 2,797                               | 15                    | 4                                   | 2,900                               | 14                    | 11                                  |

#### 8 SECOND QUARTER PRODUCT REVENUE ANALYSIS

|                         | World                                     |                       | U                                   | S   |                       | Western Europ                             | e                     |                                     | Established RO                            | w                     |                                     | Emerging ROW                              |                       |                                     |  |  |
|-------------------------|---|-----------------------|-------------------------------------|---|-----------------------|---|-----------------------|-------------------------------------|---|-----------------------|-------------------------------------|---|-----------------------|-------------------------------------|--|--|
|                         | 2 <sup>nd</sup><br>Quarter<br>2011<br>\$m | Actual<br>Growth<br>% | Constant<br>Currency<br>Growth<br>% | 2 <sup>nd</sup><br>Quarter<br>2011<br>\$m | Actual<br>Growth<br>% | 2 <sup>nd</sup><br>Quarter<br>2011<br>\$m | Actual<br>Growth<br>% | Constant<br>Currency<br>Growth<br>% | 2 <sup>nd</sup><br>Quarter<br>2011<br>\$m | Actual<br>Growth<br>% | Constant<br>Currency<br>Growth<br>% | 2 <sup>nd</sup><br>Quarter<br>2011<br>\$m | Actual<br>Growth<br>% | Constant<br>Currency<br>Growth<br>% |  |  |
| Gastrointestinal:       |   |                       |                                     |   |                       |   |                       |                                     |   |                       |                                     |   |                       |                                     |  |  |
| Nexium                  | 1,112                                     | (12)                  | (14)                                | 613                                       | (12)                  | 191                                       | (36)                  | (42)                                | 117                                       | 5                     | (5)                                 | 191                                       | 26                    | 24                                  |  |  |
| Losec/Prilosec          | 239                                       | (8)                   | (17)                                | 8   | (42)                  | 64  | (10)                  | (20)                                | 117                                       | 5                     | (5)                                 | 50  | (25)                  | (28)                                |  |  |
| Others                  | 36  | (5)                   | (8)                                 | 22  | (8)                   | 11  |                       | (9)                                 | 3   | 50                    | 50                                  |   | (100)                 | (100)                               |  |  |
| Total Gastrointestinal  | 1,387                                     | (11)                  | (14)                                | 643                                       | (12)                  | 266                                       | (30)                  | (37)                                | 237                                       | 6                     | (4)                                 | 241                                       | 10                    | 8                                   |  |  |
| Cardiovascular:         |   |                       |                                     |   |                       |   |                       |                                     |   |                       |                                     |   |                       |                                     |  |  |
| Crestor                 | 1,714                                     | 20                    | 15                                  | 796                                       | 17                    | 324                                       | 17                    | 7                                   | 420                                       | 31                    | 19                                  | 174                                       | 12                    | 8                                   |  |  |
| Atacand                 | 385                                       | 2                     | (4)                                 | 49  | (16)                  | 188                                       | 4                     | (6)                                 | 61  | 11                    | -                                   | 87  | 6                     | 5                                   |  |  |
| Seloken/Toprol-XL       | 232                                       | (27)                  | (29)                                | 91  | (51)                  | 21  | (5)                   | (14)                                | 10  | -                     | (20)                                | 110                                       | 11                    | 7                                   |  |  |
| Plendil                 | 62  | (2)                   | (6)                                 | 3   | (25)                  | 6   | (14)                  | (14)                                | 3   | -                     | (33)                                | 50  | 2                     | (2)                                 |  |  |
| Tenormin                | 71  | (1)                   | (10)                                | 3   | (25)                  | 15  | (6)                   | (19)                                | 30  | (6)                   | (16)                                | 23  | 15                    | 10                                  |  |  |
| Zestril                 | 39  | (3)                   | (8)                                 | 2   | -                     | 19  | (5)                   | (15)                                | 5   | 25                    | 25                                  | 13  | (7)                   | (7)                                 |  |  |
| Onglyza <sup>™</sup>    | 46  | 228                   | 228                                 | 33  | 230                   | 9   | 125                   | 125                                 | 1   | n/m                   | n/m                                 | 3   | n/m                   | n/m                                 |  |  |
| Brilinta/Brilique       | 2   | n/m                   | n/m                                 | _   | -                     | 1   | n/m                   | n/m                                 | -   | -                     | -                                   | 1   | n/m                   | n/m                                 |  |  |
| Others                  | 68  | -                     | (7)                                 | -   | (100)                 | 34  | 13                    | 3                                   | 6   | (14)                  | (29)                                | 28  | 12                    | 8                                   |  |  |
| Total Cardiovascular    | 2,619                                     | 10                    | 5                                   | 977                                       | 3                     | 617                                       | 11                    | 2                                   | 536                                       | 24                    | 12                                  | 489                                       | 10                    | 7                                   |  |  |
| Respiratory:            | 2,010                                     |                       |                                     |   |                       |   |                       |                                     |   |                       |                                     | 400                                       |                       | <u> </u>                            |  |  |
| Symbicort               | 802                                       | 21                    | 14                                  | 206                                       | 14                    | 378                                       | 13                    | 3                                   | 103                                       | 72                    | 57                                  | 115                                       | 31                    | 24                                  |  |  |
| Pulmicort               | 236                                       | 9                     | 4                                   | 88  | 5                     | 49  | (4)                   | (12)                                | 30  | 7                     | (4)                                 | 69  | 30                    | 24                                  |  |  |
| Rhinocort               | 230<br>55                                 | (15)                  | (18)                                | 19  | (34)                  | 49<br>12                                  | (4)                   |                                     | 5   | 67                    | 33                                  | 19  |                       |                                     |  |  |
|                         |   |                       |                                     | 2   |                       |   |                       | - (10)                              | 6   | 07                    |                                     |   | (14)                  | (14)                                |  |  |
| Others                  | 55  | (14)                  | (22)                                |   | (82)                  | 30  |                       | (10)                                |   |                       |                                     | 17  |                       | (12)                                |  |  |
