

## Condensed Consolidated Statement of Comprehensive Income

For the year ended 31 December	2009 \$m	2008 \$m
<b>Revenue</b>	32,804	31,601
Cost of sales	(5,775)	(6,598)
<b>Gross profit</b>	27,029	25,003
Distribution costs	(298)	(291)
Research and development	(4,409)	(5,179)
Selling, general and administrative costs*	(11,332)	(10,913)
Other operating income and expense	553	524
<b>Operating profit</b>	11,543	9,144
Finance income	462	854
Finance expense	(1,198)	(1,317)
<b>Profit before tax</b>	10,807	8,681
Taxation	(3,263)	(2,551)
<b>Profit for the period</b>	7,544	6,130
<b>Other comprehensive income:</b>		
Foreign exchange arising on consolidation	388	(1,336)
Foreign exchange differences on borrowings forming net investment hedges	(68)	291
Gain on cash flow hedge in connection with debt issue	1	1
Net available for sale gains taken to equity	2	2
Actuarial loss for the period	(569)	(1,232)
Income tax relating to components of other comprehensive income	192	368
Other comprehensive income for the period, net of tax	(54)	(1,906)
<b>Total comprehensive income for the period</b>	7,490	4,224
<b>Profit attributable to:</b>		
Owners of the parent	7,521	6,101
Non-controlling interests	23	29
	7,544	6,130
<b>Total comprehensive income attributable to:</b>		
Owners of the parent	7,467	4,176
Non-controlling interests	23	48
	7,490	4,224
Basic earnings per \$0.25 Ordinary Share	\$5.19	\$4.20
Diluted earnings per \$0.25 Ordinary Share	\$5.19	\$4.20
Weighted average number of Ordinary Shares in issue (millions)	1,448	1,453
Diluted average number of Ordinary Shares in issue (millions)	1,450	1,453

\* During 2009, AstraZeneca recorded provisions of \$524 million (including \$4 million of interest accruing on the \$520 million settlement in principal) in respect of the US Attorney's Office Investigation into sales and marketing practices involving *Seroquel* and \$112 million in respect of average wholesale price litigation (see Note 4).

## Condensed Consolidated Statement of Comprehensive Income

For the <b>quarter</b> ended 31 December	2009 \$m	2008 \$m
<b>Revenue</b>	8,945	8,193
Cost of sales	(1,665)	(2,112)
<b>Gross profit</b>	7,280	6,081
Distribution costs	(91)	(71)
Research and development	(1,314)	(1,355)
Selling, general and administrative costs*	(3,465)	(2,856)
Other operating income and expense	(85)	93
<b>Operating profit</b>	2,325	1,892
Finance income	130	217
Finance expense	(291)	(293)
<b>Profit before tax</b>	2,164	1,816
Taxation	(602)	(557)
<b>Profit for the period</b>	1,562	1,259
<b>Other comprehensive income:</b>		
Foreign exchange arising on consolidation	(42)	(897)
Foreign exchange differences on borrowings forming net investment hedges	27	179
Gain on cash flow hedge in connection with debt issue	1	1
Net available for sale gains taken to equity	-	3
Actuarial loss for the period	(504)	(1,082)
Income tax relating to components of other comprehensive income	136	286
Other comprehensive income for the period, net of tax	(382)	(1,510)
<b>Total comprehensive income for the period</b>	1,180	(251)
<b>Profit attributable to:</b>		
Owners of the parent	1,553	1,248
Non-controlling interests	9	11
	1,562	1,259
<b>Total comprehensive income attributable to:</b>		
Owners of the parent	1,174	(275)
Non-controlling interests	6	24
	1,180	(251)
Basic earnings per \$0.25 Ordinary Share	\$1.07	\$0.86
Diluted earnings per \$0.25 Ordinary Share	\$1.07	\$0.86
Weighted average number of Ordinary Shares in issue (millions)	1,450	1,447
Diluted average number of Ordinary Shares in issue (millions)	1,455	1,447

\* During the fourth quarter 2009, AstraZeneca recorded provisions of \$4 million for interest accruing on the \$520 million settlement in principal in respect of the US Attorney's Office Investigation into sales and marketing practices involving *Seroquel* and \$94 million in respect of average wholesale price litigation (see Note 4).

# Condensed Consolidated Statement of Financial Position

	As at 31 Dec 2009 \$m	As at 31 Dec 2008 \$m
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, plant and equipment	7,307	7,043
Goodwill	9,889	9,874
Intangible assets	12,226	12,323
Derivative financial instruments	262	449
Other investments	184	156
Deferred tax assets	1,292	1,236
	<u>31,160</u>	<u>31,081</u>
<b>Current assets</b>		
Inventories	1,750	1,636
Trade and other receivables	7,709	7,261
Derivative financial instruments	24	-
Other investments	1,484	105
Income tax receivable	2,875	2,581
Cash and cash equivalents	9,918	4,286
	<u>23,760</u>	<u>15,869</u>
<b>Total assets</b>	<u>54,920</u>	<u>46,950</u>
<b>LIABILITIES</b>		
<b>Current liabilities</b>		
Interest bearing loans and borrowings	(1,926)	(993)
Trade and other payables	(8,687)	(7,178)
Derivative financial instruments	(90)	(95)
Provisions	(1,209)	(600)
Income tax payable	(5,728)	(4,549)
	<u>(17,640)</u>	<u>(13,415)</u>
<b>Non-current liabilities</b>		
Interest bearing loans and borrowings	(9,137)	(10,855)
Derivative financial instruments	-	(71)
Deferred tax liabilities	(3,247)	(3,126)
Retirement benefit obligations	(3,354)	(2,732)
Provisions	(477)	(542)
Other payables	(244)	(149)
	<u>(16,459)</u>	<u>(17,475)</u>
<b>Total liabilities</b>	<u>(34,099)</u>	<u>(30,890)</u>
<b>Net assets</b>	<u>20,821</u>	<u>16,060</u>
<b>EQUITY</b>		
<b>Capital and reserves attributable to equity holders of the Company</b>		
Share capital	363	362
Share premium account	2,180	2,046
Other reserves	1,919	1,932
Retained earnings	16,198	11,572
	<u>20,660</u>	<u>15,912</u>
<b>Non-controlling interests</b>	<u>161</u>	<u>148</u>
<b>Total equity</b>	<u>20,821</u>	<u>16,060</u>

## Condensed Consolidated Statement of Cash Flows

For the <b>year</b> ended 31 December	2009 \$m	2008 \$m
<b>Cash flows from operating activities</b>		
Profit before taxation	10,807	8,681
Finance income and expense	736	463
Depreciation, amortisation and impairment	2,087	2,620
Decrease/(increase) in working capital and short-term provisions	1,329	(210)
Other non-cash movements	(200)	87
Cash generated from operations	14,759	11,641
Interest paid	(639)	(690)
Tax paid	(2,381)	(2,209)
<b>Net cash inflow from operating activities</b>	<b>11,739</b>	<b>8,742</b>
<b>Cash flows from investing activities</b>		
Movement in short term investments and fixed deposits	(1,371)	1
Purchase of property, plant and equipment	(962)	(1,095)
Disposal of property, plant and equipment	138	38
Purchase of intangible assets	(624)	(2,944)
Disposal of intangible assets	269	-
Purchase of non-current asset investments	(31)	(40)
Disposal of non-current asset investments	3	32
Interest received	113	149
Payments made by subsidiaries to non-controlling interest	(11)	(37)
<b>Net cash outflow from investing activities</b>	<b>(2,476)</b>	<b>(3,896)</b>
<b>Net cash inflow before financing activities</b>	<b>9,263</b>	<b>4,846</b>
<b>Cash flows from financing activities</b>		
Proceeds from issue of share capital	135	159
Repurchase of shares	-	(610)
Issue of loans	-	787
Repayment of loans	(650)	-
Dividends paid	(2,977)	(2,739)
Movement in short term borrowings	(137)	(3,959)
<b>Net cash outflow from financing activities</b>	<b>(3,629)</b>	<b>(6,362)</b>
<b>Net increase/(decrease) in cash and cash equivalents in the period</b>	<b>5,634</b>	<b>(1,516)</b>
Cash and cash equivalents at the beginning of the period	4,123	5,727
Exchange rate effects	71	(88)
<b>Cash and cash equivalents at the end of the period</b>	<b>9,828</b>	<b>4,123</b>
<b>Cash and cash equivalents consists of:</b>		
Cash and cash equivalents	9,918	4,286
Overdrafts	(90)	(163)
	<b>9,828</b>	<b>4,123</b>

