

## 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 2009 and their respective responsibilities can be found on pages 84 and 85 of the AstraZeneca Annual Report and Form 20-F Information 2008. John Patterson retired from the Board on 31 March 2009. Håkan Mogren retired from the Board on 30 April 2009.

Approved by the Board and signed on its behalf by

David Brennan  
Chief Executive Officer

30 July 2009

# 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 2009 (but not for the quarter ended 30 June 2009) 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 4, 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"). 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 2009 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

8 Salisbury Square  
London EC4Y 8BB

30 July 2009

# Condensed Consolidated Statement of Comprehensive Income

For the <b>six months</b> ended 30 June	<b>2009</b> \$m	<b>2008</b> \$m
<b>Revenue</b>	15,659	15,633
Cost of sales	(2,847)	(2,957)
<b>Gross profit</b>	12,812	12,676
Distribution costs	(134)	(141)
Research and development	(2,039)	(2,533)
Selling, general and administrative costs*	(5,204)	(5,571)
Other operating income and expense	579	299
<b>Operating profit</b>	6,014	4,730
Finance income	207	402
Finance expense	(610)	(710)
<b>Profit before tax</b>	5,611	4,422
Taxation	(1,750)	(1,289)
<b>Profit for the period</b>	3,861	3,133
<b>Other comprehensive income:</b>		
Foreign exchange arising on consolidation	230	254
Foreign exchange differences on borrowings forming net investment hedges	(75)	(162)
Net available for sale losses taken to equity	(3)	(4)
Actuarial loss for the period	(115)	(37)
Income tax relating to components of other comprehensive income	52	80
Other comprehensive income for the period, net of tax	89	131
<b>Total comprehensive income for the period</b>	3,950	3,264
<b>Profit attributable to:</b>		
Owners of the parent	3,853	3,123
Non-controlling interests	8	10
	3,861	3,133
<b>Total comprehensive income attributable to:</b>		
Owners of the parent	3,948	3,249
Non-controlling interests	2	15
	3,950	3,264
Basic earnings per \$0.25 Ordinary Share	\$2.66	\$2.14
Diluted earnings per \$0.25 Ordinary Share	\$2.66	\$2.14
Weighted average number of Ordinary Shares in issue (millions)	1,447	1,456
Diluted average number of Ordinary Shares in issue (millions)	1,448	1,457

\* 2009 includes provisions totalling \$430 million with respect to various federal and state investigations and civil litigation matters relating to drug marketing and pricing practices (see Note 4).

## Condensed Consolidated Statement of Comprehensive Income

For the quarter ended 30 June	2009 \$m	2008 \$m
<b>Revenue</b>	7,958	7,956
Cost of sales	(1,464)	(1,455)
<b>Gross profit</b>	6,494	6,501
Distribution costs	(70)	(75)
Research and development	(1,059)	(1,297)
Selling, general and administrative costs*	(2,828)	(2,834)
Other operating income and expense	314	178
<b>Operating profit</b>	2,851	2,473
Finance income	94	144
Finance expense	(337)	(338)
<b>Profit before tax</b>	2,608	2,279
Taxation	(891)	(651)
<b>Profit for the period</b>	1,717	1,628
<b>Other comprehensive income:</b>		
Foreign exchange arising on consolidation	468	(26)
Foreign exchange differences on borrowings forming net investment hedges	(211)	(2)
Net available for sale gains taken to equity	8	10
Actuarial gain/(loss) for the period	455	(327)
Income tax relating to components of other comprehensive income	(73)	106
Other comprehensive income for the period, net of tax	647	(239)
<b>Total comprehensive income for the period</b>	2,364	1,389
<b>Profit attributable to:</b>		
Owners of the parent	1,707	1,620
Non-controlling interests	10	8
	1,717	1,628
<b>Total comprehensive income attributable to:</b>		
Owners of the parent	2,360	1,384
Non-controlling interests	4	5
	2,364	1,389
Basic earnings per \$0.25 Ordinary Share	\$1.18	\$1.11
Diluted earnings per \$0.25 Ordinary Share	\$1.18	\$1.11
Weighted average number of Ordinary Shares in issue (millions)	1,448	1,456
Diluted average number of Ordinary Shares in issue (millions)	1,448	1,457

\* 2009 includes provisions totalling \$430 million with respect to various federal and state investigations and civil litigation matters relating to drug marketing and pricing practices (see Note 4).

# Condensed Consolidated Statement of Financial Position

	As at 30 Jun 2009 \$m	As at 31 Dec 2008 \$m	As at 30 Jun 2008 \$m
<b>ASSETS</b>			
<b>Non-current assets</b>			
Property, plant and equipment	7,262	7,043	8,479
Goodwill	9,887	9,874	9,903
Intangible assets	12,098	12,323	13,638
Derivative financial instruments	285	449	116
Other investments	171	156	199
Deferred tax assets	1,371	1,236	1,391
	<b>31,074</b>	<b>31,081</b>	<b>33,726</b>
<b>Current assets</b>			
Inventories	1,866	1,636	2,269
Trade and other receivables	7,361	7,261	7,335
Derivative financial instruments	38	-	11
Other investments	42	105	47
Income tax receivable	2,624	2,581	2,474
Cash and cash equivalents	7,195	4,286	4,340
	<b>19,126</b>	<b>15,869</b>	<b>16,476</b>
<b>Total assets</b>	<b>50,200</b>	<b>46,950</b>	<b>50,202</b>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Interest bearing loans and borrowings	(1,498)	(993)	(3,841)
Trade and other payables	(7,366)	(7,178)	(7,409)
Derivative financial instruments	(65)	(95)	-
Provisions	(957)	(600)	(484)
Income tax payable	(5,257)	(4,549)	(4,257)
	<b>(15,143)</b>	<b>(13,415)</b>	<b>(15,991)</b>
<b>Non-current liabilities</b>			
Interest bearing loans and borrowings	(10,163)	(10,855)	(11,032)
Derivative financial instruments	-	(71)	-
Deferred tax liabilities	(3,170)	(3,126)	(4,172)
Retirement benefit obligations	(3,103)	(2,732)	(2,117)
Provisions	(520)	(542)	(579)
Other payables	(159)	(149)	(216)
	<b>(17,115)</b>	<b>(17,475)</b>	<b>(18,116)</b>
<b>Total liabilities</b>	<b>(32,258)</b>	<b>(30,890)</b>	<b>(34,107)</b>
<b>Net assets</b>	<b>17,942</b>	<b>16,060</b>	<b>16,095</b>
<b>EQUITY</b>			
<b>Capital and reserves attributable to equity holders of the Company</b>			
Share capital	362	362	363
Share premium account	2,065	2,046	1,923
Other reserves	1,932	1,932	1,887
Retained earnings	13,437	11,572	11,801
	<b>17,796</b>	<b>15,912</b>	<b>15,974</b>
<b>Non-controlling interests</b>	<b>146</b>	<b>148</b>	<b>121</b>
<b>Total equity</b>	<b>17,942</b>	<b>16,060</b>	<b>16,095</b>