| Total Respiratory       | 1,148                                     | 14                    | 7                                   | 315                                       | 3                     | 469                                       | 10                    |                                     | 144                                       | 48                    | 35                                  | 220                                       | 22                    | 16                                  |  |  |
| Oncology:               |   | ()                    | ()                                  |   | ()                    |   | (                     | ()                                  |   |                       |                                     |   | _                     | (-)                                 |  |  |
| Arimidex                | 181                                       | (59)                  | (62)                                | 10  | (95)                  | 55  | (62)                  | (65)                                | 76  | 6                     | (4)                                 | 40  | 5                     | (5)                                 |  |  |
| Zoladex                 | 302                                       | 8                     | 3                                   | 10  | (17)                  | 69  | 1                     | (7)                                 | 123                                       | 9                     | (4)                                 | 100                                       | 15                    | 21                                  |  |  |
| Casodex                 | 138                                       | (9)                   | (17)                                | (3)                                       | (138)                 | 22  | (27)                  | (33)                                | 91  | 5                     | (7)                                 | 28  | 8                     | 8                                   |  |  |
| Iressa                  | 139                                       | 49                    | 38                                  | -   | (100)                 | 33  | 267                   | 233                                 | 51  | 9                     | (2)                                 | 55  | 53                    | 44                                  |  |  |
| Others                  | 162                                       | 56                    | 48                                  | 67  | 91                    | 53  | 66                    | 53                                  | 17  | 21                    | 7                                   | 25  | 9                     | -                                   |  |  |
| Total Oncology          | 922                                       | (14)                  | (19)                                | 84  | (65)                  | 232                                       | (18)                  | (25)                                | 358                                       | 8                     | (4)                                 | 248                                       | 18                    | 16                                  |  |  |
| Neuroscience:           |   |                       |                                     |   |                       |   |                       |                                     |   |                       |                                     |   |                       |                                     |  |  |
| Seroquel IR             | 1,150                                     | 10                    | 7                                   | 889                                       | 13                    | 144                                       | 4                     | (5)                                 | 55  | (13)                  | (22)                                | 62  | (2)                   | (8)                                 |  |  |
| Seroquel XR             | 387                                       | 28                    | 23                                  | 205                                       | 14                    | 129                                       | 59                    | 44                                  | 23  | 53                    | 40                                  | 30  | 11                    | 7                                   |  |  |
| Local Anaesthetics      | 156                                       | 1                     | (8)                                 | 4   | (60)                  | 63  | (3)                   | (12)                                | 51  | 4                     | (10)                                | 38  | 23                    | 23                                  |  |  |
| Zomig                   | 103                                       | (6)                   | (11)                                | 38  | (17)                  | 44  | 5                     | (5)                                 | 18  | 6                     | (6)                                 | 3   | (25)                  | (25)                                |  |  |
| Diprivan                | 86  | 6                     | (1)                                 | 6   | (54)                  | 11  | (15)                  | (23)                                | 21  | 11                    | (5)                                 | 48  | 33                    | 28                                  |  |  |
| Vimovo                  | 6   | n/m                   | n/m                                 | 5   | n/m                   | -   | n/m                   | n/m                                 | 1   | n/m                   | n/m                                 | -   | n/m                   | n/m                                 |  |  |
| Others                  | 9   | (10)                  | (20)                                | 1   | -                     | 5   | (43)                  | (57)                                | 2   | (50)                  | (50)                                | 1   | n/m                   | n/m                                 |  |  |
| Total Neuroscience      | 1,897                                     | 11                    | 7                                   | 1,148                                     | 11                    | 396                                       | 14                    | 4                                   | 171                                       | 4                     | (8)                                 | 182                                       | 13                    | 9                                   |  |  |
| Infection & Other:      |   |                       |                                     |   |                       |   |                       |                                     |   |                       |                                     |   |                       |                                     |  |  |
| Synagis                 | 48  | 12                    | 12                                  | 6   | (25)                  | 42  | 23                    | 23                                  | _   | _                     | _                                   | -   | _                     | _                                   |  |  |
| Merrem                  | 158                                       | (20)                  | (24)                                | 12  | (56)                  | 52  | (37)                  | (41)                                | 19  | 12                    | -                                   | 75  | 6                     | 1                                   |  |  |
| FluMist                 | -   | (100)                 | (100)                               | -   | (100)                 | -   | (07)                  | (+1)                                | -   | -                     | -                                   | -   | -                     | -                                   |  |  |
| Others                  | 34  | 31                    | (100)                               | 17  | 13                    | 4   | -                     | (33)                                | 1   | n/m                   | n/m                                 | 12  | 63                    | 38                                  |  |  |
| Total Infection & Other | <u></u> 240                               | (10)                  | (15)                                | 35  | (31)                  | 98  | (18)                  | (33)                                | 20  | 18                    | 6                                   | 87  | <u> </u>              | 4                                   |  |  |
|                         |   |                       |                                     |   |                       | 30  | (10)                  | (23)                                | 20  | 10                    | 0                                   | 01  |                       | 4                                   |  |  |
| Aptium Oncology         | 60  | 2                     | 2                                   | 60<br>20                                  | 2                     | -   | -                     | -                                   | -   | -                     | -                                   | -   | -                     | -                                   |  |  |
| Astra Tech              | 157                                       | 17                    | 8                                   | 30  | 20                    | 116                                       | 17                    | 6                                   | 10  |                       | (20)                                | 1   | <u>n/m</u>            |                                     |  |  |
| Total                   | 8,430                                     | 3                     | (2)                                 | 3,292                                     | (3)                   | 2,194                                     | (1)                   | (9)                                 | 1,476                                     | 16                    | 4                                   | 1,468                                     | 13                    | 10                                  |  |  |