## Condensed Consolidated Statement of Changes in Equity

	Share capital \$m	Share premium account \$m	Other* reserves \$m	Retained earnings \$m	Total \$m	Non-controlling interests \$m	Total equity \$m
<b>At 1 January 2008</b>	364	1,888	1,902	10,624	14,778	137	14,915
Profit for the period	-	-	-	6,101	6,101	29	6,130
Other comprehensive income	-	-	-	(1,925)	(1,925)	19	(1,906)
Transfer to other reserve	-	-	27	(27)	-	-	-
<b>Transactions with owners:</b>							
Dividends	-	-	-	(2,767)	(2,767)	-	(2,767)
Issue/(repurchase) of AstraZeneca PLC Ordinary shares	(2)	158	3	(610)	(451)	-	(451)
Share-based payments	-	-	-	176	176	-	176
Transfer from non-controlling interests to payables	-	-	-	-	-	(11)	(11)
Dividend paid to non-controlling interest	-	-	-	-	-	(26)	(26)
<b>At 31 December 2008</b>	<b>362</b>	<b>2,046</b>	<b>1,932</b>	<b>11,572</b>	<b>15,912</b>	<b>148</b>	<b>16,060</b>
	Share capital \$m	Share premium account \$m	Other* reserves \$m	Retained earnings \$m	Total \$m	Non-controlling interests \$m	Total equity \$m
<b>At 1 January 2009</b>	362	2,046	1,932	11,572	15,912	148	16,060
Profit for the period	-	-	-	7,521	7,521	23	7,544
Other comprehensive income	-	-	-	(54)	(54)	-	(54)
Transfer to other reserve	-	-	(13)	13	-	-	-
<b>Transactions with owners:</b>							
Dividends	-	-	-	(3,026)	(3,026)	-	(3,026)
Issue of AstraZeneca PLC Ordinary shares	1	134	-	-	135	-	135
Share-based payments	-	-	-	172	172	-	172
Transfer from non-controlling interests to payables	-	-	-	-	-	(9)	(9)
Dividend paid to non-controlling interest	-	-	-	-	-	(1)	(1)
<b>At 31 December 2009</b>	<b>363</b>	<b>2,180</b>	<b>1,919</b>	<b>16,198</b>	<b>20,660</b>	<b>161</b>	<b>20,821</b>

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

# Notes to the Preliminary Announcement

## 1 BASIS OF PREPARATION AND ACCOUNTING POLICIES

The preliminary announcement for the year ended 31 December 2009 has been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union and as issued by the International Accounting Standards Board. There have been no significant changes in accounting policies from those set out in AstraZeneca PLC's Annual Report and Form 20-F Information 2008. The annual financial information presented in the preliminary announcement for the year ended 31 December 2009 is based on, and is consistent with, that in the Group's audited Financial Statements for the year ended 31 December 2009, and those Financial Statements will be delivered to the Registrar of Companies following the Company's Annual General Meeting. The auditor's report on those Financial Statements is unqualified and does not contain any statement under Section 498 (2) or (3) of the Companies Act 2006.

During the year, the Group has applied IAS 1 *Presentation of Financial Statements (revised 2007)* which has introduced a number of terminology changes (including titles for the condensed financial statements) and has resulted in a number of changes in presentation and disclosure. The revised standard has had no impact on the reported results or financial position of the Group. In addition, the Group has adopted IFRS 2 *Amendment regarding Vesting Conditions and Cancellations*, IAS 23 *Borrowing Costs (revised 2007)* and Amendments to IAS 32 *Financial Instruments: Presentation* and IAS 1 *Presentation of Financial Statements*, none of which have had a significant effect on the reported results or financial position of the Group.

During the year the Company has adopted IFRS 8 'Operating Segments'. IFRS 8 requires an entity to report financial and descriptive information about its reportable segments. Reportable segments are operating segments or aggregations of operating segments that meet specified criteria. In addressing these criteria, it was determined that AstraZeneca is engaged in a single business activity of pharmaceuticals and that the Group does not have multiple operating segments. Our pharmaceuticals business consists of the discovery and development of new products, which are then manufactured, marketed and sold. All of these functional activities take place (and are managed) globally on a highly integrated basis. We do not manage these individual functional areas separately.

We consider that the SET is AstraZeneca's chief operating decision making body (as defined by IFRS 8). The operation of SET is principally driven by the management of the commercial operations, research & development and manufacturing & supply. The SET also includes Finance, HR and General Counsel representation.

All significant operating decisions are taken by SET. While members of the SET have responsibility for implementation of decisions in their respective areas, operating decision making is at SET-level as a whole. Where necessary these are implemented through cross functional sub-committees that consider the group-wide impact of a new decision. For example, product launch decisions would be initially considered by the SET and, on approval, passed to an appropriate sub-team for implementation. The impacts of being able to develop, produce, deliver and commercialise a wide range of pharmaceutical products drive the SET decision-making process.

In assessing performance the SET reviews financial information on an integrated basis for the Group as a whole, substantially in the form of, and on the same basis as, the Group's IFRS financial statements. The high upfront cost of discovering and developing new products, coupled with the relatively insignificant and stable unit cost of production, means that there is not the clear link that exists in many manufacturing businesses between the revenue generated on an individual product sale and the associated cost (and hence margin) generated on a product. Consequently the profitability of individual drugs or classes of drugs is not considered a key measure of performance for the business and is not monitored by the SET.

Resources are allocated on a group-wide basis according to need. In particular, capital expenditure, in-licensing and research & development resources are allocated between activities on merit, based on overall therapeutic considerations and strategy under the aegis of the Group's Research & Development Executive Committee to facilitate a group-wide single combined discovery and development strategy. The Group's recent acquisitions in the Biologics area, MedImmune and Cambridge Antibody Technology, have been integrated into the existing management structure of AstraZeneca both for allocation of resources and for assessment and monitoring of performance purposes. As such, although Biologics is a relatively new technological area for the Group, it does not operate as a separate operating segment.

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 despite the current uncertain economic outlook and as such, the preliminary announcement has 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 2008 and the Third Quarter and Nine Months Results 2009.

The financial information included in the preliminary announcement does not constitute statutory accounts of the Group for the years ended 31 December 2009 and 2008. Statutory accounts for the year ended 31 December 2008 have been reported on by the Group'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 237(2) or (3) of the Companies Act 1985.

## 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 2009 \$m	Cash flow \$m	Non-cash movements \$m	Exchange movements \$m	At 31 Dec 2009 \$m
Loans due after one year	(10,855)	-	1,794	(76)	(9,137)
Current instalments of loans	(650)	650	(1,756)	(34)	(1,790)
Total loans	(11,505)	650	38	(110)	(10,927)
Other investments - current	105	1,361	14	4	1,484
Net derivative financial instruments	283	10	(97)	-	196
Cash and cash equivalents	4,286	5,560	-	72	9,918
Overdrafts	(163)	74	-	(1)	(90)
Short term borrowings	(180)	137	-	(3)	(46)
	4,331	7,142	(83)	72	11,462
Net (debt)/funds	(7,174)	7,792	(45)	(38)	535

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

## 3 RESTRUCTURING AND SYNERGY COSTS

Profit before tax for year ended 31 December 2009 is stated after charging restructuring and synergy costs of \$659 million (\$881 million in 2008). These have been charged to profit as follows:

	4 <sup>th</sup> Quarter 2009 \$m	4 <sup>th</sup> Quarter 2008 \$m	Full Year 2009 \$m	Full Year 2008 \$m
Cost of sales	49	277	188	405
Research and development	38	50	68	166
Selling, general and administrative costs	198	189	403	310
Total	285	516	659	881

## 4 LEGAL PROCEEDINGS AND CONTINGENT LIABILITIES

AstraZeneca is involved in various legal proceedings considered typical to its business, including litigation relating to product liability, commercial disputes, infringement of intellectual property rights, the validity of certain patents and antitrust law. 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 2008 and Third Quarter and Nine Month results 2009. AstraZeneca made provisions of \$98 million in the fourth quarter of 2009 bringing the total for the year to \$636 million. The substantial majority of the fourth quarter charge is in relation to average wholesale price litigation in the US, which is described in more detail below. As discussed in the Company's Annual Report and Form 20-F Information 2008, 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 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 2008 and herein.

### Matters disclosed in respect of the fourth quarter of 2009

#### ***Atacand* (candesartan cilexetil)**

##### *Patent litigation – Canada*

As previously disclosed, in April 2009, AstraZeneca Canada Inc. (AstraZeneca Canada) received a Notice of Allegation from Sandoz Canada Inc. (Sandoz Canada) in respect of Canadian Patent Nos. 2,040,955 (the '955 patent) and 2,083,305 (the '305 patent) listed on the Canadian Patent Register for *Atacand*. Sandoz Canada indicated it would await the expiry of the '955 patent, but alleged that the '305 patent is not infringed and is not properly listed on the Canadian Patent Register.

As previously disclosed, in May 2009, AstraZeneca filed a Notice of Allowance in federal court seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance (NOC) to Sandoz Canada for its 4, 8 and 16mg candesartan cilexetil tablets until the expiration of the '305 patent. In December 2009, AstraZeneca Canada discontinued the proceeding. Sandoz Canada may not receive a NOC until the expiry of the '955 patent.

#### *Patent litigation – EU*

In Portugal, in December 2009 a request was filed with the Lisbon Administrative Court of First Instance seeking a preliminary injunction in the administrative courts in order to get a suspension of the effect of decisions taken by administrative bodies in Portugal to grant Sandoz Farmacêutica Limitada marketing authorisations for generic candesartan cilexetil.

#### **Atacand HCT (candesartan cilexetil - hydrochlorothiazide)**

##### *Patent litigation – US*

As previously disclosed, in September 2008 and March 2009, AstraZeneca and Takeda Pharmaceutical Company Limited (Takeda) received Paragraph IV Certification notice-letters from Matrix Laboratories Limited (Matrix) notifying the parties that it had submitted a New Drug Application seeking FDA approval to market a generic version of the 32/12.5, 32/25 and 16/12.5mg dose forms of *Atacand HCT*. Matrix's notice alleges non-infringement, invalidity or unenforceability in respect of US Patent Nos. 5,534,534 (the '534 patent), 5,721,263 (the '263 patent) and 5,958,961 (the '961 patent). Matrix did not challenge the two listed compound patents US Patent Nos. 5,705,517 (the '517 patent) and 5,196,444 (the '444 patent), the latest of which expires in June 2012. As a result, Matrix cannot market its candesartan cilexetil/hydrochlorothiazide combination product before December 2012, when the six-month paediatric exclusivity period expires. AstraZeneca and Takeda did not file a complaint for patent infringement.

In December 2009, AstraZeneca and Takeda received a Paragraph IV Certification notice-letter from Sandoz Inc. (Sandoz) notifying the parties that it has submitted an Abbreviated New Drug Application (ANDA) seeking FDA approval to market a generic version of *Atacand HCT* in the 32/12.5, 32/25 and the 16/12.5mg dose forms. AstraZeneca now lists six unexpired patents in the Orange Book directed to *Atacand HCT*. Sandoz's notice-letter alleges that the '534 patent, the '263 patent and the '961 patent are invalid, unenforceable or not infringed. Sandoz did not challenge the '517 patent, the '444 patent or US Patent No. 7,538,133, the latest of which expires in June 2012. As a result, Sandoz cannot market its candesartan cilexetil/hydrochlorothiazide combination product before December 2012, when the six-month paediatric exclusivity period expires. AstraZeneca and Takeda did not file a complaint for patent infringement.

##### *Patent litigation – Canada*

In August 2009, AstraZeneca Canada received a Notice of Allegation from Sandoz Canada in respect of Canadian Patent Nos. 2,040,955 (the '955 patent), 2,083,305 (the '305 patent) and 2,125,251 (the '251 patent) listed on the Canadian Patent Register for *Atacand Plus* (candesartan cilexetil-hydrochlorothiazide (HCT)). Sandoz Canada has confirmed that it will await the expiry of the '955 patent, but alleges that the '305 patent is not infringed and is not properly listed on the Canadian Patent Register and that the '251 patent is not infringed, invalid and not properly listed. In September 2009, AstraZeneca filed a Notice of Application in federal court seeking an order prohibiting the Minister of Health from issuing a NOC to Sandoz for its 16/12.5mg candesartan cilexetil-HCT tablets until the expiration of the '305 and '251 patents.

In January 2010, AstraZeneca Canada received a Notice of Allegation from Mylan Pharmaceuticals ULC (Mylan ULC) in respect of the '955 patent, the '305 patent and the '251 patent. Mylan ULC alleges the '305 and '251 patents are invalid, infringed and not properly listed. AstraZeneca is reviewing Mylan ULC's notice.

AstraZeneca has full confidence in, and will vigorously defend and enforce, its intellectual property protecting *Atacand* and *Atacand HCT*.

#### **Crestor (rosuvastatin)**

##### *Patent litigation – US*

As previously disclosed, AstraZeneca, IPR Pharmaceuticals, Inc., and AstraZeneca's licensor, Shionogi Seiyaku Kabushiki Kaisha, have filed separate lawsuits in the US District Court for the District of Delaware, against various subsidiaries of eight companies for infringement of the patent covering rosuvastatin calcium, the active ingredient in *Crestor* tablets. In September 2009, AstraZeneca filed a Motion for Summary Judgment of No Inequitable Conduct. Defendants Apotex Inc. and Aurobindo Pharm Ltd also then each renewed their respective motions directed to the Court's jurisdiction over their parent and subsidiary entities seeking separate trials in Florida and New Jersey respectively. In December 2009, Magistrate Judge Leonard Stark issued his Report and Recommendation Regarding Motions for Summary Judgment and to Dismiss, and Order on Evidentiary Motions denying AstraZeneca's summary judgment motion and denying or granting the other pre-trial motions of the parties. In December 2009, Aurobindo Pharm Ltd and AstraZeneca filed objections to certain recommendations in the magistrate's report and recommendations. A decision by Judge Farnan on the magistrate's report and recommendations is pending.

In October 2009, by joint stipulation, AstraZeneca and Sandoz, Inc. entered into a standstill agreement staying the patent infringement action against Sandoz. Both parties agreed to be bound by the first final non-appealable decision rendered in the remaining *Crestor* cases with respect to the validity and enforceability of US Patent No. RE37,314, which covers the active ingredient in *Crestor*.

In December 2009, Judge Farnan modified requirements and procedures for the parties' pre-trial submissions and reset the beginning trial date to 22 February 2010.



#### *Other US patent litigation*

As previously disclosed, in October 2008, Teva Pharmaceuticals Industries Ltd. (Teva Pharma) filed a patent infringement lawsuit against AstraZeneca Pharmaceuticals LP, AstraZeneca PLC, AstraZeneca UK Limited and IPR Pharmaceuticals, Inc. in the Eastern District of Pennsylvania, alleging that *Crestor* infringed one of its formulation patents – US Patent No. RE 39,502 (the '502 patent).

In September 2009, AstraZeneca filed a Motion for Summary Judgment of Invalidity Due to Prior Invention. Also in September 2009, Teva Pharma filed a reissue application with the US Patent and Trademark Office with respect to the '502 patent. In October 2009, Teva Pharma filed a motion to stay the litigation in its entirety during the pendency of the reissue prosecution. AstraZeneca opposed Teva Pharma's motion, arguing that the summary judgment motion should be fully briefed and decided prior to any stay of the litigation. In January 2010, the Court denied Teva Pharma's motion for a stay and ordered it to respond to AstraZeneca's summary judgment motion.

#### *Patent litigation – Canada*

In addition to the previously disclosed NOC proceedings currently pending against Novopharm Limited (Novopharm) and Apotex Inc. (Apotex), separate, parallel patent infringement actions were filed in September 2009 against Novopharm and Apotex in the Federal Court of Canada with respect to the 2,072,945 patent listed on the Canadian Patent Register for *Crestor* (the '945 patent). In November 2009, the federal court dismissed the Statement of Claim against Novopharm as premature without prejudice to re-file. AstraZeneca Canada has appealed the dismissal.

In August 2009, AstraZeneca Canada received a Notice of Application from ratiopharm Inc. (ratiopharm) with respect to the '945 patent and the Canadian Patent No. 2,313,783 (the '783 patent). Ratiopharm claims that the '945 patent and the '783 patent are not infringed and invalid. In October 2009, AstraZeneca filed a Notice of Application in federal court seeking an order prohibiting the Minister of Health from issuing a NOC to ratiopharm for its 5, 10, 20 and 40mg rosuvastatin calcium tablets until the expiration of the '945 and '783 patents.

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

#### ***Faslodex (fulvestrant)***

In November 2009, AstraZeneca received a Paragraph IV Certification notice-letter from Teva Parenteral Medicines, Inc. (Teva Parenteral) stating that Teva Parenteral had submitted an ANDA seeking approval to manufacture and sell fulvestrant injection 50mg/ml, and alleging invalidity, unenforceability and non-infringement of the two patents listed in the FDA's Orange Book with respect to *Faslodex*. On 7 January 2010, AstraZeneca filed a lawsuit against Teva Parenteral, Teva Pharmaceuticals USA, Inc. and Teva Pharma in the US District Court for the District of Delaware for infringement of the patents.

#### ***Losec/Prilosec (omeprazole)***

##### *Patent litigation – US*

As previously reported, from 2001 to 2005, AstraZeneca entered into patent infringement litigation against numerous generic companies including Lek Pharmaceutical and Chemical Company d.d. and Lek Services USA, Inc. (together Lek), Impax Laboratories Inc. (Impax) (manufacturers of the generic product distributed in the US by Teva Pharma Ltd (Teva), Apotex Corp. and Apotex, Inc. (together Apotex Group), Andrx Pharmaceuticals, Inc. (Andrx), and Laboratorios Esteve, SA and Esteve Quimica, SA (together Esteve) (manufacturers of the omeprazole product distributed in the US by Mylan Pharmaceuticals Inc.). The basis for these proceedings included that conduct of these companies would infringe in US Patent Nos. 4,786,505 (the '505 patent) and 4,853,230 (the '230 patent) formulation patents relating to omeprazole. In January 2010, AstraZeneca settled with Impax and Teva, who are marketing Impax's product. AstraZeneca received a one-time payment for past infringing sales. AstraZeneca continues to pursue damages and additional remedies from Andrx and Apotex Group.

#### ***Nexium (esomeprazole)***

##### *Sales and marketing practices*

As previously disclosed, AstraZeneca entities have been sued in various state and federal courts in the US in purported representative class actions involving the marketing of *Nexium*. The Florida and Arkansas cases have been dismissed at the trial court level and both of these dismissals have been affirmed on appeal.

As previously disclosed, the case in the Delaware federal court was initially dismissed in November 2005, but the decision was vacated in March 2009 by the Court of Appeals for reconsideration in light of the US Supreme Court's pre-emption decision in *Wyeth v. Levine*. AstraZeneca has moved to dismiss the case on alternative grounds and intends to vigorously defend the case.

##### *Patent litigation – US*

As previously disclosed, in January 2006, AstraZeneca received a Paragraph IV Certification notice-letter from IVAX Pharmaceuticals Inc. stating that IVAX Corporation (together IVAX Group) had submitted an ANDA for approval to market 20 and 40mg esomeprazole magnesium delayed-release capsules. In March 2006, AstraZeneca commenced willful patent infringement litigation in the US District Court for the District of New Jersey against IVAX Group, its parent Teva Pharma, and their affiliates (together Teva Group). In December 2008, the Court granted AstraZeneca's motion to add Cipla, Ltd. as a defendant in the IVAX Group/Teva Group litigation.

In January 2010, AstraZeneca entered into an agreement to settle the IVAX Group/Teva Group litigation. Teva Group conceded that all patents-at-issue in its US *Nexium* patent litigations are valid and enforceable. Teva Group also conceded that its ANDA product would infringe six of the *Nexium* patents-in-suit. AstraZeneca has granted Teva Group a license for its ANDA product to enter the US market, subject to regulatory approval, on 27 May 2014. This date and the settlement are consistent with AstraZeneca's previously disclosed settlement with Ranbaxy Pharmaceuticals, Inc. and Ranbaxy Laboratories Limited. As a result of settlement and entry of a consent judgment, the litigation against IVAX Group/Teva Group and Cipla, Ltd. has been dismissed.

AstraZeneca received a Paragraph IV Certification notice-letter in December 2007 from Dr Reddy's Laboratories Ltd (DRL) stating that DRL had submitted an ANDA for 20 and 40mg esomeprazole magnesium delayed-release capsules alleging invalidity and/or non-infringement in respect of certain AstraZeneca US patents. In January 2008, AstraZeneca commenced patent infringement litigation in the US District Court for the District of New Jersey against DRL in response to DRL's Paragraph IV certifications regarding *Nexium*. Although previously consolidated with the above referenced IVAX Group/Teva Group and Cipla, Ltd. litigations, the DRL litigation proceeds. No trial date has been set.

In September 2009, AstraZeneca received a Paragraph IV Certification notice-letter from Lupin Limited (Lupin) informing AstraZeneca that Lupin had submitted an ANDA for approval to market 20mg and 40mg esomeprazole magnesium delayed-release capsules relating to patents listed in the FDA's Orange Book with reference to *Nexium*. In October 2009, AstraZeneca commenced patent infringement litigation against Lupin in the US District Court for the District of New Jersey. The Lupin litigation proceeds in its early stages. No trial date has been set.

In January 2010, AstraZeneca received a Paragraph IV Certification notice-letter from Sun Pharma Global FZE (Sun) notifying AstraZeneca that Sun had submitted an NDA for esomeprazole sodium for injection 20mg/vial and 40mg/vial relating to patents listed in the FDA's Orange Book. AstraZeneca is reviewing Sun's notice.

#### *Patent litigation – Canada*

In December 2009, AstraZeneca Canada received a Notice of Allegation from Mylan ULC relating to all patents listed on the Canadian Patent Register for *Nexium*. AstraZeneca is reviewing Mylan ULC's notice and considering its options.

AstraZeneca Canada received several notices of allegation from Apotex in late 2007 in respect of patents listed on the Canadian Patent Register for 20mg and 40mg copies of *Nexium* tablets. AstraZeneca responded by commencing seven court applications in January 2008 under the Patented Medicines (Notice of Compliance) Regulations. Apotex cannot obtain a NOC for its esomeprazole tablets until the earlier of the end of September 2010 or the disposition of all of the court applications in Apotex's favour. The application hearing has been scheduled to take place from 31 May to 4 June 2010.

#### *Patent litigation – Brazil*

AstraZeneca has filed two law suits before the Federal Courts of Brasilia seeking judicial declaration confirming that all conditions established in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement have been satisfied and therefore entitling AstraZeneca exclusive marketing rights for *Nexium* through 2012. AstraZeneca is awaiting trial decision on the merits.

#### *Patent Litigation – EU*

As previously disclosed, during 2009, marketing authorisations for generic products containing 20 and 40mg esomeprazole magnesium were granted in Europe to companies in the Sandoz group. Denmark was the reference member state and the other EU countries included in the decentralised regulatory procedure were Austria, Bulgaria, Czech Republic, Estonia, Finland, Hungary, Ireland, Latvia, Lithuania, Norway, Poland, Portugal, Romania, Slovenia and Spain.

In Denmark, Sandoz A/S launched its esomeprazole magnesium products in June 2009. AstraZeneca filed an application in June 2009 with the District Court of Copenhagen in Denmark seeking an interlocutory injunction to restrain Sandoz A/S from marketing products containing generic esomeprazole magnesium in Denmark. AstraZeneca considers that the products marketed by Sandoz A/S infringe intellectual property owned by AstraZeneca relating to *Nexium*. On 5 January 2010, the District Court of Copenhagen granted AstraZeneca a preliminary injunction against Sandoz A/S. The injunction prohibits Sandoz A/S from selling, offering for sale or marketing the pharmaceutical products "Esomeprazole Sandoz" and other pharmaceutical products containing esomeprazole magnesium with an optical purity of  $\geq 99.8\%$  enantiomeric excess in Denmark. Sandoz A/S may appeal this decision to the Eastern High Court of Denmark within 4 weeks. An appeal will have no suspensive effect on the injunction, and the injunction will be in force during an appeal process.

As previously disclosed, in October 2009, the Lisbon Administrative Court of First Instance granted AstraZeneca a preliminary injunction suspending the efficacy of the marketing authorisations and the price approvals for Sandoz Farmacêutica Limitada's generic esomeprazole magnesium. The decision has been appealed by the Portuguese authorities.

In Austria, AstraZeneca filed two applications on 15 December 2009 with the Vienna Commercial Court seeking interlocutory injunctions to restrain Hexal Pharma GmbH and 1A Pharma GmbH, both companies in the Sandoz group, from marketing products containing generic esomeprazole magnesium in Austria. AstraZeneca considers that the generic products infringe the optical purity patent covering *Nexium*.

In Slovenia AstraZeneca filed an application on 8 January 2010 with the District Court of Ljubljana seeking an interlocutory injunction to restrain Lek d.d., a company within the Sandoz group, from selling products containing esomeprazole magnesium in Slovenia. AstraZeneca considers that the generic products infringe the optical purity patent covering *Nexium*.

In July 2008 Sandoz AS, Sandoz A/S and Hexal AG initiated an invalidity case regarding two esomeprazole related patents in Norway. In December 2009 the Court delivered its judgment. The Court invalidated a formulation patent while it upheld a substance related to esomeprazole. Both parties have appealed.

In July 2008 AstraZeneca initiated a declaratory action in Finland requesting the Court to confirm that Sandoz AS and Sandoz A/S would infringe a patent relating to esomeprazole if they were to commercialise their generic esomeprazole product in Finland. In September 2008, Hexal AG and Sandoz Oy Ab and Sandoz A/S initiated an invalidity case requesting the Court to invalidate the same patent.

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

#### *Patent proceedings*

As previously disclosed, in July 2009, the European Patent Office (EPO) published the grant of two patents that relate to *Nexium* (the Esomeprazole Magnesium Patent) and *Nexium IV* (the Esomeprazole Sodium Patent). These two patents were granted on the basis of two divisional applications of European Patent No. 0652872 (the Parent Patent). The Parent Patent, a substance patent covering *Nexium*, was revoked by the EPO Board of Appeal in December 2006 following post-grant opposition and appeal proceedings. The Esomeprazole Magnesium Patent also covers *Nexium*, although the claims are different and narrower than the Parent Patent.

The divisional applications were supported by new evidence that was not available at the time the EPO Board of Appeal made its decision to revoke the Parent Patent. The new patents are due to remain in force until May 2014. The claims of the Esomeprazole Magnesium Divisional Application are limited to preparations and uses thereof having a very high optical purity, namely esomeprazole magnesium with an optical purity of  $\geq 99.8\%$  enantiomeric excess. Hexal AG and Teva Pharma filed Notices of Opposition against the grant of the Esomeprazole Magnesium Patent in July 2009.

#### **Prilosec OTC (omeprazole magnesium)**

##### *Patent litigation – US*

As previously disclosed, in June 2007 Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Limited (together Dr. Reddy's) notified AstraZeneca that Dr. Reddy's had submitted an ANDA seeking FDA approval to market a 20mg delayed release omeprazole magnesium product for the OTC market. In July 2007, AstraZeneca commenced patent infringement litigation against Dr. Reddy's in the Southern District of New York. In July 2009, AstraZeneca appealed this ruling to the Federal Circuit Court of Appeals and in December 2009, the Court affirmed the District Court's summary judgment of non-infringement.

#### **Pulmicort Respules (budesonide inhalation suspension)**

##### *Patent litigation – US*

As previously disclosed, In March 2009, AstraZeneca filed a lawsuit in the US District Court for the District of New Jersey against Apotex Group seeking a declaratory judgment of patent infringement. Apotex Group thereafter filed counterclaims alleging non-infringement and invalidity. The lawsuit follows the FDA's approval of an ANDA filed by Apotex Group and concerns Apotex Group's intent to market an FDA-approved generic version of *Pulmicort Respules* in the US prior to the expiration of AstraZeneca's patents. In May 2009, the Court issued a Preliminary Injunction barring Apotex Group from launching its generic version of *Pulmicort Respules* until further order of the Court. Apotex Group appealed the issuance of the Preliminary Injunction to the Court of Appeals for the Federal Circuit. Oral argument on the appeal is scheduled for 5 February 2010.

The litigations involving Apotex Group and Breath Ltd. (now owned by Watson Pharmaceuticals, hereinafter Watson) have been consolidated under a common scheduling order. In April 2009, the US Patent and Trademark Office issued AstraZeneca a new patent directed to sterile formulations of budesonide inhalation suspensions. AstraZeneca listed the new patent in the FDA's Orange Book, referencing *Pulmicort Respules*. AstraZeneca amended its pleadings against Apotex Group and Watson alleging infringement of the newly issued patent. The consolidated litigation proceeds.

Under the terms of the previously reported 2008 settlement agreement resolving patent litigation respecting Teva's generic copies of *Pulmicort Respules*, Teva was granted an exclusive license to market its generic product on or after 15 December 2009. Teva launched its generic product in December 2009.

AstraZeneca has full confidence in, and will vigorously defend and enforce, its intellectual property protecting *Pulmicort Respules*.

#### **Seroquel (quetiapine fumarate)**

##### *Sales and marketing practices*

As previously disclosed, in May 2007, the New Jersey Ironworkers Local Union No. 68 filed a class action suit against AstraZeneca on behalf of all individuals and non-governmental entities that paid for *Seroquel* from January 2000 to date, which was dismissed with prejudice in November 2008 and then appealed by the plaintiffs. AstraZeneca intends to vigorously defend against the appeal, which is scheduled to be heard by the Eleventh Circuit Court of Appeals in February 2010.

As previously disclosed, in September 2008, the Pennsylvania Employees Benefit Trust Fund (PEBTF) served AstraZeneca Pharmaceuticals LP with a complaint filed in the Pennsylvania Court of Common Pleas of Philadelphia County seeking economic damages stemming from allegedly improper marketing practices that caused the PEBTF to reimburse for allegedly overpriced *Seroquel* prescription and the medical care of PEBTF members allegedly injured from *Seroquel* use. In July 2009, the MDL Court dismissed PEBTF's complaint with prejudice. PEBTF has elected to forgo a federal appeal of that decision, and instead is pursuing an appeal in the Pennsylvania Superior Court on the dismissal of an earlier-filed state court action. AstraZeneca intends to vigorously defend itself against this lawsuit.

#### *Product liability*

As previously disclosed, AstraZeneca Pharmaceuticals LP, either alone or in conjunction with one or more affiliates, has been sued in numerous individual personal injury actions involving *Seroquel*.

As previously disclosed, four putative class actions have been filed in Canada, in the provinces of British Columbia, Alberta, Ontario and Quebec. The actions in British Columbia and Alberta are not moving forward at this time and no date has yet been scheduled for the certification hearing in Ontario. The Motion for Authorization (certification hearing) in the Quebec action was heard in December 2009. A decision is expected in early 2010.

As of 4 December 2009, AstraZeneca was defending 10,399 served or answered lawsuits in the US involving 22,099 plaintiff groups. To date, approximately 2,664 additional cases have been dismissed by order or agreement and approximately 1,642 of those cases have been dismissed with prejudice. Approximately 60% of the plaintiffs' currently pending *Seroquel* claims are in state courts (primarily Delaware, New Jersey, New York, California and Alabama) with the other 40% pending in the federal court, where most of the cases have been consolidated for pre-trial purposes into a Multi-District Litigation (MDL).

AstraZeneca is also aware of approximately 177 additional cases (approximately 3,459 plaintiffs) that have been filed but not yet served and has not determined how many additional cases, if any, may have been filed. Some of the cases also include claims against other pharmaceutical manufacturers such as Eli Lilly & Company, Janssen Pharmaceutica, Inc. and/or Bristol-Myers Squibb Company.

In January and February 2009, the federal judge presiding over the *Seroquel* MDL in the District Court for the Middle District of Florida granted AstraZeneca's motions for summary judgment in the first two *Seroquel* product liability cases set for trial and dismissed those cases. The plaintiff in one of these cases filed a notice of appeal to the United States Court of Appeals for the Eleventh Circuit, which was argued on 11 December 2009. The federal MDL court has stayed all remaining Florida cases pending a decision on that appeal. In November 2009, the MDL court stated that it would remand non-Florida cases to the federal district courts from which they were transferred originally, recommended that these cases be transferred to the courts of plaintiffs' states of residence and also suggested a stay of proceedings in all remanded cases pending the MDL court's evaluation of a pre-identified group of cases, currently numbering 37. The MDL court further ordered mediation before any cases are remanded. A mediation session was conducted in mid-January 2010.

In addition to the *Seroquel* MDL in federal court, AstraZeneca is defending *Seroquel* product liability suits in multiple state courts. Cases have been consolidated by state courts in Delaware, New Jersey and New York in order to manage the large volume of claims pending in those jurisdictions. AstraZeneca is also defending *Seroquel* product liability claims in California, Alabama and Missouri.

As previously disclosed, in May 2009, the judge presiding over the *Seroquel* litigation in the Superior Court of Delaware granted AstraZeneca's motion for summary judgment in the first *Seroquel* product liability case set for trial and dismissed the case. Immediately after this decision, plaintiffs voluntarily dismissed the next case scheduled for trial in June 2009 as well as additional cases scheduled for trial in November 2009. Plaintiff filed a notice of appeal of this decision to the Delaware Supreme Court, but later dismissed that appeal voluntarily. On 7 January 2010, the Delaware court granted AstraZeneca's motions for summary judgment in two trials scheduled to begin in mid-January 2010 and dismissed those cases. As a result, the first trial is now scheduled to begin in New Jersey state court in mid-February 2010. Although trial had been scheduled in Missouri for the first quarter of 2010, the trial date is being rescheduled at the request of the court.

AstraZeneca intends to litigate these cases on their individual merits and will defend against the cases vigorously.

AstraZeneca has product liability insurance dating from 2003 that is considered to respond to the vast majority of the *Seroquel*-related product liability claims. This insurance provides coverage for legal defence costs and potential damages amounts. The insurers that issued the applicable policies for 2003 have reserved the right to dispute coverage for *Seroquel*-related product liability claims on various grounds, and AstraZeneca currently believes that there are likely to be disputes with some or all of its insurers about the availability of some or all of this coverage. In December 2009 AstraZeneca formally requested payment from some of its insurers for legal costs incurred in defending the *Seroquel*-related product liability claims. It may be necessary for AstraZeneca to commence legal proceedings against some or all of its insurers in order to recover payment.

As of 31 December 2009 legal defence costs of approximately \$656 million (2008: \$512 million) have been incurred in connection with *Seroquel*-related product liability claims. The first \$39 million is not covered by insurance. At 31 December 2009 AstraZeneca has recorded an insurance receivable of \$521 million (2008: \$426 million) representing the maximum insurance receivable that AstraZeneca can recognise under applicable accounting principles at this time. This amount may increase as AstraZeneca believes that it is more likely than not that the vast majority of costs incurred to date in excess of \$39 million will ultimately be recovered through this insurance, although there can be no assurance of additional coverage under the policies, or that the insurance receivable we have recognised will be realisable in full.

In addition, given the status of the litigation currently, legal defence costs for the *Seroquel* claims, before damages, if any, are likely to exceed the total stated upper limits of the applicable insurance policies.

#### *Patent litigation – US*

In September 2009, the Court of Appeals for the Federal Circuit affirmed the District Court's judgement against Teva Pharmaceuticals USA Inc. and Sandoz. In December 2009, based on the Federal Circuit's decision and its July 2008 decision, the Court entered final judgment against Sandoz. regarding the ANDA products in the new, stayed action resulting from its February 2009 notice-letter.

In December 2009 and January 2010 respectively, AstraZeneca filed motions for orders declaring the cases involving Teva Pharmaceuticals USA Inc. and Sandoz "exceptional" under 35 U.S.C. §285, thereby allowing recovery of attorneys' fees from each non-prevailing party. The §285 matter proceeds.

#### *Patent litigation – Brazil*

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 (SPC). A preliminary order was granted shortly thereafter. Later in 2006 the Brazilian Patent Office (BPTO) filed its bill of review against the preliminary order. AstraZeneca replied and in August 2006, the Federal Court of Appeals denied BPTO's bill of review confirming the preliminary order in favour of AstraZeneca. AstraZeneca is awaiting a trial decision on the merits.

#### *Patent litigation – Portugal*

Since 2007, AstraZeneca has filed requests with the Portuguese courts seeking suspension of the effect of decisions taken by administrative bodies in Portugal to grant other companies marketing authorisations for generic quetiapine fumarate. Many preliminary injunction and main actions are pending before the courts. The courts have generally agreed with AstraZeneca's position and suspended the market authorisations in the preliminary injunction actions until definitive decision on the merits in the main actions.

### **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, defendants caused entities to overpay for prescription drugs.

As previously disclosed, in May 2007, AstraZeneca reached a settlement agreement resolving the Class 1 claims in Massachusetts. The settlement, which was approved by the Court in December 2008, will involve payments of up to \$24m to reimburse individual class members submitting claims, plus attorneys' fees of \$8.58m. AstraZeneca has agreed that a portion of any unclaimed settlement amounts will be donated to charitable organisations funding cancer patient care and research. Notice of the proposed settlement was mailed to potential class members in December 2007. A provision of \$27m was established in 2007. In November 2009, the Court of Appeals rejected a challenge to the settlement.

As previously disclosed, in June 2007 and November 2007, the Multi-District Litigation (MDL) Court issued decisions on liability and damages on Classes 2 and 3. AstraZeneca believes the decisions to be in error and filed an appeal. In September 2009, a panel of the First Circuit Court of Appeals affirmed the District Court's opinion and judgment. In November 2009, the First Circuit Court of Appeals denied AstraZeneca's petition seeking reconsideration of the panel's decision. In December 2009, AstraZeneca reached an agreement in principle to resolve the case, inclusive of pre- and post-judgment interest and plaintiffs' attorney fees. The settlement is subject to final Court approval. AstraZeneca took a provision of \$12.9 million with respect to this matter in the third quarter of 2009, and there is no material increase in reserve with respect to the settlement.

As previously disclosed, in September 2008, the MDL Court granted, in part, the plaintiffs' motion for class certification of third party payers in states other than Massachusetts. The Court certified multi-state versions of Class 2 and Class 3 relating to *Zoladex*. AstraZeneca believes the decision to be in error. In December 2009, AstraZeneca reached an agreement in principle to resolve, inclusive of pre- and post-judgment interest, administration fees and plaintiffs' attorney fees, the *Zoladex* claims subject to the Court's multi-state class certification opinion and *Zoladex* claims in the lawsuit but not certified for class action treatment. The settlement is subject to negotiation of terms and final Court approval. AstraZeneca took a provision of \$90 million in the fourth quarter of 2009 in respect to this settlement.

As previously disclosed, the average wholesale price case filed by the Alabama Attorney General resulted in a jury verdict against AstraZeneca on the state's claims of fraudulent concealment and misrepresentation. In October 2009, the Supreme Court of Alabama overturned the trial court's judgement against AstraZeneca and rendered judgement in AstraZeneca's favour instead. In January 2010, the Alabama Supreme Court denied the State of Alabama's petition for reconsiderations of that decision. No provision has been made in respect of this matter.

As previously disclosed, in October 2009, a Kentucky jury found AstraZeneca liable under the Commonwealth of Kentucky's Consumer Protection statute and Medicaid Fraud statute, and awarded \$14.72 million in compensatory damages and \$100 in punitive damages for drugs reimbursed by the Commonwealth of Kentucky Medicaid Agency. On 26 January 2010, the trial court rendered a decision awarding statutory penalties of \$5.4 million. The court also awarded pre-judgment interest of 8% beginning 15 October 2009 until the judgment date, and awarded post-judgment interest of 9% beginning on the date of judgment. Interest would accrue only on the compensatory damages amount. AstraZeneca believes the Court made several material and reversible errors during the course of the trial and in awarding penalties. AstraZeneca will seek post-judgment relief and will consider filing an appeal if necessary. No provision has been made in respect of this matter.

In November 2009, AstraZeneca reached a settlement to resolve the claims of the state of Hawaii for an immaterial amount which has been provided.

The allegations made in respect of the average wholesale price lawsuits are denied and will be vigorously defended.

### **Verus Pharmaceuticals Litigation**

As previously disclosed, in May 2009, Verus Pharmaceuticals Inc. filed a lawsuit against AstraZeneca AB and its subsidiary, Tika Läkemedel AB (Tika), alleging breaches of several related collaboration agreements to develop novel pediatric asthma treatments. The complaint purports to state claims for fraud, breach of contract, unjust enrichment, and conversion. AstraZeneca AB and Tika have moved to dismiss the complaint and intend vigorously defend this matter.

### **Pain Pump Litigation**

As previously disclosed, AstraZeneca LP, AstraZeneca Pharmaceuticals LP, Zeneca Holdings Inc., and/or AstraZeneca PLC have been named among other defendants in 288 lawsuits, involving 475 plaintiffs, pending in various US jurisdictions, alleging generally that the use of *Marcaine*, *Sensorcaine*, *Xylocaine* and/or *Naropin*, with or without epinephrine, administered in pain pumps that were implanted into patients in connection with arthroscopic surgery, caused chondrolysis. As of 21 January 2010, approximately 220 plaintiffs have voluntarily dismissed, or are in the process of dismissing, their cases against the AstraZeneca defendants. In addition, thirteen cases, involving 17 plaintiffs were dismissed by the court on AstraZeneca motions, although some claims were refiled. AstraZeneca has likewise filed motions to dismiss or for summary judgment in numerous cases that are currently pending.

As previously disclosed, in October 2009, AstraZeneca Pharmaceuticals LP was served with a putative class action lawsuit brought by a single plaintiff on behalf of "several hundred" class members and against more than 20 defendants, including AstraZeneca Pharmaceuticals LP and AstraZeneca PLC, filed in Texas State District Court. The putative class is purportedly defined as all individuals who received local anaesthetics intra-articularly for up to 72 hours or more via a pain pump and includes no geographical limitations. The complaint seeks unspecified compensatory and exemplary damages from the AstraZeneca defendants under various product liability theories. The case was removed to federal court by a co-defendant, and both AstraZeneca Pharmaceuticals LP and the Company filed motions to dismiss. Plaintiff then proceeded to voluntarily dismiss the Company, but AstraZeneca Pharmaceuticals LP's motion remains fully briefed and currently pending.

It was previously reported that plaintiffs moved to consolidate the federal pain pump cases under the MDL process, but the Judicial Panel on MDL denied that motion in August 2008. In November 2009, three plaintiffs' firms filed a renewed motion for MDL consolidation for most, but not all, of the pain pump cases pending in federal court. In addition, plaintiffs in Minnesota federal court, New Jersey state court, and California state court have filed motions or otherwise asked the courts to consolidate the pain pump cases pending in those jurisdictions pursuant to a common case management plan. AstraZeneca is opposing these attempts at consolidation.

### **EU Commission Sector Enquiry**

As previously disclosed, AstraZeneca, together with several other companies, was the subject of an EU Commission Sectoral Inquiry into competition in the pharmaceutical industry which commenced in January 2008. The final report, published in July 2009, recommended improvements to certain patent and regulatory processes as well as greater competition law scrutiny in certain areas. The final report does not identify any wrongdoing by any individual companies, but the Commission noted that a number of investigations are underway. AstraZeneca is not aware that it is the subject of a Commission investigation. The final report noted that the Commission was considering further monitoring of settlement agreements between originator and generic companies. Pursuant to this, in January 2010 the Commission requested copies of settlement agreements entered into between July 2008 and December 2009 from a number of companies, including AstraZeneca. AstraZeneca will cooperate fully with the request.

### **Tax**

AstraZeneca faces a number of transfer pricing audits in jurisdictions around the world and, in some cases, is in dispute with the tax authorities. These disputes usually result in taxable profits being increased in one territory and correspondingly decreased in another. Our balance sheet positions for these matters reflect appropriate corresponding relief in the territories affected. The total net accrual included in the Financial Statements to cover the worldwide exposure to transfer pricing audits is \$2,327 million, an increase of \$699 million due to a number of new audits, revisions of estimates relating to existing audits, offset by a number of negotiated settlements and exchange rate effects.

Management continues to believe that AstraZeneca's positions on all its transfer pricing audits and disputes are robust and that AstraZeneca is appropriately provided. For transfer pricing audits where AstraZeneca and the tax authorities are in dispute, AstraZeneca estimates the potential for reasonably possible additional losses above and beyond the amount provided to be up to \$575 million (2008: \$400 million); however, management believes that it is unlikely that these additional losses will arise.

Of the remaining tax exposures, AstraZeneca does not expect material additional losses. It is not possible to estimate the timing of tax cash flows in relation to each outcome, however, it is anticipated that a number of significant disputes may be resolved over the next one to two years. Included in the provision is an amount of interest of \$565 million (2008: \$365 million). Interest is accrued as a tax expense.

## 5 FULL YEAR TERRITORIAL REVENUE ANALYSIS

	Full Year 2009 \$m	Full Year 2008 \$m	% Growth	
			Actual	Constant Currency
US	14,778	13,510	9	9
Canada	1,203	1,275	(6)	3
North America	15,981	14,785	8	9
Western Europe**	9,277	9,743	(5)	3
Japan	2,341	1,957	20	7
Other Established ROW	853	843	1	12
Established ROW*	12,471	12,543	(1)	4
Emerging Europe	1,091	1,215	(10)	7
China	811	627	29	27
Emerging Asia Pacific	780	802	(3)	6
Other Emerging ROW	1,670	1,629	3	13
Emerging ROW	4,352	4,273	2	12
Total Revenue	32,804	31,601	4	7

\* Established ROW comprises Western Europe (including France, UK, Germany, Italy, Sweden and others), Japan, Australia and New Zealand.

\*\* For the full year 2009, Western Europe revenue growth excluding Synagis would be -5 percent on an actual basis and 3 percent on a constant currency basis.

## 6 FOURTH QUARTER TERRITORIAL REVENUE ANALYSIS

	4 <sup>th</sup> Quarter 2009 \$m	4 <sup>th</sup> Quarter 2008 \$m	% Growth	
			Actual	Constant Currency
US	3,947	3,784	4	4
Canada	341	296	15	4
North America	4,288	4,080	5	4
Western Europe**	2,562	2,298	11	2
Japan	667	602	11	1
Other Established ROW	263	190	38	8
Established ROW*	3,492	3,090	13	2
Emerging Europe	308	291	6	6
China	212	171	24	24
Emerging Asia Pacific	203	184	10	5
Other Emerging ROW	442	377	17	10
Emerging ROW	1,165	1,023	14	10
Total Revenue	8,945	8,193	9	4

\* Established ROW comprises Western Europe (including France, UK, Germany, Italy, Sweden and others), Japan, Australia and New Zealand.

\*\* For the fourth quarter 2009, Western Europe revenue growth excluding Synagis would be 12 percent on an actual basis and 2 percent on a constant currency basis.



## 7 FULL YEAR PRODUCT REVENUE ANALYSIS

	World				US	
	Full Year 2009 \$m	Full Year 2008 \$m	Actual Growth %	Constant Currency Growth %	Full Year 2009 \$m	Actual Growth %
<b>Gastrointestinal:</b>						
<i>Nexium</i>	4,959	5,200	(5)	(1)	2,835	(9)
<i>LOSEC/Prilosec</i>	946	1,055	(10)	(10)	64	(63)
Others	106	89	19	24	51	55
<b>Total Gastrointestinal</b>	<b>6,011</b>	<b>6,344</b>	<b>(5)</b>	<b>(2)</b>	<b>2,950</b>	<b>(11)</b>
<b>Cardiovascular:</b>						
<i>Crestor</i>	4,502	3,597	25	29	2,100	25
<i>Seloken/Toprol-XL</i>	1,443	807	79	84	964	227
<i>Atacand</i>	1,436	1,471	(2)	5	263	-
<i>Tenormin</i>	296	313	(5)	(5)	15	(17)
<i>Zestril</i>	184	236	(22)	(17)	18	(10)
<i>Plendil</i>	241	268	(10)	(7)	14	(44)
ONGLYZA™*	11	-	n/m	n/m	11	n/m
Others	263	271	(3)	3	20	n/m
<b>Total Cardiovascular</b>	<b>8,376</b>	<b>6,963</b>	<b>20</b>	<b>25</b>	<b>3,405</b>	<b>48</b>
<b>Respiratory:</b>						
<i>Symbicort</i>	2,294	2,004	14	23	488	91
<i>Pulmicort</i>	1,310	1,495	(12)	(10)	804	(18)
<i>Rhinocort</i>	264	322	(18)	(15)	129	(29)
<i>Oxis</i>	63	71	(11)	-	-	n/m
<i>Accolate</i>	66	73	(10)	(8)	48	(9)
Others	135	163	(17)	(9)	-	n/m
<b>Total Respiratory</b>	<b>4,132</b>	<b>4,128</b>	<b>-</b>	<b>6</b>	<b>1,469</b>	<b>-</b>
<b>Oncology:</b>						
<i>Arimidex</i>	1,921	1,857	3	7	878	16
<i>Casodex</i>	844	1,258	(33)	(34)	148	(49)
<i>Zoladex</i>	1,086	1,138	(5)	-	54	(25)
<i>Iressa</i>	297	265	12	8	5	(29)
<i>Ethyol</i>	15	28	(46)	(46)	13	(54)
Others	355	408	(13)	(10)	114	(34)
<b>Total Oncology</b>	<b>4,518</b>	<b>4,954</b>	<b>(9)</b>	<b>(7)</b>	<b>1,212</b>	<b>(9)</b>
<b>Neuroscience:</b>						
<i>Seroquel</i>	4,866	4,452	9	12	3,416	13
Local anaesthetics	599	605	(1)	4	40	18
<i>Zomig</i>	434	448	(3)	-	182	(3)
<i>Diprivan</i>	290	278	4	6	45	15
Others	48	54	(11)	(4)	8	(11)
<b>Total Neuroscience</b>	<b>6,237</b>	<b>5,837</b>	<b>7</b>	<b>10</b>	<b>3,691</b>	<b>12</b>
<b>Infection and Other:</b>						
<i>Synagis</i>	1,082	1,230	(12)	(12)	782	(15)
<i>Non Seasonal Flu</i>	389	-	n/m	n/m	389	n/m
<i>Merrem</i>	872	897	(3)	5	177	(14)
<i>FluMist</i>	145	104	39	39	145	39
Other Products	143	220	(35)	(31)	82	(29)
<b>Total Infection and Other</b>	<b>2,631</b>	<b>2,451</b>	<b>7</b>	<b>10</b>	<b>1,575</b>	<b>17</b>
Aptium Oncology	393	395	(1)	(1)	393	(1)
Astra Tech	506	529	(4)	2	83	4
<b>Total</b>	<b>32,804</b>	<b>31,601</b>	<b>4</b>	<b>7</b>	<b>14,778</b>	<b>9</b>

\* ONGLYZA™ is recorded as alliance revenue. This does not represent ex-factory sales, but rather AstraZeneca's share of the gross profit from its collaboration with Bristol-Myers Squibb on this product.

## 8 FOURTH QUARTER PRODUCT REVENUE ANALYSIS

	World				US	
	4 <sup>th</sup> Quarter 2009 \$m	4 <sup>th</sup> Quarter 2008 \$m	Actual Growth %	Constant Currency Growth %	4 <sup>th</sup> Quarter 2009 \$m	Actual Growth %
Gastrointestinal:						
<i>Nexium</i>	1,278	1,324	(3)	(7)	717	(14)
<i>LOSEC/Prilosec</i>	250	264	(5)	(12)	15	(55)
Others	25	23	9	-	9	(10)
Total Gastrointestinal	1,553	1,611	(4)	(8)	741	(15)
Cardiovascular:						
<i>Crestor</i>	1,257	987	27	20	552	13
<i>Seloken/Toprol-XL</i>	324	207	57	53	197	124
<i>Atacand</i>	387	351	10	1	66	3
<i>Tenormin</i>	79	77	3	(4)	4	-
<i>Zestril</i>	43	52	(17)	(23)	5	-
<i>Plendil</i>	60	67	(10)	(13)	4	(60)
ONGLYZA™*	2	-	n/m	n/m	2	n/m
Others	75	62	21	13	9	-
Total Cardiovascular	2,227	1,803	24	17	839	27
Respiratory:						
<i>Symbicort</i>	666	514	30	22	153	70
<i>Pulmicort</i>	387	397	(3)	(5)	230	(12)
<i>Rhinocort</i>	65	78	(17)	(21)	28	(35)
<i>Oxis</i>	19	15	27	20	-	n/m
<i>Accolate</i>	17	18	(6)	(11)	12	(14)
Others	37	37	-	(5)	-	n/m
Total Respiratory	1,191	1,059	12	7	423	4
Oncology:						
<i>Arimidex</i>	499	451	11	6	220	24
<i>Casodex</i>	189	284	(33)	(38)	18	(77)
<i>Zoladex</i>	300	278	8	1	17	-
<i>Iressa</i>	79	73	8	3	1	(50)
<i>Ethyol</i>	4	5	(20)	(20)	4	(20)
Others	98	104	(6)	(12)	30	(35)
Total Oncology	1,169	1,195	(2)	(8)	290	(10)
Neuroscience:						
<i>Seroquel</i>	1,261	1,160	9	6	872	5
Local anaesthetics	166	147	13	3	10	25
<i>Zomig</i>	115	112	3	(3)	46	(6)
<i>Diprivan</i>	79	65	22	14	11	10
Others	15	11	36	27	3	50
Total Neuroscience	1,636	1,495	9	5	942	5
Infection and Other:						
<i>Synagis</i>	401	506	(21)	(21)	263	(31)
<i>Non Seasonal Flu</i>	237	-	n/m	n/m	237	n/m
<i>Merrem</i>	236	217	9	3	48	(14)
<i>FluMist</i>	51	33	55	55	51	55
Other Products	30	49	(39)	(41)	19	(30)
Total Infection and Other	955	805	19	17	618	25
Aptium Oncology	72	101	(29)	(29)	72	(29)
Astra Tech	142	124	15	6	22	10
Total	8,945	8,193	9	4	3,947	4

\* ONGLYZA™ is recorded as alliance revenue. This does not represent ex-factory sales, but rather AstraZeneca's share of the gross profit from its collaboration with Bristol-Myers Squibb on this product.

## Convenience Translation of Key Financial Information

For the quarter ended 31 December	2009 \$m	2008 \$m	2009 £m	2008 £m	2009 SEKm	2008 SEKm
<b>Revenue</b>	8,945	8,193	5,566	5,675	64,078	63,692
<b>Reported</b>						
Operating profit	2,325	1,892	1,447	1,310	16,655	14,708
Profit before tax	2,164	1,816	1,346	1,258	15,502	14,118
Earnings per share	\$1.07	\$0.86	£0.67	£0.60	SEK7.66	SEK6.69
<b>Core</b>						
Operating profit	3,044	2,685	1,894	1,860	21,806	20,873
Profit before tax	2,883	2,609	1,794	1,807	20,653	20,282
Earnings per share	\$1.42	\$1.25	£0.88	£0.87	SEK10.17	SEK9.72
For the year ended 31 December	2009 \$m	2008 \$m	2009 £m	2008 £m	2009 SEKm	2008 SEKm
<b>Revenue</b>	32,804	31,601	20,411	21,888	234,993	245,666
<b>Reported</b>						
Operating profit	11,543	9,144	7,182	6,334	82,689	71,085
Profit before tax	10,807	8,681	6,724	6,013	77,416	67,486
Earnings per share	\$5.19	\$4.20	£3.23	£2.91	SEK37.18	SEK32.65
<b>Core</b>						
Operating profit	13,621	10,958	8,475	7,590	97,575	85,187
Profit before tax	12,885	10,495	8,017	7,269	92,302	81,588
Earnings per share	\$6.32	\$5.10	£3.93	£3.53	SEK45.27	SEK49.13
<b>Dividend per Ordinary Share</b>	\$2.30	\$2.05	£1.41	£1.33	SEK16.84	SEK15.36
<b>Net cash inflow from operating activities</b>	11,739	8,742	7,304	6,055	84,093	67,960
<b>Increase/(decrease) in cash &amp; cash equivalents</b>	5,634	(1,516)	3,506	(1,050)	40,359	(11,785)
<b>Capital and Reserves Attributable to Equity Holders</b>	20,660	15,912	12,855	11,021	147,999	123,700

All Sterling (£) and Swedish krona (SEK) equivalents are shown for convenience and have been calculated using the current period end rates of \$1= £0.622219 and \$1= SEK7.16355 respectively. Dividend per Ordinary Share is shown as the actual amount payable using the rates at the date of declaration of the dividend.

## Shareholder Information

### ANNOUNCEMENTS AND MEETINGS

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Announcement of first quarter 2010 results	29 April 2010
Annual General Meeting	29 April 2010
Announcement of second quarter and half year 2010 results	29 July 2010
Announcement of third quarter and nine months 2010 results	28 October 2010

### DIVIDENDS

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The record date for the first interim dividend payable on 14 September 2009 (in the UK, Sweden and the US) was 7 August 2009. Ordinary shares traded ex-dividend on the London and Stockholm Stock Exchanges from 5 August 2009. ADRs traded ex-dividend on the New York Stock Exchange from the same date.

The record date for the second interim dividend for 2009 payable on 15 March 2010 (in the UK, Sweden and the US) will be 5 February 2010. Ordinary shares will trade ex-dividend on the London and Stockholm Stock Exchanges from 3 February 2010. ADRs will trade ex-dividend on the New York Stock Exchange from the same date.

Future dividends will normally be paid as follows:

First interim	Announced in July and paid in September
Second interim	Announced in January and paid in March

### TRADEMARKS

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Trademarks of the AstraZeneca group of companies appear throughout this document in italics. AstraZeneca, the AstraZeneca logotype and the AstraZeneca symbol are all trademarks of the AstraZeneca group of companies. Trademarks of companies other than AstraZeneca appear with a ® or ™ sign and include: Abraxane®, a registered trademark of Abraxis BioScience, LLC., ONGLYZA™, a trademark of Bristol-Myers Squibb Company, Plavix® and Iscover®, trademarks of Sanofi-Aventis SA and TRILIPIX™, a trademark of Fournier Industrie Et Sante.

### ADDRESSES FOR CORRESPONDENCE

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<b>Registrar and Transfer Office</b>	<b>US Depository</b>	<b>Registered Office</b>	<b>Swedish Central Securities Depository</b>
Equiniti Limited Aspect House Spencer Road Lancing West Sussex BN99 6DA UK	JP Morgan Chase & Co PO Box 64504 St Paul MN 55164-0504 US	15 Stanhope Gate London W1K 1LN UK	Euroclear Sweden AB PO Box 7822 SE-103 97 Stockholm Sweden
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### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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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: This preliminary announcement contains 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 at the date of preparation of this preliminary announcement 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. These forward-looking statements are subject to numerous risks and uncertainties. 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 risk of expiration or early loss of patents (including patents covering competing products), marketing exclusivity or trademarks; the risk of patent litigation; failure to obtain patent protection; the impact of fluctuations in exchange rates; our debt-funding arrangements; bad debts; the adverse impact of a sustained economic downturn; risks relating to owning and operating a biologics and vaccines business; competition; price controls and price reductions; taxation; the risk of substantial product liability claims; the performance of new products; environmental/occupational health and safety liabilities; the development of our business in emerging markets; product counterfeiting; the risk of adverse outcome of litigation and/or government investigations and risk of insufficient insurance coverage; the difficulties of obtaining and maintaining regulatory approvals for new products; the risk of failure to observe continuing regulatory oversight; the risk that R&D will not yield new products that achieve commercial success; the risk that acquisitions and strategic alliances formed as part of our externalisation strategy may be unsuccessful; the risk of reliance on third parties for supplies of materials and services; the risk of failure to manage a crisis; the risk of delay to new product launches; information technology and outsourcing; risks relating to productivity initiatives and reputation.