## Condensed Consolidated Statement of Cash Flows

For the <b>six months</b> ended 30 June	<b>2009</b> \$m	<b>2008</b> \$m
<b>Cash flows from operating activities</b>		
Profit before taxation	5,611	4,422
Finance income and expense	403	308
Depreciation, amortisation and impairment	849	1,163
Decrease/(increase) in working capital	258	(445)
Other non-cash movements	(173)	276
Cash generated from operations	6,948	5,724
Interest paid	(320)	(324)
Tax paid	(1,294)	(1,108)
<b>Net cash inflow from operating activities</b>	<b>5,334</b>	<b>4,292</b>
<b>Cash flows from investing activities</b>		
Movement in short term investments and fixed deposits	68	2
Purchase of property, plant and equipment	(404)	(504)
Disposal of property, plant and equipment	37	22
Purchase of intangible assets	(140)	(2,741)
Disposal of intangible assets	269	-
Purchase of non-current asset investments	(19)	(32)
Disposal of non-current asset investments	1	-
Interest received	36	91
Dividends paid by subsidiaries to minority interest	(10)	(37)
<b>Net cash outflow from investing activities</b>	<b>(162)</b>	<b>(3,199)</b>
<b>Net cash inflow before financing activities</b>	<b>5,172</b>	<b>1,093</b>
<b>Cash flows from financing activities</b>		
Proceeds from issue of share capital	19	35
Repurchase of shares	-	(208)
Dividends paid	(2,103)	(2,007)
Movement in short term borrowings	(139)	(374)
<b>Net cash outflow from financing activities</b>	<b>(2,223)</b>	<b>(2,554)</b>
<b>Net increase/(decrease) in cash and cash equivalents in the period</b>	<b>2,949</b>	<b>(1,461)</b>
Cash and cash equivalents at the beginning of the period	4,123	5,727
Exchange rate effects	20	1
<b>Cash and cash equivalents at the end of the period</b>	<b>7,092</b>	<b>4,267</b>
<b>Cash and cash equivalents consists of:</b>		
Cash and cash equivalents	7,195	4,340
Overdrafts	(103)	(73)
	<b>7,092</b>	<b>4,267</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	-	-	-	3,123	3,123	10	3,133
Other comprehensive income	-	-	-	126	126	5	131
Transfer to other reserve	-	-	(16)	16	-	-	-
<b>Transactions with owners:</b>							
Dividends	-	-	-	(1,967)	(1,967)	-	(1,967)
Issue/(repurchase) of AstraZeneca PLC Ordinary shares	(1)	35	1	(207)	(172)	-	(172)
Share-based payments	-	-	-	86	86	-	86
Transfer from non-controlling interests to payables	-	-	-	-	-	(5)	(5)
Dividend paid to non-controlling interest	-	-	-	-	-	(26)	(26)
<b>At 30 June 2008</b>	<b>363</b>	<b>1,923</b>	<b>1,887</b>	<b>11,801</b>	<b>15,974</b>	<b>121</b>	<b>16,095</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	-	-	-	3,853	3,853	8	3,861
Other comprehensive income	-	-	-	95	95	(6)	89
Transfer to other reserve	-	-	-	-	-	-	-
<b>Transactions with owners:</b>							
Dividends	-	-	-	(2,171)	(2,171)	-	(2,171)
Issue of AstraZeneca PLC Ordinary shares	-	19	-	-	19	-	19
Share-based payments	-	-	-	88	88	-	88
Transfer from non-controlling interests to payables	-	-	-	-	-	(3)	(3)
Dividend paid to non-controlling interest	-	-	-	-	-	(1)	(1)
<b>At 30 June 2009</b>	<b>362</b>	<b>2,065</b>	<b>1,932</b>	<b>13,437</b>	<b>17,796</b>	<b>146</b>	<b>17,942</b>

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

# Notes to the Interim Financial Statements

## 1 BASIS OF PREPARATION AND ACCOUNTING POLICIES

These condensed consolidated interim financial statements (“interim financial statements”) for the six months ended 30 June 2009 have been prepared in accordance with IAS 34 *Interim Financial Reporting* as adopted by the European Union. 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 2008, except where new or revised accounting standards have been applied.

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.

In addition, the Group has adopted IFRS 8 *Operating Segments*. AstraZeneca’s pharmaceutical business is one operating segment because it is managed as a fully-integrated business whereby manufacturing and research and development are essential upstream activities without which there could be no sales and marketing. The manufacturing and research and development functions are managed and operate on a global basis and are not dedicated to individual marketing or therapy areas. Major decisions are taken through cross-functional committees recognising the integrated nature of the business. In assessing performance and making resource allocation decisions, the Senior Executive team (SET) (which is AstraZeneca’s chief operating decision making body) 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 SET also reviews sales performance on both a geographical and product/therapy area basis.

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 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 2008.

The comparative figures for the financial year ended 31 December 2008 are not the Company’s statutory accounts for that financial year. Those accounts 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 DEBT

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

	At 1 Jan 2009 \$m	Cash flow \$m	Non-cash movements \$m	Exchange movements \$m	At 30 Jun 2009 \$m
Loans due after one year	(10,855)	-	766	(74)	(10,163)
Current instalments of loans	(650)	-	(703)	-	(1,353)
Total loans	(11,505)	-	63	(74)	(11,516)
Other investments - current	105	(78)	12	3	42
Net derivative financial instruments	283	10	(35)	-	258
Cash and cash equivalents	4,286	2,887	-	22	7,195
Overdrafts	(163)	62	-	(2)	(103)
Short term borrowings	(180)	139	-	(1)	(42)
	4,331	3,020	(23)	22	7,350
Net debt	(7,174)	3,020	40	(52)	(4,166)

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

## 3 RESTRUCTURING AND SYNERGY COSTS

Profit before tax for the six months ended 30 June 2009 is stated after charging restructuring and synergy costs of \$262 million (\$248 million in the first half of 2008). These have been charged to the income statement as follows:

	2 <sup>nd</sup> Quarter 2009 \$m	2 <sup>nd</sup> Quarter 2008 \$m	Half Year 2009 \$m	Half Year 2008 \$m
Cost of sales	84	24	115	56
Research and development	24	32	24	86
Selling, general and administrative costs	82	75	123	106
Total	190	131	262	248

## 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 anti-trust 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.

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.

As previously and herein disclosed, AstraZeneca is defending its interests in various federal and state investigations and civil litigation matters relating to drug marketing and pricing practices. In view of the current status of these matters, the Company now believes that it is possible to make a reasonable estimate of the losses expected and accordingly has recorded provisions in the aggregate amount of \$430 million, being our best estimate of the loss expected for all matters relating to drug marketing and pricing practices where we can now make a reasonable estimate. No further details can be provided at this time because to do so could seriously prejudice the Company. These provisions are in addition to the amounts disclosed in the Annual Report and Form 20-F Information 2008.

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 2008 and herein.

## **Matters previously disclosed in respect of the first quarter of 2009 and April 2009**

### **Crestor (rosuvastatin)**

#### *Patent litigation - US*

As previously disclosed, in January 2008 abbreviated new drug application-filers sued by AstraZeneca in the District of Delaware for infringement of the Patent No. RE37,314 (the '314 patent), responded to AstraZeneca's pleadings, some submitting jurisdictional motions seeking dismissals of parties and claims. In November 2008, the Court issued a magistrate's Report and Recommendation Regarding Motions to Dismiss deciding the defendants' various jurisdictional motions. In January 2009, the Court adopted the magistrate's recommendations.

In March 2009, Magistrate Judge Leonard Stark heard argument and reserved judgment in the Court's Markman Hearing in respect of claim construction of the '314 patent claims. Discovery proceeds under an amended schedule.

As previously disclosed, in October 2008, Teva Pharmaceuticals Industries Ltd. (Teva), filed a patent infringement lawsuit against AstraZeneca Pharmaceuticals LP, AstraZeneca PLC, AstraZeneca UK Limited and IPR Pharmaceuticals, Inc. in the Eastern District of Pennsylvania. In January 2009, AstraZeneca PLC and AstraZeneca UK Limited moved for dismissal on jurisdictional grounds. The Court administratively dismissed the motions without prejudice to allow time for discovery. In April 2009, AstraZeneca PLC and AstraZeneca UK Limited renewed those motions, which will proceed. In March 2009, AstraZeneca moved to transfer the case to the US District Court, District of Delaware. On 8 April 2009, AstraZeneca also moved to strike Teva's jury demand. Discovery is continuing.

#### *Patent litigation - Canada*

On 1 April 2009, AstraZeneca Canada Inc. received a Notice of Allegation from Cobalt Pharmaceuticals, Inc. (Cobalt) in respect of Canadian Patent Nos. 2,072,945 (the '945 patent) and 2,313,783 (the '783 patent) listed on the Patent Register in Canada for *Crestor*. Cobalt claims that the '945 patent is not infringed and invalid; and that the '783 patent is not infringed and invalid.

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

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

#### *Patent litigation*

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 abbreviated new drug application (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 response to Dr. Reddy's Paragraph IV certifications. In July 2008, Dr. Reddy's filed a motion for summary judgment of non-infringement of the patents-in-suit. In March 2009, the Court granted Dr. Reddy's motion for summary judgment of non-infringement of the patents-in-suit. AstraZeneca is considering options including appeal of the Court's summary judgment decision to the United States District Court for the Federal Circuit.

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

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

#### *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*. In June 2008, AstraZeneca filed oppositions to the class certification motions filed in the California and Massachusetts cases, and also filed motions for summary judgment in California and Massachusetts. In March 2009, the California Court granted AstraZeneca's motions for summary judgment, ending the claims of all named plaintiffs. The Court also denied plaintiffs' motion for class certification. Oral argument on the Massachusetts motions is scheduled for 6 and 7 May 2009.

As previously disclosed, the US Court of Appeals for the 3rd Circuit had affirmed the dismissal of a similar case filed in Delaware Federal Court, and the plaintiffs had filed a petition for certiorari in the US Supreme Court. In March 2009, the US Supreme Court granted certiorari, vacated the 3rd Circuit decision and remanded the case back to the 3rd Circuit for reconsideration in light of the Supreme Court's pre-emption decision in *Wyeth v. Levine*. AstraZeneca expects a briefing schedule to be established within the next few months.

#### *Patent litigation*

As previously disclosed in December 2008, AstraZeneca received a Paragraph IV Certification notice-letter from Sandoz, Inc. (Sandoz) that Sandoz had submitted an ANDA for 20mg and 40mg esomeprazole magnesium delayed-release capsules alleging invalidity and/or non-infringement in respect of certain AstraZeneca US patents. In January 2009, AstraZeneca commenced patent infringement litigation in the District of New Jersey in response. No trial date has been set.

As previously disclosed, in May and June 2008, AstraZeneca received a complaint from IVAX Pharmaceuticals Inc. and IVAX Corporation (together IVAX) and a complaint from Dr. Reddy's for declaratory judgments of non-infringement and/or invalidity for patents that were not previously at issue in the ongoing infringement litigations. In August 2008, the Court dismissed the IVAX and Dr. Reddy's declaratory judgment actions as to certain patents and stayed the declaratory judgment actions as to remaining patents at issue. In January 2009, the Court vacated the August 2008 Orders that had dismissed and stayed the declaratory judgment actions. As a result, the IVAX and Dr. Reddy's declaratory judgment actions are proceeding. No trial date has been set.

As previously disclosed, in January 2006 AstraZeneca received a Paragraph IV Certification notice-letter from IVAX that IVAX had submitted an ANDA to the FDA for 20mg and 40mg esomeprazole magnesium delayed-release capsules. The ANDA contained Paragraph IV certifications of invalidity and/or non-infringement in respect of certain AstraZeneca US patents listed in the FDA Orange Book with reference to *Nexium*. In March 2006, AstraZeneca commenced wilful patent infringement litigation in the US District Court for the District of New Jersey against IVAX, its parent Teva Pharmaceuticals, and their affiliates. In December 2008, the Court granted AstraZeneca's motion to add Cipla, Ltd. as a defendant in the IVAX/Teva litigation. In January 2008, AstraZeneca commenced patent infringement litigation in the US District Court for the District of New Jersey against Dr. Reddy's in response to Dr. Reddy's Paragraph IV certifications regarding *Nexium*. In March 2009, the Court consolidated the IVAX/Teva, Cipla and Dr. Reddy's patent infringement litigations. The Court has indicated trial in the consolidated patent infringement litigation as soon as January 2010.

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

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

##### *Patent litigation*

In March 2009, AstraZeneca filed a lawsuit in the US District Court for the District of New Jersey against Apotex, Inc. and Apotex Corp. (together Apotex) seeking a declaration of patent infringement. The lawsuit follows the FDA approval of an ANDA filed by Apotex and concerns Apotex's intent to market a generic version of AstraZeneca's *Pulmicort Respules* in the US prior to the expiration of AstraZeneca's patents. On 16 April, the Court issued a Temporary Restraining Order barring Apotex from launching its generic version of *Pulmicort Respules* until further order of the Court. On 27 April, the Court commenced a hearing to determine whether to continue the injunction.

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

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

##### *Sales and marketing practices*

In February 2009, the State of New Mexico filed a lawsuit against AstraZeneca, similar to the previously disclosed suits filed by Pennsylvania, Arkansas, Montana and South Carolina, which seek compensation for costs incurred by the state for the treatment of Medicaid and other public assistance beneficiaries who allegedly developed diabetes, hyperglycemia and other conditions as a result of using *Seroquel* without adequate warning. In addition, these lawsuits seek reimbursement of payments made by the state Medicaid programs for prescriptions that relate to so-called non-medically accepted indications of *Seroquel*.

##### *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 of 13 April 2009, AstraZeneca was defending approximately 9,976 served or answered lawsuits involving approximately 16,198 plaintiff groups. To date, approximately 2,383 additional cases have been dismissed by order or agreement and approximately 1,500 of those cases have been dismissed with prejudice.

On 30 January 2009 and 6 February 2009, the federal judge presiding over the *Seroquel* Multi-District Litigation (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. The federal MDL court has stayed all remaining Florida cases pending a decision on that appeal and is currently evaluating the procedural posture of all non-Florida cases.

The first trial is scheduled to begin in Delaware state court on 29 June 2009. AstraZeneca expects that an additional two to four trials may be scheduled to commence in 2009. AstraZeneca is also aware of approximately 59 additional cases 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 & Co., Janssen Pharmaceutica, Inc. and/or Bristol-Myers Squibb Company. AstraZeneca intends to litigate these cases on their individual merits and will defend against the cases vigorously.

##### *Patent litigation*

In December 2008, Teva announced that the US Food and Drug Administration (FDA) had tentatively approved its generic quetiapine tablets. In July 2008, the US District Court, District of New Jersey had granted AstraZeneca's motion for summary judgment of No Inequitable Conduct. Teva and Sandoz appealed to the Federal Circuit Court of Appeals. In December 2008, the parties completed briefing. A three-judge panel of the Federal Circuit Court of Appeals heard oral argument in March 2009. The Court reserved judgment. A decision is pending.

In February 2009, AstraZeneca received a second Paragraph IV Certification notice-letter from Sandoz advising that it had amended its ANDA seeking approval to market a generic version of 25mg *Seroquel* tablets before expiration of AstraZeneca's patents covering the product. The amended ANDA seeks approval to market 50mg, 100mg, 150mg, 200mg, 300mg and 400mg tablets. In March 2009, AstraZeneca filed a second lawsuit in US District Court, District of New Jersey against Sandoz alleging infringement of AstraZeneca's patent covering the active ingredient of *Seroquel* tablets. The filing of this additional lawsuit triggered a 30-month stay of FDA final approval for Sandoz's 50mg, 100mg, 150mg, 200mg, 300mg and 400mg ANDA products.

#### *Patent litigation - Seroquel XR*

AstraZeneca lists two patents in the FDA's Orange Book referencing *Seroquel XR*: US Patent No. 4,879,288 (the '288 patent) covering quetiapine fumarate, the active ingredient, and US Patent No. 5,948,437 (the '437 patent) covering extended-release formulations, processes and methods in respect of quetiapine fumarate.

In October and November 2008, AstraZeneca received a third and fourth Paragraph IV Certification notice-letter from Handa Pharmaceuticals (Handa) advising that it had submitted an ANDA seeking approval to market generic versions of 50mg and 150mg *Seroquel XR* tablets before expiration of AstraZeneca's patents covering the product. In October 2008, AstraZeneca filed a second lawsuit in District of New Jersey against Handa alleging infringement of AstraZeneca's patents covering the active ingredient and formulation of *Seroquel XR* 50mg tablets. In December 2008, AstraZeneca filed a third lawsuit against Handa alleging infringement of AstraZeneca's patents covering the active ingredient and formulation of *Seroquel XR* 150mg tablets. The filing of these additional lawsuits triggered 30-month stays of FDA final approval for Handa's 50mg and 150mg ANDA products.

For purposes of discovery, the three Handa actions and the previously disclosed Accord action have been consolidated under a common scheduling order. The consolidated matter proceeds.

In December 2008, AstraZeneca received a Paragraph IV Certification notice-letter from Biovail Laboratories International SRL (Biovail) stating that it had submitted an ANDA seeking approval to market generic versions of 200mg, 300mg and 400mg *Seroquel XR* tablets before the expiration of AstraZeneca's two listed patents covering *Seroquel XR* alleging non-infringement and invalidity in respect of AstraZeneca's patents. In January 2009, AstraZeneca filed a lawsuit in the District of New Jersey against Biovail alleging infringement of AstraZeneca's '288 and '437 patents covering *Seroquel XR* 200mg, 300mg and 400mg tablets. The filing of this lawsuit triggered a 30-month stay of FDA final approval for Biovail's ANDA products.

In January 2009, AstraZeneca received a second Paragraph IV Certification notice-letter from Accord advising that it had submitted an ANDA seeking approval to market a generic version of 150mg *Seroquel XR* tablets before expiration of AstraZeneca's '437 patent covering the product. In February 2009, AstraZeneca filed a second lawsuit in the District of New Jersey against Accord alleging infringement of AstraZeneca's patent covering the formulation of *Seroquel XR* 150mg tablets. The filing of this additional lawsuit triggered a 30-month stay of FDA final approval for Accord's 150mg ANDA product.

The three matters proceed in co-ordinated discovery. In April 2009, AstraZeneca moved to stay discovery respecting the '288 patent covering the active ingredient in *Seroquel XR*, pending the decision of the Federal Circuit Court of Appeals in the above described related case of AstraZeneca v. Teva and Sandoz, which pertains to ANDAs for *Seroquel*.

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

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

##### *Patent litigation - Canada*

On 3 April 2009, AstraZeneca Canada Inc. received a Notice of Allegation from Sandoz Canada Inc. (Sandoz) in respect of Canadian Patent Nos. 2,040,955 (the '955 patent) and 2,083,305 (the '305 patent) listed on the Patent Register in Canada for *Atacand*. Sandoz 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 Patent Register.

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

#### **Pain Pump Litigation**

As previously disclosed, starting in February 2008, AstraZeneca LP, AstraZeneca Pharmaceuticals LP, Zeneca Holdings Inc., and/or AstraZeneca PLC have been named as defendants and served in approximately 51 lawsuits, involving approximately 58 plaintiffs, filed in various US jurisdictions, alleging injuries caused by third-party pain pumps. The complaints in these cases generally allege that the use of *Marcaine*, *Sensorcaine*, *Xylocaine* and/or *Naropin*, with or without epinephrine, in pain pumps that were implanted into patients in connection with arthroscopic surgery, caused chondrolysis. Other named defendants in these cases are other manufacturers and distributors of bupivacaine and lidocaine and other pain medications, pain pump manufacturers, and in some cases the surgeons. To date, 38 plaintiffs have dismissed their cases against the AstraZeneca defendants while the case was in preliminary stages, and a 39th plaintiff's case was involuntarily terminated when the court granted AstraZeneca's motion to dismiss. The AstraZeneca defendants have filed a motion to dismiss in one additional case. In addition, two active plaintiffs have voluntarily dismissed AstraZeneca PLC but have maintained their suits against other AstraZeneca defendants.

Rights to market *Sensorcaine*, *Xylocaine* and *Naropin* in the US were sold to Abraxis Bioscience Inc. (Abraxis) in June 2006 but many of these lawsuits may be a retained liability under the terms of the Asset Purchase Agreement with Abraxis. To date, AstraZeneca has tendered approximately fifteen of the claims to Abraxis, twelve of which have been dismissed as described above.

It was previously reported that plaintiffs moved to consolidate the federal pain pump cases under the Multi-District Litigation (MDL) process. The Judicial Panel on MDL denied that motion in August 2008. Accordingly, the cases will continue as individual lawsuits.

AstraZeneca intends to vigorously defend these cases.

## **Tax**

As previously disclosed, AstraZeneca and Her Majesty's Revenue & Customs (HMRC) have made a joint referral to the UK Court in respect of transfer pricing between our UK and one of our overseas operations for the years 1996 to date as there continues to be a material difference between the Group's and HMRC's positions. An additional referral in respect of controlled foreign company aspects of the same case was made during 2008. Absent a negotiated settlement, litigation is set to commence in 2010. Management continues to believe that AstraZeneca's positions on all its transfer pricing audits and disputes are robust and that AstraZeneca is adequately provided.

## **Matters disclosed in respect of the second quarter of 2009 and July 2009**

### ***Accolate (zafirlukast)***

#### *Patent litigation - US*

As previously disclosed, in June 2008, AstraZeneca commenced patent infringement litigation against Dr. Reddy's Laboratories, Inc. (DRL) in the US District Court for the District of New Jersey for infringement of US Patent Nos. 5,319,097 (the '097 patent), 5,482,963 (the '963 patent) and 6,143,775 (the '775 patent). In exchange for DRL's covenant not to utilise the processes covered by the '097 patent and the '775 patent, the parties agreed to dismiss without prejudice all claims and counterclaims relating to these two patents.

Claim construction briefs relating to the '963 patent have been filed by the parties; no hearing date has been set.

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

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

#### *Patent litigation – Canada*

As previously disclosed, on 3 April 2009, AstraZeneca Canada Inc. received a Notice of Allegation from Sandoz Canada Inc. (Sandoz) in respect of Canadian Patent Nos. 2,040,955 (the '955 patent) and 2,083,305 (the '305 patent) listed on the Patent Register in Canada for *Atacand*. Sandoz 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 Patent Register. On 14 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 to Sandoz for its 4, 8 and 16mg candesartan cilexetil tablets until the expiration of the '305 patent.

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

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

#### *Patent litigation – US*

On 4 May 2009, Magistrate Judge Leonard Stark issued his Report and Recommendation Regarding Claim Construction, which set out his recommendations for claim construction of the RE37,314 (the '314 patent) patent claims. On 21 May 2009, Mylan and Par filed objections to the report. A decision by the District Court Judge is pending. Discovery otherwise proceeds under an amended schedule.

As previously disclosed, in October 2008, Teva Pharmaceuticals Industries Ltd. (Teva), filed a patent infringement lawsuit against AstraZeneca Pharmaceuticals LP, AstraZeneca PLC, AstraZeneca UK Limited and IPR Pharmaceuticals, Inc. in the Eastern District of Pennsylvania. AstraZeneca PLC and AstraZeneca UK Limited moved for dismissal on jurisdictional grounds. By agreement, Teva has voluntarily dismissed its claims against AstraZeneca PLC and AstraZeneca UK Limited without prejudice. As previously reported in March 2009, AstraZeneca moved to transfer the case to the US District Court, District of Delaware and in April 2009, AstraZeneca moved to strike Teva's jury demand. Decisions on those motions are pending. Discovery is proceeding.

#### *Patent litigation – Canada*

As previously disclosed, in April 2009, AstraZeneca Canada Inc. (AZ Canada) received a Notice of Allegation from Cobalt Pharmaceuticals, Inc. (Cobalt) in respect of Canadian Patent Nos. 2,072,945 (the '945 patent) and 2,313,783 (the '783 patent) listed on the Patent Register in Canada for *Crestor*. Cobalt claims that the '945 patent is not infringed and invalid and that the '783 patent is not infringed and invalid. On 14 May 2009, AstraZeneca filed a Notice of Application (NOA) in federal court seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance (NOC) to Cobalt for its 5, 10, 20 and 40mg rosuvastatin calcium tablets until the expiration of the '945 and '783 patents.

In May 2009, AZ Canada received a Notice of Allegation from Sandoz Canada Inc. (Sandoz) with respect to the '945 and '783 patents. Sandoz claims that the '945 patent is invalid and that the '783 patent is not infringed and invalid. On 2 July 2009, AstraZeneca filed a NOA in federal court seeking an order prohibiting the Minister of Health from issuing a NOC to Sandoz 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*.

### **Entocort EC (budesonide)**

As previously reported, AstraZeneca lists two patents in the FDA's Orange Book referencing *Entocort EC*. In 2008, in responses to Paragraph IV Certification notice-letters from Barr Laboratories (Barr) and Mylan Pharmaceuticals Inc. (Mylan) notifying AstraZeneca that each had submitted an ANDA to the FDA seeking approval to market a generic form of AstraZeneca's *Entocort EC* prior to the expiration of the two patents, AstraZeneca initiated patent infringement actions in US District Court, District of Delaware. Trial is scheduled to begin on 17 May 2010. Discovery proceeds.

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

### **Exanta (ximelagatran)**

As previously disclosed, in an opinion dated 3 June 2008, the United States District Court for the Southern District of New York dismissed in its entirety the consolidated amended complaint that had alleged claims on behalf of purchasers of AstraZeneca publicly traded securities during the period April 2003 to September 2004 under sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5. Plaintiffs appealed this decision to the US Court of Appeals for the Second Circuit, except for the ruling regarding two of the four individual defendants. On 25 June 2009, the Second Circuit Court of Appeals summarily affirmed the trial court's dismissal of the action.

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

#### *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*. Plaintiffs have appealed the March 2009 summary judgment and class certification rulings by the California court. In May 2009, the Massachusetts court held oral argument on AstraZeneca's motion for summary judgment and plaintiffs' motion for class certification. Those motions are pending.

As previously disclosed, the US Court of Appeals for the 3rd Circuit had affirmed the dismissal of a similar case filed in Delaware federal court, and the plaintiffs had filed a petition for certiorari in the US Supreme Court. In March 2009, the US Supreme Court granted certiorari, vacated the 3rd Circuit decision and remanded the case back to the 3rd Circuit for reconsideration in light of the Supreme Court's pre-emption decision in *Wyeth v. Levine*. The 3rd Circuit remanded the case to the district court for further proceedings. AstraZeneca intends to vigorously defend the case.

#### *Patent litigation - US*

As previously disclosed, in March 2006, AstraZeneca commenced an infringement action in the US District Court for the District of New Jersey against IVAX Corporation and two affiliates for submission of an ANDA to the FDA for 20mg and 40mg esomeprazole magnesium delayed-release capsules. In December 2008, the Court granted AstraZeneca's motion to add co-defendant Cipla, Ltd. to that lawsuit. In January 2008, AstraZeneca commenced infringement action in the US District Court for the District of New Jersey against Dr. Reddy's in response to Dr. Reddy's Paragraph IV certifications regarding *Nexium*. In March 2009, the Court consolidated the IVAX/Teva/Cipla, and Dr. Reddy's patent infringement litigations. Trial in the now consolidated matter is set for January 2010.

As previously disclosed, AstraZeneca received a Paragraph IV Certification notice-letter from Sandoz, Inc. (Sandoz) in December 2008 that it had submitted an ANDA for 20mg and 40mg esomeprazole magnesium delayed-release capsules. In January 2009, AstraZeneca filed a patent infringement action in the District of New Jersey in response. In July 2009, the Court stayed the Sandoz patent infringement litigation until after trial in the above referenced consolidated patent infringement litigation. No trial date has been set in the Sandoz patent infringement litigation.

As previously disclosed, in May and June 2008, AstraZeneca received declaratory judgment complaints from IVAX Pharmaceuticals Inc. and Dr. Reddy's. The actions cover patents that were not previously at issue in the ongoing ANDA infringement litigations. The declaratory judgment actions are proceeding separately from the ANDA actions. No trial date has been set.

#### *Patent litigation – Canada*

As previously disclosed, AstraZeneca Canada Inc. received several notices of allegation from Apotex Inc. (Apotex) in late 2007 in respect of patents listed on the Patent Register in Canada for 20 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 Notice of Compliance (marketing approval) 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 - EU*

On 17 June 2009, AstraZeneca filed an application with the District Court of Copenhagen in Denmark seeking an interlocutory injunction proceeding to restrain Sandoz A/S from marketing products containing generic esomeprazole magnesium in Denmark. By way of background, on 2 April 2009, the Danish Medicines Agency granted Sandoz A/S approval to market a generic version of *Nexium* (esomeprazole magnesium). Sandoz launched its esomeprazole magnesium products in Denmark on 2 June 2009. AstraZeneca considers that the products marketed by Sandoz A/S infringe intellectual property owned by AstraZeneca relating to *Nexium*. Marketing authorisations were granted in March 2009 to Sandoz d.d. for products containing 20mg and 40mg esomeprazole with Denmark as reference member state. Sandoz has also launched its esomeprazole magnesium products in Slovenia on 22 July 2009 and Hungary on 27 July 2009. Other EU countries included in the decentralised procedure are: Austria, Bulgaria, Czech Republic, Estonia, Finland, Ireland, Latvia, Lithuania, Norway, Poland, Portugal, Romania and Spain.

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

#### *Patent proceedings*

On 22 July 2009, the European Patent Office (EPO) published the grant of two patents that relate to *Nexium* (the "Esomeprazole Magnesium Patent") and *Nexium I.V* (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 on 19 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 Board 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 at least 99.8% enantiomeric excess.

#### **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 abbreviated new drug application (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 response to Dr. Reddy's Paragraph IV certifications. In March 2009, the Court granted Dr. Reddy's motion for summary judgment of non-infringement of the patents-in-suit; and in July 2009, AstraZeneca appealed the Court's summary judgment decision to the United States Court of Appeals for the Federal Circuit.

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

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

##### *Patent Litigation - US*

In March 2009, AstraZeneca filed a lawsuit in the US District Court for the District of New Jersey against Apotex, Inc. and Apotex Corp. (together Apotex) seeking a declaration of patent infringement. The lawsuit followed the FDA approval of an ANDA filed by Apotex and concerns Apotex's intent to market a generic version of AstraZeneca's *Pulmicort Respules* in the US prior to the expiration of AstraZeneca's patents. On 22 May, the Court issued a Preliminary Injunction barring Apotex from launching its generic version of *Pulmicort Respules* until further order of the Court. Apotex has appealed the issuance of the Preliminary Injunction to the Court of Appeals for the Federal Circuit.

The Apotex litigation and the previously disclosed Breath action have been consolidated under a common scheduling order. The consolidated matter proceeds.

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, the US Attorney's Office in Philadelphia, working with a number of states, is directing an investigation relating to *Seroquel* involving a review of sales and marketing practices, including allegations that AstraZeneca promoted *Seroquel* for non-indicated (off-label) uses. AstraZeneca understands that this investigation is the subject of a sealed *qui tam* lawsuit filed under the False Claims Act. A second investigation may relate to selected physicians who participated in clinical trials involving *Seroquel*. The company has been cooperating in the investigation and is in discussions with the government. Any potential liability stemming from these investigations is subject to the outcome of the investigative process, possible continued discussions with the government and potential litigation.

##### *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 of 13 July 2009, AstraZeneca was defending approximately 10,381 served or answered lawsuits involving approximately 19,391 plaintiff groups. To date, approximately 2,556 additional cases have been dismissed by order or agreement and approximately 1,535 of those cases have been dismissed with prejudice.

As previously disclosed, on 30 January 2009 and 6 February 2009, the federal judge presiding over the *Seroquel* Multi-District Litigation (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. The federal MDL court has stayed all remaining Florida cases pending a decision on that appeal and has indicated that after resolving certain procedural and evidentiary issues, the MDL court intends to begin remanding non-Florida cases to the federal district courts from which they were transferred originally.

On 26 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 has filed a notice of appeal of this decision to the Delaware Supreme Court.

The first trial is now scheduled to begin in Missouri state court on 6 October 2009. AstraZeneca is also aware of approximately 117 additional cases (295 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 & Co., Janssen Pharmaceutica, Inc. and/or Bristol-Myers Squibb Company. 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 for *Seroquel*-related product liability claims. 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.

As of 30 June 2009, legal defence costs of approximately \$593 million have been incurred in connection with *Seroquel*-related product liability claims. This amount is approximately equal to the maximum insurance receivable that AstraZeneca will recognise under applicable accounting principles at this time with respect to the applicable insurance policies. Accordingly, beginning in the second half of 2009, management anticipates defence costs and damages, if any, that may be incurred in connection with *Seroquel*-related product liability claims will result in a charge to the income statement. There can be no assurance that additional coverage under the policies will be available or that the insurance receivable we have recognised as of 30 June 2009 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 approximate, and may exceed, the total stated upper limits of the applicable insurance policies in any event.

#### *Patent litigation - US*

In June 2009, Dr. Reddy's Laboratories Ltd. (Dr. Reddy's) announced its receipt of tentative approval from the US Food and Drug Administration (FDA) for its generic quetiapine tablets in 25mg doses. Dr. Reddy's did not submit a Paragraph IV certification challenging the AstraZeneca patents covering *Seroquel*, which do not expire until 2011, with paediatric exclusivity through 26 March 2012.

#### **Seroquel XR**

##### *Patent litigation - US*

As previously disclosed, AstraZeneca has brought lawsuits against Handa Pharmaceuticals, Biovail Laboratories International SRL and Accord healthcare, Inc. alleging infringement of AstraZeneca's patents covering *Seroquel XR*.

The three matters proceed in co-ordinated discovery. The Court has stayed discovery respecting the '288 patent covering the active ingredient in *Seroquel XR*, pending the decision of the Federal Circuit Court of Appeals in the previously disclosed case of *AstraZeneca v. Teva and Sandoz*, which pertains to ANDAs for *Seroquel*.

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

#### **Additional Government Investigations and Lawsuits relating to Drug Marketing Practices**

As previously disclosed, AstraZeneca is involved in multiple US federal and state investigations into drug marketing and pricing practices. In connection with one of the investigations led by the US Attorney's Office in Philadelphia, the US Attorney's Office and the states of California, Delaware, the District of Columbia, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, Tennessee, Texas, and Virginia declined to intervene in a *qui tam* lawsuit alleging that AstraZeneca violated federal and state laws in its dealings with Medco Health Solutions, a pharmacy benefit manager. The individual *qui tam* plaintiff has chosen to continue to pursue the lawsuit on behalf of the federal government and the states. On 2 July 2009, AstraZeneca Pharmaceuticals LP and AstraZeneca LP were served with the complaint.

AstraZeneca denies the allegations and intends to vigorously defend this matter.

#### **Anti-trust**

##### *EU Commission Sector Enquiry*

As previously disclosed, AstraZeneca, together with several other companies, was the subject of an EU Commission (Commission) Sectoral Inquiry into competition in the pharmaceutical industry. On 8 July 2009 the Commission published its Final Report. The Report's conclusions were grouped into four main areas: greater competition law scrutiny and enforcement; a Community patent and unified litigation system; a streamlined marketing authorisation process; and improved pricing and reimbursement systems including measures to promote generic competition. The report acknowledged the importance of patents to incentivise the development of new, innovative medicines. 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.



### **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. In June 2009, the court presiding over the putative class action in Arizona granted AstraZeneca's motion for summary judgment and denied plaintiffs' motion for class certification as moot. The plaintiffs are expected to appeal.

In May 2009, AstraZeneca reached a settlement to resolve the claims of the states of Nevada and Montana. Those cases have now been dismissed with prejudice.

On 7 July 2009, the state court in Kentucky held oral argument on AstraZeneca's motion for summary judgment. AstraZeneca's trial in Kentucky is currently scheduled to commence in September 2009.

### **340B Class Action Litigation**

As previously disclosed, in August 2005, AstraZeneca was named as a defendant, along with multiple other pharmaceutical manufacturers, in a class action suit filed by the County of Santa Clara on behalf of similarly situated California counties and cities that allegedly overpaid for drugs covered by the federal '340B' programme. A hearing on class certification was held on 23 April 2009, and on 5 May 2009 the court denied class certification without prejudice and established Bayer Corporation as a lead-track defendant for summary judgment and trial.

### **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 cases 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 17 July 2009, the AstraZeneca defendants were currently defending lawsuits involving approximately 153 active plaintiffs. To date, 47 plaintiffs have dismissed their cases against the AstraZeneca defendants while the case was in preliminary stages, and a 48th plaintiff's case was involuntarily terminated when the court granted AstraZeneca's motion to dismiss.

As previously disclosed, rights to market *Sensorcaine*, *Xylocaine* and *Naropin* in the US were sold to Abraxis Bioscience Inc. (Abraxis) in June 2006 but many of these lawsuits may be a retained liability under the terms of the Asset Purchase Agreement with Abraxis.

### **Pennsylvania Employees Benefit Trust Fund Litigation**

As previously disclosed, in September 2008, the Pennsylvania Employees Benefit Trust Fund (PEBTF) served AstraZeneca Pharmaceuticals LP with a lawsuit, later transferred to the *Seroquel* MDL, that sought economic damages stemming from allegedly improper marketing practices. On 20 July 2009, the MDL Court dismissed PEBTF's complaint with prejudice. It is currently unclear whether PEBTF will appeal the dismissal.

### **Verus Pharmaceuticals Litigation**

On 26 May 2009, Verus Pharmaceuticals filed a lawsuit in the Supreme Court of the State of New York 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 several claims for fraud, breach of contract, unjust enrichment, and conversion. AstraZeneca and Tika removed the lawsuit to federal court on 22 June 2009. AstraZeneca disputes the claims and intends to vigorously defend this case.

## 5 HALF YEAR TERRITORIAL SALES ANALYSIS

	1 <sup>st</sup> Half 2009 \$m	1 <sup>st</sup> Half 2008 \$m	% Growth	
			Actual	Constant Currency
US	7,172	6,527	10	10
Canada	562	659	(15)	3
North America	7,734	7,186	8	9
Western Europe**	4,423	5,011	(12)	2
Japan	1,106	896	23	11
Other Established ROW	356	406	(12)	16
Established ROW*	5,885	6,313	(7)	4
Emerging Europe	523	609	(14)	10
China	388	288	35	29
Emerging Asia Pacific	376	414	(9)	6
Other Emerging ROW	753	823	(9)	8
Emerging ROW	2,040	2,134	(4)	11
Total Sales	15,659	15,633	-	8

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

\*\* For the half year 2009, Western Europe sales growth excluding Synagis would be -12 percent on an actual basis and 3 percent on a constant currency basis.

## 6 SECOND QUARTER TERRITORIAL SALES ANALYSIS

	2 <sup>nd</sup> Quarter 2009 \$m	2 <sup>nd</sup> Quarter 2008 \$m	% Growth	
			Actual	Constant Currency
US	3,548	3,126	13	13
Canada	295	337	(12)	4
North America	3,843	3,463	11	13
Western Europe**	2,247	2,606	(14)	2
Japan	609	518	18	11
Other Established ROW	195	216	(10)	17
Established ROW*	3,051	3,340	(9)	5
Emerging Europe	259	322	(20)	6
China	198	155	28	25
Emerging Asia Pacific	192	210	(9)	6
Other Emerging ROW	415	466	(11)	5
Emerging ROW	1,064	1,153	(8)	8
Total Sales	7,958	7,956	-	9

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

\*\* For the second quarter 2009, Western Europe sales growth excluding Synagis would be -13 percent on an actual basis and 4 percent on a constant currency basis.

## 7 HALF YEAR PRODUCT SALES ANALYSIS

	World				US	
	1 <sup>st</sup> Half 2009 \$m	1 <sup>st</sup> Half 2008 \$m	Actual Growth %	Constant Currency Growth %	1 <sup>st</sup> Half 2009 \$m	Actual Growth %
<b>Gastrointestinal:</b>						
<i>Nexium</i>	2,438	2,561	(5)	2	1,429	(4)
<i>Losec/Prilosec</i>	456	542	(16)	(12)	31	(69)
Others	47	41	15	24	23	92
<b>Total Gastrointestinal</b>	<b>2,941</b>	<b>3,144</b>	<b>(6)</b>	<b>-</b>	<b>1,483</b>	<b>(7)</b>
<b>Cardiovascular:</b>						
<i>Crestor</i>	2,098	1,688	24	34	1,025	33
<i>Seloken/Toprol-XL</i>	705	396	78	87	474	251
<i>Atacand</i>	679	734	(7)	6	127	(3)
<i>Tenormin</i>	143	157	(9)	(5)	7	(22)
<i>Zestril</i>	94	124	(24)	(15)	8	-
<i>Plendil</i>	121	136	(11)	(6)	6	(45)
Others	118	143	(17)	(6)	-	(100)
<b>Total Cardiovascular</b>	<b>3,958</b>	<b>3,378</b>	<b>17</b>	<b>27</b>	<b>1,647</b>	<b>55</b>
<b>Respiratory:</b>						
<i>Symbicort</i>	1,066	989	8	24	210	108
<i>Pulmicort</i>	603	794	(24)	(20)	367	(30)
<i>Rhinocort</i>	136	172	(21)	(15)	73	(27)
<i>Oxis</i>	28	38	(26)	(8)	-	-
<i>Accolate</i>	32	37	(14)	(11)	24	(8)
Others	67	88	(24)	(10)	-	-
<b>Total Respiratory</b>	<b>1,932</b>	<b>2,118</b>	<b>(9)</b>	<b>2</b>	<b>674</b>	<b>(10)</b>
<b>Oncology:</b>						
<i>Arimidex</i>	946	920	3	10	443	15
<i>Casodex</i>	481	674	(29)	(28)	116	(19)
<i>Zoladex</i>	504	565	(11)	(1)	23	(34)
<i>Iressa</i>	143	125	14	10	2	(33)
<i>Ethyol</i>	9	20	(55)	(55)	8	(60)
Others	167	199	(16)	(10)	55	(34)
<b>Total Oncology</b>	<b>2,250</b>	<b>2,503</b>	<b>(10)</b>	<b>(5)</b>	<b>647</b>	<b>(3)</b>
<b>Neuroscience:</b>						
<i>Seroquel</i>	2,374	2,162	10	15	1,693	18
Local anaesthetics	285	309	(8)	4	19	(5)
<i>Zomig</i>	208	221	(6)	2	89	(1)
<i>Diprivan</i>	134	144	(7)	(1)	23	15
Others	22	30	(27)	(13)	3	(50)
<b>Total Neuroscience</b>	<b>3,023</b>	<b>2,866</b>	<b>5</b>	<b>12</b>	<b>1,827</b>	<b>16</b>
<b>Infection and Other:</b>						
<i>Synagis</i>	599	600	-	-	502	3
<i>Merrem</i>	415	439	(5)	8	89	(1)
<i>FluMist</i>	2	-	n/m	n/m	2	n/m
Other Products	78	113	(31)	(24)	44	(21)
<b>Total Infection and Other</b>	<b>1,094</b>	<b>1,152</b>	<b>(5)</b>	<b>1</b>	<b>637</b>	<b>-</b>
Aptium Oncology	217	196	11	11	217	11
Astra Tech	244	276	(12)	1	40	-
<b>Total</b>	<b>15,659</b>	<b>15,633</b>	<b>-</b>	<b>8</b>	<b>7,172</b>	<b>10</b>

## 8 SECOND QUARTER PRODUCT SALES ANALYSIS

	World				US	
	2 <sup>nd</sup> Quarter 2009 \$m	2 <sup>nd</sup> Quarter 2008 \$m	Actual Growth %	Constant Currency Growth %	2 <sup>nd</sup> Quarter 2009 \$m	Actual Growth %
<b>Gastrointestinal:</b>						
<i>Nexium</i>	1,246	1,323	(6)	1	724	(4)
<i>Losec/Prilosec</i>	245	290	(16)	(10)	13	(75)
Others	23	21	10	19	11	83
<b>Total Gastrointestinal</b>	<b>1,514</b>	<b>1,634</b>	<b>(7)</b>	<b>-</b>	<b>748</b>	<b>(8)</b>
<b>Cardiovascular:</b>						
<i>Crestor</i>	1,129	916	23	33	547	32
<i>Seloken/Toprol-XL</i>	417	206	102	112	298	320
<i>Atacand</i>	356	388	(8)	6	66	(4)
<i>Tenormin</i>	77	87	(11)	(5)	3	(25)
<i>Zestril</i>	47	65	(28)	(17)	4	-
<i>Plendil</i>	60	70	(14)	(7)	3	(40)
Others	62	75	(17)	(4)	-	-
<b>Total Cardiovascular</b>	<b>2,148</b>	<b>1,807</b>	<b>19</b>	<b>30</b>	<b>921</b>	<b>62</b>
<b>Respiratory:</b>						
<i>Symbicort</i>	551	518	6	24	111	95
<i>Pulmicort</i>	311	383	(19)	(14)	194	(23)
<i>Rhinocort</i>	72	92	(22)	(15)	36	(29)
<i>Oxis</i>	16	21	(24)	(5)	-	-
<i>Accolate</i>	16	19	(16)	(16)	12	(14)
Others	31	45	(31)	(18)	-	-
<b>Total Respiratory</b>	<b>997</b>	<b>1,078</b>	<b>(8)</b>	<b>4</b>	<b>353</b>	<b>(5)</b>
<b>Oncology:</b>						
<i>Arimidex</i>	483	490	(1)	7	224	11
<i>Casodex</i>	245	358	(32)	(29)	62	(21)
<i>Zoladex</i>	272	310	(12)	(1)	12	(37)
<i>Iressa</i>	75	67	12	10	1	-
<i>Ethyol</i>	5	6	(17)	(17)	4	(33)
Others	87	107	(19)	(11)	29	(33)
<b>Total Oncology</b>	<b>1,167</b>	<b>1,338</b>	<b>(13)</b>	<b>(6)</b>	<b>332</b>	<b>(5)</b>
<b>Neuroscience:</b>						
<i>Seroquel</i>	1,249	1,112	12	18	893	22
Local anaesthetics	153	171	(11)	2	11	(8)
<i>Zomig</i>	107	114	(6)	3	46	-
<i>Diprivan</i>	70	76	(8)	(1)	13	44
Others	12	15	(20)	(7)	2	(33)
<b>Total Neuroscience</b>	<b>1,591</b>	<b>1,488</b>	<b>7</b>	<b>14</b>	<b>965</b>	<b>20</b>
<b>Infection and Other:</b>						
<i>Synagis</i>	54	81	(33)	(33)	31	(3)
<i>Merrem</i>	213	226	(6)	9	43	(2)
<i>FluMist</i>	-	-	-	-	-	-
Other Products	35	58	(40)	(33)	23	(15)
<b>Total Infection and Other</b>	<b>302</b>	<b>365</b>	<b>(17)</b>	<b>(7)</b>	<b>97</b>	<b>(6)</b>
Aptium Oncology	112	98	14	14	112	14
Astra Tech	127	148	(14)	-	20	(5)
<b>Total</b>	<b>7,958</b>	<b>7,956</b>	<b>-</b>	<b>9</b>	<b>3,548</b>	<b>13</b>

## Shareholder Information

### ANNOUNCEMENTS AND MEETINGS

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Announcement of third quarter and nine months 2009 results	29 October 2009
Announcement of fourth quarter and full year 2009 results	28 January 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) is 7 August 2009. Ordinary shares will trade ex-dividend on the London and Stockholm Stock Exchanges from 5 August 2009. 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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### 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>
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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: These 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 at the date of preparation of these 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. 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.