## Shareholder Information ANNOUNCEMENTS AND MEETINGS

Announcement of third quarter and nine months 2011 results Announcement of fourth quarter and full year 2011 results

DIVIDENDS

The record date for the first interim dividend payable on 12 September 2011 is 5 August 2011. Shares will trade ex-dividend from 3 August 2011.

Future dividends will normally be paid as follows:

First interim

Second interim

Announced in July and paid in September Announced in January and paid in March

27 October 2011

2 February 2012

#### TRADEMARKS

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#### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

In order, among other things, to utilise the 'safe harbour' provisions of the US Private Securities Litigation Reform Act 1995, we are providing the following cautionary statement: The interim financial statements contain certain forward-looking statements with respect to the operations, performance and financial condition of the Group. Although we believe our expectations are based on reasonable assumptions, any forward-looking statements, by their very nature, involve risks and uncertainties and may be influenced by factors that could cause actual outcomes and results to be materially different from those predicted. The forward-looking statements reflect knowledge and information available at the date of preparation of the interim financial statements and AstraZeneca undertakes no obligation to update these forward-looking statements. We identify the forward-looking statements by using the words 'anticipates', 'believes', 'expects', 'intends' and similar expressions in such statements. Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond our control, include, among other things: the loss or expiration of patents, marketing exclusivity or trademarks; the risk of substantial adverse litigation/government investigation claims and insufficient insurance coverage; exchange rate fluctuations; the risk that R&D will not yield new products that achieve commercial success; the risk that strategic alliances and acquisitions will be unsuccessful; the impact of competition, price controls and price reductions; taxation risks; the risk of substantial product liability claims; the impact of any failure by third parties to supply materials or services; the risk of failure to manage a crisis; the risk of delay to new product launches; the difficulties of obtaining and maintaining regulatory approvals for products; the risk of failure to observe ongoing regulatory oversight; the risk that new products do not perform as we expect; the risk of environmental liabilities; the risks associated with conducting business in emerging markets; the risk of reputational damage; the risk of product counterfeiting; the risk that regulatory approval processes for biosimilars could have an adverse effect on future commercial prospects; and the impact of increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation.